

SA Health

Code of Practice for the Storage and Transport of Drugs of Dependence

November 2012

Version 1.0



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1. Scope

This Code describes:

- 1.1 The level of security required for the storage of <u>drugs of dependence</u> by manufacturers, wholesale dealers, pharmacists, <u>health service facilities</u>, and other persons who manufacture, possess, sell, supply or administer <u>drugs of dependence</u> in South Australia; and
- 1.2 How to pack, dispatch, and transport <u>drugs of dependence</u> within or from South Australia for manufacturers, wholesale dealers, pharmacists, common or contract carriers, and other persons involved in the transportation of these drugs.

2. Application

The principles and requirements in this Code apply to the storage and transport of all declared <u>drugs of dependence</u>, other than drugs stored or transported by patients, or their agents, pursuant to lawful prescription or supply.

3. Interpretation

In this Code unless the contrary intention appears—

the Act means the Controlled Substances Act 1984 (SA);

common carrier means a company that provides transport services to the general public, without discrimination, and that is generally obliged to take consignments that do not conflict with the carrier's policies and underpinning-regulations;

contract carrier means a company that provides transport services as part of individual private contractual arrangements, without obligation to take any specific consignment. These carriers may limit their operations to a discrete number of clients only.

dose means

- 3.1 For divided preparations (e.g. tablets, capsules, patches, ampoules etc.) one discrete dosage unit;
- 3.2 For undivided preparations (e.g. bulk powders, mixtures etc.) the normal amount administered as a single adult human therapeutic dose, or in the case of veterinary practice a single adult animal therapeutic dose relevant to the animal under treatment;

drugs of dependence means those substances or classes of substances declared to be drugs of dependence under the Controlled Substances (Poisons) Regulations 2011 (SA);

health service facility has the corresponding meaning as in the *Controlled Substances* (Poisons) Regulations 2011;

key means any means for unlocking a drug storage cabinet, safe, or strongroom and includes a combination, personal identification number (PIN), password, electronic card, or other device;

registered health practitioner means an individual who is registered under the *Health Practitioner Regulation National Law* to practise a health profession, other than as a student:

supervised means that a <u>registered health practitioner</u> is physically on the premises near where drugs of dependence are stored;

a veterinary surgeon has the same meaning as in the *Veterinary Practice Act 2003* (SA).

ward means a ward, operating theatre, clinic, day surgery unit, section or department of a health service facility in which patients are treated.

Part 1 - Storage¹

4.1 Restricted Access to Drug Cabinets, Safes, and Strongrooms

No person is permitted access to a drug cabinet, safe, or strongroom <u>key</u> other than a <u>registered health practitioner</u>, veterinary surgeon, permit holder, or a licence holder who is permitted under <u>the Act</u> to possess <u>drugs of dependence</u>, and is working at the premises on which a drug cabinet, safe, or strongroom is located.²

- 4.1.1 At all times, while on duty, the designated <u>registered health practitioner</u> for the time being responsible for the <u>ward</u>, medical, dental or veterinary surgery, pharmacy, day surgery unit or <u>health service facility</u>, or the permit or licence holder, must keep the <u>key</u> to the drug cabinet, safe, or strongroom in his or her possession.³
- 4.1.2 Where the key is a combination, PIN, or password, it must not be further divulged by the person to whom the combination, PIN, or password was given. Combinations and passwords must be changed at regular intervals and deactivated when the registered health practitioner, or permit or licence holder, ceases working at the premises specified in [4.1.1].
- 4.1.3 No person other than those specified in [4.1] may:
- 4.1.3.1 Lock or unlock a drug cabinet, safe, or strongroom; or
- 4.1.3.2 Add to, or in any other way interfere with, drugs stored in the cabinet, safe, or strongroom.
- 4.1.4 A drug cabinet, safe, or strongroom must only be unlocked and accessed for the following purposes and be re-locked immediately after use:
- 4.1.4.1 Storage of drugs; or
- 4.1.4.2 Supply, administration, destruction of drugs; or
- 4.1.4.3 Examination and counting of drugs for audit and recording-keeping purposes.

¹ In determining which of the following storage area categories applies, organisations are encouraged to consider the specific activities undertaken at the premises or area of premises. If doubt remains, advice may be sought from the Drugs of Dependence Unit.

² To avoid doubt, nothing in this clause prevents a health service facility further restricting the category of registered health practitioner working at the facility who is permitted access to a key for a drug cabinet, safe, or strongroom in certain circumstances.

³ It is sufficient compliance with this clause that a registered health practitioner retains legal possession of the key when a ward is closed by storing the key in a suitable locked location within the health service facility providing equivalent security to the drug cupboard, safe, or strongroom to which the key relates.

4.2 **Health Service Facility and Surgery**

- 4.2.1 All drugs of dependence stored in a health service facility, ward, day surgery unit, or medical, dental or veterinary surgery must be placed in a securely locked storage cabinet that meets or exceeds the following requirements:
- 4.2.1.1 Where the quantity of drugs stored is not more than 15 doses —
- a) Made of 15mm thick hardwood; and
- b) Fitted with a 5 lever key lock, or equivalent locking mechanism; and
- c) Securely fixed to the wall or floor; or
- 4.2.1.2 Where the quantity of drugs stored is more than 15 doses and the immediate area in which the cabinet is situated is <u>supervised</u> at all times, the requirements specified in [4.2.1.1 a), b), and c)]; or
- 4.2.1.3 Where the quantity of drugs stored is more than 15 doses and the immediate area in which the cabinet is situated is not supervised at all times⁴ the requirements of Australia / New Zealand Standard for Safes and Strongrooms (AS/NZS 3809:1998) - Resistance Grade 1; or
- 4.2.1.4 As approved by the Manager, Drugs of Dependence Unit.

4.3 **Pharmacy**

- 4.3.1 All drugs of dependence stored in a pharmacy must be placed in a securely locked drug safe that meets or exceeds the following requirements:
- 4.3.1.1 Where the quantity of drugs held at any time is equivalent to 500 doses or less, and the area in which the drug safe is located is supervised 24 hours per day, the requirements of Australia / New Zealand Standard for Safes and Strongrooms (AS/NZS 3809:1998) - Resistance Grade 0; or
- 4.3.1.2 Where the quantity of drugs held at any time is equivalent to 500 doses or less, and the area in which the drug safe is unsupervised for periods of time, requirements of Australia / New Zealand Standard for Safes and Strongrooms (AS/NZS 3809:1998) - Resistance Grade I; or
- 4.3.1.3 Where the quantity of drugs held at any time is equivalent to more than 500, but less than 1000, doses, the requirements of Australia / New Zealand Standard for Safes and Strongrooms (AS/NZS 3809:1998) - Resistance Grade II; or
- 4.3.1.4 Where the quantity of drugs held at any time is equivalent to more than 1000 doses, the requirements of Australia / New Zealand Standard for Safes and Strongrooms (AS/NZS 3809:1998) - Resistance Grade III; or
- 4.3.1.5 Where the pharmacy is fitted with an alarm system monitored by a security company, or the premises are supervised 24 hours a day, or the premises are patrolled by a security guard when not supervised, the Resistance Grade specified at [4.3.1.2], [4.3.1.3], or [4.3.1.4] may be reduced by one Resistance Grade, respectively.
- 4.3.1.6 For the purposes of this Code, a drug safe having the following specifications is

⁴ For example, overnight; when a theatre is temporarily closed.

- deemed to be equivalent to Resistance Grade I —
- a) Constructed of steel plate built not less than 10mm thick;
- b) Continuous welding of all edges;
- c) Fitted with a flush-fitting door constructed of mild steel plate not less than 10mm thick, with a clearance around the door of not more than 1.6mm;
- d) Fitted with a fixed locking bar welded to the inside face of the door near the hinged-edge which engages in a rebate in the safe body when the door is closed:
- e) Fitted with a five-lever key lock, or locking mechanism providing equivalent security, securely affixed to the rear face of the door;
- f) Attached to a wall or floor of the pharmacy premises away from external walls where it is not visible from outside the room in which it is situated and:
- fa) Where mounted on a brick or concrete wall or floor, be attached to such wall or floor by means of suitably sized expanding bolts through 9.5mm diameter holes drilled in the rear or bottom of the safe; or
- fb) Where mounted on a timber-frame wall or floor, be attached to such wall or floor frame by means of suitably sized coach screws through 9.5mm diameter holes drilled in the rear or bottom of the safe;
- fc) Where the wall or floor is constructed of material other than brick or concrete, or with a frame other than timber, be attached to such wall, floor, or frame in such manner as to provide equivalent security to a mounting made pursuant to [fa] or [fb].

4.4 Analysis, Research, Instruction or Training Permit Holders

- 4.4.1 All <u>drugs of dependence</u> stored by the holder of an analysis, research, instruction, or training permit must:
- 4.4.1.1 Be placed and securely locked in a drug safe that meets or exceeds the requirements of Australia / New Zealand Standard for Safes and Strongrooms (AS/NZS 3809:1998) – Resistance Grade I; and
- 4.4.1.2 Stored in premises fitted with an alarm system monitored by a security company or patrolled by a security guard; or
- 4.4.1.3 As approved by the Manager, Drugs of Dependence Unit.

4.5 Manufacturer and Wholesale Dealer

- 4.5.1 All <u>drugs of dependence</u> stored by a manufacturer or wholesale dealer must be placed in a securely locked safe or strongroom that meets or exceeds the requirements of Australia / New Zealand Standard for Safes and Strongrooms (AS/NZS 3809:1998) Resistance Grade VII;
- 4.5.1.1 The safe or strongroom must be situated away from the external walls of the premises; and
- 4.5.1.2 The premises and the area in which the safe or strongroom is situated must be

fitted with an alarm system monitored by a security company; or

4.5.1.3 As approved by the Manager, Drugs of Dependence Unit.⁵

4.6 Other Places of Storage

Subject to the above requirements, where drugs are temporarily or permanently stored in any other place, ⁶ any such place of storage must be so constructed, secured, and used as to prevent the unauthorised removal of, or interference with, the drugs.

4.7 Quick-Reference to Storage Requirements

| Storage place | <u>Doses</u> stored | Hours per day <u>supervised</u> | Security Level |
|--|---------------------|---------------------------------|--|
| | ≤ 15 | _ | Locked hardwood cabinet |
| | > 15 | 24 | |
| Health Service Facilities, Medical, Dental, Veterinary Surgeries | > 15 | < 24 | AS/NZS 3809:1998 Resistance Grade I |
| | | | As approved by Manager, DDU |
| | ≤ 500 | 24 | AS/NZS 3809:1998 Resistance Grade 0 |
| | ≤ 500 | < 24 | AS/NZS 3809:1998 Resistance Grade I |
| | | 24 – monitored alarm system | AS/NZS 3809:1998 Resistance Grade 0 |
| Pharmacies | 501 - 999 | < 24 | AS/NZS 3809:1998 Resistance Grade II |
| | | 24 – monitored alarm system | AS/NZS 3809:1998 Resistance Grade I |
| | ≥ 1000 | < 24 | AS/NZS 3809:1998 Resistance Grade III |
| | | 24 – monitored alarm system | AS/NZS 3809:1998 Resistance Grade II |

⁵ The Manager, Drugs of Dependence Unit must have regard to the quantity of drugs of dependence stored at the manufacturer or wholesale dealer premises at any instant when determining applicable storage requirements.

⁶ For example, in a vehicle or aeroplane.

| Permit or Licence Holders | Any quantity | _ | AS/NZS 3809:1998 Resistance Grade III |
|--|--------------|---------------------------------|--|
| Manufacturers and Wholesale Dealers | Any quantity | Monitored alarm system required | AS/NZS 3809:1998 Resistance Grade VII As approved by Manager, DDU |

5. Part 2 - Transport

5.1 Packaging for Transport

The following requirements apply when packaging <u>drugs of dependence</u> for delivery or transport:

5.1.1 Drugs of dependence must be enclosed in a package that does not contain any other goods and which is labelled with the following statement:

SCHEDULE 8 - PLEASE CHECK CAREFULLY

- 5.1.2 A multi-part document (packing-slip) stating the contents of the package must be enclosed within or securely attached to the package.
- 5.1.3 The package in [5.1.1] must itself then be enclosed in a carton, or other opaque container, addressed to the purchaser or consignee. This carton or container must give no indication that it contains a drug of dependence.
- 5.1.4 Where possible, drug parcels should be consigned to a particular person.

5.2 Road Transport

- 5.2.1 The following requirements apply when delivering <u>drugs of dependence</u> by road:
- 5.2.1.1 Drugs are to be packaged in accordance with [5.1.1].
- 5.2.1.2 The contents of parcels containing <u>drugs of dependence</u> must not be disclosed to common or contract carrier employees. Common carriers must not be routinely used.
- 5.2.1.3 Vehicles must not be marked so as to identify their carriage of drugs.
- 5.2.1.4 Vehicles must be kept locked at all times and keys not left in the vehicle.
- 5.2.1.5 All reasonable precautions must be taken to ensure that the time between collection and delivery of consigned drugs is minimised.
- 5.2.1.6 Large-scale deliveries of <u>drugs of dependence</u> must be consigned with a contract carrier:
- a) Who uses standard cargo containers or fully enclosed trucks on which the enclosure is metal or other substantial material sufficient to retard unauthorised access to the cargo. The containers or enclosures must be fitted with high-standard security locks that are kept locked at all times en route;

- b) Uses vehicles fitted with automatic logs;
- c) Who operates a service where no avoidable stops are made, and if scheduled stops are made, the vehicle is not left unattended unless parked in a secure area; and
- d) Who provides a terminal where cargo being loaded or unloaded is not easily accessible to unauthorised personnel and is under CCTV surveillance;
- 5.2.1.7 The consignor of <u>drugs of dependence</u> must notify the consignee that the consignment has been dispatched and provide the expected time and place of delivery; and
- 5.2.1.8 A signature must be obtained from the consignment-recipient each time the consignment changes hands, with receipts exchanged.

5.3 **Postal Transport**

<u>Drugs of dependence</u> must not be sent via Australia Post unless exempted under the *Crimes Act 1914* (Cth). If an exemption is applicable then the following requirements apply:

- 5.3.1 Drugs are to be packaged in accordance with [5.1.1]; and
- 5.3.2 The sender of drugs must notify the receiver that the consignment has been dispatched and provide the expected time and place of delivery.

5.4 Rail Transport

- 5.4.1 The following requirements apply when delivering <u>drugs of dependence</u> by rail:
- 5.4.1.2 Bulk consignments of <u>drugs of dependence</u> must not be sent by rail;
- 5.4.1.3 Drugs are to be packaged in accordance with [5.1.1];
- 5.4.1.4 Where small quantities of drugs are sent by rail, they should be included in a larger consignment of other cargo;
- 5.4.1.5 Where large quantities of drugs are sent by rail, the parcel must be insured with the railway or be consigned in such manner that the consignment will be specially handled;
- 5.4.1.6 A signature must be obtained from the consignment-recipient each time the consignment changes hands, with receipts exchanged; and
- 5.4.1.7 The sender of drugs must notify the receiver that the consignment has been dispatched and provide the expected time and place of delivery.

5.5 Air Transport

- 5.5.1 The following requirements apply when delivering <u>drugs of dependence</u> by air freight:
- 5.5.1.1 Drugs are to be packaged in accordance with [5.1.1];
- 5.5.1.2 The contents of parcels must not be revealed unnecessarily to airline

employees;

- 5.5.1.3 <u>Drugs of dependence</u> consigned by air freight must be classified as "vulnerable", unless the consignment is part of normal delivery between a wholesale dealer to a pharmacy;
- 5.5.1.4 Care must be taken to ensure that cargo handling, storage, loading, and unloading at either end of the consignment's journey is inaccessible to unauthorised persons;
- 5.5.1.5 Consignors must ascertain the flight number on which drugs will be carried and insist on notification of any change before flight commencement;
- 5.5.1.6 Parcels must not be delivered to a city terminal for transport to the airport in airline-operated vehicles. Parcels must be taken to the cargo establishment at the airport in a transport company or contract carrier's vehicle;
- 5.5.1.7 Delivery to and collection from the carrier's premises must be timed with the object of the drugs spending the minimum practicable time at those premises;⁷
- 5.5.1.8 A signature must be obtained from the consignment-recipient each time the consignment changes hands, with receipts exchanged; and
- 5.5.1.9 The consignor must notify the consignee that the consignment has been dispatched and provide the expected time and place of delivery.

5.6 Health Service Facility Drug Transport Systems

All drug transport systems (DTS) installed in <u>health service facilities</u> must be constructed and operated in a way that ensures the secure delivery <u>of drugs of dependence</u> to intended recipients.

5.6.1 All DTS must be approved by the Manager, Drugs of Dependence Unit.

5.7 Receiving Drugs of Dependence

The consignee must ensure that he or she, or a <u>registered health practitioner</u>, veterinary surgeon, a permit or licence holder, or a person authorised under a permit or licence will be on hand to receive the consignment of <u>drugs of dependence</u>.

- 5.7.1 A signed receipt must be given for the consignment.8
- 5.7.2 The receiver must immediately check the contents of the parcel.
- 5.7.3 In the event a discrepancy is identified the receiver must immediately notify the consignor and consignee (if the receiver is not the consignee). If the consignment remains irreconcilable, then the consignor must within 24 hours notify both South Australia Police and the Controlled Substances Licensing section of the South Australian Department for Health and Wellbeing.

⁷ For example, all reasonable steps must be taken not to store consignments at a depot over a weekend or public holiday.

⁸ It is sufficient compliance with this clause that a signature is endorsed on a carrier's delivery schedule.