

## Drugs of Dependence Unit

# The *Controlled Substances Act 1984* (SA) Pharmacists' Obligations

The *Controlled Substances Act 1984* (SA) and the *Controlled Substances (Poisons) Regulations 2011* (SA) regulate the prescription, supply, and administration of drugs and poisons in South Australia. This legislation is administered by the Drugs of Dependence Unit, SA Health. The following is a non-exhaustive guide to the major legal obligations only. Reference should be made to the legislation for further information (available at [www.legislation.sa.gov.au](http://www.legislation.sa.gov.au)).

Pharmacists are expected to be familiar and comply with the information contained in this circular.

The Act provides pharmacists with certain privileges not available to the general public. In exchange for these privileges, it expects pharmacists to be aware of the requirements of the Act, to act lawfully and act responsibly at all times. These privileges may be withdrawn by order of the Minister responsible for the Act if a conviction is obtained or an opinion is formed that the pharmacist has acted irresponsibly in handling prescription drugs. <sup>[SECTION 57]</sup>

References to:

"SECTIONS" refer to sections of the *Controlled Substances Act 1984* (SA) and

"REGULATIONS" refers to regulations of the *Controlled Substances (Poisons) Regulations 2011* (SA).

"Pharmacist" refers to a person registered under the *Health Practitioner Regulation National Law (South Australia) Act 2010*. <sup>[SECTION 4]</sup>

Substances used for therapeutic purposes are divided into four schedules with increasing controls:

- > Schedule 2 / Pharmacy Medicine – Pharmacy and Medicine Sellers – Pharmacist advice should be available
- > Schedule 3 / Pharmacist Only Medicine – Pharmacy only – Expert advice is required on use of the drug - Pharmacist advice is required and a Pharmacist must take part in the sale
- > Schedule 4 / Prescription Only Medicine – Professional diagnosis and monitoring is required – prescribed or supplied by a Medical Practitioner, Dentist or Veterinary Surgeon, Dispensed by pharmacist on prescription.
- > Schedule 6/ Poison – Substances with a moderate potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label.
- > Schedule 7 / Dangerous Poison – Substances with a high potential for causing harm at low exposure and which require special precautions during manufacture, handling or use.
- > Schedule 8 / Controlled Drug or Drug of Dependence – As for S4 but because of their high abuse potential, additional security, records and accountability is required.

"Prescription Drugs" are S4 & S8 poisons.

"Controlled Drugs" are Drugs of Dependence and other drugs that have no medical use and a high abuse potential.

# Drugs of Dependence Unit

HELP IS AVAILABLE: Pharmacists are encouraged to telephone the Drugs of Dependence Unit (Phone 1300 652 584 or email [HealthDrugsofDependenceUnit@sa.gov.au](mailto:HealthDrugsofDependenceUnit@sa.gov.au) ) to discuss cases where guidance or advice is required.

## GENERAL CONTROLS

- > Possession, prescribing, supply & administration of S4 & S8 drugs are prohibited. [SECTIONS 18, 31 & 32]
- > Pharmacists and other health workers are exempted only while acting in the ordinary course of their profession or in accordance with the Regulations.
- > Patients are exempted where the drug has been lawfully prescribed or supplied.

### **Manufacture** [SECTIONS 13,14,15,18, & 31]

Pharmacists may manufacture, produce, pack, sell or supply scheduled poisons where such activity is part of ordinary pharmacy practice. Mass production is considered to be manufacturing and requires a licence.

### **Purchase** [REGULATION 40]

- > Persons authorised to possess or persons licensed to possess may purchase S4 & S8 drugs by written and signed order from a pharmacy.
- > Drugs must be purchased in the name of the authorised person and he or she takes responsibility for them.
- > If purchasing as a licensed person, the licence should be viewed before the sale.
- > If drugs are to be purchased in the name of the practice, the practice must obtain a license to possess such drugs.
- > The cancelled Order for a drug of dependence must be forwarded to the Drugs of Dependence Unit by the 7th day of the following month.

### **Sale or Supply** [SECTIONS 14,15,18 & 31]

Pharmacists are authorised to sell or supply all classes of drugs and poisons but must be satisfied the supply is lawful.

### **Sale or Supply of Schedule 3 Medicine (Pharmacist Only)** [REGULATION 13]

A Pharmacist must personally (not through an assistant) give oral directions, supplemented where practicable with written directions, for the safe and proper use of a schedule 3 medicine to the person who is being supplied the medicine.

Certain S3 medicines must be labelled according to the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) [REGULATION 26]. These medicines are:

- > Dihydrocodeine in cough preparations.
- > Doxylamine in preparations also containing codeine.
- > Promethazine in preparations also containing codeine.
- > Pseudoephedrine.

For further information refer to [Project STOP](#)

# Drugs of Dependence Unit

## **Sale or Supply of Pseudoephedrine** [REGULATION 14]

- > Pharmacists must not sell or supply pseudoephedrine (either as S3 or S4) unless the person presenting for the supply provides a specified form of photo-identification or his or her birth certificate. Accepted forms of photo-identification include a current driver's licence, firearms licence, non-Australian passport, proof of age card or student identification card.
- > The records of sale or supply must be made in an electronic form that is accessible via the internet to the Chief Executive of the Department for Health and Wellbeing and the Commissioner of Police.

## **Sale or Supply of Schedule 7 Poisons** [SECTION 16, REGULATIONS 12, 21]

- > Schedule 7 poisons must not be sold to a person under 18 years of age, a person not known to the pharmacist (unless evidence of identity is produced) or for domestic or garden use.
- > A record of the sale must be kept including the intended use of the poison and the licence number is applicable.

## **Supply of Needles and Syringes** [REGULATION 8A]

The Controlled Substances (Controlled Drugs, Precursors and Plants) Regulations 2000 permits a pharmacist to supply needles, syringes and advice regarding their safe use to drug users.

## **Containers** [SECTION 24 REGULATION 26]

Prescribed medicines (medicines listed in Schedule 1 to Therapeutic Goods Order No. 80) must be provided in child resistant packaging or containers except where the pharmacist believes that the person would suffer undue hardship through difficulty in opening a container that complies with that Order.

## **Labels** [SECTION 24 REGULATION 26]

All poisons must be labelled with the original manufacturers label or labelled with the name (trade and approved), form and strength of the medicine, directions for safe use including route of administration, name of patient, date dispensed, reference number linking to the prescription record if dispensed, name and address of pharmacy.

Drugs for patient use must be labelled according to the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). Warning labels such as a drowsiness warning label may also be required.

## **Storage** [SECTION 25, REGULATION 27, Code of Practice for the Storage & Transport of Drugs of Dependence]

S4 drugs must be stored to prevent public access.

No poison can be stored:

- 1) in a container that is normally used for food or beverages or is similar to a container that is normally used for food or beverages,
- 2) if Schedule 3, where the public has access, or
- 3) if Schedule 2, 5 or 6, where public has access unless
  - a) it is a Schedule 6 hair colouring preparation, or
  - b) it is above 1.2m from the floor, or
  - c) it is in a blister pack or a child resistant package or container, or
  - d) it is in a container over 5 litres or is over 5 kilograms in weight

# Drugs of Dependence Unit

S8 drugs must be stored to prevent unauthorised access, i.e. generally in a locked safe or vault.

Minimum specifications depend on the number of doses stored. The standard 10mm steel pharmacy safe is sufficient if 500 or less doses, or 1,000 or less doses if there is 24 hour alarm monitoring.

Larger quantities, or where there is less monitoring, require greater security.

For further information refer to the Code of Practice for the Storage and Transport of Drugs of Dependence.

## **Transport** [SECTION 25, REGULATION 28&239]

S8 drugs must be transported in a manner consistent with the Code of Practice for the Storage and Transport of Drugs of Dependence.

Using Australia Post to transport S8 drugs is prohibited, unless the particular distribution program is exempted under the Crimes Act 1914 (Cth). Where it is necessary to transport S8 drugs, for example to remote locations, this must be arranged through a courier service and comply with relevant provisions of the Code of Practice for the Storage and Transport of Drugs of Dependence.

## **Record keeping**

- > S8 drugs - must maintain a drug of dependence register and record all transactions.  
[REGULATION 41]
- > All records must be kept a minimum of two years from date of last entry on the record.  
[REGULATION 49]

## **Restriction on Advertising of a drug** [REGULATION 32]

A Pharmacist may not advertise a schedule 3, 4 or 8 medicine except where the following applies:

1. the advertisement appears in a journal circulated predominantly among health professionals
2. it is a Schedule 3 poison listed in Appendix H of the Standard of the Uniform Scheduling of Medicines and Poisons (SUSMP)
3. Advertisements for Schedule 3, 4 or 8 medicine that consist of a price list that complies with the Price Information Code of Practice published by the Therapeutic Goods Administration.

## **Vicarious Liability** [REGULATION 50]

An employer may be held responsible for the actions of an employee.

## **Sale or supply of drugs to authorised health professionals** [SECTION 18, REGULATION 35 & 37]

- > Persons authorised to possess or persons licensed to possess (such as medical practitioners, nurse practitioners, dentists, veterinarians) may purchase S4 and S8 drugs by written and signed order (not prescription) from a pharmacy.
- > A medical practitioner must not (unless an emergency exists) prescribe or supply a drug of dependence for self- treatment or for the treatment of his or her spouse or other family member unless authorised by the Minister.
- > Drugs must be purchased in the name of the authorised person and he or she takes responsibility for them.

## Drugs of Dependence Unit

- > If purchasing as a licensed person, the licence should be viewed by the pharmacist before the sale.
- > If drugs are to be purchased in the name of the practice, the practice must obtain a license to possess such drugs.
- > The cancelled order for a drug of dependence must be forwarded to the Drugs of Dependence Unit by the 7th day of the following month.

### **Pharmacists are permitted to supply Schedule 4 drugs on receipt of a written order to** <sup>[REGULATION 21]</sup>

- > a council or health service for use in an immunisation program,
- > a health professional authorised to supply or administer the drug such as a medical practitioner, nurse practitioner or dentist,
- > the owner of animals for mass treatment of those animals, where the owner
  - has an order from a veterinary surgeon for the drug or
  - the drug is an antibiotic ordered from an inspector under the Livestock Act 1997 (SA) and the order is countersigned by the Chief Inspector,
- > a Master or Medical Officer of a ship where the drugs are required to be carried by law,

### **For Drugs of Dependence** <sup>[REGULATION 40].</sup>

- > A drug of dependence may be supplied on receipt of an order.
- > The pharmacist must not supply unless:
  - satisfied the person ordering is lawfully authorised to possess the drug, (this includes medical practitioners, dentists, veterinary surgeons and licence holders),
  - if not known to the pharmacist, provides satisfactory identification, and
  - unless a receipt is provided.
- > Cancelled orders (unless supplying to a health service) must be forwarded to DDU each month with the prescription returns.

### **Other Prescribers** <sup>[SECTION 18, REGULATION 18]</sup>

- > Other professions are permitted to administer (and thus purchase and possess), prescribe or supply a limited range of Schedule 4 medicines.
- > Podiatrists, dental therapists, dental hygienists, oral health therapists and optometrists are able to administer the schedule 4 medicines listed in regulation 18.
- > Optometrists and podiatrists whose registration is endorsed with a scheduled medicines endorsement are authorised to prescribe, supply or administer scheduled medicines in accordance with that endorsement.
- > Eligible midwives acting in the ordinary course of their profession whose registration is endorsed with a scheduled medicines endorsement are authorised to prescribe schedule 4 and schedule 8 drugs, in accordance with that endorsement. <sup>[SECTION 18 AND 18A]</sup>

## PRESCRIPTION DRUG CONTROLS

### **Prescription requirements** <sup>[REGULATION 33 & 34]</sup>

- > Prescriptions for S4 & S8 drugs must be legible, written in ink and include the\*\*:
  - o Name, address and telephone number of the prescriber,
  - o Date the prescription was written,
  - o Full name and address of the patient,

## Drugs of Dependence Unit

- Name of the drug and if necessary, the strength and form of the drug,
- Dosage instructions for the safe use of the drug,
- Quantity to be dispensed,
- Number of repeats if applicable
- Prescriber's personal signature.

\*\* This does not apply to a medical practitioner who writes a medication chart prescription for an S4 medicine that may be supplied under the Medication Charts Program (when that Program comes into operation). Refer to the National Health (Residential Medication Chart) Determination.

- > For Drugs of Dependence (S8 drugs), prescriptions must also include:
  - The date of birth of the patient,
  - The quantity in words and numerals and

Prescriptions are valid for a period of 12 months from the date of prescribing and 6 months in the case S8 drugs.

### **Dispensing requirements** [REGULATION 35]

Only valid prescriptions may be dispensed

The pharmacist must:

- > Dispense from an original or a copy attached to an original repeat authorisation (do not dispense from a repeat authorisation as this may contain an error).
- > Endorse the prescription (or copy if dispensing from a copy) with his or her name, business name and address, date dispensed and a unique prescription number.
- > Enter details of the prescription into a prescription record on the same day as it is dispensed.
- > Cancel the prescription when it is dispensed for the last time.
- > Retain the original unless not cancelled.
- > If for a drug of dependence, forward an electronic record of the prescription to the Drugs of Dependence Unit by the 7th day of the following month. If no drugs of dependence sales or dispensing occurred, a nil return must be forwarded.
- > Repeats cannot be dispensed earlier than stipulated unless the pharmacist is satisfied the patient will be out of the state, has lost the previous supply and the pharmacist notifies the prescriber. If intervals are not stipulated, dispensing must not occur earlier than needed based on the prescribed dose.
- > Where there is reasonable cause to believe the prescription has been altered, forged or obtained by false pretences, the prescription must not be dispensed and in the case of forgery, forwarded to the Police and a copy to the Drugs of Dependence Unit.

### **In the case of a drug of dependence:**

- > If the patient is not known or the prescriber's signature is not known, no more than two days' supply may be dispensed until the prescription is verified with the prescriber.
- > A pharmacist must not hand over drugs until the prescription (or copy) is signed and dated by the person collecting the drugs and if the person is not known, produced satisfactory evidence of his or her identity.
- > A medical practitioner must not (unless an emergency exists) prescribe or supply a drug of dependence for self- treatment or for the treatment of his or her spouse or other family member unless authorised by the Minister.

# Drugs of Dependence Unit

## **Dispensing a medicine supplied under the Medication Charts Program**

[REGULATION 35(12)]

- > The requirements under regulation 35 in relation to dispensing prescriptions do NOT apply if a pharmacist or medical practitioner dispenses a medicine supplied under the Medication Charts Program on a medication chart prescription, and the supply is in accordance with the National Health (Residential Medication Chart) Determination.
- > A pharmacist or medical practitioner who dispenses a medicine under the Medication Charts Program must still:
  - Record specified details about the prescriber, the resident and the drug when he or she dispenses a drug on a medication chart prescription
  - Not dispense a drug
    - If the prescription is out of date (more than 12 months old), has been cancelled, is partly/wholly illegible, does not comply with the Act or Regulations or if there is reasonable grounds to suspect the prescription has been forged or fraudulently altered.

## **Sale or supply of a schedule 4 drug under the Continued Dispensing Program**

[REGULATION 21]

- > A pharmacist may sell or supply a schedule 4 drug without dispensing a prescription if the drug is a pharmaceutical benefit that may be supplied under the Continued Dispensing Program. The sale or supply of the drug must comply with the National Health (Continued Dispensing) Determination.
- > Where supply is made under this program, the maximum quantity permitted under the Pharmaceutical Benefits Scheme for that medicine may be supplied.
- > Under the Continued Dispensing Program, the medicine may only be supplied to the person once in a 12 month period.
- > A pharmacist must not supply a medicine under the Continued Dispensing Program unless the person has previously had a valid prescription and the person's therapy is stable, and information about the supply is provided to the most recent prescriber.
- > Only applies to 'statins' for the treatment of high cholesterol, and the oral contraceptive pill.

## **Dispensing from a verbal instruction.** [REGULATION 33]

- > A prescriber may, where there is a good reason, give a prescription by telephone, facsimile, or other electronic means.
- > The same information as required for a written prescription must be provided. Unless the prescription was faxed and endorsed with the name of the single pharmacy to dispense the prescription, the prescriber must forward a written prescription as confirmation as soon as practical or if a drug of dependence, within 24 hours.

## **Methadone and Buprenorphine dispensing**

These drugs of dependence may be used in opioid pharmacotherapy (Opioid Dependence Substitution Program and Suboxone Opioid Substitution Program) with supervised administration of doses and, when appropriate, limited take-away doses. All requirements covering drugs of dependence, including prescription records, labelling of dispensed doses for patient self-administration, storage, drug register and monthly electronic prescription reports apply as for other drugs of dependence.

# Drugs of Dependence Unit

## Recording the supply of drugs of dependence <sup>[REGULATION 40]</sup>

A drug of dependence may be supplied on receipt of an order where the pharmacist is satisfied the person ordering is lawfully authorised to possess the drug, (this includes patients, medical practitioners, dentists, veterinary surgeons and licence holders).

If the person is not known to the pharmacist he or she must provide satisfactory identification before the drug is supplied, and provide the pharmacist with a signed and dated receipt for the drug.

S8 drugs: pharmacists must maintain a drug of dependence register and record all drug transactions.

All records must be retained, protected and available for inspection for a period of two years from date of last entry on the record. <sup>[REGULATION 35]</sup>

The supply must be recorded with the following details and the pharmacist must sign the record:

- i. his or her name and business address
- ii. the name and address of the person to whom the drug was supplied
- iii. the date on which the drug was supplied
- iv. the name or ingredients of the drug
- v. the amount, and if applicable the strength of the drug
- vi. if the drug was sold or supplied on order, the invoice number (if any) for the sale or supply of the drug
- vii. the total amount of the drug now in stock on the premises

Cancelled orders (unless supplying to a health service) must be forwarded to Drugs of Dependence Unit each month with the electronic prescription report.

## Emergency supply <sup>[REGULATION 35 & 40]</sup>

A drug of dependence must NOT be supplied without prior receipt of a lawful order or prescription (written, verbal, fax or by other permitted electronic transmission)

A Schedule 4 drug may be supplied to a person by a pharmacist without an order or prescription provided

- i. the person is currently under treatment with the drug,
- ii. the continued supply is essential for health reasons,
- iii. there is good reason why the person cannot supply a prescription,
- iv. the drug is not one listed in the table in regulation 19(1) and
- v. the supply does not exceed three (3) days or the smallest standard pack if a mixture, cream or ointment

## Destruction of drugs of dependence <sup>[REGULATION 45]</sup>

Destruction must not occur unless witnessed by another pharmacist, registered health practitioner, an authorised officer, police officer, registered veterinary surgeon or a person who has been authorised in writing by the Chief Executive of the SA Ambulance Service to administer drugs of dependence.

Information including the full names and signatures of the person and the witness to the destruction, name, strength and amount of drug; and the date and time of destruction must be recorded.

Destruction and disposal of drugs of dependence must not pose a risk to public health or safety. <sup>[REGULATION 48]</sup>

## Drug seeking behaviours

It is an offence for a person to obtain or attempt to obtain a prescription drug by fraud or have in his or her possession or utter a forged document to obtain a prescription drug. <sup>[SECTION 30]</sup>



## Drugs of Dependence Unit

Pharmacists should take all reasonable actions to ensure they are treating a genuine medical condition and treatment does not contribute to the induction of drug dependence, maintenance of drug dependence without a proper treatment plan or add to the pool of drugs available for illicit drug trafficking.

Supply without due diligence may be considered to be “irresponsible” and result in the serving of an Order which effectively removes privileges granted to a pharmacist to handle prescription drugs. [SECTION 57]

Pharmacists may contact the Drugs of Dependence Unit if suspicious of a person seeking prescription drugs. Unit officers, acting for the Minister for Mental Health and Substance Abuse, are empowered to provide information regarding medical history to a Medical Practitioner where an opinion is formed the person is drug dependent and acting illegally. The Minister also publishes a “Privileged Circular” periodically listing those major drug seekers at the time with the aim to restrict or stop further supplies of drugs to those persons. [SECTION 58]

### FORGED OR FRAUDULENTLY ALTERED PRESCRIPTIONS

[SECTION 30]

- > It is an offence to obtain or attempt to obtain a prescription drug by fraud or false pretences or present or have possession of a forged document for this purpose.
- > Pharmacists must
  - a) not dispense a prescription they have reasonable cause to believe has been forged or obtained fraudulently and
  - b) if forged, retain the prescription and forward it together with the Notification Form for Forged or Fraudulently Altered Prescriptions to the police.
  - c) A copy of the prescription and form is to be forwarded to the Drugs of Dependence Unit also.
- > Forms for this are available from the Drugs Dependence Unit’s website.
- > Pharmacists are a prescribed profession and able to access publications by the Minister to warn of persons known or suspected of consuming medicines in a manner that places their health at risk, obtain drugs unlawfully or for an unlawful purpose (e.g. drug seekers, pseudoephedrine seekers, persons presenting forged prescriptions). Contact the Drugs of Dependence Unit to enable access to a secure section of the DDU website. [SECTION 58]

### Special provision relating to certain drugs [REGULATION 19]

#### Schedule 4 drugs

##### a) Ovulatory Stimulants

Clomiphene, cyclofenil, follitropin-alpha, follitropin-beta, luteinising hormone, or urofollitrophin may only be supplied if prescribed or ordered by a specialist in endocrinology, obstetrics and gynaecology or a medical practitioner providing services to a fertility unit, an endocrinology unit, or an obstetric and gynaecological unit in a teaching hospital.

##### b) Retinoids

Acitretin, bexarotene and etretinate (for human use) and isotretinoin (for human internal use) and may only be supplied if prescribed or ordered by a specialist in dermatology, oncology or haematology (or a medical registrar working under such a specialist), or such other specialist individually authorised by the Minister.

## Drugs of Dependence Unit

Tretinoin (for human internal use) may only be supplied if prescribed or ordered by a specialist in oncology or haematology (or a medical registrar working under such a specialist) or such other specialist individually authorised by the Minister.

### c) Thalidomide and Lenalidomide

Thalidomide or lenalidomide for human use may only be supplied if prescribed or ordered by a specialist in oncology or haematology (or a medical registrar working under such a specialist), or a medical practitioner individually authorised by the Minister.

### d) Endothelin Receptor Antagonists

Ambrisentan, bosentan, and sitaxentan may only be prescribed or ordered by a relevant specialist (or a medical registrar working under such a specialist) or a medical practitioner individually authorised by the Minister.

### Schedule 8 drugs

### e) Dronabinol (delta-9-tetrahydrocannabinol)

Prescribers must be authorised by the Secretary of the Commonwealth Department of Health and Wellbeing to prescribe or order dronabinol (contact the TGA). Authority to prescribe will not be granted by the South Australian Minister for Mental Health and Substance Abuse unless the applying prescriber can demonstrate he or she is in possession of a Commonwealth authority.

## Administrative and other powers of the Drugs of Dependence Unit [SECTION 57]

Convictions against the Act, or where the Minister forms an opinion a prescription drug (S4 or S8) has been prescribed, supplied, or administered in an “irresponsible manner”, may result in a Prohibition Order that effectively removes the ability of a pharmacist to handle these drugs. Other courses of action may include prosecution and or reporting the alleged conduct to the Australian Health Practitioner Regulation Agency.

Pharmacists are encouraged to telephone the Drugs of Dependence Unit to discuss cases where guidance or advice is required.

---

## For more information

**Drugs of Dependence Unit**

**PO Box 6**

**Rundle Mall ADELAIDE SA 5000**

**Telephone: 1300 652 584 (Office hours)**

**Fax: 1300 658 447**

**Email: [HealthDrugsofDependenceUnit@sa.gov.au](mailto:HealthDrugsofDependenceUnit@sa.gov.au)**

**[www.sahealth.sa.gov.au/drugsofdependence](http://www.sahealth.sa.gov.au/drugsofdependence)**

© SA Health, Government of South Australia. All rights reserved.



SA Health