Government of Western Australia
Department of Health
Public Health and Clinical Services

Poisons Regulations 1965 discussion paper

Contents

Introduction

Medicines, Poisons and Therapeutic Goods Bill

The current legislation for Poisons in WA is the ageing *Poisons Act 1964* (the Act) and the Poisons Regulations 1965 (the Regulations). Replacement legislation in the Medicines, Poisons and Therapeutic Goods Bill 2013 (the Bill) has been presented to Parliament. More information on the Bill can be accessed at the Department's website under the 'Publications and information' table. If the Bill is passed, replacement of the Poisons Regulations 1965 will be required.

The Bill contains an updated legal framework for the efficient and effective management of medicines and poisons. Some new aspects of the Bill will need completely new regulations to describe their operation in more detail. Many of the existing regulations will need to be retained but may need some amendment.

Poisons Regulations 1965

The existing Regulations set out the detailed controls to protect the public from harms associated with medicines and poisons. Controls include restriction on supplying or using a poison, storage and disposal, packaging and labelling, record keeping and reporting, and advertising. They vary according to the risk posed by a particular medicine or poison.

The Regulations have existed in their current form for 48 years, but have seen significant amendments and additions over this time. With changes to practice, new technologies, increased and different types of medicines and other legislative changes, these controls may no longer be appropriate for the level of risk. An electronic copy of the Poisons Regulations 1965 can be found on the State Law Publisher website.

New regulations

The Pharmaceutical Service Branch of the Department of Health is consulting over the development of new subsidiary legislation and is asking stakeholders what they think about the Regulations. Because the Poisons Regulations 1965 are 197 pages long and contain 175 individual clauses in legal language, they can be difficult to understand.

Discussion document

This discussion document has been written as part of the consultation process to assist stakeholders. It outlines the intent and effect of each regulation in simple language, going through each of the parts, divisions and subdivisions in order. It includes notes about how the Bill may affect the existing controls and identifies areas where the Regulations require attention.

Stakeholders should use the discussion paper to help familiarise themselves with the Regulations as they are now. It should also help when considering the suitability of existing controls. Stakeholders should consider the risk to the public the best controls to reduce that risk. The potential impact of each control on business, consumers and government should always be kept in mind.

The meaning of each regulation is explained in turn. The relevant regulation is given in brackets for reference. Key changes that may occur with the Bill are outlined in boxes. Some questions have also been provided to stimulate initial discussion, based on issues that the Department of Health is already aware of.

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Part 1 - Preliminary

This part contains preliminary information on the regulations, including definitions of terms.

- A notable definition is that of 'supply', which states that nurses are not 'supplying' when administering a medicine under the direction of an authorised practitioner
- Part 1 also sets out exemptions from the Act for certain poisons and paints in the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP).

Part 2A - Endorsed Health Practitioners

This part provides for selected Endorsed Health Practitioners to prescribe medicines in accordance with the endorsement of their professional board:

- Endorsed optometrists may prescribe topical eye medicine on their National Medicines List
- Endorsed podiatrists may prescribe in accordance with their National Medicines List
- Endorsed midwives may prescribe according to their National Prescribing Formulary.

Key changes in the Medicines, Poisons and Therapeutic Goods Bill:

- authorises health professionals to administer, possess, prescribe or supply, in lawful practice as outlined in Regulations.
- specific health practitioner groups are not named.

Issues to consider in new regulations:

- how should authorities be outlined in regulations?
- how should prescribing and other authorities be linked to endorsements and scope of practice defined by National Health Practitioner Boards?

Part 2 - Licences and permits

Division 1 – General

This division outlines the types of licences and permits authorising the supply of poisons.

Rules for licences and permits:

- A remote site may be designated as a remote area nursing post (11).
- The CEO may designate the area where nurse practitioners are authorised to possess, use, supply or prescribe medicines as per 23(2)(e) of the Act (11A).
- A licence may be granted to manufacture poisons, distribute or sell by wholesale, or sell by retail (12).
- A permit may be granted to purchase poisons to use for industrial, educational or research purposes, or to provide health services.

Types of licences and permits

Licence / Permit	Authorises
wholesale	purchase, manufacture or supply of poisons from a specified premises, in accordance with conditions outlined in regulations
pharmacy	sale or supply poisons from the pharmacy cited on the licence
retail	sale of Schedule 2 poisons from the premises cited on the licence sale of Schedule 7 poisons from the premises cited on the licence
samples	supply of Schedule 2, 3 or 4 poisons to medical practitioners, nurse practitioners, veterinary surgeons, dentists, pharmacists or authorised health practitioners under certain conditions.
industrial	purchase of industrial poisons listed on the permit
educational, advisory, research	purchase for educational, advisory or research purposes specified on the permit
health services	purchase of poisons by private hospitals, day surgeries, doctors' surgeries, ambulance services, and companies providing medical support to industry/mining
departmental and hospital	purchase and use of poisons specified on the permit by State or Commonwealth Departments or public hospitals
licence to cultivate prohibited plants	licence holders may cultivate prohibited plants

Key changes in the Medicines, Poisons and Therapeutic Goods Bill:

- allows the issue of licences (to supply) and permits (to use) for a 12 month period
- removal of Schedule 6 wholesale and pharmacy licences
- recognises licenses issued by other authorities
- corporate licenses may be issued.

Issues to consider in new regulations:

- what specific license and permit types are needed?
- what should each type be allowed to do in relation to medicines or poisons?

Division 2 – Needle and syringe programs

This division outlines the obligations for the coordination of needle and syringe programs:

- The CEO can approve a needle and exchange program and program coordinator (12A).

- Coordinators must meet certain requirements, maintain a register of participants and provide an annual report (12A, 12C).
- Coordinators must meet rules for disposal of used needles and syringes, including use of approved receptacles (12F).
- A person not suitable to be a coordinator may be directed not to be involved (12E).

Key changes in the Medicines, Poisons and Therapeutic Goods Bill:

- it is an offence to handle a prohibited Schedule 9 poison
- it is a defence if this is done for the purposes of an approved needle and syringe program.

Issue to consider in new regulations:

- What rules are required for needle and syringe exchange programs?

Division 3 – Restrictions and obligations

This division outlines restrictions on licences and permits:

- A person must be 21 years of age to apply for a licence or permit (15).
- Only a licensee (or a person on their behalf) can sell poisons to persons over 15 years of age (16).
- Licences and permits are not transferable (17).
- Licences must be displayed in an obvious place (18).

Key changes in the Medicines, Poisons and Therapeutic Goods Bill:

- licensees must be 21 years of age, fit and proper, have sufficient knowledge and resources, and suitable premises
- regulations may be made relating to licences and permits.

Issue to consider in new regulations:

- What regulations are required for conditions to be met by different types of Licences and Permits?

Part 3 – Containers and labels

Division 1 – Containers

This division outlines the requirements for poisons containers.

Rules for packaging poisons:

- Poisons containers and labels must comply with the SUSMP (19).

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- Poisons may not be supplied in paper bags or envelopes (19AA).
- Food, drink and condiment containers must be clearly distinguishable from poisons containers (19A).

Key changes in the Medicines, Poisons and Therapeutic Goods Bill

- It is an offence to supply a medicine or poison except in accordance with Regulations.

Issues to consider in new regulations:

- regulations have not previously differentiated between medicines and poisons in their requirements
- regulations for Schedule 5, 6 and 7 poisons will be nationally consistent via adoption of updated regulatory controls from the Poisons Standard (SUSMP)
- what regulations are required for the safe labelling and packaging of Schedule 2, 3, 4 and 8 medicines?
- are controls other than those of the SUSMP required for medicines?

Division 2 – Labels

This division outlines the requirements for poisons labels.

Rules for labeling poisons:

- Labels for medicines dispensed, or poisons supplied, by a health practitioner for human therapeutic use must contain certain words including ‘Keep out of reach of children’, name and strength or amount of the poison, and name of the patient (21).
- SUSMP Appendix K medicines must have label statements in letters at least 1.5mm high in a clearly contrasting colour (21A).
- Carcinogenicity or teratogenicity warnings must be approved (24A).

Key changes in the Medicines, Poisons and Therapeutic Goods Bill:

- It is an offence to supply a medicine or poison except in accordance with regulations.

Issue to consider in new regulations:

- What regulations are required for the safe labelling of dispensed Schedule 2, 3, 4 and 8 medicines?

Division 3 – General

- Non-compliant containers or labels may be approved if there is no public risk (25).

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- Some containers or labels may be prohibited in the interests of safety (26).

Key changes in the Medicines, Poisons and Therapeutic Goods Bill:

- It is an offence to supply a medicine or poison except in accordance with regulations.

Issues to consider in new regulations:

- short term exceptions from the SUSMP are necessary as when schedule classifications change, items already in the market place become non-compliant
- what other rules might be relevant for safe packaging and labelling?

Part 4 – Storage, disposal and loss or theft of poisons

This part outlines the requirements for disposal of poisons or if poisons are lost or stolen.

Rules for lost medicines:

- Poisons should be stored in such a way as to avoid contamination of food or drink, and away from children (30).
- Poisons must be disposed of without risk to the public (31)
- The Police must be notified of lost or stolen poisons (32).

Key changes in the Medicines, Poisons and Therapeutic Goods Bill:

- it is an offence to store, handle, transport or dispose of a medicine or poison except in accordance with regulations
- regulations may be made relating to storage, handling, transport or disposal.

Issues to consider in new regulations:

- regulations have not previously differentiated between medicines and poisons in their requirements
- regulations for Schedule 5, 6 and 7 poisons will be nationally consistent via adoption of updated regulatory controls from the Poisons Standard (SUSMP)
- what regulations are required for the safe storage, handling, transport or disposal of Schedule 2, 3, 4 and 8 medicines?
- what requirements should be met for lost or stolen medicines and poisons?

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Part 4A - Electronic prescribing systems

This part sets out the rules for the administration of electronic prescribing systems.

Rules for electronic prescribing systems:

- Electronic systems may be approved when meeting certain conditions, including security, access procedures, protection of personal information and Appendix K (32B).
- Electronic systems must have a designated administrator.
- An administrator commits an offence by accessing a system when not permitted, revealing access codes to another person, or through inappropriate use (32C).
- A system identifier is considered correct unless there is evidence otherwise (32E).
- An administrator must provide electronic records if requested (32E).

Key changes in the Medicines, Poisons and Therapeutic Goods Bill:

- allows for regulations relating to the supply of medicines from an automated machine and the location of the machine
- it is an offence to alter or forge a prescription or mislead a person to obtain a medicine.

Issues to consider in new regulations:

- electronic prescription transfer is being developed under the National Dispense and Prescription Repository
- what national standards or requirements exist that might be adopted to govern electronic exchange of information required to prescribe or dispense medicines?
- what protections are required to prevent prescription forgeries or methods to obtain medicines for diversion and abuse?

Part 5 – Sale, supply and use of poisons

Division 1 – Restrictions

This division outlines restrictions on the sale, supply and use of poisons, including storage and advertising.

Rules for supply of medicines:

- Only licensed retailers can sell medicines to a person under the age of 16 (33).
- Veterinary medicines may not be sold or administered to humans (33A).

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- Paints containing substances listed in the SUSMP must be manufactured and sold according to the SUSMP (33B).
- Retail stores must store Schedule 2 substances out of public access (35).
- Pharmacists (or pharmacy interns) must personally sell Schedule 3 substances, determine therapeutic need and record the sale of Appendix J substances (35A).
- An approved recording system must be used for pseudoephedrine sales (35A).
- Photographic evidence of the identity of pseudoephedrine purchasers is required (35A).
- Pharmacies must store Schedule 3 poisons in a location only accessible to pharmacy staff (35B).
- Schedule 3 substances may only be advertised in publications for authorised health professionals or the wholesale and manufacturing drug industry (35C).
- Schedule 4 medicines can only be advertised in publications for medical practitioners, veterinary surgeons, dentists or nurse practitioners (35D).

Key changes in the Medicines, Poisons and Therapeutic Goods Bill:

- a Schedule 2 or 3 medicine may only be supplied in accordance with regulation
- it is an offence if not supplied for appropriate therapeutic purposes or amounts, or in a way that may endanger public safety.

Issue to consider in new regulations:

- What requirements for storage, labelling, record keeping, advertising, assessment of therapeutic need or other controls are necessary for Schedule 2 or 3 medicines.

Division 2 – Schedule 4 poisons

This section outlines the restrictions around the sale, supply and use of Schedule 4 poisons (prescription medicines).

Supply of prescription medicines

Regulation 36 sets out the requirements for supply of prescription medicines:

- An authorised person must provide a written order to obtain prescription medicines.
- Written orders must be kept for at least two years and must be produced if required.
- Prescription medicines may be supplied on a prescription from an authorised practitioner.
- A three-day supply (or one individual standard pack) can be supplied in an emergency without a prescription to someone under treatment with that medicine.
- A medicine can be supplied without a prescription under Continued Dispensing rules.
- Only medical practitioners, pharmacists, veterinary surgeons, nurse practitioners (or their directly supervised assistants) can dispense a prescription medicine.

- A prescription may only be dispensed (repeated) as many times as indicated on the prescription.
- The date of dispensing, pharmacy name and address must be marked on the paper prescription or recorded on the electronic system.
- If a prescription does not indicate repeats or the maximum number of repeats have been reached, the script must be cancelled on paper or in an electronic prescribing system.
- Prescriptions must be less than one year old and not illegible, defaced, or altered.
- Pharmacists must inform the CEO if they refuse to dispense an invalid prescription.
- Details of supply must be recorded in a prescription book.
- A prescription book can be a bound book, computer records, photographic system, client record cards or other approved system.
- The prescription book must be kept for two years and produced if required.
- Registered nurses at remote area nursing posts may supply non-psychoactive medicines on standing orders or under verbal instruction from an authorised prescriber.
- Registered nurses at remote area nursing posts must label medicines supplied and keep a record of supply in the patient's clinical record for two years.

Issues to consider in new regulations

- what requirements should apply to paper based prescriptions?
- what records of supply are necessary?
- what supply without a prescription in an emergency or other situation is acceptable?

Exemptions to supply rules

Regulations 36AA, 36AAB, 37A, 37B and 37C exempt the supply of prescription medicines from some requirements.

Exemption	Conditions
registered nurses at approved rural or remote sites may supply starter packs to out-patients if directed by a medical or nurse practitioner	the patient must have an acute medical condition, not be under treatment by another medical or nurse practitioner and the nearest pharmacy must be more than 25 km away details must be recorded within 72 hours
registered nurses may supply a psychiatric emergency pack to an outpatient if directed by a psychiatrist or medical practitioner	the patient is in need of urgent psychiatric intervention and can not obtain the medication in any other way details must be recorded within 72 hours

H1N1 Pandemic Influenza vaccine	administration by a registered nurse in the course of their employment by the Department or hospital details must be recorded in an approved form
Appendix B vaccines	may only be a vaccine contained listed in Appendix B administration by a registered nurse in the course of their employment by the Department, hospital, local government, or aboriginal health service administration in accordance with an approved code
public health programmes	administration of specified poisons for treatment of specified conditions in an approved public health program administration by a registered nurse in the course of their employment by the Department or hospital administration in accordance with an approved code

Issues to consider in new regulations:

- what demand for consumer access to prescription medicines is not met through usual channels?
- what are the most appropriate and safe mechanisms for consumer to access medicines outside usual channels?
- what authorities and controls should apply for persons who do not hold routine authorisation to supply medicines as a registered health practitioner?

Storage of prescription medicines:

- Pharmacists must store prescription medicines in an area of the pharmacy that is inaccessible to the public (36A).
- An authorised prescriber must store prescription medicines in a lockable container, cupboard or room at their usual place of practice (36A).
- An authorised prescriber may have emergency supplies outside their practice if in their person possession (36A).
- A record must be made in a client's record card when a prescription medicine is supplied or administered (36B).

Key changes in the Medicines, Poisons and Therapeutic Goods Bill:

- it is an offence to store, handle, transport or dispose of a medicine or poison except in accordance with regulations
- regulations may be made relating to storage, handling, transport or disposal.

Issues to consider in new regulations:

- what rules should apply to prevent the unsafe or unauthorised access to medicines?
- what record keeping and accountability should apply to the supply of medicines?

Writing of prescriptions

Regulation 37 outlines rules for prescriptions. Prescriptions must:

- include the name and address of the prescriber, name and address of the patient, name and quantity of the substance, directions for use, date issued and maximum number of times it can be dispensed
- be marked ‘dental purposes use’ for a dentist and ‘veterinary use only’ or ‘animal treatment only’ for a veterinary surgeon
- have unusual doses marked as intended by the prescriber
- be written in ink in the prescriber’s own handwriting
- not be written in code
- contain the prescriber’s signature in his/her own handwriting.

Format of prescriptions:

- Prescriptions may be on paper, issued via a computer–generated prescribing system compliant with Appendix L, or be issued via a compliant electronic prescribing system (paperless system) (37)
- The National Inpatient Medication Chart (NIMC) is a prescription when used for a patient discharged from a public hospital (38A)
- The National Residential Medication Chart (still being developed) is a prescription when used for a person in residential care (38B).

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Issues to consider in new regulations

- what details should a paper based or other prescription contain?
- what safeguards are needed to prevent forgeries and unauthorised access to medicines?

Emergency dispensing:

- In an emergency an authorised prescriber can direct dispensing of a prescription medicine by telephone or electronic means if followed by a written prescription within 24 hours (38).
- Up to 72 hours of treatment of a veterinary medicine may be supplied without a prescription if the pharmacist is satisfied the purchaser cannot obtain a prescription. A record of supply must be made in the prescription book (39).

Issues to consider in new regulations

- what emergency access to prescription drugs do consumers need in an emergency?
- what controls are needed to prevent unsafe or unauthorised access to medicines?

Administration in hospitals:

- A medication may only be administered to a patient in hospital by an authorised person if authorised in writing on a medication chart by an authorised prescriber (Regulation 38AA).
- Administration may be verbally authorised but must be confirmed in writing on the medication chart by the prescriber within 24 hours (38AA).

Issues to consider in new regulations:

- how do the needs of hospitals and similar healthcare facilities for access to medicines differ from those in the general community setting?
- what requirements should apply to storage, prescribing, recordkeeping and accountability for medicines in hospitals?

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Prescribing certain medicines

Regulations 38C to 38P restrict the prescribing of certain medicines.

Poison	Prescribing restriction
clomiphene and cyclofenil	gynaecologist or obstetrician, medical practitioner authorised by the CEO, veterinary surgeon for veterinary trials
etretinate or acitretin	physician or dermatologist, possibility of pregnancy must be excluded labelling must contain the words 'WARNING – CAUSES BIRTH DEFECTS'
prostaglandins	veterinary surgeon for the treatment of animals, dinoprost or dinoprostone – physician, gynaecologist, obstetrician or other authorised medical practitioner
isotretinoin	physician or dermatologist, possibility of pregnancy must be excluded patient to wait one month after ceasing the treatment before falling pregnant
thalidomide	physician or dermatologist, possibility of pregnancy must be excluded patient to wait one month after ceasing the treatment before falling pregnant
chloramphenicol	medical practitioner or nurse practitioner for human use endorsed optometrist as a topical ocular preparation, veterinary surgeon for use in animals not for human consumption (e.g. offal or meat)
fsh and luteinising hormone	physician, gynaecologist or obstetrician, other authorised medical practitioner, veterinary surgeon
carnidazole	veterinary surgeons for the treatment of pigeons
oxolinic acid	veterinary surgeons for the treatment of fish
clozapine	psychiatrist or other authorised medical practitioner
certain nitrofuran derivatives	medical practitioner or nurse practitioner or endorsed midwife (nitrofurantoin) veterinary surgeon for feed or treatment of animals not consumed by humans
bosentan	physician or dermatologist, possibility of pregnancy must be excluded patient to wait three months after ceasing the treatment before falling pregnant
teripatide	physician, rheumatologist, immunologist, endocrinologist, geriatrician, other authorised medical practitioner

Issues to consider in new regulations:

- what specific medicines require further restriction based on a higher degree of consumer risk?
- what is the best method of restricting medications of concern to specific prescriber groups?
- what other national standards or programs might be used to achieve the same outcome?

Supply and possession in other circumstances

Regulations 39A, 39BA, 39BB, 39B, 39C outline other circumstances where prescription medicines may be supplied.

Use	Supply or use conditions
stockfeed manufacturers	manufacturers with a permit may sell stockfeed containing antibiotic or sulphonamide to a person with a written order from a veterinary surgeon
certificated commercial vessels	masters of a commercial vessel may possess prescription medicines to complete the vessel equipment in accordance with W*A Marine Act 1982* a written order from the master of the vessel is required for supply the medicine must be stored appropriately and recorded when administered
racing yachts	racing yacht owners may possess prescription medicines to complete the equipment of the yacht in accordance with the *Racing Rules of Sailing* a written order from the owner is required for supply the medicine must be stored appropriately and recorded when administered
other ships and aircraft	masters of other ships may possess prescription medicines to complete equipment in accordance with legislation for ships registered within and outside Australia person in charge of an aircraft may possess prescription medicines specified by the Department of Transport (Commonwealth) for medical treatment aboard the aircraft a written order is required for supply
ships carrying livestock	masters of ships carrying livestock may possess prescription medicines for compliance with the *Australian Livestock Export Standards March 2001* and *Marine Orders* of the *Navigation Act* a written order from the owner is required for supply the medicine must be stored appropriately

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Issues to consider in new regulations:

- what rules of supply should apply to ships and aircraft?
- are there situation where different rules should apply – why and where?

Possession of prescription medicines:

- Only a medical practitioner, nurse practitioner, pharmacist, dentist, endorsed optometrist, endorsed podiatrist, endorsed midwife, veterinary surgeon, analyst, director of nursing or other person authorised by the CEO may procure a prescription medicine (40).
- This authorisation extends to the extent required for that person's lawful profession, and in quantities for that purpose (40).
- Prescription medicines supplied on written order can only be delivered to the person to whom the medicine is sold or supplied, or someone with written permission from that person.

Key changes in the Medicines, Poisons and Therapeutic Goods Bill:

- it is an offence to supply to a person a medicine which has not been prescribed or if the recipient is not an appropriately authorised health professional or Licence/Permit holder
- it is an offence to supply a medicine if it is believed it will not be used, supplied or administered in accordance with medical instructions
- authorised persons can instruct their employees to handle medicines and poisons, provided the employee is acting within their skills and knowledge
- prescribing of a medicine cannot be delegated to an employee.

Issues to consider in new regulations:

- what specific controls should there be on possession of prescription medicines?
- are there any groups who should be authorised to possess prescription medicines?

Division 3 – General

This Division outlines the general requirements for sale, supply and use of poisons.

General rules for poisons:

- The CEO may revoke a person's authority or make conditions relating to Schedule 6 poisons (41).
- Retailers of Schedule 7 poisons must keep a record of sale in a register in a specified format for two years and produce this if required (41A).

- Antibiotics for intramammary infusion in animals must be packed in an applicator device for this purpose and coloured with brilliant blue (41AA).
- Camphor and naphthalene may only be sold as balls, blocks, discs, or pellets, and must be in an enclosed device (41AB).
- Wholesale procurers, suppliers and manufacturers of Schedule 3, 4 or 7 poisons must make a record of each supply, keep this for two years and provide information when requested (Regulation 41B).
- Schedule 7 poisons must be stored in an area that only the owner, employees or authorised persons can access (41C).

Issue to consider in new regulations:

- Regulations for Schedule 5, 6 and 7 poisons will be nationally consistent via adoption of updated regulatory controls from the Poisons Standard (SUSMP).

Schools and child care services

- Schools and child care services may obtain and provide emergency treatment of adrenaline for anaphylaxis and salbutamol for acute asthma to pupils (41D).

Issue to consider in new regulations:

- How should supply of Schedule 3 medicines for emergency use by persons other than health practitioners be controlled?

Part 6 — Drugs of addiction

This part describes the regulatory requirements of Schedule 8 medicines (drugs of addiction) including supply and prescription, dispensing and delivery and restrictions on supply.

Division 1 — General

Authorisations for Schedule 8 medicines:

- A medical practitioner, pharmacist, veterinary surgeon, registered analyst, registered nurse at a hospital, registered midwife at a hospital, or person with a Permit can procure and possess a Schedule 8 medicine for the purposes of their profession or employment (42).
- A person with a prescription may possess a Schedule 8 medicine in the amounts specified.
- Dentists may possess specified amounts of pethidine, papaveretum, codeine phosphate, methadone, morphine, oxycodone and pentazocine.
- Licensed pharmacists may procure, manufacture, dispense, compound, sell or supply Schedule 8 medicines at their premises in the course of their retail business (43).

- The CEO may revoke the authority of a health practitioner or apply conditions in relation to Schedule 8 or specified drugs (43A).

Key changes in the Medicines, Poisons and Therapeutic Goods Bill:

- authorises health professionals to administer, possess, prescribe or supply, in lawful practice as outlined in regulations
- if there are grounds, authorisation may be cancelled, suspended or conditions imposed.

Issues to consider in new regulations

- how should authorities will be outlined in Regulations?
- what limitations should apply to Schedule 8 authorisations?

General:

- A person may be authorised to possess Schedule 9 poisons for educational, experimental or research purposes including chemical analysis, anaesthesia of exotic animals and training animals for the detection of these substances (43B).
- Schedule 8 medicines may only be advertised in professional publications for authorised health practitioners (43C).

Record keeping:

- A register of each Schedule 8 medicines transaction must be kept (44).
- For every transaction the drug name, quantity and form, transaction date, name and address of person and prescriber, and balance on hand must be recorded (44).
- A register is required for each separate location at which Schedule 8 medicines are kept (44).
- The register must be in an approved form and must be available on request (44B).
- Records must be in ink, made by the authorised person, and not be altered, obliterated or deleted (44B).
- An incorrect entry may be amended by making a footnote, initialling and dating the entry (44B).
- Schedule 8 medicines records, registers, prescription books and invoices must be kept for seven years and be available for inspection or surrendered (with any stocks) if required (47).
- If the register is lost or destroyed the CEO must be notified and a stock-take performed (47).
- False or untrue entries and records are not permitted (47).
- Printouts from a computerised recording system used to provide monthly returns must be kept for one year at the place of dispensing (47).

Destroying drugs of addiction

Regulation 44A outlines requirements for destroying drugs of addiction:

- A person authorised to supply a drug of addiction is authorised to destroy a drug of addiction.
- Drugs of addiction may not be wilfully destroyed.
- Drugs of addiction may be destroyed under the supervision of a Departmental officer authorised for this regulation, or a police officer.
- Destruction by an authorised person requires witness by a pharmacist, medical practitioner, nurse practitioner or director of nursing.
- Other than a pharmacist, a witness may not be of the same profession.
- A register must be kept of medicines destroyed with date of destruction, name, strength and quantity of the poison destroyed, reason, and name of the witness.
- Pharmacists must provide records of destruction as part of their monthly return which is signed, or in the case of a computerised system includes the name of the person and witness.
- Licensed wholesalers must provide a weekly report of all Schedule 8 medicine transactions made during that week on an approved form (48).

Electronic drug of addiction registers

Regulation 44C outlines the requirements of an electronic drug of addiction Register. The register must:

- be maintained by the authorised person responsible for the Register
- not allow unauthorised access
- not allow deletion of entries
- require an access code and password known only to the authorised person accessing the system
- record the access code next to the authorised person making an entry which may not be altered
- a secure record of the access codes issued must be maintained
- in legal proceedings an access code next to an entry is taken as the person who was issued the code having made that entry.

Inventory of drugs of addiction:

- An inventory of stock must be conducted monthly, or when the control of the S8s is transferred (45).
- Inventory results must be recorded in the Register (45).
- The authorised person must report any discrepancies to the CEO in writing (Regulation 45).

Other Authorised persons

Regulations 49, 49A and 49B outline other circumstances where Schedule 8 medicines may be supplied.

Authorised person	Procurement and supply	Order requirements	Use conditions
master of certificated commercial vessel	signed written order certifying the poison is necessary to complete vessel equipment under the *WA Marine Act 1982*	date name of vessel machinery and hull number. name, address, signature quantity, form, and strength of medicine	stored to prevent theft, loss or unauthorised use record kept of poisons stored aboard record of administration: date poison, strength, quantity name of patient name / address of authorising medical practitioner
owner of racing yacht	signed written order certifying necessary for equipment under the 'Racing Rules of Sailing' by Yachting Australia Inc.	date name of yacht registration of yacht. name of organising yacht club name, address and signature quantity, form, and strength of poison	stored to prevent theft, loss or unauthorised use record kept of poisons stored record of administration: date poison, strength, quantity name of patient name / address of authorising medical practitioner
master of ship other than commercial vessel or racing yacht	signed written order, certifying necessary for ship equipment, according to *Navigation Act 1912*, State navigation authority, country where ship is registered, or International Medical Guide for Ships	N/A	any person supplying must notify the CEO or nearest police station within 24 hours
person in charge of an aircraft	signed written order certifying necessary for medical treatment on aircraft, in quantity not exceeding max permitted by Department of Transport		

Issues to consider in new regulations

- what rules of supply should apply to ships and aircraft?
- are there other situations where different supply rules should apply – where and why?

Storage in hospitals:

- In a hospital the Chief Pharmacist is responsible for Schedule 8 medicines. If there is no pharmacy department, the director of nursing or another authorised person is responsible (50).
- A practitioner authorised to prescribe Schedule 8 medicines can administer Schedule 8 medicines to an inpatient at a hospital (50).
- An authorised prescriber can authorise administration to a patient by written order on the patient medication chart (50).
- An authorised prescriber can authorise administration to a patient by verbal order if this is endorsed in writing on the medication chart within 24 hours (50).

Issues to consider in new regulations

- how do the needs of hospitals and health institutions to access medicines differ from those in the general community setting?
- what requirements should apply to storage, prescribing, recordkeeping and accountability for Schedule 8 medicines in hospitals?

Division 2 — Supply and prescription

Subdivision 1 – Prescriptions generally

Prescriptions for drugs of addiction:

Regulation 51 outlines requirements for prescribing drugs of addiction.

- Prescriptions must include the name and address of the prescriber; the name, address and date of birth of the patient; description and quantity of the drug; directions for use of the drug, including dose; date issued and maximum number of repeats.
- A veterinary prescription must contain the name and address of the animal's owner, description and quantity of the drug, precise direction for use and date written.
- Each prescription may include only one drug of addiction unless for another form or strength of the same medicine.
- Dentists must include on prescriptions 'for dental treatment only' and veterinary surgeons must include 'for animal treatment only'.
- Unusual doses must be underlined and initialled, or indicate the dose was intended.

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- An electronic prescription must be via an approved system.
- A paper prescription must be in ink in the prescriber's own handwriting.
- A computer-generated prescription must be issued via an approved system and have details written in ink in the prescriber's own handwriting.
- A computer-generated prescribing program must comply with Appendix L or be approved by the CEO.
- Paper and computer-generated prescriptions must be signed in the prescriber's own handwriting.
- A prescriber may type the prescription if physically unable to write and approved by the CEO to do so.

Issues to consider in new regulations

- what record keeping and reporting and other controls are necessary to assure public protection from the diversion and misuse of Schedule 8 medicines?
- what details should a paper based or other prescription contain?
- what safeguards are needed to prevent forgeries and unauthorised access to medicines?

Hospitals:

- The National Inpatient Medication Chart in a public hospital is a prescription for discharge medicines if all details are completed in ink in the prescriber's handwriting (51AAA).

Subdivision 2 – Supply and prescription to drug addicts

This Subdivision sets out the rules and conditions of the Community Program for Opioid Pharmacotherapy (CPOP).

Opioid pharmacotherapy:

- An addict must disclose their addiction when seeking Schedule 8 medicines (51AA).
- Schedule 8 medicines not for the treatment of addiction can be administered to an addict for medical purposes (51BA).
- Schedule 8 medication not for the treatment of addiction can only be prescribed or supplied to an addict for medical purposes if approved by the CEO (51BA).
- A prescriber may only supply or prescribe pharmacotherapy to an addict if authorised and according to the CPOP policies manual (51B).
- The CEO can appoint a prescriber as an authorised prescriber, and an authorised prescriber as a specialist prescriber (51C).
- The CEO can appoint an authorised prescriber for an addict for a specified period, in writing, with conditions (51CA).
- A specialist prescriber can nominate a co-prescriber in writing for up to one year (51CB).

- A prescriber at the same practice as an authorised prescriber can prescribe according to an existing authorisation (51D).
- Pharmacotherapy may be prescribed for an addict in hospital for up to one month by an existing authority, if safe to do so (51DA).
- Pharmacotherapy may be prescribed for an addict in custody for up to one month by an existing authority, if safe to do so (51DB).
- If person is unable to obtain a prescription, a specialist prescriber can prescribe pharmacotherapy for up to one month according to an existing authority, if safe to do so (51DC).
- A pharmacist (or assistant under direct supervision) may dispense a Schedule 8 medication to a drug addict other than a pharmacotherapy (51E).
- A pharmacy may not dispense a pharmacotherapy unless authorised and according to the CPOP policies manual (51EA).

Key changes in the Medicines, Poisons and Therapeutic Goods Bill:

- regulations may be made relating to supply or prescription of drugs of addiction to a drug dependent person
- it is an offence to supply or prescribe in these circumstances except in accordance with the regulations.

Issues to consider in new regulations:

- CPOP provides a framework for drug dependent persons to receive maintenance treatment in the community with minimal disruption
- CPOP policies and procedures can be viewed on the Drug and Alcohol Office website.
- what are the current and future needs to consider for pharmacotherapy progams?

Subdivision 2A – Supply and prescription of Schedule 8 poisons to persons other than drug addicts

This Subdivision outlines rules for supply and prescription of Schedule 8 medications. Regulation 51F restricts the treatment of persons who are not drug addicts:

- Prescribers need approval to prescribe Schedule 8 medicines for more than 60 days per year.
- An approval may restrict the medication, amount, dispensing pharmacy, daily limit and specified repeat intervals.
- Prescriptions must comply with any specified conditions.
- Authorisations are for a specified term only.
- Pharmacists must comply with any specified conditions when suppling Schedule 8 medicines.

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- Methadone and buprenorphine may only be prescribed for intractable pain not related to drug addiction.

Issues to consider in new regulations:

- Schedule 8 medications are addictive and their use has increased dramatically in Australia over the past decade
- prescribing is regulated to prevent dependence and community harm
- Schedule 8 Prescribing Code. This document can be viewed on the Department of Health website.
- what continued safeguards are required to minimise dependence?

Subdivision 3 – Supply and prescription of stimulants

This subdivision describes the rules and conditions of the stimulant program:

- A stimulant prescriber must be authorised by the CEO (51FB).
- An authorised prescriber is issued a Stimulant Prescribing Number (SPN) (51FG).
- Prescribers must comply with the Stimulant Prescribing Code (51FC).
- The CEO can order in writing that a stimulant is prescribed/supplied in a certain way or not prescribed/supplied (51FD).
- Prescribers must notify their intention to treat a patient with a stimulant (51FE).
- Prescribers must re-notify of any change to dose, drug, patient details or for cessation of treatment (51FE).
- The prescriber who has notified a patient is the current prescriber (51FF).
- If a notification is received from a different prescriber they become the current prescriber and the CEO must inform the previous prescriber (51FF).
- An SPN prescriber can appoint a co-prescriber by notifying the CEO and co-prescriber (51FH).
- Co-prescribers (and prescribers at the same practice) can prescribe according to the appointment and notification of the current prescriber (51FH).
- The CEO may cancel appointment of a co-prescriber in writing (51FH).
- A clinic at a public hospital with more than one SPN prescriber can be authorised as a public sector clinic in the name of a clinic ‘manager’(51FJ).
- The CEO must be informed of a change of manager (51FK).
- The CEO must be notified of commencement or cessation of SPN prescribers at the clinic (51FJ).
- A current clinic must notify its intention to treat a patient with a stimulant, or any intended change to treatment (51FE).
- The clinic that has notified a patient is the current clinic (51FF).
- If a notification is received from a different clinic they become the current clinic and the CEO must inform the previous clinic (51FF).

- Stimulants may be prescribed and supplied for a patient in hospital or in custody for up to three months in accordance with an existing notification (51FB).

Issues to consider in new regulations

- the Stimulant Regulatory Scheme provides a framework for supply of stimulant medications such as dexamphetamine for medical purposes while reducing misuse, abuse and diversion
- Stimulant Prescribing Code. This document can be viewed online on the Department of Health website.
- what continued safeguards are required to minimise misuse of stimulants?

Subdivision 4 – Supply and prescription of other poisons

This Subdivision outlines the rules for supply of dronabinol and flunitrazepam.

Dronabinol and flunitrazepam:

- Medical practitioners can only prescribe dronabinol if authorised by the Therapeutic Goods Administration (51GA).
- Medical practitioners must be authorised by the CEO to prescribe flunitrazepam (51GB).
- An authorisation can specify conditions, amounts and duration which must be observed (51GB).
- An authorisation number will be issued which must be marked on any prescription dispensed using it (51GB).

Prescribing by dentists:

- Dentists can only prescribe or supply Schedule 8 medicines included in the PBS Schedule for dental treatment (51H).
- Dentists require authorisation to prescribe for more than seven days or 60 days per year (Regulation 51H).

Issues to consider in new regulations

- what specific restrictions should apply to dentists or other prescribers?

Division 3 — Dispensing and delivery

This division sets out the conditions for dispensing and delivering drugs of addiction.

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Supply of Schedule 8 medications on prescription

Regulation 52 sets out the requirements for dispensing a Schedule 8 medicine:

- Schedule 8 medicines can only be dispensed in accordance with a valid prescription
- Only an authorised practitioner (or supervised assistant) can dispense Schedule 8 medicines.
- The dispenser must ensure the script is compliant and issued by an authorised prescriber.
- The medication can only be dispensed for the number of times and at the intervals specified.
- The dispenser must sign, date and stamp prescriptions with the dispensary name and address (or similarly mark this in an electronic prescribing system).
- A veterinary prescription may not include repeats.
- If repeats are prescribed, the dispenser must mark the amount dispensed and indicate how many repeats remain (or similarly mark this in an electronic prescribing system).
- The dispensed prescription (and repeats) must be retained at the premises it was dispensed at.
- The CEO may approve the transfer of repeats to another dispenser.
- If repeats are not indicated or the maximum repeats are reached, the script must be ‘cancelled’ (or similarly marked in an electronic prescribing system).
- The dispensing transaction must be entered into the Drugs of Addiction Register.
- The prescription number; patient name, address and date of birth (or name and address of person caring for an animal in veterinary use); medicine name and quantity; directions for use; date issued; name and address of the prescriber; and indication that the prescribers signature is verified must be recorded in the Prescription Book.
- The prescription number must be marked on the medicines label.
- The medicine supplied must exactly match that which has been prescribed.
- The dispenser must verbally verify a prescription unless they are familiar with and recognise the prescriber’s signature.
- Prescriptions are valid for six months from date of issue.
- Prescriptions may not be dispensed if illegible, defaced or altered.
- Pharmacist suspecting a false prescription must take steps to ensure its genuineness.
- A false prescription must be cancelled, signed, dated and forwarded to the CEO with reasons for cancellation.
- Any document or record of supply must be produced upon request.

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Key changes in the Medicines, Poisons and Therapeutic Goods Bill:

- the CEO must keep a record of information relating to the supply and prescribing of drugs of addiction according to Regulations
- the CEO may disclose information to a client's treating health practitioner.

Issues to consider in new regulations:

- the Commonwealth Government is building an Electronic Recording and Reporting of Controlled Drugs (ERRCD) system
- what recording, reporting and other controls are necessary to prevent diversion of Schedule 8 medications?

Other dispensing rules:

- A prescription issued on an approved electronic system or a paper script must be verified with the prescriber unless the dispenser is familiar with the prescriber's hand writing (53A).
- If a prescription cannot be verified then only two days of treatment may be supplied (53A).
- Pharmacies must provide the Department with a monthly report of transactions seven days after the end of the month, on the original of an approved duplicate form or on a signed and verified computer printout (52C).

Dispensing in emergencies:

- A prescriber may verbally request dispensing of an emergency supply if a prescription is forwarded to the dispenser within 24 hours (53).
- The CEO must be notified if the script is not received with in 72 hours (53).

Issues to consider in new regulations

- evidence suggests abuse and diversion of controlled drugs from legitimate medical sources is increasing
- what emergency access to Schedule 8 medicines required?
- what protections are required to prevent manipulation and abuse of emergency access provisions?

Non-prescription supplies:

- Non-prescription supplies require a written and signed order (54).
- Supply may be on a telephone or fax order if followed within seven days by a signed and dated dispatch note or invoice to the supplier (54).
- Non-prescription supplies must be recorded on an approved duplicate form or computer system, signed and dated by the dispenser (52A).

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- An authorised person may authorise another person in writing to receive orders on their behalf (54).
- Schedule 8 medicines must be packaged securely away from other goods and in plain non-identifying packaging (54A).
- Common carriers may transport Schedule 8 medicines for their business (55).

Issue to consider in new regulations:

- What controls are necessary to ensure the security of wholesale or non-patient movement and transport of larger quantities of controlled drugs?

Division 4 — Safe custody

This Division outlines the rules for the storage and security of drugs of addiction.

Storing Schedule 8 medicines:

- An authorised person with less than 200 tablets, 20 ampoules, 500 mL liquid, or 7.5 grams (56A) must store them in a safe meeting the requirements of Clause 1 of Appendix M (56).
- If in possession of more than these amounts the additional security requirements of Appendix M are applicable (56).
- The CEO may approve other security arrangements in writing (56).
- Safes may not be in public areas, unless the safe owner is present when the public is present (56B).
- Safe keys must be on the person or in possession of the authorised person (56C).
- The safe must be locked except when items are being transferred in or out (56D).
- Combination-lock safes may be unlocked during business hours if closed and in view of the authorised person (56D).
- While present on the premises, a pharmacist may use a poisons cupboard or lockable drawer (56E) if the keys are in their personal possession and the cupboard or drawer is locked except when items are transferred in or out (56F).
- In a hospital ward a lockable cupboard may solely store Schedule 8 medicines (56G).
- A registered nurse or midwife in charge of the ward must keep the cupboard keys and ensure the cupboard is locked except when medicines are transferred in or out (56H).

Key changes in the Medicines, Poisons and Therapeutic Goods Bill

- a prescriber who reasonably believes a person is drug dependent or oversupplied with drugs of addiction must make a report to the CEO
- is an offence to supply or prescribe a drug of addiction to a drug dependent or oversupplied person without authorisation.

Division 5 — Restrictions on supply:

- Labels must clearly show the total quantity and percentage for mixtures and the number of tablets (Regulation 57).
- A Schedule 8 medicine may not be knowingly prescribed, supplied or administered for the purposes of addiction (Regulation 58).

Issues to consider in new regulations:

- what controls are necessary to ensure the secure storage of controlled drugs?
- what technologies or other practices might be considered to ensure accountability and ensure business efficiency?

Part 7 — Miscellaneous provisions:

- The CEO may publish a cancellation, suspension or revocation of an authorisation, licence or permit in the *Government Gazette* (59).
- If prescribed by an approved generic name, any brand of that medicine may be dispensed (n 64).
- If prescribed by brand, any brand of the same medicine may be supplied unless 'no substitution' or similar instructions are marked (64).
- For a public hospital any brand of the same medicine regardless of the brand prescribed (64).

Key changes in the Medicines, Poisons and Therapeutic Goods Bill

- if the CEO takes action against a health professional a relevant regulatory authority may be notified
- the CEO may publish an action in the Gazette or on a website for this purpose

Appendices

Appendix J – Schedule 3 poisons sales to be recorded

Substances in Schedule 3 requiring a record of sale:

- pseudoephedrine
- hydrocortisone
- hydocortisone acetate

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Appendix K – Criteria for electronic prescribing systems:

- Permanent records of access codes (person, date issued, date cancelled) must be kept.
- Each entry must have a unique, sequential number with time, date and access code of person making the entry.
- Access codes must be updated according to good industry practice.
- Back-up arrangements for records must be maintained.
- A record of the system administrator must be kept for seven years.
- The system must generate printed reports of persons given access codes, system access, system entries, entries by drug or patient.

Appendix L – Specified criteria for the generation of prescriptions by computer:

- Only the prescriber can generate a prescription.
- The prescription is on a pre-printed form with prescriber contact details.
- The total number of items prescribed is marked on the prescription.
- Directions for use must be included.
- Prescriptions details must be included in the patient's clinical record.
- A unique identification number must be marked on the prescription.
- A record of the prescription must be kept for at least one year.
- For Schedule 8 medicines the statement *'prescriber must write these prescription details in his or her own handwriting'* must appear.

Appendix M – Safes and additional security for storing drugs of addiction

Free standing safes must:

- weigh more that 500 kg
- if less that 1000 kg must be bolted to a concrete floor by a licenced security operator
- lock with key or combination
- be of steel plate 12 mm thick and have 2 x 25 mm locking bolts
- be eligible for $30,000 insurance cover.

Under floor safes must:

- be embedded in concrete by a licenced security operator
- lock by combination
- have a 25 mm steel lid
- be eligible for $30,000 insurance cover.

- Safes must be protected by an alarm compliant with AS 2201.3.
- Safes must have a movement detection device to detect interference.
- Alarm and detection devices must be monitored by dedicated direct line installed by a licenced security operator.

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Regulations required under the Medicines Poisons and Therapeutic Goods Bill

The Bill makes provision for regulations in various clauses. In some cases similar regulations already exist in the Poisons Regulations 1965 and are outlined as above.

As some clauses of the Bill are entirely new and have no equivalent clause in the Poisons Act 1964, entirely new Regulations are also required.

Strictly Controlled substances:

- Appendix C of SUSMP lists a number of poisons which are of sufficient danger and for which no legitimate or safe medical or other use exist such that their prohibition is warranted.
- At present substances may be prohibited by proclamation of the Governor.
- Appendix C is replicated via this mechanism.
- Appendix substances may not be supplied, but there is no penalty for their possession.
- The Bill allows regulations to classify a substance as strictly controlled.
- The regulations may authorise persons to supply or use a strictly controlled substance.

Vending machines:

- The Poisons Act 1964 prohibits all forms of automated machines to supply a poison.
- Under the Bill it is an offence to supply a poison from a vending machine except as outlined in regulations.
- Automated supply must ensure the purchaser is identified and receipt of supply is verifiable.
- Automated supply must not pose a risk to the public through loss of protections from direct human involvement.
- Automated supply must not result in a loss of security or increase in diversion due to lack of direct human monitoring and observation of storage of poisons.
- Dangerous poisons may not be suitable for automated supply.
- Automated supply machines should not increase medicine-related harm or reduce therapeutic evaluation and intervention by health professionals where necessary.
- Automated medicines supply may improve efficiency, accountability and reduce medicine-related errors.

Schedule 4 reportable poisons:

- At present certain substances (such as anabolic steroids) are declared Specified Drugs.
- Unauthorised possession and use of Specified Drugs are offences under the *Misuse of Drugs Act 1981.*
- The Bill allows for regulations to define a poison with a propensity for abuse, misuse or illicit use to be a Schedule 4 reportable poison.
- For the purposes of the Bill, a Schedule 4 reportable poison may be considered a drug of addiction.

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