

Requirements for managing drugs in general practice

Information for medical practitioners

This summary has been prepared by the Drugs and Poisons Regulation Group (DPRG) to assist in understanding storage and recording requirements in general practice. Please refer to the Drugs, Poisons and Controlled Substances Act 1981 and Regulations 2006 (at www.legislation.vic.gov.au) for full details or to the DPRG website (www.health.vic.gov.au/dpu) for summary sheets relating to other issues.

Storage requirements

Schedule 8 poisons (labelled Controlled Drug) are drugs with strict legislative controls, including but not limited to morphine, pethidine, methadone and fentanyl.

- When **transported** for use in another location, S8 poisons must be stored in a locked receptacle (e.g. doctor's bag) in the doctor's possession. If the receptacle is necessarily out of the doctor's immediate possession for a brief period, it should be secured, out of sight, in a lockable facility (e.g. lockable vehicle or cupboard) to prevent unauthorised access.
- S8 poisons must otherwise be stored in a locked facility, fixed to the floor or wall, and providing not less security than a (10 mm thick) mild steel drug cabinet (see regulation 35(1) for details of minimum standards).
- **Exception:** Up to 6 divided doses (e.g. morphine ampoules), for emergency use, may be stored in a locked facility that does not comply with regulation 35(1).

Schedule 4 poisons (labelled Prescription Only Medicine) include all other drugs for which prescriptions are generally required, e.g. oral contraceptives, antibiotics, some compound analgesics (e.g. Panadeine Forte[®]), pseudoephedrine, nitrous oxide and many others.

- S4 poisons (including professional sample packs) must be stored in a **lockable** storage facility, e.g. cupboard, drawer, fridge, filing cabinet, treatment room, storeroom.
- It is strongly recommended that **prescription pads** and pages for computer-generated prescriptions are similarly secured.

Drugs of dependence is the term used to describe all S8 poisons **plus** specified S4 poisons that are subject to misuse and trafficking, e.g. benzodiazepines, propoxyphene (Digesic[®], Doloxene[®]), anorectic drugs (Duromine[®]) and anabolic steroids.

- **Schedule 4 drugs of dependence** may be stored in the same manner as other Schedule 4 poisons **or** in the drug cabinet with Schedule 8 poisons.

Schedule 2 and 3 poisons (labelled Pharmacy Medicine or Pharmacist Only Medicine respectively) must only be supplied (in an open shop) by pharmacists.

- Medical practitioners may supply Schedule 2 and Schedule 3 poisons in a similar manner to Schedule 4 poisons (i.e. for the treatment of patients under their care).
- To prevent unlawful supply, it is **recommended** that Schedule 2 and Schedule 3 poisons are stored and handled in a similar manner to Schedule 4 poisons.

Access to Schedule 4 and Schedule 8 poisons

In most clinics, Schedule 4 and Schedule 8 poisons (including doctor's bag emergency drugs and professional samples) are obtained on the authorisation of the medical practitioner(s).

These drugs are the responsibility of the corresponding medical practitioner(s). Nurses are **not** generally authorised to have unsupervised access to the drugs - **except** when authorised by a medical practitioner to administer specific drugs to a specific patient under the care of the nurse.

Access to Schedule 8 poisons

Storage facilities 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. Keys & combinations must **not** be accessible to or known by unauthorised persons.

Access to Schedule 4 poisons

Schedule 4 poisons may be stored in a facility that is locked to prevent unauthorised access **OR** may be stored in a treatment room (or other area), which does not have to be locked when a medical practitioner is present, in which case, it is the responsibility of the medical practitioner(s) to determine how unauthorised access is to be prevented or restricted.

Vaccines

Schedule 4 vaccines, which require refrigeration, must be secured in a lockable container or in a lockable refrigerator, unless the refrigerator is secured within a lockable room.

Nurse Immunisers, employed or contracted by medical practitioners, may have access to vaccines that are specifically approved by the Secretary (Department of Health) for use in vaccinations and to Schedule 4 poisons necessary for the treatment of anaphylactic reactions to the vaccines. For further information and the list of vaccines, please refer to the DPRG website (www.health.vic.gov.au/dpu/approve.htm).

Nurse Immunisers should familiarise themselves with legislative issues that are applicable to their situation.

Where there is a Health Services Permit (HSP)

In medical clinics that hold an HSP, nurses may be designated as the persons responsible for ensuring compliance with purchase and storage requirements and may be authorised to have access to Schedule 4 and Schedule 8 poisons when a medical practitioner is not present.

There is a category of HSP, which would be applicable to a medical clinic, for which application and annual fees are lower than for other health services. Nonetheless, the vast majority of medical clinics do not need and choose not to have an HSP.

All relevant application forms, details of fees, plus instructions of how to complete them are available on the DPRG website at: <http://www.health.vic.gov.au/dpu/health.htm>

Note: An HSP does not remove the responsibility of medical practitioners to be able to personally account for Schedule 8 poisons that are supplied in their names, e.g. doctors' bag supplies that are subsidised by the Pharmaceutical Benefit Scheme.

Recording requirements

Records of all transactions (including administration) in Schedule 4 and Schedule 8 poisons must be retained in a readily retrievable form for 3 years and produced, on demand, in writing to an authorised officer of the DPRG (Refer to regulation 40 for details of the information that must be recorded).

For Schedule 8 poisons, a separate record (usually a drug register or administration book) is required, in a form that shows the true and accurate balance remaining after each transaction and that cannot be altered without detection (regulation 41). Loose-leaf books are **not** acceptable.

Note: One medical practitioner may manage the purchase, storage and record keeping on behalf of all medical practitioners at a clinic but it is recommended that each medical practitioner maintains a separate register to account for Schedule 8 poisons supplied to him or her.

Destruction of Schedule 8 poisons

If a medical practitioner wishes to destroy expired or unwanted Schedule 8 poisons, the destruction must be witnessed by a pharmacist, dentist, veterinary practitioner, nurse, nurse practitioner or another medical practitioner. Two nurses are not authorised to perform the task unless the principal person is a nurse practitioner.

Both participants in the destruction must sign the corresponding record book.

Administration of Schedule 4 and Schedule 8 poisons

Regulation 47 requires a nurse to refer to authoritative instructions before administering Schedule 4 or Schedule 8 poisons, namely:

- written instructions of a medical practitioner
- oral instructions of a medical practitioner if, in the opinion of the medical practitioner, an emergency exists
- written transcription (of emergency oral instructions) by the nurse who received those instructions
- directions for use on a container supplied by a medical practitioner or pharmacist (e.g. administration of a person's own lawfully supplied medication)

Other standards

Compliance with the drugs and poisons legislation does not ensure compliance with other professional standards and the fact that a clinic has been accredited does not ensure compliance with the legislation. However, failure to comply with the legislation renders a person liable to prosecution.

Matters to be reported to the DPRG

Victoria Police and the DPRG must be notified when:

- drugs or records are lost or stolen;
- a medical practitioner has reason to believe a person has obtained Schedule 8 or Schedule 4 poisons (or prescriptions) by false pretences.

The DPRG should also be notified of the loss or theft of prescription pads.

For further information

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September 2010