

Drugs of Dependence Unit

The Controlled Substances Act 1984

Dentists' 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 dental practitioner's legal representative.

References to:

"SECTIONS" refer to sections of the Controlled Substances Act 1984 and

"REGULATIONS" refers to regulations within the Controlled Substances (Poisons) Regulations 2011.

The term "Dentist" refers to a person registered as a Dentist under the Health Practitioner Regulation National Law (South Australia) Act 2010. ^[SECTION 4]

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

- > Schedule 2 / Pharmacy Medicine – Available from Pharmacies and Medicine Sellers – Pharmacist advice should be available
- > Schedule 3 / Pharmacist Only Medicine – Available from Pharmacies 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 – Available pharmacies only - 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 and accountability is required.

Prescription Drugs are S4 & S8 drugs. ^[REGULATION 5, 6 & 7]

Prescription Drug Controls

- > Possession, prescribing, supply & administration of S4 & S8 drugs is generally prohibited.
- > Dentists 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]
- > Dental therapists, dental hygienists and oral health therapists may purchase, and administer local anaesthetics S4 drugs. ^[REGULATION 18]

A dentist 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]
- >

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- > 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]

Purchase ^[REGULATION 40]

- > A Dentist may purchase S4 & S8 drugs by written and signed order from a licensed wholesaler or pharmacy.
- > The use of these drugs must be recorded and accounted for.
- > Drugs must be purchased in the name of the Dentist and he or she takes responsibility for them.
- > If drugs are to be purchased in the name of the dental practice, the practice must obtain a license to possess such drugs.

Storage ^[REGULATION 27] & **Code of Practice for the Storage & Transport of Drugs of Dependence**]

- > 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)

Record keeping

- > S4 & S8 drugs - must record in the patient file drugs provided to the patient
- > S8 drugs - must maintain a drug of dependence register and record all drug 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 (S8) in a Health Service Facility ^[REGULATION 44]

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

Prescribing ^[REGULATIONS 33 & 34]

- > Prescriptions for S4 & S8 drugs must include:
 - o The name, address and telephone number of the prescriber,
 - o The date on which the prescription is written
 - o The words "For dental treatment only"
 - o The full name and address of the patient,
 - o The name of the drug and if necessary, the strength and form of the drug,
 - o The dosage instructions for the safe use of the drug,
 - o The quantity to be dispensed and
 - o The personal signature of the prescribing dentist

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- > For Drugs of Dependence (S8 drugs) must also include:
 - o The date of birth of the patient,
 - o The quantity in words and numerals and
- > Prescriptions are valid for 12 months from the date of prescribing and 6 months in the case of S8 drugs.

Prescribing and supplying dental patients with drugs of dependence

Prescribing and supplying drugs of dependence for a patient who has received drugs of dependence regularly during a period exceeding two months (including from other prescribers); or the dentist knows, or has reasonable cause to believe, is drug dependent, requires an authority from the Minister. – see Circular: Treatment with a Drug of Dependence ^[SECTION 18A]

Labelling of drugs supplied by a dentist ^[REGULATION 26]

Drugs must be labelled. The label must be the original manufacturers' label or the label must include the drug name, strength and form, dosing instructions for safe use, the name of the patient, the date supplied and the (business) name and address of the supplier. Warning labels such as a drowsiness warning label may be required.

Dental Therapists, Dental Hygienists, Oral Health Therapists

A Dental Therapist, Dental Hygienist or Oral Health Therapist is permitted to purchase, possess and administer to his or her patients a Schedule 4 anaesthetic drug if listed in the Regulations. ^[REGULATION 18]

The anaesthetic must be one of the following Schedule 4 drugs:

Articaine	Benzocaine	Bupivacaine	Levobupivacaine
Lignocaine	Mepivacaine	Prilocaine	Ropivacaine

Destruction of Drugs of Dependence ^[REGULATION 45]

- > Must not pose a threat to public health or safety ^[REGULATION 48]
- > Destruction must not occur unless witnessed by another dentist, 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.

Vicarious Liability ^[REGULATION 50]

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

Administrative Powers

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

Dentists 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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Examples of Drugs of Dependence

	<i>Generic Name</i>	<i>Trade or Proprietary Names</i>
1. OPIOIDS	<i>buprenorphine</i> <i>codeine (with no other active drug)*</i> <i>fentanyl</i> <i>hydromorphone</i> <i>methadone</i> <i>morphine</i> <i>oxycodone</i> <i>pethidine</i> <i>remifentanyl</i>	<i>Norspan, Subutex,</i> <i>Suboxone, Temgesic,</i> <i>Linctus Codeine</i> <i>Durogesic, Actiq</i> <i>Dilaudid, Dilaudid HP, Jurnista</i> <i>Biodone Forte, Physeptone, Methadone Syrup</i> <i>Anamorph, DepoDur, Kapanol, MS Contin, MS Mono</i> <i>Ordine, Sevredol, Momex</i> <i>Endone, OxyContin</i> <i>Oxynorm, Proladone</i> <i>Ultival</i>
2. STIMULANTS	<i>cocaine</i> <i>dexamphetamine</i> <i>methylphenidate</i>	 <i>Attenta, Concerta, Ritalin</i>
3. SEDATIVES	<i>alprazolam (from 1 February 2014)</i> <i>flunitrazepam</i> <i>pentobarbitone (except for injection)</i>	<i>Xanax, Kalma</i> <i>Hypnodorm,</i> <i>Pentone</i>
4. OTHER	<i>ketamine</i>	<i>Ketalar</i>

*Codeine when combined with another therapeutically active ingredient such as aspirin or paracetamol (eg Codral Forte®, Mersyndol Forte® and Panadeine Forte®), is not included as a drug of dependence.

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Examples of Schedule 4 Drugs

<i>(Trade or Proprietary Names)</i>		
<i>Antibiotics</i>	<i>Antibiotics</i>	
<i>Sedatives</i>	<i>Benzodiazepines</i>	
<i>Analgesics</i>	<i>Codeine 30mg when combined with another active ingredient</i>	<i>Panadeine Forte, Mersyndol Forte</i> <i>Codral Forte</i>
<i>Anaesthetic agents</i>	<i>Nitrous oxide,</i>	
<i>Local Anaesthetics</i>	<i>Lignocaine >10%</i>	

For more information

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