

Drugs of Dependence Unit

The Controlled Substances Act 1984 Medical Practitioners' Obligations

The *Controlled Substances Act 1984* and the *Controlled Substances (Poisons) Regulations 2011* regulate the supply and prescribing 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 (available via www.legislation.sa.gov.au), and where necessary advice sought from Drugs of Dependence Unit staff and or the medical practitioner's legal representative.

References to

"SECTIONS" refer to those parts of the *Controlled Substances Act 1984* and

"REGULATIONS" refers to those parts of the *Controlled Substances (Poisons) Regulations 2011*.

"Medical Practitioner" refers to a person registered under the *Health Practitioner Regulation National Law (South Australia) 2010*. [SECTION 4]

This circular should be read in conjunction with the circular "*Treatment with a Drug of Dependence*", also available from the Drugs of Dependence Unit website.

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
- > Schedule 8 / Controlled Drug or Drug of Dependence – As for S4 but because of their high abuse potential, additional controls are required.

"Prescription Drugs" refer to S4 & S8 drugs. [REGULATIONS 5, 6 and 7]

Prescription Drug Controls

- > Possession, prescribing, supply & administration of S4 & S8 drugs are prohibited.
- > Medical Practitioners are exempted only while acting in the ordinary course of their profession.
- > Patients are exempted where they have been lawfully prescribed and supplied the drug. [SECTIONS 18 & 31]

A medical practitioner must not (unless an emergency exists) prescribe or supply a drug of dependence:

- > To treat him or herself; [REGULATION 37]
- > for the treatment of his or her spouse, domestic partner, parent, grandparent, child, grandchild, brother or sister unless authorised by the Minister; [REGULATION 37]
- > to a patient where the medical practitioner knows or has reason to believe the person is drug dependent without authority from the Minister; [SECTION 18A]
- > for a patient who has received drugs of dependence regularly for a period exceeding two months without authority from the Minister. [SECTION 18A]

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Purchase of drugs for use in medical treatment [REGULATION 40]

- > A medical practitioner may purchase S4 and S8 drugs by written and signed order (not prescription) from a licensed wholesaler or pharmacy.
- > The use of these drugs must be recorded and accounted for.
- > Drugs are to be purchased in the name of the medical practitioner and he or she takes responsibility for them.
- > If drugs are to be purchased in the name of the practice, the practice must hold a license to possess such drugs.

Storage [REGULATION 27]

- > S4 drugs must be stored to prevent public access.
- > S8 drugs must be stored to prevent unauthorised access.
 - o Must be in a locked cabinet.
 - o If more than 15 doses, must be in a metal safe (unless supervised at all times)
 - o Refer to the *Code of Practice for the Transportation and Storage of Drugs of Dependence* – available on the SA Health website (www.sahealth.sa.gov.au – search controlled substances legislation)

Record keeping

- > S4 & S8 drugs – must record in the patient file drugs provided to the patient
- > S8 drugs – medical practitioners must maintain a drug of dependence register and record all transactions (including administration). [REGULATION 42]
- > All records must be kept a minimum of two years from date of last entry on the record. [REGULATION 49]

Administration of Drugs of Dependence in a Health Service Facility [REGULATION 44]

- > Administration orders must be in writing and signed by the Medical Practitioner.
- > Verbal administration orders are permitted but must be repeated to a second person and signed within 48 hours.
- > Administration must be witnessed by another person and both persons must sign the drug register.

Supply of a drug [REGULATION 26]

- > Drugs must be labelled. The label when supplied by a medical practitioner to a patient must be
 - (a) the original manufacturers' label or
 - (b) the label to include the drug name, strength and form, dosing instructions for safe use, the name of the patient, the date supplied, an identifier to link to the prescription and the (business) name and address of the supplier.
- > Warning labels such as a drowsiness warning label may be required.

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Prescribing [REGULATIONS 33 & 34]

- > Prescriptions for S4 & S8 drugs must be legible, written in ink and include the^{**}:
 - Name, address and telephone number of the prescriber,
 - Date the prescription was written,
 - Full name and address of the patient,
 - 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 for S4 and S8 drugs are valid for a period of 12 and 6 months, respectively, from the date of prescribing.
- > Prescriptions may be written by computer or other aid but must include the personal signature of the prescriber.

Destruction of a Drug of Dependence [REGULATION 45]

- Destruction must not occur unless witnessed by another 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 [REGULATION 48]

Vicarious Liability [REGULATION 50]

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

Administrative and other powers of the Drugs of Dependence Unit

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 medical practitioner to handle these drugs. Other courses of action may include prosecution and or reporting the alleged conduct to the Australian Health Practitioner Regulation Agency.

Medical practitioners are encouraged to telephone the Drugs of Dependence Unit (**Phone 1300 652 584**) to discuss cases where guidance or advice is required.

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Special provision relating to certain drugs

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 & gynaecological unit in a teaching hospital. [REGULATION 19]

(b) Retinoids

Acitretin, bexarotene, etretinate and isotretinoin (for internal use) 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. Tretinoin (for 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 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 (Section 19, Therapeutic Goods Act 1989 Cth). 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. [SECTION 18A]

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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. [SECTION 30]
- > Medical Practitioners should take all reasonable actions to ensure they are treating a genuine medical condition and treatment or prescribing 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.
- > Prescribing or 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 medical practitioner to handle prescription drugs. [SECTION 57(1)]
- > Medical Practitioners may contact the Drugs of Dependence Unit (1300 652 584) 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” to Medical Practitioner from time to time listing those major drug seekers at the time with the aim to restrict or stop further supplies of drugs to those persons. [SECTIONS 58]
- > The Commonwealth Medicare Australia’s Prescription Shopper Information Service (1800 631 181) may also be contacted to determine if a person has been identified as a drug-seeker (practitioners will first have to register with Medicare Australia for this service).

For more information

Drugs of Dependence Unit

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Rundle Mall ADELAIDE SA 5000

Telephone: 1300 652 584 (Office hours)

Fax: 1300 658 447

Email: HealthDrugsofDependenceUnit@sa.gov.au

www.sahealth.sa.gov.au/drugsofdependence

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