

# THE HEALTH (DRUGS AND POISONS) REGULATION 1996

What Pharmacists Need to Know

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Drugs & Poisons Policy & Regulation Unit Environmental Health Branch

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FAX: (07) 3328 9354 The Health (Drugs and Poisons) Regulation 1996 and the Health Regulation 1996 are made under the provisions of the Health Act 1937. What Pharmacists Need to Know is a Queensland Health resource aimed at providing pharmacists with a quick reference guide to relevant provisions of the regulations and pharmacists' obligations under the Act.

Queensland Health looks forward to further promoting and maintaining a strong working relationship with the Queensland pharmacy profession to realise our mission of promoting, maintaining and improving the health and well-being of all people in Queensland.

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## Introduction

Queensland pharmacists have many responsibilities and obligations under the *Health (Drugs and Poisons) Regulation 1996* ("the Regulation") and the *Health Regulation 1996*. This booklet has been developed to provide pharmacists with a guide to the main regulatory provisions impacting on the practice of pharmacy. Included in Appendix A is a quick index to the *Health (Drugs and Poisons) Regulation 1996*. This document is not an extract from the Regulation or a summary of all important or relevant information. The Regulation should be used if legal interpretations are required.

The terms 'controlled drug' and 'restricted drug' are used throughout this document and refer to Schedule 8 and Schedule 4 substances respectively. The schedules are contained in the *Standard for the Uniform Scheduling of Drugs and Poisons* (SUSDP).

Both regulations listed above are available on the internet at www.legislation.qld.gov.au. The *Pharmacists Registration Act 2001* and *The Pharmacists Registration Regulation 2001* can also be accessed from this website. The SUSDP is available from National Marketing and Mailing Pty Ltd, by phoning (02) 6269 1000.

## Drugs and Poisons Policy and Regulation Unit Environmental Health Branch Queensland Health

The Drugs and Poisons Policy and Regulation Unit is responsible for the maintenance of the drugs, poisons and therapeutic goods regulatory system in Queensland. This includes the setting of strategic policy, co-ordination of state-wide and area-wide compliance and enforcement activities, undertaking special investigations and development and review processes relative to the program area's legislation, namely relevant parts of the *Health Act 1937*, the *Pest Management Act 2001* and regulations, the *Health (Drugs and Poisons) Regulation 1996 and* the *Health Regulation 1996*.

## **General endorsements**

Sections 64, 171, 257 and 258 of the Regulation

A pharmacist is authorised only to the extent necessary to practise pharmacy, and subject to the provisions of the Regulation, to;

- a) obtain, possess, dispense or sell (other than by wholesale) on a purchase order a controlled drug and/or a restricted drug
- b) dispense or sell (other than by wholesale) an S2, S3 or S7 poison at a dispensary
- c) for a pharmacist practising pharmacy at a public sector hospital, supply a controlled drug and/or restricted drug, on the oral or written instruction of a doctor or nurse practitioner, to a person being discharged from the hospital or an outpatient of the hospital
- d) administer or supply a controlled drug and/or a restricted drug, under a drug therapy protocol, on the oral or written instruction of a doctor who holds a treatment approval
- e) during a declared public health emergency in relation to an infectious medical condition, a pharmacist is authorised to administer or supply oseltamivir or zanamivir under a drug therapy protocol.

A trainee pharmacist is authorised to;

- a) possess a controlled drug and/or a restricted drug at a dispensary under a pharmacist's direction
- b) dispense a controlled drug, a restricted drug and/or an S2 or S3 poison at or from a dispensary under a pharmacist's direction and personal supervision
- c) administer a controlled drug and/or a restricted drug under a drug therapy protocol at a dispensary under a pharmacist's direction and personal supervision
- d) sell an S3 poison at a dispensary under a pharmacist's direction and personal supervision
- e) sell an S2 or S7 poison at a dispensary under a pharmacist's direction.

A competent adult employee of a pharmacist is authorised to sell an S2 or S7 poison at a dispensary.

## Prescribing information for pharmacists

#### Who can prescribe drugs and scheduled poisons

For more detail on the restrictions to the prescribing authorities below, refer to Appendix B.

- Dentists restricted drugs; S2 and S3 poisons; some controlled drugs
- Medical doctors controlled drugs; restricted drugs; S2, S3 and S7 poisons
- Optometrists some restricted drugs (with limitations)
- Nurse practitioners controlled drugs, restricted drugs and S2 and S3 poisons (with limitations)
- Surgical podiatrists some controlled drugs, restricted drugs and S2 and S3 poisons as detailed in Appendix 2B of the Regulation
- Veterinary surgeons controlled drugs; restricted drugs; S2, S3 and S7 poisons

#### Who cannot prescribe drugs and scheduled poisons

Generally, any person or professional not listed above is not authorised under the Regulation to prescribe a controlled drug, a restricted drug or any other scheduled poison. This includes chiropractors, naturopaths, homeopaths, physiotherapists, podiatrists other than a surgical podiatrist, nurses other than nurse practitioners or optometrists who do not hold prescribing authority. A 'doctor' refers only to a medical doctor.

#### **Optometrist prescribing list**

#### Section 170

In March 2005, amendments were made to the Regulation to allow optometrists in Queensland to use and prescribe approved restricted drugs for the treatment of ocular disorders in accordance with the Ocular Therapeutics Protocol. This protocol was developed by the Optometrists Board of Queensland and states the circumstances and conditions under which an optometrist may administer, supply or prescribe a restricted drug and also states the qualifications that an optometrist must attain before doing so.

Of important note, optometrists must not administer, supply or prescribe a restricted drug unless they are endorsed by the Optometrists Board of Queensland to do so. Approved registrants will have a qualification on the register that reads "Therapeutically Endorsed". An optometrist must complete an approved course in ocular therapeutics in order to become endorsed.

A list of therapeutically endorsed optometrists and a list of registered restricted drugs which may be prescribed are available on the Pharmacists Board of Queensland website at www.pharmacyboard.qld.gov.au. These and the Ocular Therapeutics Protocol are available from the Optometrists Board of Queensland at www.optomboard.qld.gov.au.

## Regulated restricted drugs

Sections 185 - 189 of the Regulation

Some Schedule 4 restricted drugs are regulated and may not be prescribed by all doctors. These drugs and the conditions under which they may be prescribed are detailed in sections 185 to 189 of the Regulation. Generally, these may be prescribed only by certain classes of medical specialists or following approval by Queensland Health.

These regulated restricted drugs include:

- acitretin, etretinate, isotretinoin and tretinoin
- thalidomide
- bexarotene
- dinoprost and dinoprostone
- urofollitropin (Human FSH), luteinising hormone, clomiphene (clomifene) and cyclofenil
- clozapine
- bosentan
- teriparatide.

The Pharmaceutical Society of Australia (Queensland Branch) publishes a poster guide to regulated restricted and regulated controlled drugs for quick reference in the pharmacy. Copies are available from the PSA ph: (07) 3844 4900.

## Medical Board of Queensland

The Medical Board of Queensland website has a link to search for registration details of a medical practitioner.

www.medicalboard.qld.gov.au

#### Office of Health Practitioner Registration Boards

The Office of Health Practitioner Registration Boards website has links to search registration boards to ascertain if health professionals other than medical practitioners, including those with and without prescribing authorities, are registered to practice and prescribe in Queensland. www.healthregboards.qld.gov.au

The Pharmacists Board of Queensland has a link to search for registration details of pharmacists. www.pharmacyboard.qld.gov.au

## **Dispensing information for pharmacists**

## Ensuring prescriptions comply with the Regulation

Sections 82 and 193 of the Regulation

A pharmacist must ensure that a prescription is legitimate and complies with the Regulation (sections 79, 80, 190 and 191) before it may be dispensed. If a prescription does not comply, the pharmacist should contact the prescriber so that the prescription can be amended or re-issued. A pharmacist is not authorised to alter a prescription or dispense a prescription that appears to be

altered by someone other than the prescriber. A prescriber must initial and date any amendments made on a prescription.

## Quality standards for dispensing controlled and restricted drugs

Sections 4A, 81A 192A and 273A of the Regulation

A pharmacist must not dispense a controlled drug or restricted drug or sell an S2 or S3 poison unless the pharmacist:

- has prepared or adopted a quality standard for dispensing or selling these drugs; and
- complies with the quality standard when dispensing or selling these drugs.

A quality standard may be prepared by the pharmacist or adopted from an organisation (i.e. PSA or QCPP). If the Pharmacists Board of Queensland recognises a quality standard, then the quality standard prepared by the pharmacist must be at least equivalent to the recognised standard. Section 4A of the Regulation gives a description of a quality standard and states the principles that should lie behind the quality standards.

The Pharmacists Board of Queensland has endorsed the Pharmacy Guild of Australia Quality Care Pharmacy Program and the Pharmaceutical Society of Australia quality standards relevant to these sections. A pharmacist adopting and following either of these quality standards is complying with the Regulation in this regard.

## Length of time a prescription is valid

Sections 82(2)(g) and 193(2)(g) of the Regulation

A prescription for a controlled drug or a restricted drug, including any repeats, is valid for one year from the date it was written.

## **Oral and faxed prescriptions**

Sections 81 and 192 of the Regulation

An oral prescription may be given by a doctor for a controlled or restricted drug if the doctor believes an emergency exists to do so. The prescription must be written and sent within 24 hours of the oral prescription being given, and received by the pharmacist within 72 hours, otherwise the pharmacist must provide a written report to the Chief Executive of Queensland Health.

Queensland Health's legal and policy position on the issue of faxed prescriptions is that all pharmacists must receive the original prescription from the doctor before dispensing (handing over) the medication. This does not apply to the supply of medications in an emergency situation. (See Emergency Supply below).

## **Emergency supply**

Section 194 of the Regulation

A pharmacist may dispense a restricted drug without a prescription if an emergency exists, the person is under medical treatment requiring the drug, and the drug is necessary for the person's continuing care. The maximum quantity that may be dispensed for an emergency supply is three (3) days' treatment or, in the case of a pre-packed liquid, cream, ointment or aerosol, the minimum standard pack. The details of all emergency supplies must be recorded as outlined in section 194 of the Regulation.

A pharmacist must not dispense an emergency supply of a controlled drug. If a person requires a controlled drug, a pharmacist must first obtain a written or an oral prescription from a doctor.

## **Dispensing interstate prescriptions**

Section 82 and 196 of the Regulation

A pharmacist may dispense prescriptions written by a doctor, dentist or veterinary surgeon registered in another State, but not if the prescription is written for:

- controlled drugs
- regulated restricted drugs
- anabolic steroids
- diethylpropion
- ephedrine
- phentermine
- pseudoephedrine.

## Trainee pharmacists

Appendix 9 of the Regulation

A 'trainee pharmacist' is defined under the Regulation as a person undertaking a training course at a location mentioned in Schedule 1 of the *Pharmacists Registration Regulation 2001*.

## Dispensary requirements

Section 25, schedule 4 & schedule 5 of the Health Regulation 1996

The occupier of a dispensary must ensure the following items are available at the dispensary:

- a refrigerator, fitted with a device capable of registering the minimum and maximum temperature, for use for storing therapeutic products at appropriate temperatures
- three metric certified dispensing measures
- a funnel
- two spatulas
- a tablet counting tray
- a current copy of each of the following documents:
  - the Health (Drugs and Poisons) Regulation 1996
  - the Standard for the Uniform Scheduling of Drugs and Poisons
  - the register of medical practitioners, Queensland
  - the register kept under the Dental Practitioners Registration Act 2001, section 215
  - the roll of veterinary surgeons of Queensland.

Documents may be electronic in form.

If a dispensary is used to dispense an extemporaneous preparation, the occupier must ensure the following additional items are available at the dispensary:

- a set of mechanical or electronic counter scales, capable of weighing up to 1kg with an appropriate set of metric weights (if necessary)
- a dispensing balance capable of weighting up to 50g that is either electronic or mechanical with an appropriate set of metric weights (if necessary)
- a certified 10mL, 20mL, 50mL, 100mL, 200mL and 1L dispensing measure
- a mortar and pestle
- a stirring rod

- an ointment slab
- an electric or gas heating appliance for use in dispensing a drug or poison.

## Supplying scheduled poisons to businesses and the public

#### Selling drugs on a purchase order

Sections 89, 90, 93, 200, 201, 203 and Appendix 3 of the Regulation

A pharmacist may sell a controlled drug to an approved person only on a purchase order that contains the following information:

- the date it is written
- the name and address of the person placing the order
- the description and quantity or volume of the controlled drug
- a distinguishing purchase order number used by the purchaser
- the signature of the dentist, doctor, pharmacist or veterinary surgeon placing the order, or

the signature of the relevant person as detailed in appendix 3 of the regulation.

If the purchase order is placed by:

- an optometrist it must have 'section 170' written on it
- a podiatrist it must have 'section 172' written on it
- a surgical podiatrist it must have 'section 172A' written on it.

The pharmacist must write on the front of the purchase order the date the drug is sold, the name and address of the dispensary at or from which the drug is sold and sign the order. If the purchase order is for a controlled drug or a regulated restricted drug, the pharmacist must send the purchase order to the Chief Executive within fourteen days after selling the drug. A purchase order for a restricted drug must be kept at the pharmacy for two years after the date the drug was sold.

#### Selling drugs by wholesale

Sections 17, 49, 143, 230 and Appendix 2 of the Regulation

The general authorities for the sale of scheduled drugs by pharmacists do not include undertaking wholesale sales of scheduled drugs and poisons to other businesses. For this, a pharmacist requires a wholesale licence. Contact Drugs and Poisons Policy and Regulation to obtain an application form. A wholesale licence is not required for the supply of drugs for doctors' bags.

#### Selling S2 and S3 poisons to children under 16 years

Section 286 of the Regulation

A pharmacist must not dispense or supply an S2, S3, S6 or S7 poison to a child under 16 years, unless the pharmacist is acting on a prescription or a doctor's/nurse practitioner's written instruction at a hospital. A pharmacist should always consider their professional and ethical obligations when placed in the position of aiding or dealing with a child.

## Dispensing to ships' masters

#### Sections 69, 178, 264A and 277 of the Regulation

A pharmacist may sell a controlled drug or a restricted drug to a ship's master on a purchase order, if the pharmacist has prior written approval from Queensland Health to do so. Purchase orders for controlled and restricted drugs must be signed by the ship's master if the drugs are listed in those allowed under the *Navigation Act 1912* or the *Transport Operations (Marine Safety) Act 1994*. For controlled drugs or restricted drugs not provided for under these Acts, a doctor must sign the purchase order.

A pharmacist may sell an S2 or S3 poison to a ship's master on a purchase order signed by the ship's master. For the requirements for the sale of an S3 poison for first aid use on a ship, refer to section 277 of the Regulation.

## Selling S3 salbutamol and S3 terbutaline for first aid

#### Section 256B and 277 of the Regulation

A pharmacist or wholesaler may sell S3 salbutamol or S3 terbutaline to persons with certain asthma management training for the purpose of possessing these medications at a workplace or community event in the event that it is necessary to perform first aid. The purchaser must hold an asthma management qualification approved by the Chief Executive. The pharmacist must be satisfied that the purchaser holds this qualification before supplying. The sale of these scheduled medications for this purpose is exempt from the labelling and counselling requirements outlined in Section 277 of the Regulation.

#### Advertising of drugs and scheduled poisons

## Sections 131, 220 and 292 of the Regulation

The advertising of controlled drugs, restricted drugs and some Schedule 3 poisons to the general public is prohibited in Queensland under the Regulation. However, advertising of price lists that comply with the Queensland Health Price Information Code of Practice is permitted. This code allows retail pharmacies to provide price information for medicines and details conditions under which this may be advertised to the general public. The code can be accessed via the Queensland Health website www.health.qld.gov.au

## **Drugs of dependence**

## **Recognising impairment and dependence**

Many drugs can be misused and occasionally pharmacists can be asked to dispense or supply medications that may be misused by people they suspect are drug dependent. Pharmacists can sometimes be faced with a difficult situation when exercising their duty of care and responsibility in deciding whether or not to supply or dispense medication. There are some behaviours that may be suggestive of a person with drug dependence. For example:

- presenting prescriptions for controlled drugs or restricted drugs of dependency from multiple doctors (doctor shopping)
- attempting to fill a repeat prescription for a controlled drug within the specified time frame between dispensings
- regular purchase of over-the-counter medications containing substances which may be abused, such as codeine or sedating antihistamines.

If a pharmacist suspects drug seeking behaviour, there are options which may assist the person in getting the help and support they need, rather than just allowing or denying the supply of the medication. The use of appropriate discussion with the patient is useful in establishing if there are any causes for concern around a person's drug use. It is also appropriate to discuss any concerns with the patient's treating medical practitioner and inform the Drugs of Dependence Unit on ph: (07) 3896 3900. Patients can also be referred to the Alcohol and Drug Information Service (ADIS) on ph: (07) 3837 5989.

## **Doctor/prescription shopping**

Sections 197, 212, 213 and 213A of the Regulation

There are provisions under the Regulation to limit a person obtaining multiple prescriptions for drugs of dependency from several prescribers. A person must not obtain a controlled drug or a restricted drug of dependency, or a prescription for these from a doctor without disclosing the details of all the controlled drugs, restricted drugs of dependency and prescriptions for these obtained in the two months prior to the consultation. A doctor or a dentist must have approval from Queensland Health before he or she may prescribe, supply, dispense or administer a controlled drug or a restricted drug of dependency to a drug dependent person.

If a pharmacist is asked to dispense more of a restricted drug of dependency for a person than appears to be reasonably necessary, or more frequently than appears to be reasonably necessary, the pharmacist must immediately give the Chief Executive a written notice about the circumstances and the quantity, volume or time that is was dispensed for the person. If a pharmacist suspects that a person is obtaining prescriptions for controlled drugs from multiple doctors illegitimately, they should contact the Drugs of Dependence Unit.

## Presentation of forged prescriptions

Sections 82 and 193 of the Regulation

The most common drugs appearing on forged or altered prescriptions are the higher strength slowrelease morphine and oxycodone preparations, followed by other controlled drugs. It is important to remember that a prescription must not be dispensed unless it contains all the information required by the Regulation.

If there is any suspicion as to the validity of a presented script:

- contact the prescriber to confirm *all* of the details are as originally prescribed
- avoid alerting the patient of any suspicion.

In the event that the validity of a prescription cannot be verified (eg after hours), the pharmacist must retain the prescription for the time reasonably necessary to confirm it is genuine.

If the prescription is believed to be forged or altered in any way:

- the prescription should be immediately cancelled by indicating on the prescription that it is not to be dispensed, writing the date, name or initials of the pharmacist and the name and address of the pharmacy
- the prescription should not be given back to the person. If the prescription is returned to the person in the interest of personal safety, a copy should be made or details recorded
- record details of the incident, a description of the person or confirmation of identity and any other useful information that may be obtained, such as a licence plate number
- contact the local police to report the incident
- inform the Drugs of Dependence Unit of these details and whether or not the prescription was dispensed, on ph: (07) 3896 3900.

It is important that pharmacists always consider the safety of themselves, their staff and other people.

There are some circumstances that may alert the pharmacist to a possible forged prescription:

- the time of presentation of a forged prescription is often after hours when the prescriber cannot be contacted
- the patient may attempt to make verification of the prescription difficult
- the prescriber or surgery address appearing on the prescription is located a significant distance from the pharmacy where the forged prescription is presented
- the prescriber's contact phone number is a mobile phone number or the prescriber may appear to be expecting a phone call
- the prescriber is unknown to the pharmacy
- the patient has no previous medical history with the pharmacy
- the patient does not have proof of identification or may be acting as a 'carer'
- the prescription is for unusually larger quantities of drugs than would be necessary and the patient may be unconcerned with the price (eg. expensive private prescriptions for anabolic steroids)

In the case of forged computer generated prescriptions:

- the prescriber's name may be genuine but the prescriber is unknown to the surgery at the specified address
- the printed details are not properly aligned on the prescription.

Pharmacies which have been successfully deceived are likely to be repeatedly targeted.

## Restricted drugs of dependency

Appendix 8 of the Regulation lists the restricted drugs of dependency. These are Schedule 4 medications with tighter controls relating to prescribing and generally include benzodiazepines. See 'doctor/prescription shopping'.

## Drug misuse by doctors

The identification and treatment of doctors who are drug dependent is a complex issue, with the Medical Board of Queensland and the Drugs of Dependence Unit both trying to protect the community from associated harm, as well as looking after the current and future welfare of the doctor concerned.

## Pharmacists' role

Pharmacists are in an ideal position to recognise other health professionals who may be misusing prescription medications. In many cases, community pharmacists are the primary reporters of self-administering doctors. Injectable pethidine is the most commonly misused drug by doctors, followed by morphine and other controlled drugs.

Early detection is paramount for the treatment of these impaired doctors, and detection and advice received from pharmacists in the community is a valuable resource in addressing this difficult problem.

If you notice any suspicious behaviour or irregular prescribing patterns by a doctor, it is important to report these activities to the Drugs of Dependence Unit. Many impaired doctors usually display similar behaviour and some of the following activities could be issues of concern:

• ordering large amounts of injectable controlled drugs (pethidine, morphine) for surgery use

- personally collecting patients' medication
- prescribing drugs that may be misused for family members or clinic staff
- personally presenting at unusual hours to either collect or order drugs
- regular restocking of particular controlled drugs for doctor's bags (eg, morphine ampoules).

This is not an exclusive list and does not apply to doctors who carry out these activities infrequently. A pharmacist may contact the Drugs of Dependence Unit if he or she is concerned about the activities of a doctor on ph: (07) 3896 3900.

## **Queensland Opioid Treatment Program**

Opioid substitution treatment decreases the risks associated with illicit drug use for the individual and the community at large. It is a specific treatment modality for people with opioid dependence, in particular heroin. Opioid treatment in Queensland is most commonly provided through Alcohol, Tobacco and Other Drug Services and approved general practitioners. Public treatment services are typically staffed by prescribing doctors, nurses and allied health professionals who provide a range of services (eg. counselling/psychotherapy, general medical care, psychiatric treatment, social services).

Methadone and buprenorphine are prescribed to help stabilise the lives of drug dependent people, remove them from the illicit drug taking milieu, reduce their need to engage in criminal activity to support their illicit drug use and reduce their risk of contracting blood borne viruses (Hepatitis C and HIV) from injecting drug use.

Pharmacists can participate in the supply and administration of methadone and buprenorphine, when in accordance with a drug therapy protocol.

For further information about participating in the Queensland Opioid Treatment Program, contact the Drugs of Dependence Unit, on ph:(07) 3896 3900.

## Pharmacists' role

Pharmacists play a key role in the delivery of opioid treatment services, both in terms of providing a more structured environment and by being flexible and convenient for patients who can be dosed near to where they live or work. Generally the pharmacist:

- develops a positive relationship with the patient
- monitors the patient's day to day level of intoxication
- dispenses/supplies the dose
- seeks to ensure that the dose has been appropriately ingested and not diverted
- encourages the patient to take the dose at approximately the same time each day
- maintains contact with the prescriber regularly to report signs of intoxication, other drug use, non-attendance for dosing and any problems or crises that may present.

#### Methadone, buprenorphine and the PBS

Methadone and buprenorphine are listed in the Pharmaceutical Benefits Schedule for the treatment of opioid dependence, as the Commonwealth Government provides funding for the Opioid Dependence Treatment Program under Section 100 of the Pharmaceutical Benefits Scheme.

## Recording doses of methadone and buprenorphine

Section 87(2) of the Regulation

If supplying or administering a controlled drug on a written instruction under a drug therapy protocol, the transaction must be recorded no later than seven days after the end of the month in which the final administration or supply of the drug occurred. Individual doses of methadone and buprenorphine can be recorded on the doctor's written instructions and the full quantity can be made as one entry in the controlled drug book each month.

## Queensland needle and syringe program

Queensland Health and the Pharmacy Guild of Australia oversee a needle and syringe program to reduce the spread of blood-borne viral infections among injecting drug users, and thereby the general community. The program supplies sterile injecting equipment while incorporating health promotion strategies aimed at improving the health of injecting drug users and reducing risk behaviours associated with injecting drug use. A focus of the program has been developing partnerships with the community to respond to community concerns, such as inappropriate disposal of used injecting equipment.

The Pharmacy Guild of Australia produces an information booklet for pharmacists and a series of calender cards for injecting drug users who access Queensland pharmacies. Contact the Queensland Branch of The Pharmacy Guild of Australia or Queensland Health for more information.

Queensland Branch The Pharmacy Guild of Australia (07) 3831 3788 guild.qld@guild.org.au www.guild.org.au/qld/

Resource Development Officer Queensland Needle and Syringe Program (07) 3896 3715 qnsp@health.qld.gov.au www.health.qld.gov.au

## **Controlled drugs**

## Multiple items on a controlled drug prescription

Section 79 of the Regulation

A prescription for more than one controlled drug may only be dispensed if the items are the same generic drug. For example, a script may be dispensed if it prescribes both oxycodone immediate release and a slow release oxycodone preparation. If the prescription prescribes more than one item, each item must be numbered consecutively and a line must be ruled under the last item.

## Time intervals between repeats

Sections 79 and 82 of the Regulation

A prescription for a controlled drug must state the time that must elapse between each dispensing of the drug. A pharmacist must not dispense the drug earlier than the time frame stipulated on the prescription.

## Keeping records

Sections 86, 87, 99, 133, 199 and 302 of the Regulation

The pharmacist or the authorised person who dispenses a controlled drug must personally record the transaction on the day of the transaction. Controlled drugs records must be kept in good condition for two years after the last entry that is made. This also applies to records required for restricted drugs and other scheduled poisons.

## Negative stock entries in a controlled drugs record book

Negative stock entries in a controlled drug book should not occur. If a pharmacist does not have enough stock to dispense a prescription, a pharmacist should not record a negative entry to account for stock owed to a patient, but should use the same prescription number for two separate entries.

## Purchasing a controlled drugs record book

A controlled drugs register which meets the legislative requirements for a controlled drugs record book can be purchased from The Pharmacy Guild of Australia. When ordering, the Queensland version should be specified to ensure the register meets the requirements of the Regulation.

## Procedures for the destruction of controlled drugs

Sections 86 and 99 of the Regulation

If a controlled drug is returned to the pharmacy for destruction, the pharmacist must record it in the controlled drugs record book. Drugs returned for destruction can be recorded on a single page in the controlled drugs record book. For detailed procedures on the destruction of controlled drugs, see Appendix C.

## **Delivery of controlled drugs**

## Sections 91 and 92 of the Regulation

Controlled drugs may be sent by registered post or a carrier or transport service. The drugs must be contained in a securely closed package containing a packing slip or similar document with 'Controlled drugs – check carefully' printed on it in bold-faced sans serif capital letters with a height of at least 12.5mm. The packing slip must be placed so it is visible as soon as the package is opened. The package must not contain goods other than controlled drugs. The outside of the package should not identify the contents as being controlled drugs. If a description is required, the pharmacist may describe the contents as 'therapeutic goods'.

## Regulated controlled drugs

## Sections 77, 78 and 79 of the Regulation

Section 77 and 78 of the Regulation lists regulated controlled drugs and the conditions under which they may be prescribed and dispensed. It is important that repeat prescriptions for these drugs, like all controlled drugs, are not dispensed within the written time frame specified.

Amphetamine, dexamphetamine, methylamphetamine, methylphenidate and phenmetrazine (specified condition drugs) may be prescribed if:

- the doctor has approval; or
- the drug is for the treatment of narcolepsy, brain damage in a child at least 4 years or attention deficit disorder in a child at least 4 years; or
- the doctor is a paediatrician or child psychiatrist and prescribes the drug for the treatment of brain damage or attention deficit disorder in a child.

The prescription must be annotated with the words 'specified condition'.

Dronabinol may only be prescribed by a doctor or a class of doctors with approval from the Chief Executive and only under the approval. Prescriptions must be annotated with the word 'approved'.

The Pharmaceutical Society of Australia (Queensland Branch) has published a poster guide to regulated controlled and regulated restricted drugs for quick reference in the pharmacy.

## Pseudoephedrine

## Identifying a 'drug-runner'

'Drug-runners' or 'pseudo-runners' attempt to obtain pseudoephedrine-based products from pharmacies to use in the production of illicit amphetamines or to on-sell to other people for this purpose. The practice is often large-scale, systematic and well-organised. Drug-runners are not always easily identifiable as many are experienced at pretending they are genuine customers. They may be a known customer of the pharmacy and will often ask for a pseudoephedrine product by name. Experienced drug-runners will generally know what type of questions will be asked and will avoid pharmacies where the staff is known to be vigilant.

## Dispensing and selling pseudoephedrine

## Sections 196, 277 and 285A of the Regulation

All pseudoephedrine products containing more than 800mg per pack (for liquid preparations) or more than 720mg per pack (for other preparations) are Schedule 4 restricted drugs. All other products containing less than these quantities are Schedule 3. Therefore, from a legal stand point, to sell pseudoephedrine a pharmacist must be presented with a legitimate prescription or follow the Regulation for the sale of S3 pseudoephedrine. For the appropriate sale of S3 pseudoephedrine, Section 277 requires that the pharmacist must be reasonably satisfied that the purchaser has a therapeutic need for the drug and the pharmacist must confirm the purchaser's identity, if not already reasonably sure, with an acceptable form of identification (ie. a driver's license). The pharmacist must also record the transaction in accordance with the Regulation. A pharmacist may not dispense a prescription for pseudoephedrine written by a doctor not registered to practice in Queensland.

## **Project Stop**

Project Stop, an initiative of The Pharmacy Guild of Australia (Queensland Branch), is a webbased program used to record and track sales of pseudoephedrine. It provides pharmacists, police and health authorities with real-time access to suspicious pseudoephedrine reports and enables the tracking of potential 'drug-runners'. Project Stop is a free service and pharmacists do not need to be members of The Pharmacy Guild to access and use the program. A public website with more information has been developed – www.projectstop.com.au. Pharmacists can contact the Project Stop support line on ph: 1300 137 608.

## **Organisations and contacts**

## Pharmacists Board of Queensland

The Pharmacists Board of Queensland is the body responsible for the registration of pharmacists in Queensland. Before a person in Queensland may practice as, or hold themselves out to be, a pharmacist, he or she must first register with the Board. The Board is the statutory authority established to enact the provisions of the Pharmacists Registration Act 2001, Pharmacists Registration Regulation 2002 and the Health Practitioners (Professional Standards) Act 1999.

The Pharmacists Board of Queensland can assist with queries regarding the Pharmacists Registration Act, Special Purpose registration for Queensland, Australian and overseas trained pharmacists and graduates, pre-registration issues relating to registration and other issues associated with registration such as renewals, qualifications, disciplinary issues and complaints.

Office of Health Practitioner Registration Boards GPO Box 2438 **BRISBANE QLD 4001** Registrations: (07) 3225 2532 Board Support: (07) 3247 4866 Professional Adviser – Pharmacy: (07) 3225 2502 pharmacy@healthregboards.qld.gov.au www.pharmacyboard.qld.gov.au

# Pharmaceutical Defence Limited (PDL)

In collaboration with Guild Insurance, PDL can arrange insurance for pharmacists, including professional indemnity. They also offer peer support, legal representation and advice and financial support for pharmacists and pharmacy organisations.

Pharmaceutical Defence Limited has published 'Guidelines to Good Dispensing' and 'Dealing with Complaints', which may be useful to keep in the dispensary or pharmacy.

Pharmaceutical Defence Limited 40 Burwood Road **HAWTHORN VIC 3122** (03) 9810 9900 admin@pdlappco.com.au www.pdl.org.au

## The Pharmacy Guild of Australia (Queensland Branch)

The Guild is a national employers' organisation providing support and representation for pharmacy owners by liaising and negotiating with governments, manufacturers, wholesalers and other organisations in or around the health care delivery system. Branch activities centre on the day-to-day servicing of members in such fields as industrial relations, marketing, staff training and product and economic information.

Queensland Branch 132 Leichhardt St PO Box 457 **SPRING HILL QLD 4004** (07) 3831 3788 guild.qld@guild.org.au www.guild.org.au/qld/

## Pharmaceutical Society of Australia (Queensland Branch) (PSA)

The Pharmaceutical Society of Australia is a national professional organisation for pharmacists in Australia. The society is the leading advocacy organisation for pharmacists, influencing attitudes, opinions and policies through representation, networking, consultation, continuing education, practice support, standards, guidelines and a range of publications and health promoting programs and resources.

Pharmaceutical Society of Australia Queensland Branch

PO Box 8171 WOOLLOONGABBA QLD 4102 (07) 3844 4900 admin@psaqld.org.au www.psa.org.au

## The Society of Hospital Pharmacists of Australia (SHPA)

SHPA specialises in advocacy for the professional interests of hospital pharmacists and technicians, as well as those delivering a full range of professional pharmacy services across the entire health system.

The Society of Hospital Pharmacists of Australia PO Box 1774 **COLLINGWOOD VIC 3066** (03) 9486 0177 shpa@shpa.org.au www.shpa.org.au

## Australian College of Pharmacy Practice and Management (ACPPM)

ACPPM is involved in the development and delivery of education, training and research programs to contribute to the advancement of practice and management within the pharmacy and pharmaceutical industries. It is an autonomous organisation providing vocational and higher education to pharmacists.

ACP National Secretariat Suite 2, 2 Giles Court **DEAKIN ACT 2610** (02) 6273 8989 info@acp.edu.au www.acp.edu.au

# The Association of Professional Engineers, Scientists and Managers Australia (APESMA)

The Pharmacist Division of APESMA represents employee community pharmacists practising in Australia. The objective of the Pharmacist Division is to ensure that employee community pharmacists are remunerated according to their qualifications, skills, responsibility and professional standing and that members have an effective and independent voice in all matters affecting their profession.

Pharmacists Division 163 Eastern Road **SOUTH MELBOURNE VIC 3205** (03) 9695 8836 pharmacist@apesma.asn.au www.apesma.asn.au

Contacts	
АСРРМ	(02) 6273 8989
	info@acp.edu.au
	www.acp.edu.au
APESMA	(03) 9695 8836
	pharmacist@apesma.asn.au
	www.apesma.asn.au
National Mailing and Marketing Pty Ltd - SUSDP	(02) 6269 1000
Drugs and Poisons Policy and Regulation	(07) 3328 9310
- Policy and legislation queries	
- Health (Drugs and Poisons) Regulation, Health	
Regulation information	
Pseudoephedrine Enforcement Taskforce	(07) 3234 1215
- suspected false prescribing or supply of	
pseudoephedrine	(07) 2806 2000
Drugs of Dependency Unit - forwarding of filled controlled drug prescriptions	(07) 3896 3900
- report forged prescriptions, suspected doctor shopping	
- suspected self-prescribing	
Fraud Hotline - Medicare Australia	13 15 24
- report fraud or non-compliance against Medicare	
Australia programs	
Medicare Australia	13 22 90
- funding/reimbursement enquiries	pbs@mediareaustralia.gov.au
<ul> <li>patient concession/entitlement status, forms</li> </ul>	www.medicareaustralia.gov.au
PDL	(03) 9810 9900
	admin@pdlappco.com.au
	www.pdl.org.au
PSA (Queensland Branch)	(07) 3844 4900
	admin@psaqld.org.au
	www.psa.org.au
Pharmacists Board of Queensland	Registrations: (07) 3225 2532
- registration issues incl, renewals, qualifications,	Board Support: (07) 3247 4866
pharmacy ownership, professional standards,	Professional Adviser – Pharmacy: (07) 3225 2502
disciplinary issues and complaints	pharmacy@healthregboards.qld.gov.au
	www.pharmacyboard.qld.gov.au
The Pharmacy Guild of Australia (Queensland	(07) 3831 3788
Branch)	guild.qld@guild.org.au
Designed Of an Origina and fair Diversion of the	www.guild.org.au/qld/
Project Stop Support for Pharmacists	1300 137 608
- help with the Project Stop program	support@eguild.org.au
Queensland Health Scientific Services	(07) 3274 9105
- destruction of controlled drugs	Soo The Dharmony Cuild of Australia (Ouespaland
Queensland Needle and Syringe Program	See The Pharmacy Guild of Australia (Queensland
	Branch)
SHPA	(03) 9486 0177
	shpa@shpa.org.au
Travelling with PBS medicines	www.shpa.org.au
- taking or sending PBS medication out of the country	1800 500 147
- taking of senting FBS medication out of the country	

Useful websites	
Access to the Health (Drugs and Poisons)	www.legislation.qld.gov.au
Regulation 1996 and the Health Regulation 1996	
Medical Board of Queensland	www.medicalboard.qld.gov.au
Office of Health Practitioner Registration Boards	www.healthregboards.qld.gov.au
Population Health Units (Queensland Health)	
Central Area	www.health.qld.gov.au/ph/central
Tropical Area	www.health.qld.gov.au/ph/tropical
Southern Area	www.health.qld.gov.au/ph/southern
Pharmaceutical Benefits Scheme	www.pbs.gov.au
Queensland Health	www.health.qld.gov.au

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without approval from the chief executiveAppendix 7List of regulated poisonsAppendix 7Restricted drugs of dependencyAppendix 7
List of regulated poisons Appendix 7 Restricted drugs of dependency
Restricted drugs of dependency
Before being prescribed or administered with a restricted drug of 212
dependency, a patient must advise the doctor or dentist of all controlled
drugs and restricted drugs of dependency that s/he has obtained over the
previous two months 213 & 213 A
A doctor or dentist must not dispense, prescribe, administer or supply a drug
dependant person with a restricted drug of dependency without approval Appendix 8
from the chief executive
List of restricted drugs of dependency
Royal Flying Doctor Service bases and outposts
A person in charge of a base may obtain and possess controlled and 54 & 157
restricted drugs under certain conditions
A person in charge of an outpost may possess and administer or supply 54 & 157
controlled and restricted drugs under certain conditions
Must provide a purchase order   89 & 200
Rural hospitals – definition and listAppendices 8A & 9
Safe keeping of drugs and poisons
All drugs and poisons must be kept out of children's reach and in such a 132, 221 & 293
way to prevent the drug or poison from contaminating food, drink and other
drugs and poisons
Salbutamol – sale to persons with first aid training256B & 277
Schedule 3 poisons – sale of S3 poisons277
Schedule 3 asthma relievers256B & 277
Schedule 7 poisons – records of sales to be kept 285
Self-administration of controlled drugs by authorised persons
A doctor, dentist, pharmacist, vet etc. must not self-administer a controlled 123
drug unless it has been prescribed or supplied by a dentist or doctor for a
dental or medical condition

Ships' masters	
May obtain and possess controlled and restricted drugs and Schedule 2 or 3	69,178 & 274(2)
poisons under certain conditions	270
May administer Schedule 2 or 3 poisons under certain conditions	90,201 & 274
Must provide a purchase order	90 & 201
A pharmacist must be approved by the chief executive to sell a	
controlled or restricted drug to a ship's master. (Applications for	
approvals can be made to a Population Health Unit Network Environmental	
Health Service listed in the contacts section of this booklet)	
State analysts	
May obtain, manufacture, possess, use or destroy controlled and restricted	70, 179 & 265
drugs and Schedule 2, 3 and 7 poisons	70, 175 & 205
Stock check for new management	88
If a pharmacist takes over the management of a dispensary for seven days	00
or more, s/he must carry out an audit of the controlled drug stock.	
Storage of controlled drugs	Appendix 6
- at an institution (detention centre, hospital, nursing home or prison)	118
- generally	119
Storage of poisons generally	284
Storage of restricted drugs	211
Strychnine - obtaining, possession, use and sale	240 – 242
Surgical Podiatrists	
May, under certain conditions:	172A, 260A, Appendix
- obtain, possess, prescribe and administer a limited range of Schedule 2, 3	2B
and 4 poisons	
See Podiatrists	
<b>Terbutaline</b> – sale to persons with first aid training	256B & 277
Thalidomide	1000 6 111
Script must:	
- be written under approval or by a specialist in dermatology or internal	186B
medicine; and	190(2)(j)
- be endorsed 'approved' by the prescriber	190(2)(j)
Transaction – definition	6
Tretinoin	8
Script must:	
	196
- be written under approval or by a specialist in dermatology or internal	186
medicine; and	190(2)(j)
- be endorsed 'approved' by the prescriber	400,040,0,000
Unsafe disposal or use of drugs and poisons	130, 219 & 290
Urofollitrophin	
Script must:	
- be written under approval or by a specialist in obstetrics and gynaecology	187
or internal medicine; and	
- be endorsed 'approved' by the prescriber	190(2)(j)
Verbal prescription - see Oral prescription	81 & 192
Veterinary drugs and poisons	124, 125, 214, 215,
Must not be dispensed, prescribed, sold, used or administered for human	288 & 289
therapeutic use	
Veterinary surgeons	
May obtain, possess, administer, dispense, prescribe or sell a controlled or	71, 180 & 266
restricted drug or a Schedule 2, 3 or 7 poison under certain conditions	
Must endorse a prescription 'for animal treatment only'	79(4)(l) & 190(2)(k)
Must not write a repeat prescription for a controlled or restricted drug	80(2) & 191(2)
authorising more than two dispensings	
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## Appendix B Prescribing Endorsements for Health Professionals

## Dentists

A dentist may prescribe a restricted drug, an S2 or S3 poison for a person's dental treatment. A dentist may prescribe codeine or pentazocine for a maximum of 3 days supply and for dental treatment only.

A dentist may not make a repeat prescription for a controlled drug.

A dentist may not make a prescription for a controlled drug or a restricted drug more than the official dose.

Prescriptions for controlled and restricted drugs must be annotated with 'for dental treatment only'.

## **Medical doctors**

A medical doctor may prescribe a controlled drug, a restricted drug, an S2, S3 or S7 poison.

## Optometrists

An optometrist must successfully complete an approved course in ocular therapeutics to be authorised to prescribe a restricted drug.

Prescriptions for restricted drugs must be annotated with 'for ocular treatment only'.

## **Nurse practitioners**

A nurse practitioner may prescribe a controlled drug or a restricted drug under a drug therapy protocol.

A nurse practitioner may prescribe an S2 or S3 poison.

## Surgical podiatrists

A surgical podiatrist may prescribe a restricted drug or poison listed in appendix 2B of the Regulation on the conditions stated in appendix 2B.

A surgical podiatrist may prescribe oxycodone (in short acting form) as an oral preparation for no more than 10 doses of 5mg each.

Prescriptions for controlled drugs and restricted drugs must be annotated with 'for treatment of foot conditions only'.

## Veterinary surgeons

A veterinary surgeon may prescribe a controlled drug, a restricted drug or an S2, S3 or S7 poison.

Prescriptions for controlled drugs and restricted drugs must include the name and address of the owner of the animal.

A prescription for a controlled drug may authorise one repeat dispensing and must specify the time between each dispensing.

A prescription for a restricted drug may only have one repeat.

Prescriptions for controlled drugs and restricted drugs must be annotated with 'for animal treatment only'.

## Appendix C

Procedure

#### Destruction of Controlled Drugs

The following procedure should be adopted when forwarding expired/unwanted controlled drugs (ie. NOT applicable to other scheduled drugs and poisons) for destruction.

(Endeavour to keep a blank copy of the letter for the next time one is needed.)

Complete the top section of the letter attached with all relevant details:

- Business name (eg Smith's Pharmacy, Stanley Private Hospital, Black's Nursing Home,) address and telephone number
- > Name, strength, form and quantity of each type of drug to be destroyed
- > Name and usual signature of the person who prepared the list
- Name and signature of the witness
- Date of forwarding
- > Approval Number of pharmacy (not applicable for aged care facilities or hospitals).

Mark each package with the number corresponding to the package number in the list. If there are more than fifteen packages, amend the numbers on the second sheet to go 16, 17 etc (refer to form in Attachment 1).

All items in the parcel must be cushioned and held sufficiently firmly to prevent damage in transit. Do not allow glass bottles to clash together.

**Put** your (sender's) **company name and address** on the **outside** of the completed parcel It also keeps the parcel sealed, when we register it for later processing.

For the laboratory to identify the parcel, please describe the contents as "THERAPEUTIC GOODS FOR DESTRUCTION".

Endorse your controlled drugs record book and adjust progressive balances. Entries should be marked "forwarded to analyst for destruction."

For clarification on any other issue, either contact the analyst on 3274 9104, or ring your local Environmental Health Officer (refer to Attachment 2 contact list).

If the packaged pharmaceuticals are sent by courier, the sender should ensure that they receive a delivery confirmation receipt. The acknowledgement should be delivered to the sender for their records. If the package is sent by registered post, a delivery confirmation receipt should be sent to you.

Forward the parcel by **courier** or **registered mail** to the analyst:

Forensic and Scientific Services Investigative Chemistry 39 Kessels Road Coopers Plains Qld 4108

N.B. You should contact Australia Post to determine their current guidelines on sending pharmaceuticals in the post.



Forensic and Scientific Services

То:	Business:
Forensic and Scientific	
Services	Address:
Investigative Chemistry	Doot codo: Tolophono:
39 Kessels Road	Post code: Telephone:
Coopers Plains Qld 4108	Approval Number (pharmacies only)
	(Please print)

Please receive the following controlled drugs for destruction.

Package	Description of controlled drugs	Strength	Form	Quantity	Pharmacy Use
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					

OWNER/AGENT		WITNESS
Name	Name	
Signature	Signature	
Date	Date	

## Please put your business name on the outside of the package

N.B. You should contact Australia Post to determine their current guidelines on sending pharmaceuticals in the post.

If the packaged pharmaceuticals are sent by courier, the sender should ensure that they receive a delivery confirmation receipt. The acknowledgement should be delivered to the sender for their records. If the package is sent by Registered Post, a delivery confirmation receipt should be sent to you.

Lab use only: I, the undersigned, certify that I received the above drugs on the The list of drugs is correct. The drugs have been destroyed.		1	1	
Laboratory No	State Analyst			Date

OFFICE	TELEPHONE NUMBER	FAX NUMBER
Brisbane Northside – Population Health Unit	(07) 3624 1111	(07) 3624 1159
Brisbane Southside – Population Health Unit	(07) 3000 9148	(07) 3000 9121
Bundaberg – Population Health Unit	(07) 4150 2780	(07) 4150 2729
Cairns – Population Health Unit	(07) 4050 3600	(07) 4031 1440
Charleville – Population Health Unit	(07) 4656 8100	(07) 4654 2615
Gold Coast – Population Health Unit	(07) 5509 7222	(07) 5561 1851
Hervey Bay – Population Health Unit	(07) 4120 6000	(07) 4120 6009
Logan - Population Health Unit	(07) 3412 6070	(07) 3299 3045
Longreach – Population Health Unit	(07) 4658 0859	(07) 4658 0869
Mackay – Population Health Unit	(07) 4968 6611	(07) 4968 6610
Mt Isa – Population Health Unit	(07) 4744 4846	(07) 4745 4573
Redcliffe – Population Health Unit	(07) 3142 1800	(07) 3142 1825
Rockhampton – Population Health Unit	(07) 4920 6989	(07) 4921 3230
Sunshine Coast – Population Health Unit	(07) 5409 6600	(07) 5443 5488
Thursday Island – Primary Health Care Centre	(07) 4069 0400	(07) 4069 2862
Toowoomba – Population Health Unit	(07) 4631 9888	(07) 4639 4772
Townsville – Population Health Unit	(07) 4753 9000	(07) 4753 9011
West Moreton – Population Health Unit	(07) 3810 1500	(07) 3810 1155
Drugs of Dependence Unit – PA Hospital	(07) 3896 3900	(07) 3896 3933
Drugs and Poisons Policy and Regulation Unit – Environmental Health Branch	(07) 3328 9310	(07) 3328 9354