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| Possession and storage (S4 and S8 poisons) |
| Requirements for health practitioners |
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# Introductory notes

The *Drugs Poisons and Controlled Substances Act 1981* (the Act) and the Drugs Poisons and Controlled Substances Regulations 2017 (the regulations) indicate who may possess Schedule 4 and 8 poisons; the extent to which possession is lawful; and the legislative requirements for use, storage and supply of Schedule 4 and 8 poisons. Current versions of the Act and the regulations, which should be considered in concert and not in isolation, can be accessed at [Victorian Law Today](http://www.legislation.vic.gov.au/) <http://www.legislation.vic.gov.au/>.

This is one of a series of documents prepared by Medicines and Poisons Regulation (MPR) to assist multiple or specific categories of health practitioners to understand the more common legislative requirements. Refer to the [Medicines and poisons webpage](http://www.health.vic.gov.au/dpcs) <http://www.health.vic.gov.au/dpcs> on the Health.vic website for other ‘Documents to print or download’ and for a link to the Poisons Standard, which contains details of poisons schedules plus labelling and packaging requirements.

# Clarifying the meaning of key terms

The following explanations are provided in relation to terms that are in common use or contained within the Act and regulations.

* ‘**Administer**’ means to personally introduce a medicine to a person’s body or, in some cases, to personally supervise its introduction.
* ‘**Supply**’ means to provide a medicine that is to be used or administered at a later time.
* ‘**Dispense**’ is a commonly used term that is **not interchangeable** with ‘supply’. For example, a pharmacist might dispense a prescription with the intention of supplying the medicine but the supply might not occur until a later time (if at all). To avoid misunderstandings, the terms ‘administer’ and ‘supply’ are used in the legislation.
* ‘**Prescribe**’ is a term that commonly relates to the action of a practitioner who authorises treatment that may be carried out by another person. The 2017 Regulations describe this action in accordance with the three different mechanisms by which the treatment may be authorised; namely **‘issuing a prescription**’, ‘**writing a chart instruction**’ and ‘**authorising administration**’.
* In Victoria, the term ‘**drug of dependence**’ is used to describe substances, listed in Schedule 11 of the Act, which are known to be subject to misuse and trafficking. Note: The term is not limited to Schedule 8 and 9 poisons as some Schedule 4 poisons (e.g. benzodiazepines, pseudoephedrine, testosterone and other anabolic steroids) are also classified as drugs of dependence. However, most regulations relate primarily to whether a drug is a Schedule 4 or Schedule 8 poison (rather than a drug of dependence).
* The term ‘**as soon as practicable**’, where it appears in the legislation, is not to be interpreted as ‘when it is convenient’; for example, a person who is required to forward a document ‘as soon as practicable’ is required to do so not later than would be achieved by forwarding the required document via Australia Post.

The various **registered health practitioners** identified in the Act are defined as being persons who are registered under the Health Practitioner Regulation National Law (i.e. registered in Australia).

# Health practitioners authorised under the Act

The following registered health practitioners are authorised to obtain, possess, use, sell or supply scheduled poisons in the lawful practice of their professions (s.13). However, it should be noted that there are limitations that are applicable to each health practitioner category; some of these limitations are shown by way of example:

* Medical practitioners are authorised to obtain, possess, use, sell or supply and prescribe MOST scheduled poisons for the medical treatment of patients under their care but they are not authorised to possess or prescribe some substances without special approval.
* Pharmacists are authorised to obtain, possess, use, sell or supply MOST scheduled poisons in the lawful practice of their profession but only at premises that have been registered by the Victorian Pharmacy Authority.
* Dentists are authorised to obtain, possess, use, sell or supply and prescribe MANY scheduled poisons for the dental treatment of patients under their care but are not authorised to possess or prescribe methadone.
* Veterinary practitioners are authorised to obtain, possess, use, sell or supply and prescribe MOST scheduled poisons for the medical treatment of animals under their care but they are not authorised to possess or prescribe some substances without special approval.
* Nurse practitioners are authorised obtain, possess, use, sell or supply and prescribe scheduled poisons for the medical treatment of patients under their care, in accordance with the endorsement on their registration and scope of practice.
* Authorised midwives
* Authorised optometrists
* Authorised podiatrists
* Authorised registered nurses (Rural and isolated practice)

The various ‘Authorised’ practitioners (shown above) will have endorsements on their registrations, which authorise them to supply and (possibly) prescribe certain scheduled poisons under certain circumstances, when and as ‘approved by the Minister’. Details of Ministerial approvals can be found on the [Medicines and poisons webpage](http://www.health.vic.gov.au/dpcs) <http://www.health.vic.gov.au/dpcs> on the Health.vic website.

# Health practitioners authorised under the regulations

Nurses, midwives, podiatrists and optometrists, whose registrations have not been endorsed by their registration boards, are authorised under the regulations.

The authorisation of these practitioners, to possess and use scheduled poisons, is largely limited to **administration** of medicines (regulations 7 and 8) and does **not** include an authorisation to **supply** or prescribe scheduled poisons. For further information, please refer to the ‘Document to print or download’ that relates to the corresponding health practitioner – as indicated in the introductory notes.

# Possession and responsibility

## Health Services Permit holders (HSP)

Where an HSP is applicable (e.g. hospitals), possession, storage, use, recording of transactions and compliance with other requirements are primarily the responsibility of the HSP holder with the manner in which compliance is to be achieved detailed within the conditions of the HSP and in the online form, which is specific to that permit holder, most recently completed by the permit holder when obtaining, reviewing or amending the HSP for that health service.

Whilst these requirements will be similar to those contained in the regulations, the most recently completed MPR online form might contain requirements that are more specific or additional to regulatory requirements. The most recently completed MPR online form, which is commonly controlled by the Director of Nursing or Director of Pharmacy, should be available for perusal by relevant staff. In some cases, it may be available on a hospital’s intranet.

## Health practitioners in private practice

Where a registered health practitioner is not practising under the auspices of an HSP, compliance of the manner in which scheduled poisons are obtained, possessed, used, recorded and destroyed will be the sole responsibility of the health practitioner to whom the scheduled poisons were supplied.

# Obtaining Schedule 4 and Schedule 8 poisons

Licensed wholesalers and pharmacists must only supply scheduled poisons to an authorised person (or permit holder) and must record the details of the authorised person (e.g. registered health practitioner, permit holder) to whom supply is made, regardless of to whom an invoice for payment might be directed (e.g. a corporate entity or business name). The supplier might also require the provision of a written order (e.g. a doctors bag order form) before supply is made. The authorised person to whom supply is made must thereafter be able to account for all transactions in the corresponding scheduled poisons.

# Practitioners in other roles

The authorisation of registered health practitioners applies **only** to the lawful practice of their professions, which means that registered health practitioners cannot possess or use Schedule 4 and Schedule 8 poisons when acting in another role. However, when acting in another role, a health practitioner’s authorisation and responsibilities will be those that apply to the corresponding role (regulation 7). Common examples of other roles are shown below:

* A health practitioner for whom a medicine has been lawfully prescribed or supplied by another health practitioner (e.g. a prescription from a medical practitioner that is dispensed and supplied by a pharmacist) will have responsibilities consistent with those of any **patient** who has been supplied, lawfully, with that medicine.
* A nurse who assists a person in the administration of their own lawfully-supplied medicine will have responsibilities consistent with those of a **carer;** rather than those of a nurse.
* A health practitioner who transports a lawfully-supplied medicine to the patient for whom it is intended will have responsibilities consistent with those of a **courier**.

# Self-administration and self-prescribing

Self-administration of a Schedule 4 or Schedule 8 poison is **prohibited** unless the medicine has been lawfully prescribed **and** supplied by another registered health practitioner (e.g. medical practitioner) or supplied by a pharmacist on a prescription from another registered health practitioner (regulation 105).

**Note**: This does **not** mean that, once a medicine has been prescribed by another registered health practitioner, a health practitioner may continue the treatment with medicine obtained from a wholesale supplier or by issuing a prescription and naming themselves as the patient.

# Storage of Schedule 4 and Schedule 8 poisons

Where registered health practitioners are supplied with Schedule 4 or Schedule 8 poisons, for use in the lawful practice of their profession (i.e. not in connection with a Health Services Permit), they are personally responsible for complying with the following requirements.

Schedule 8 poisonsmust be stored in a locked facility, fixed to the floor or wall, which provides not less security than a (10 mm thick) mild steel drug cabinet. Schedule 8 poisons must not be stored with any other items other than other drugs of dependence – Refer to regulation 74 for full details of specifications.

Expert advice received by the department indicates that fixing a storage cabinet to the floor or wall can achieve this requirement as follows:

* HARD CORE WALL: The cabinet to be secured by use of four (4) Loxin or Dyna Bolts, each 10mm by 50mm minimum.
* STUD AND PLASTER OR HOLLOW BLOCK: The cabinet to be secured by use of four (4) 10mm coach bolts through wall and through 3mm mild steel backing plate, which must, at minimum, be the same size as the back of the drug cabinet.

### Exceptions

The following exceptions to the preceding specifications are included in regulations 74 and 75:

* For use in an emergency, Schedule 8 poisons in divided doses (e.g. morphine ampoules) may be stored in a lockable storage facility that does not meet the preceding requirements – provided the total number of divided doses (e.g. ampoules) of all Schedule 8 poisons in that facility does not exceed six.
* When being transported for use in another place, Schedule 8 poisons may be stored in a portable, lockable container.
* Holders of a Health Services Permit (HSP) and pharmacies co-located with an HSP holder, where patients are treated on site, may use electronic storage and recording equipment for storage of Schedule 8 poisons if specified conditions are met.
* An approved provider of an aged care service, where a resident has been supplied with a Schedule 8 poison on a prescription, may store those Schedule 8 poisons in a lockable room or in a lockable storage facility which is firmly fixed to a floor or wall.

Schedule 4 poisons(including professional samples) must be stored in a lockable storage facility (e.g. cupboard, drawer, fridge, filing cabinet or room) (regulation 73).

**Note**: It is common for holders of a Health Services Permit to store a **limited** number of life-saving drugs in an unlocked storage facility when those drugs might be needed for administration in an emergency (i.e. when the establishment is operational). Where this occurs, the permit holder will implement a means of deterring and detecting misappropriation (e.g. tamper-evident seals), as indicated in the most recently completed MPR online form for the HSP.

# Access to Schedule 4 and Schedule 8 poisons

In relation to Schedule 4 and Schedule 8 poisons, the term ‘unauthorised access’ applies to any person who is not specifically authorised (under the Act or regulations) to possess a substance contained within a storage facility. Accordingly, keys and combination codes should not be accessible to unauthorised staff members; cleaning and maintenance staff must not have access to storage facilities.

A storage facility for **Schedule 8 poisons** must remain locked to prevent access to unauthorised persons at all times except when it is necessary to open it to carry out an essential operation.

A storage facility for **Schedule 4 poisons** must be locked to prevent unauthorised access at all times, except when it is necessary to open it to carry out an essential operation **or** where Schedule 4 poisons are stored within a dispensing area or treatment room within a pharmacy or clinic **and** a suitably registered health practitioner is present.

**Note**: The provision for storage of Schedule 4 poisons within a treatment room or dispensary area:

* does **not** relieve the health practitioner of the requirement to take all reasonable steps to restrict access; it merely acknowledges that the presence of the health practitioner might fulfil this need
* does **not** mean that the health practitioner must remain in the treatment room or dispensary but it also does **not** mean that Schedule 4 poisons may be stored in an unlocked treatment area or dispensary merely because a health practitioner is present somewhere on the premises
	+ If a health practitioner is otherwise occupied for extended periods and unable to observe persons entering or leaving the storage area, adequate security might not be achieved.
* allows health practitioners to determine which steps are compatible with the practicality of continually locking and unlocking treatment rooms or storage facilities in their own clinics
	+ If in doubt, it is recommended that Schedule 4 poisons are stored in lockable facilities that are locked when a health practitioner is not readily able to provide personal supervision.

## Access by employees

A practitioner’s employee may possess Schedule 4 and Schedule 8 poisons, which have been lawfully dispensed and labelled, by the practitioner, for transport to (or collection by) the patient (or patient’s agent), provided the drugs are in a package or container that clearly identifies the patient for whom they are intended (regulation 7). Unauthorised persons (including nurses) are not generally authorised to possess or supply Schedule 4 and Schedule 8 poisons to a patient in other circumstances.

Nurses (and other health practitioners authorised under the regulations, rather than the Act) **might** be authorised to possess and administer Schedule 4 or Schedule 8 poisons to patients under their care but this authorisation does not mean that such practitioners may have unsupervised access to Schedule 4 or Schedule 8 poisons in other circumstances unless a Health Services Permit or other regulatory authorisation exists (e.g. nurse immunisers in accordance with the ‘Approval of the Secretary’).

# Matters to be reported to MPR and/or police

Registered health practitioners are required to notify Victoria Police and/or MPR (as indicated below) when:

* a scheduled poison is lost by or stolen from them – notify police **and** MPR (regulation 152)
* a discrepancy in records of transaction (e.g. Schedule 8 poison register) remains unresolved after the discrepancy has been investigated – notify MPR **only** (regulation 112)
* records, required to be kept in relation to Schedule 4 or Schedule 8 poisons, are lost, stolen or destroyed – notify MPR **only** (regulation 113)
* a person is suspected to have obtained, from the practitioner by means of a false pretence, an order or prescription for a Schedule 4 or 8 poison (regulation 26) or for a Schedule 3 poison that is a drug of dependence – notify police **and** MPR (regulation 147)
* a person is suspected to have obtained, from the practitioner by means of a false pretence, a Schedule 4 or Schedule 8 poison (regulation 44) or a Schedule 3 poison that is a drug of dependence – notify police **and** MPR (regulation 147)
* a person is suspected to haveobtained **or attempted to obtain**, by means of a false pretence (including the presentation of forged or fraudulently altered prescriptions), a Schedule 4 or Schedule 8 poison from a **pharmacist** – notify police **and** MPR (regulation 69)

## How to notify MPR

To report the loss or theft of Schedule 4 and Schedule 8 poisons or discrepancies in records:

* For holders of a **Health Services Permit** or a **residential aged care service**, submit the ‘*Lost scheduled item form*’, which is available on the MPR website in the section for ‘*online forms’*
* For health practitioners, who are **not** employed by the holder of a Health Services Permit, to forward relevant details to the MPR email address dpcs@health.vic.gov.au.
* For fraudulent or fraudulently altered prescriptions, **pharmacists** should submit the ‘*Notification of forged or altered prescription*’ form, which is available on the MPR website in the section for ‘*online forms’*.
* For the loss or theft of prescription pads or prescription pages, other health practitioners are requested to submit the ‘*Notification of lost and stolen prescriptions*’ form, which is available on the MPR website in the section for ‘*online forms*’.

# For further information

## Department of Health (DH)

### Medicines and Poisons Regulation

GPO Box 4057, Melbourne 3001

Fax: 1300 360 830

Email: dpcs@health.vic.gov.au

Web: www2.health.vic.gov.au/dpcs

**For queries relating to the Act or regulations, please:**

* refer to the ‘Documents to print or download’ that are available on the MPR website (see below); or
* if you are unable to address your query by referring to those documents, please forward your query via e-mail (to dpcs@health.vic.gov.au) and indicate, in the ‘Subject’ field, that your query is to be directed to:
	+ The Health Practitioner Compliance team – for matters relating to compliance by medical practitioners, veterinary practitioners, dentists and pharmacists.
	+ The Licence and Permit team – for matters relating to Health Services Permit holders (e.g. hospitals) and residential aged care services.

## Documents to print or download from the MPR website

The [Medicines and poisons webpage](http://www.health.vic.gov.au/dpcs) <http://www.health.vic.gov.au/dpcs> on the Health.vic website in the section for ‘Documents to print or download’, contains summaries of legislative requirements that have been prepared in relation to issues that relate to multiple categories of health practitioner as well as to individual categories of health practitioner. These documents, which are intended to assist health practitioners to comply with key legislative requirements, include the following:

* Issues relating to multiple categories of health practitioner, including:
	+ Possession and storage
	+ Supply, administration and recording
	+ Prescribing
	+ Criteria for lawful prescriptions
	+ All reasonable steps and other key terms
	+ Schedule 2 and 3 poisons
* Summaries that are specific to individual categories of health practitioner:
	+ Medical practitioners
	+ Pharmacists
	+ Nurses and midwives
	+ Nurses and midwives with registration endorsement (e.g. nurse practitioners, authorised midwives, etc.)
	+ Dentists (and other dental practitioners)
	+ Optometrists (and orthoptists)
	+ Podiatrists
	+ Veterinary practitioners

## Other possible sources of information

### Australian Health Practitioner Regulation Agency (Ahpra)

Web: [www.ahpra.gov.au](http://www.ahpra.gov.au)

#### Registration Boards (for treatment of human patients)

Refer to the Ahpra website for links to individual registration boards.

### Veterinary Practitioner Registration Board of Victoria

Web: [www.vetboard.vic.gov.au](http://www.vetboard.vic.gov.au)

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