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Department of **Health**

Medicines and Poisons Regulations 2015 – Consultation Regulation Impact Statement

28 August 2015



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Definitions used in this document

The following table outlines terms commonly used in this document -

Word/Abbreviation	Meaning
<i>the Act</i>	the <i>Medicines and Poisons Act 2014</i> .
<i>adopted code</i>	a code that is adopted by regulations.
<i>administer</i>	in relation to a poison, means to give to another person/patient.
<i>authorised health professional / practitioner</i>	a health professional who has a professional authority.
<i>CEO</i>	the Chief Executive Officer of the Department.
<i>code</i>	a code, standard, rule, specification or other document.
<i>certificated commercial vessel</i>	a fishing vessel, passenger vessel or trading ship as defined in the <i>Western Australian Marine Act 1982</i> section 3(1).
<i>delegate</i>	a person with authority to make a decision under permission of the CEO.
<i>Department</i>	the Department of Health, Western Australia.
<i>direction</i>	regular and frequent supervision but does not necessarily imply continuous personal supervision.
<i>dispense</i>	in relation to a medicine or a poison — (a) supply of medicine or poison on and in accordance with a prescription duly given by a medical practitioner, a nurse practitioner, a dentist or a veterinary surgeon; and (b) in relation to a drug of addiction.
<i>distributor</i>	a person who imports, sells or otherwise supplies a poison.
<i>dosage unit</i>	an individual dose of a poison and includes a tablet, capsule, cachet, single dose powder, or a single dose sachet of powders or granules.
<i>drugs of addiction / dependence</i>	refers to Schedule 8, Schedule 9 or reportable Schedule 4 medicines.



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<p>Electronic Recording and Reporting of Controlled Drugs (ERRCD) system</p>	<p>Electronic Recording and Reporting of Controlled Drugs (ERRCD) system will involve (but will not be limited to):</p> <ul style="list-style-type: none"> • the development of a nationally consistent electronic system for the recording and reporting of controlled drugs including the collection of information relating to the prescription and dispensing of controlled drugs; • the storage of that information in a database, accessible to State/Territory health Departments in real-time; and • the provision of real-time '<i>electronic decision support tool</i>' for prescribers and distributors of controlled drugs, where prescribers and pharmacists will have access, via the internet, to a secure database of prescription histories of patients.
<p>Electronic Storage and Supply Unit (ESSU)</p>	<p>means a machine or device used or capable of being used for the purpose of supplying goods without the personal manipulation or attention at the time of supply of the supplier or an employee or agent of the supplier. Is referred to as a vending machine in the Act.</p>
<p>health professional</p>	<p>a person who is —</p> <ol style="list-style-type: none"> (a) a registered health practitioner; or (b) a veterinary surgeon; or (c) in a class of persons prescribed by the Regulations for the purposes of this definition.
<p>licence</p>	<p>a licence granted to by the Department.</p>
<p>licensee</p>	<p>the holder of a licence.</p>
<p>manufacture</p>	<p>includes the processes of packing and repacking, refining manipulating and mixing any poison.</p>
<p>manufacturer</p>	<p>a person who manufactures, produces, or packs a poison.</p>
<p>Medical Practitioner</p>	<p>a person whose name is contained in the register of kept by the Medical Board of Australia under the <i>Health Practitioner Regulation National Law (Western Australia)</i>.</p>
<p>medicine</p>	<p>a substance that is a Schedule 2, 3, 4 or 8 poison.</p>
<p>obtain</p>	<p>in relation to a poison, means to get or acquire.</p>



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permit	a permit granted to purchase poisons to use for industrial, educational, research purposes or to provide health services.
permit holder	the holder of a permit.
personal supervision	close and continuous control requiring the actual presence of the person exercising the supervision.
pharmacy	a registered pharmacy as defined in the <i>Pharmacy Act 2010</i> section 3(1);
pharmacist	a person registered under the Health Practitioner Regulation National Law (Western Australia) in the pharmacy profession;
poison	a substance that is a Schedule 2, 3, 4, 5, 6, 7, 8, 9 or 10 poison; These are further explained in table below;
possess	in relation to a poison, means to have in their possession;
prescribe	in relation to a poison, means to issue a prescription for the poison;
prescriber	in relation to a Schedule 4 or 8 poison, means an authorised health professional who has authority to prescribe the poison;
prescription	in relation to a Schedule 4 or 8 poison, means a document (whether written or electronic) that — <ul style="list-style-type: none"> (a) sets out particulars of the poison, or a substance that contains the poison, that is, for therapeutic purposes, to be — <ul style="list-style-type: none"> (i) used by, or administered to, a person named in the document; or (ii) administered to an animal described in the document; and (b) is issued for the purpose of enabling the poison to be supplied for that purpose; and (c) complies with any requirements prescribed by the regulations.
professional authority	<ul style="list-style-type: none"> (a) an authorisation under section 25 to administer, possess, prescribe, supply or use a medicine; or (b) an authorisation under section 26 to manufacture a medicine or use or possess a Schedule 7 poison.



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registered health practitioner	a health practitioner who is registered under the <i>Health Practitioner Regulation National Law (Western Australia)</i> to practice as a health profession.
1965 Regulations	refers to the Poisons Regulations 1965.
supply	in relation to a poison, means to supply the poison, or a substance that contains the poison, to another person, but does not include administering a poison or substance directly to another person or to an animal.

Poison Schedule

The Poisons Standard¹ defines the scheduling standard of poisons based on the level of control required. Thus scheduling classification from 1-10 is outlined below.

Schedule 1 — [Blank]
Schedule 2 — Pharmacy medicines Substances: the safe use of which may require advice from a pharmacist and which should be available from a pharmacy or, where a pharmacy service is not available, from a licensed person.
Schedule 3 — Pharmacist only medicines Substances: the safe use of which requires professional advice but which should be available to the public from a pharmacist without a prescription.
Schedule 4 — Prescription only medicines, or Prescription Animal Remedy Substances: the use or supply of which should be by or on the order of persons permitted under the Act to prescribe and should be available from a pharmacist on prescription.
Schedule 5 — Caution Substances: with a low potential for causing harm, the extent of which can be reduced through the use of appropriate packaging with simple warnings and safety directions on the label.
Schedule 6 — Poison Substances: with a moderate potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label.

¹ Commonwealth of Australia. Standard for the Uniform Scheduling of Drugs and Poisons. 2015. <https://www.comlaw.gov.au/Details/F2015L00844>



Schedule 7 — Dangerous Poison

Substances: with a high potential for causing harm at low exposure and which require special precautions during manufacture, handling or use. These poisons should be available only to specialised or authorised users who have the skills necessary to handle them safely. Special regulations restricting their availability, possession, storage or use may apply.

Schedule 8 — Controlled Drug

Substances: which should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence.

Schedule 9 — Prohibited Substance

Substances: which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of the CEO.

Schedule 10 – Strictly Controlled Substance

Substances: which require strict control of the supply and use of the substance to protect the health, safety and welfare of the public.



Executive Summary

Purpose of the CRIS document

The purpose of this paper is to:

- provide background information on the development of subsidiary legislation to replace the *Poisons Regulations 1965*;
- outline current issues with existing regulations and identify proposed changes to address these issues;
- outline potential impacts of the proposed changes in the regulations which have already been identified; and
- outline the opportunities to provide comment, feedback regarding the proposed changes and impact of these changes.

Background:

The assent of the Medicines and Poisons 2014 (the Act) was tabled in Parliament on 2 July 2014. The Act replaced the aged Poisons Act 1964 in regulating medicines and poisons in WA. The Poisons Act 1964 was supported by the Poisons Regulation 1965 (1965 Regulations). It is proposed that new subsidiary legislation be developed to support the Act and supersede the 1965 Regulations.

The Act contains an updated legal framework for the efficient and effective management of medicines and poisons. Regulations set out the detailed controls to protect the public from harm associated with medicines and poisons. Some of the existing regulations contained in the 1965 Regulations may be retained or amended to reflect different aspects of the Act and where appropriate new regulations may be required.

Development of the Regulations will be conducted under the overarching framework for controls and known impacts determined by the Act. The Regulations will address the regulation gaps evident due to new inclusions in the Act. It must be noted that development of the Act included broad stakeholder consultation and impact assessment. Further targeted consultation will be undertaken in the formulation of regulations particularly in areas of reform including: corporate licences, professional authority, and enhanced controls for drugs of addiction.

Objectives:

The objective of the Act and Regulations are to protect public health and safety, through regulation of medicines and poisons. To achieve reform relating to regulatory failure areas of:

- National consistency;
- Excessive regulatory burden;
- Improved control over supply of drugs of addiction; and



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- Access by new categories of qualified health practitioners

The legislation aims to control those substances nationally assessed as harmful and therefore requiring protection from unrestricted public access.

Options Identified:

The Consultation RIS identifies the following three options in relation to poison regulation:

Option 1: Status quo – Retention of the current 1965 Regulations

This option proposes that the existing Regulations provide significant control and should be adhered to with no further alteration.

Option 2: Amend the 1965 Regulations

This option proposes the development of exemptions to support the Act in control areas as per current regulatory practice.

Option 3: Develop a new regulatory framework, *Medicine and Poisons Regulations 2015*.

This option proposes the replacement of the 1965 Regulations with a new regulatory framework, the Medicine and Poisons Regulations 2015 to support the Act.

Extensive consultation has shown the third option is more efficient and will support the Act to achieve reduction in regulatory burden, national consistency and provide clarity regarding controls required over Scheduled medicine and poisons to ensure public safety.

Guide to the document

This CRIS is divided into two sections and three appendices, as outlined below.

Section 1– Background

This section provides important background information. It explains what a poison is and why there is medicine and poisons legislation. It provides an overview of the Act and 1965 Regulations. The first section explains what has happened in the lead up to this consultation RIS including development of the Act. It also describes in broad terms the regulatory problems that are being responded to regarding medicines and poisons in WA. This section explains objectives of effective medicines and poisons regulations in general. It outlines the three individual options that could be used to address the identified problems with the 1965 Regulations. This section also discusses stakeholder feedback to date and identifies the broad policy objectives, which have been developed in consideration of, review of the 1965 Regulations. It identifies the regulatory control areas that require amendment.

Section 2 - Review of Regulations

This section is likely to be of greatest individual interest to stakeholders. It will outline the background regarding specific regulatory areas and detail the known issues in each of these regulatory areas. Additional detail on proposed regulatory change and the justification for considering change in specific areas is provided.



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It includes an assessment of proposed changes in each of the following regulatory areas:

- Professional Authority (2.4);
- Structured Prescribing Arrangements (2.5);
- Electronic Prescribing (2.6);
- Electronic Storage and Supply Units (2.7);
- Licensing and Permits (2.8);
- Control by Poison Schedule (2.9);
- Control by Medicine Schedule (2.10);
- Drugs of Addiction (2.11);
- Drugs of Dependence Records (2.12);
- Electronic Real Time Controlled Drug Reporting (2.13);
- Destroying Drugs of Addiction (2.14);
- Storage and Transport of Drugs of Addiction (2.15); and
- Ships and Vessels (2.16).

These areas will be used to frame the stakeholder feedback utilising an online consultation tool, to gather stakeholder feedback.

Section 3 – Consultation

The final section describes the consultation that has happened to date in the lead up to the production of this consultation RIS. It also describes consultation that is now occurring as part of the consultation RIS process.

Appendices

Appendices are utilised to provide additional or supplementary documentation to support the proposed changes. They will also contain copies of discussion papers and other consultation items, which have been issued or gathered as part of this process. Readers are particularly advised to review the document "Poisons Regulations 1965 – Discussion Paper" in Appendix 2, which assisted in the formulation of proposed changes outlined in Section 2.

Consultation

Significant consultation regarding proposed Regulations has already been completed. The CRIS will form the final stage of the consultation process for the proposed Medicine and Poisons Regulations 2015 at which point public and stakeholder views will be sought.

Organisations and individuals with an interest in the regulations are invited to review the options and provide feedback through the consultation process. The Department will use an online consultation tool for managing, publicising and collating the consultation activity. The



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feedback will be used to update the RIS and assist in making decisions about what changes will be made. Consultation will be facilitated via <https://consultation.health.wa.gov.au/>.



Part 1: Background

1.1 Medicines and Poisons

Poisons are inherently dangerous. A poison is a product or substance that can harm someone if it is used in the wrong way, by the wrong person or in the wrong amount². A person is defined in this document as any member of the public who can access a medicine or poison. A medicine is a poison that a person can consume or apply that has a therapeutic or medicinal benefit.

Medicines and poisons have a wide variety of positive, valuable or desirable effects. They have established benefits, but can also cause harm. The risk of incorrect use of poisons may lead to injury, illness, dependence or death. The potential for incorrect use is significant across the entire community. Each year in WA there are:

- almost 16,000 poisonings reported to the WA Poisons Information Centre³;
- between 10,000 and 15,000 patients admitted to hospital due to medicine misuse⁴;
- in 2013 4.7% (up from 4.2% in 2010) of the population using pharmaceuticals for a purpose other than medically intended⁵;
- societal costs of illicit drug use in Australia were \$ 8.2 billion in 2004 / 2005; and
- in 2008 / 2009 Australian Governments spent almost \$200 million in drug related harm prevention activities alone, including for pharmaceutical drug misuse⁶.

Medicines and poisons are common and can be found in almost every business and every household. As a result medicines and poisons regulation affects everyone. Examples of poisons are outlined in the Table 1.

² Western Australian Department of Health. 2015. Health http://healthywa.wa.gov.au/Healthy-WA/Articles/J_M/Medicines-and-poisons

³ Sir Charles Gardner Hospital. WA Poisons Information Centre Annual Report 2012. http://www.scgh.health.wa.gov.au/OurServices/WAPIC/pdf/WAPIC_AnnualReport.pdf

⁴ Safety and Quality Council: Second National report on Patient Safety, Improving medication Safety. Canberra: Australian Council for Safety and Quality in Health Care.

⁵ Australian Institute for Health and Welfare. National Drugs Strategy Household Survey 2013. <http://www.aihw.gov.au/alcohol-and-other-drugs/ndshs-2013/ch6/>

⁶ Australian Institute for Health and Welfare. Drugs in Australia 2010: Tobacco, alcohol and other drugs. <http://www.aihw.gov.au/WorkArea/DownloadAsset.aspx?id=10737420455>



Table 1: Medicine and poisons categories

Schedule	Poison category	Examples of common poisons
2	Pharmacy Medicine	cough and cold medicine, nasal sprays, aspirin, paracetamol, ibuprofen, antihistamines
3	Pharmacist only Medicine	asthma inhalers, cold and flu medication containing pseudoephedrine
4	Prescription Medicine	antibiotics, prescription pain killers e.g. tramadol, adrenaline, antipsychotic drugs
5	Poisons requiring caution in handling and storage	bleach, garden pesticides
6	Poisons with moderate to high toxicity	Acids, Oven Cleaners, Drain Cleaner
7	Dangerous Poisons	Cyanide
8	Controlled Drugs	Morphine, Methadone, Stimulants
9	Prohibited Drugs	Heroin

Due to the prevalence and diversity of medicines and poisons the potential risk of harm via improper use is high. To minimise this risk, the use, manufacture, prescription and availability of substances, defined as poisons, is covered by West Australian (WA) legislation. The legislation makes sure that medicines and poisons used in WA for medical, household, industrial and agricultural purposes are carefully controlled. To ensure medicines and poisons provide the most benefit to the community this legislation controls their manufacture (including packaging and labelling) and supply to consumers.

1.2 Objectives of Medicine and Poison Legislation

Medicine and poison legislation outlines controls related to who can use a poison, how they can use it and whom they can give it to. When used correctly medicines and poisons offer great benefit to the community.

Effective medicine and poisons regulation ensures:

- Promotion and protection of public health by ensuring that medicines are of the required quality, safety and efficacy;
- Medicines are appropriately manufactured, stored, distributed and dispensed;
- Illegal manufacturing and trade are prevented, detected and adequately sanctioned;



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- Health professionals and patients have the necessary information to enable them to use medicines rationally; and
- Access to medicines is not hindered by unjustified regulatory workload

The Department is cognisant of the need for legislation to be written in a language that is easily understood by stakeholders, health practitioners and members of the public. It must also seek to achieve national consistency with other legislation wherever possible. To support this need, legislation should provide controls which are proportional to the risk to ensure as much public harm as possible is diverted, while still providing the access required to adequately meet public needs to use these substances. Legislation must clearly articulate the required controls in a manner which is easy to understand and easy to enforce. With these considerations in mind, the legislation must address the need to control those substances that have been universally assessed as harmful and therefore requiring protection from unrestrained public access.

1.3 Medicines and Poisons Act 2014

The Act was passed by Parliament on 2 July 2014⁷. The Act replaces the aged Poisons Act 1964, which was supported by the 1965 Regulations. It is proposed that new subsidiary legislation be developed to support the Act and supersede the 1965 Regulations.

The Act contains an updated legal framework for the efficient and effective management of medicines and poisons. The Act provides a method for classifying poisons according to risk to public health and the development of rules required for their safe management. The risk related to the need for a specific control for a medicine or poison is dependent on how much poison there is, the toxicity of the poison, who is using the poison and how much of the poison is available to others to access.

The Act controls medicines and poisons accessibility by determining the levels of access and stipulating how to access a poison according to the levels of risk.

For example:

- *For the public to access medicines they need to get a prescription from an authorised professional e.g. medical practitioner*
- *For an individual to access a poison the Department can give a licence for having a poison.*

An individual can then access a poison from that person, who can be described as a custodian (holder or supplier) of that poisons. The custodian, in the examples described

⁷ Medicines and Poisons Act 2014.

https://www.slp.wa.gov.au/legislation/statutes.nsf/main_mrtile_13172_homepage.html



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above would be *the doctor or licensee*, both of whom will have permission to be custodians via the Act. A custodian needs to be a person with the appropriate knowledge and skills to manage the risk posed by that medicine or poison. They must be a person who can take appropriate precautions when selling that medicine or poison, or authorising a member of the public to access to that poison. Appropriate custodians are defined in the Act via:

- professional authority – outlining when and why they can provide, and when this authority can be revoked; and
- licence / permit holders – outlining when and why they can supply and when this authority can be revoked.

The Act provides high level frameworks that outlines who are suitable custodians. The frameworks include conditions that the custodians must adhere to in terms of poison labels, packaging, storage, supply and records required. The Act aims to ensure safe and acceptable use of poison via that custodian (*authorised professional, licensee, permit holder*). In addition the Act gives the means to track, control and limit the supply of poisons by these custodians.

Regulations are required to set out the detailed controls to protect the public from harm associated with medicines and poisons. The Regulations have the role of clearly defining who can have professional authority and who requires a licence and permit. Whilst the Act gives the power for authority the regulations give the detail.

For example:

- *The Act states a health professional can be authorised to administer, possess, prescribe, supply or use medicines; or*
- *The Regulations will likely list certain professions and their restrictions,*
 - *e.g. a veterinarian can prescribe for animals.*

Professional authority is already clearly established for certain professions such as medical practitioners and professions regulated via the Australian Health Practitioner Regulation Agency (AHPRA). The regulations are important to provide this clarity in unregulated areas.

For example:

- *A framework for structured prescribing arrangements for professions not clearly authorised via AHPRA e.g. Aboriginal Health Workers.*

The Regulations must also provide a mechanism for individuals, organisations and for the Department to create structured prescribing arrangements.



1.4 Current Regulations: Poisons Regulations 1965

The 1965 Regulations currently regulate the sale and supply of medicines and poisons in WA. The 1965 Regulations set out detailed controls to protect the public from harm associated with medicines and poisons.

The 1965 Regulations are 197 pages long and contain over 175 individual clauses, which have been regularly updated to accommodate medication and poisons issues over time.

Controls outlined in the 1965 Regulations include restrictions 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. Where pressing public need exists, controls outlined in these regulations have been modified or enhanced via regulatory exemptions. Exemption processes have allowed added flexibility to address health workforce or consumer medicines access issues, however they have added a significant regulatory burden on the Department and have decreased the usability and clarity of the document for health practitioners.

For example:

- *Exempting use or supply of a named medicine from provisions of the Act in specified situations i.e. registered nurses in remote area nursing posts providing medicines as part of a standing order approved by the CEO.*

The 1965 Regulations were written almost 50 years ago and other national frameworks and / or regulatory requirements have superseded some control areas. This is particularly relevant in areas such as Licensing and Professional Authorities where new regulatory authorities, e.g. *Therapeutic Goods Administration (TGA)* or *AHPRA* have provided comprehensive national frameworks. The Regulations should be complementary to rather than duplicate other national frameworks.

Development of the Act included broad stakeholder consultation and impact assessment. It must be noted that during this consultation much of the feedback provided by stakeholders related to issues with the regulations. Review of the 1965 Regulations has shown some cohesion with the Act but also some regulatory gaps, in which the 1965 Regulations do not adequately support the Act. It must be emphasised that in many instances regulations from the 1965 Regulations could be directly adopted into the 2015 Regulations.

The 1965 Regulations need update to meet changes to business, workforce and chemicals use, and to meet regulatory drift. Some of the existing provisions in the 1965 Regulations may be retained. In some areas e.g. *Electronic Storage and Supply Units*, recently introduced into existing regulation could be directly adopted into newly drafted legislation. In other areas controls are out-dated. This may be due to changes to current practice, new



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technologies (e.g. *Electronic Prescriptions*), increased uses for different types of medicines and new legislation. Sections of the 1965 Regulations may be amended to reflect different aspects of the Act and where new regulations may be required for the functioning of these new frameworks. Alternative regulatory bodies in some certain instances, could be considered to provide adequate additional protective controls, such that extra regulation is not necessary.

Introduction of new regulatory clauses will consider national consistency, recognition of new roles of health professionals, amendments to control over drugs of addiction and emerging health practice trends and issues to align with the Act. In addition, it will assist the Department in its work in daily application of the regulations by providing clarity around areas of known regulatory failure.

1.5 Consultation undertaken

The Pharmaceutical Services Branch of the Department of Health (the Department) is responsible for consulting over the development of new subsidiary legislation and asking stakeholders for their views about the proposed Regulations. Stakeholders have had an opportunity to influence decisions and actions via a range of methodology.

Through its daily activity, the Department stays informed of stakeholder views through: responding to external regulatory developments; liaison and consultation with other States and Territories regarding their legislation; continual interaction with stakeholders; and operation of audit and compliance programs, regulatory actions and prosecutions, complaint letters, and responding to ministerial and internet queries; as well as provision of general public advice. It receives ad hoc feedback from medical practitioners and pharmacists via the poisons information line and from the Schedule 8 Prescriber Information Service. There are formal links with across WA Health including Chief Pharmacists, Medical Directors, Nursing Directors, Environmental Health Branch, Communicable Disease branch and the Department of Public Health. The Department facilitates Statutory committees including, Community Program for Opioid Pharmacotherapy Management Committee, Stimulants Assessment Panel, Pesticides Advisory Committee and Poisons Advisory Committee which provide opportunities for formal discussion regarding regulatory controls. The Department also has interaction with other Government bodies including AHPRA, Department of Agriculture and Food WA, Police, and the Mental Health Commission (formally Drug and Alcohol Office).

A comprehensive consultation process was undertaken in the development of the Act. This included release of public consultation / discussion papers, targeted stakeholder consultation meetings and release of a RIS regarding the Act. Approximately 50 key stakeholder organisations participated, including Government, Medical, Nursing and Midwifery, Pharmacy, Dental, Allied Health and consumer organisations.

Development of this Consultation RIS has required a review and update of the existing medicine and poisons stakeholders. A comprehensive stakeholder engagement list is outlined in Appendix 1.



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Leveraging from the momentum achieved during consultation for the Act, consultation on the regulations commenced when the Act was presented to Parliament. To develop regulations a structured process has been applied to existing and newly identified stakeholders. This includes compilation of discussion papers, initial surveys / questionnaires and targeted interviews. Regular updates have been made available to internal and external stakeholders via briefings and updates on the Department website.

Development of the RIS and associated recommendations was developed via wide consultation including:

- Survey - August 2013;
- Distribution of Poisons Regulations Discussion Paper, contained in Appendix 2;
- Targeted interviews with Peak body representatives, including Australia Medical Association, Royal Australian College of General Practitioners (RACGP), Hospital groups, Nursing and Pharmacy representatives August 2013 to July 2015; and
- A series of face-to-face Stakeholder Forums held from August 2013 to April 2014.

This consultation process has informed the development of the options outlined below and proposed regulatory changes outlined in the Impact Analysis section of this Consultation RIS.

1.6 Regulatory Options Considered

The consultation to date and stakeholder feedback has focused on the architecture of the poisons regulations and key issues in each regulatory area.

Based on this consultation the following options were considered prior to drafting this Consultation RIS:

1. Status quo: Retention of the 1965 Regulations unchanged;
2. Amend the 1965 Regulations; or
3. New Regulations: Medicine and Poisons Regulations 2015.

1.6.1 Status quo: Retention of the current 1965 Regulations

Status quo means no changes to the existing legislation. Stakeholders have universally identified that the existing legislation has deficiencies and is currently exhibiting significant failure. The current legislation does not achieve the identified objectives of the Act, particularly in relation to harmonisation with other jurisdictions, support for recent changes to the health workforce, reduction in regulatory burden, improving transparency of controls



and providing support for initiatives to reduce diversion and misuse of pharmaceutical drugs.

Advantages:

- Short term least costly option but likely to result in increasing costs in the long term.

Disadvantages:

- National consistency with recommendations of the *Galbally*⁸ *Review* and monitoring of cross border commerce of medicines and poisons not achieved.
- Stakeholder dissatisfaction with deficiencies and regulatory failure including:
 - Limited expanded health workforce participation in providing healthcare;
 - No reduction in regulatory burden of dual licensing;
 - No improved transparency of controls in use; and
 - Limited improvement in increasing diversion and misuse of pharmaceutical drugs.

Retention of current legislation would not create any immediate costs, however there are known costs to consumers and industry at present in dealing with legislative failure. These costs would expect to increase over time.

1.6.2 Amend the 1965 Regulations

This option assumes continuation of the existing arrangements whereby controls outlined in the regulations are modified via the process of amendment and exemption. Controls outlined in the 1965 Regulations include restrictions 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. Where pressing public need exists, controls imposed in these regulations have been modified via regulation exemption. For example, exempting use or supply of a named medicine from provisions of the 1965 Regulations in specified situations i.e. registered nurses in remote area nursing posts providing medicines as part of a standing order approved by the CEO. The exemption process allows amendment, however it places significant increased regulatory burden on the Department. This option restricts development to the areas outlined in existing regulations and does not allow for introduction of new areas. In addition, continuing amendments to the 1965 Regulations are slow, costly and inefficient.

Advantages:

- Is consistent with current work processes
- Stakeholders are familiar with the current regulations

⁸ Council of Australian Governments. National Competition Review of Drugs, Poisons and Controlled Substances Legislation. 2000. <https://www.tga.gov.au/review-drugs-poisons-and-controlled-substances-legislation-galbally-review>



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Disadvantages:

- Will not address stakeholder concerns regarding the difficulties of understanding the current legislation.
- Adding additional regulations required by the Act will take increased time.
- Will require increased time to achieve primary objectives of:
 - National consistency;
 - Expanded realm of health workforce participation;
 - Reduction in regulatory burden;
 - Improved transparency of controls; and
 - Reduced diversion and misuse of pharmaceutical drugs.

The known regulatory failures are multiple and the amendments proposed by stakeholders to resolve these are significant. Achieving the primary objectives through minor alterations presents difficulty due to the advanced age of the 1965 Regulations and the numerous amendments that have been made over time. The Department supports the drafting of new regulations using contemporary legal language. Stakeholders have expressed a universal preference for significant legislative amendment in this area and an expectation of new, modern legislation, as has already occurred in most other Australian jurisdictions.

1.6.3 New Regulations: Medicine and Poisons Regulations 2015

An expectation of new regulations was evident as a result of reviews conducted with stakeholder from 2001 onwards. Stakeholder consultations have indicated the 1965 Regulations are difficult to interpret and a new approach to regulatory reforms was the preferred option.

Advantages:

- Alignment with the current Act.
- Achieves primary objectives of:
 - National consistency;
 - Expanded realm of health workforce participation;
 - Reduction in regulatory burden;
 - Improved transparency of controls; and
 - Reduced diversion and misuse of pharmaceutical drugs.
- Alleviation of stakeholder concerns and dissatisfaction.

Disadvantages:



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- Minor costs to Government (the Department) during development and implementation phases; and
- Costs in stakeholders becoming familiar with new requirements and modifying practice to comply with new regulations.

New subsidiary legislation would achieve the stated objectives. The proposed regulations will address these objectives and has been constructed in response to stakeholder requirements that balances costs and benefits to consumers, industry and Government.

The draft Medicines and Poisons Regulations 2015 is intended to continue to provide a framework for control of medicines and poisons in WA under the fundamental principle of the protection of public health and safety. Operational detail is not provided in the Act; the intention being to retreat from the prescriptive nature of past legislation to a more flexible modern approach. When the Act was drafted it was intended that it would be supported by subsidiary legislation to ensure adequate compliance and appropriate regulation.

1.7 Stakeholder Recommendations

In considering the regulations, all stakeholders have indicated the need for transparent, simplified, nationally consistent legislative reforms. Key recommendations include:

- improved clarity and flexibility regarding medicine authority for health professionals;
- reduced red tape for Licences and Permits;
- improved controls over supply of drugs of dependence;
- fairness and transparency for those taking drugs of dependence;
- improved national consistency through better alignment with the SUSMP for Poisons; and
- regulatory support for adoption of new technologies.

Regulatory failures, impact on consumers and business, and preferred options for reform were identified in the consultation process. These items will be consistently carried through to subsidiary legislation.



1.8 Preferred Option

Section 1.6 outlined potential options for Medicine and Poison Regulations to support the Act. Consultation to date has supported the recommendation that new regulations be drafted.

The preferred option is Option 3:

New Regulations: Medicine and Poisons Regulations 2015.

All Australian jurisdictions and all other major developed nations have similar legislative controls over a range of medicines and poisons. Maintaining existing legislative control for medicines and poisons in WA, per option 1 is not consistent with other national and international standards. Current poisons laws have existed for many years and are well established as the default norm. They mirror regulatory schemes found in other advanced countries. In WA, the current approach has been in place since 1964. As such, there is limited contemporary evidence on the likely impact of an increase or potential decrease in regulation of poisons. For example, there are no known scientific trials of the effect on public harm in Australia from complete removal of poisons controls.

The need for continued controls is evident in the number of poisonings seen annually in Australia. State Governments maintain publicly funded Poisons Information Centres manned 24 hours a day by highly trained health professionals. These are connected to public hospital toxicology units. The number of calls taken by these centres each year suggests that exposure to poisons and poisoning is still a frequent event in our society. The rate is relatively constant suggesting a residual risk associated with access to these substances, even within the controls in place.

WA has existing legislation that provides these controls, however it is ageing, does not meet all stated objectives, and there is known regulatory failure as identified by those primarily affected by the legislation. The option of maintaining the status quo does not address the known regulatory failures.

Regulation in this area is not new and as such emphasis has been on discussing the problems in existing regulatory areas and the potential impact of modifications necessary to support the operation of the Act. The CRIS proposes amendments that address all stated objectives and areas of regulatory failure. Due to the amount of consultation already completed, there is enough stakeholder-derived evidence available to suggest a range of proposed regulatory changes in key regulatory areas. It must be emphasised that in most instances these changes could be considered as enhancements of the existing regulations. The new Regulations will need to adopt elements of the existing regulatory controls. They will provide better protection for individuals and are intended to be written in more user friendly and understandable contemporary legal language. They will also be streamlined through formal recognition of similar controls in other similar legislation.



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The proposed regulatory changes can be summarised as achieving three main legislative objectives:

1. Improve modernisation of existing regulation e.g. electronic prescribing or ESSU;
2. Improve alignment of existing regulations with national legislation e.g. professional authorities, poisons control; and
3. Reduce red tape or regulatory burden created by existing regulation e.g. licensing and drugs of dependence changes.

It is anticipated that these changes will assist with the effective prevention of harm to patients and consumers from risks associated from medicine and poisons.



Part 2: Review of Regulations

2.1 Introduction

This section identifies the broad policy objectives, which have been developed in consideration of consultations undertaken as discussed in Part 1 of the document. This section identifies the regulatory areas requiring amendment and outlines background information, issues with existing regulation and proposed regulatory changes. Additional details on the justification for considering change in specific areas are also provided.

Development of the proposed regulations was guided by the 1965 Regulations – Discussion papers contained in Appendix 2 and 3. These discussion papers were circulated widely to key stakeholders to obtain feedback and to identify the preferred options in each of the key regulatory areas.

2.2 Policy Objectives

The following broad policy objectives have been considered in the development of the regulations:

- Improve consumer health outcomes in relation to medication and poison provision via safe access to medications and poisons;
- Provide a flexible and responsive framework that is applicable across all settings and clearly lays out minimum standards to meet public health requirements;
- Ensure national consistency in medicine and poisons regulation;
- Reduce regulatory burden particularly in regards to mandatory reporting and licencing reciprocity;
- Respond to public health and emergency health demands requiring medicines and poisons access (e.g. vaccinations) through structured prescribing arrangements; and
- Respond to current health practice and trends including expanded job roles.



2.3 Areas of Regulatory Control

Development of the new regulations will be conducted under the overarching framework of legislation determined by the Act. The proposed Regulations will address the regulation gaps evident due to the introduction of the 2014 Act, which includes new provisions. The drafting of the regulations will consider:

1. Continuing existing regulatory controls from the 1965 Regulations which are working well;
2. Introducing controls identified by stakeholders; and
3. Considering alternative regulatory schemes if required.

The options to address regulatory issues and the impact of proposed regulatory changes will be examined in the key regulatory areas outlined below:

- Professional Authority (2.4);
- Structured Prescribing Arrangements (2.5);
- Electronic Prescribing (2.6);
- Electronic Storage and Supply Units (2.7);
- Licensing and Permits (2.8);
- Control by Poison Schedule (2.9);
- Control by Medicine Schedule (2.10);
- Drugs of Addiction (2.11);
- Drugs of Dependence Records (2.12);
- Electronic Real Time Controlled Drug Reporting (2.13);
- Destroying Drugs of Addiction (2.14);
- Storage and Transport of Drugs of Addiction (2.15); and
- Ships and Vessels (2.16).

Under each of these regulatory areas, the purpose of regulatory control and an explanation of the impact of proposed changes are given. The proposed changes are clearly articulated for each area and summarised in text boxes. In each regulatory area, an impact assessment has been undertaken on the potential costs / benefits and the likely advantages and disadvantages of the proposed regulations.

Areas in which regulatory failures were not identified are not discussed further in this document.



2.4 Professional Authority

2.4.1 Background

Medicines are intended to treat ill health, to cure disease, alleviate symptoms, and decrease progression or to palliate. However all medicines have adverse effects and there is significant potential for harm from incorrect use. Limiting the supply of medicines via health practitioners ensures that only those persons who have the correct skills and qualifications to do so safely are permitted to supply or authorise supply of medicines to the public. Patients are likely to then be adequately assessed and correctly diagnosed, supplied with the most appropriate and effective medicine in the ideal form and dose, educated and instructed in correct use, and the unwanted effects reviewed so that any potential harm is identified and rapidly treated.

Health practitioners need access to medicines to administer them to patients, use them for diagnostic or treatment purposes, or to supply to individual patients for their later personal use. Those persons without the correct skills to safely supply to patients should be excluded from doing so, to reduce unwanted harm.

The use of medicines should be restricted to legitimate medical uses. Controlling public access to medicines also limits the potential for misuse and abuse, diversion into non-medical or recreational use, theft and illicit sale, deliberate misadventure and other public harm.

The objective of the Regulations should then be to adequately determine:

- health practitioners who are the safe and correct persons to use medicines;
- allowable uses for each group; and
- limits if any, to be placed on these users, where appropriate.

They should also describe which uses are not acceptable.

The professional authority can be taken away, limited or modified if there are grounds where public safety is at risk. This should be standard for any authority provided regardless of health professional grouping.

2.4.2 Current Regulations

WA uses the national Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) scheduling classification system for poisons. The level of state regulatory control for the various poisons is influenced both by the Schedule of medicine and any commensurate risks associated with its use⁹.

⁹ Standard for the Uniform Scheduling of Medicines and Poisons No.8. <http://www.comlaw.gov.au/Details/F2015L00128>



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One measure of control is to regulate professional authority i.e. ensuring that only professionals with appropriate skills, knowledge and training are authorised to handle poisons. The regulation of this professional authority is authorised in the Act:

- under section 25 to administer, possess, prescribe, supply or use a medicine;
- under section 26 to manufacture a medicine or use or possess a Schedule 7 poison.

Under national law¹⁰ the Australian Health Practitioner Regulation Agency (AHPRA) is responsible for the implementation of the National Registration and Accreditation Scheme (NRAS) across Australia. AHPRA works with 14 National Health Practitioner Boards in implementing the NRAS objectives, which include helping to 'keep the public safe by ensuring that only health practitioners who are suitably trained and qualified to practise in a competent and ethical manner are registered'¹¹.

The National Boards set the registration standards that practitioners must meet in order to register. Once registered, practitioners must continue to meet the standards and renew their registration yearly with the National Board. At a State level, the 1965 Regulations point to these registration mechanisms to authorise certain health professionals, when registered by AHPRA, to prescribe, supply, administer, possess, dispense and use various medicines and poisons.

The 1965 Regulations authorise health professionals to handle scheduled medicines in a particular way. The specific authority is detailed in a number of sections and under a number of individual regulations according to various criteria including: 'type of use'; 'schedule of medicine'; and 'professional endorsements'.

For example:

- *Part 2A details endorsed health practitioners' e.g. endorsed optometrists, midwives and podiatrists;*
- *Part 5 Regulation 40 and 42 list those persons authorised to possess Schedule 4 and Schedule 8 poisons respectively; and*
- *Part 5 Regulation 36 lists those person authorised to dispense Schedule 4 poisons.*

An individual practitioner must therefore interpret the current 1965 Regulations to determine any statutory obligations and how a particular health profession may handle a medicine. This has resulted in confusion with some people unclear on how medicines may be handled by certain health professionals.

The Act allows the authorisation of a health professional to administer, possess, prescribe, supply and use a medicine, in the lawful practice of their profession, if they are within a class prescribed by the Regulations.

The Poisons Act 1964 explicitly names the authorised class of health practitioner and outlines their specific authority as outlined in table 1.

¹⁰ Note - All States and Territories, including WA have enacted the National Law including WA in the form of the *Health Practitioner Regulation National Law (WA) Act 2010*

¹¹ Australian Health Practitioner Regulation Agency . About AHPRA. 2014. <http://www.ahpra.gov.au/About-AHPRA.aspx>



Table 1: Poisons Act 1964 - Authorities

Class	Authority					Conditions
	Manufacture	Possess	Use	Sell/Supply	Prescribe	
Pharmacist	Manufacture	Possess	Use	Sell/Supply		At pharmacy in course of retail business
Medical practitioner		Possess	Use	Supply	Prescribe	In lawful practice of profession
Veterinary Surgeon		Possess	Use	Supply	Prescribe for animal use only	In lawful practice of profession
Dentist		Possess	Use	Supply	Prescribe for 7 days	In lawful practice of profession
Nurse Practitioner		Possess	Use	Supply	Prescribe	In lawful practice of profession
Endorsed Health Practitioner		Possess	Use	Supply	Prescribe	In lawful practice of profession, pursuant to Regulations

More recently the Act has provided for authorisation of other classes of registered health practitioners if endorsed under the Health Practitioner Regulation National Law (WA). These are then detailed in the 1965 Regulations where any additional limitations are set. These are described in Table 2.

Table 2. Poisons Regulations 1965 - Endorsed Professionals

Class	Authority Limitations
Endorsed Podiatrist	Drug class, form, use and duration as set out in the Medicines List issued by the National Board
Endorsed Midwives	Drug class, form, use and duration as set out in the formulary issued by the National Board Use only of Schedule 8 drugs (no prescribing)
Endorsed Optometrist	Topical eye use only

An endorsed health practitioner, may possess, use, sell or supply, prescribe scheduled medicines according to these authorities. Use by endorsed practitioners (that is administration to a patient) is not taken to be supply under the 1965 Regulations.

The 1965 Regulations define supply stating that administration to a patient by a medical practitioner; nurse practitioner or dentist is not deemed to be supply. Administration by a registered nurse is not supply when acting under the direction of an authorised prescriber.



2.4.3 Current Regulatory Issues

These authorities as outlined in the 1965 Regulations were conceived at a time when health practitioner roles were less broad. They also pre date the National Health Practitioner Registration and Accreditation Scheme. Stakeholders have advised that the way these authorities are structured is too restrictive, prevents innovation and hampers health workforce reform with respect to medicines. It must also be noted that the regulations do not seamlessly articulate with the Health Practitioner Regulation National Law (Western Australia).

The Act does not explicitly specify authorised class of health professionals as outlined in the previous version. At the time of drafting the Act it was identified that development of increased regulation would be required to address issues regarding the changes in workforce. This includes an opportunity to recognise non-registered health practitioners. Some practitioner groups are well established and increasingly handle medicines as their professional scope of competence evolves. These include paramedics and aboriginal health workers. Some health practitioner groups are already registered professionals, but are also not recognised by the current regulations. In these cases they may work with authorised professionals and be required to handle medicines in both the direct and non-direct delivery of care to patients, but have no specific personal authority under the existing legislation to do so. An authorised practitioner may not delegate an authority effectively in these cases and must personally supervise any employee. Stakeholders provided many examples such as enrolled nurses, approved veterinary nurses and other registered dental professionals (e.g. oral health therapist, dental hygienists / therapists). Stakeholders also identified established and emerging roles for health workers not registered by AHPRA but well integrated in the health system, such as anaesthetic technicians.

Current issues regarding professional authority can be summarised as:

- **Lack of alignment with national registration standards outlined by AHPRA;**
- **Certain professions are not named and therefore it is difficult to identify restrictions;**
- **Current regulations are out dated in terms of current practice; or**
- **Current authority system does not allow changes to response in professional scope and therefore is inflexible to changing workforce needs.**

2.4.4 Proposed Regulations

The Regulations must define which practitioner groups need access to medicines and what criteria might include or exclude a person as part of a particular practitioner group. It should outline any conditions or limitations for any specific authority or practitioner group and define what legitimate practice may be for this group.

Expanding on the number of professions outlined in the 1965 Regulations, it is proposed that the new Regulations clearly define the health care workers which are allowed to: obtain,



possess, administer, supply, prescribe, dispense and manufacture Medicine or Poisons. These groups and their proposed level of authority are outlined in Table 3.

Table 3: Health Care Practitioner Specific Authority

Practitioner	Obtain	Possess	Administer	Supply	Prescribe	Dispense	Manufacture
Pharmacist	√	√	√	√		√	√
Pharmacy Technician		√					
Medical practitioner	√	√	√	√	√		
Veterinary Surgeon	√	√	√	√	√		
Approved Veterinary Nurse		√	√				
Dentist	√	√	√	√*	√		
Dental therapist Dental hygienist Dental prosthetist Oral health therapist		√	√				
Nurse Practitioner	√	√	√	√	√		
Registered Nurse		√	√	√*			
Enrolled Nurse		√	√	√*			
Endorsed Midwife	√	√	√	√*	√		
Registered Midwife		√	√	√*			
Paramedic		√	√*				
Ambulance Officer		√					
Endorsed Optometrist	√	√	√	√*	√		
Optometrist	√	√	√	√*			
Endorsed Podiatrist	√	√	√	√*	√		
Podiatrist	√	√	√	√*			
Aboriginal Health Practitioner	√	√	√*	√*			
Aboriginal Health Worker	√	√	√*				
Chinese Medicine Practitioner	√	√	√	√*			
Anaesthetic Technician		√	√*				

Explanatory Notes:

√ indicates that this profession has authority

* indicates a restriction in terms of scope of employment or structure prescribing arrangement required.

Any authority conferred in the regulations should be in alignment with limitations as set out by AHPRA.



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For example:

An optometrist prescribing will need to be endorsed, will need to meet guidelines relating to this endorsement and will be limited to the use of those drugs within scope of this endorsement.

The authority defined will also need to consider limitations around practitioner competence or scope of practice.

For example:

A nurse practitioner can only practice within a designated scope.

Where not linked to AHPRA registration the authority will need to be specific and limit boundaries for the professional group.

For example:

An anaesthetic technician should always be handling medicines under the personal supervision of an anaesthetist.

Under the 1965 Regulations nurse practitioners must work within a designated area of practice and must have clinical protocols approved within this area of practice. Identification in the regulations, as a professional group and recognition of their appropriate level of professional authority is required.

Any confirmed authority is limited to a health professional's area of practice, not beyond this to areas not concerned with the lawful practice of that profession.

For example:

A dentist can only prescribe for the purpose of dental treatment at their dental practice; or

A veterinary surgeon can only prescribe for the purpose of animal treatment; and

A veterinary surgeon may need to keep medicines at their usual place of veterinary practice and also transport these to the site of treatment of large animals, where the animal is normally kept.

Authority should not extend to the use of medicine for purposes other than the therapeutic treatment of a person within the scope of that health professional.

For example:

The prescribing or supply of medicines for another person to sell for illicit use;

The administration for recreational purposes would not be part of lawful practice.



Proposed regulatory changes, for Professional Authority, can be summarised as:

- **Defining individual professions that need access to medicines and what includes or excludes a person as part of that practitioner group;**
- **Outlines conditions or limitations for any specific authority or group and define what legitimate practice may be for this group; and**
- **Define appropriate level of authority in terms of professions ability to obtain, possess, administer, supply, prescribe, dispense and manufacture medicine and poisons.**

2.4.5 Impact Analysis

In summary, the objectives of the Regulations in relation to professional authorities are to ensure those persons with a legitimate need to access medicines for use or supply, and who are appropriately qualified and therefore are safe to use or supply to the public, have the legal authority to do so. The recognition of both registered and non-registered health practitioners has the potential to extend and improve access to medications to meet consumer and workforce need. It complements the existing processes undertaken by regulatory boards such as AHPRA.

For example:

AHPRA may allow registered dental professionals, other than a dentist, when appropriately trained, to administer medication.

The Regulations will continue to prevent unqualified persons from obtaining access to medications thereby protecting the general public from unsafe use.

During consultation to develop the Act, stakeholders advised that many are uncertain or confused about their actual authority. Stakeholders also advised that the existing authorities are barriers to consumer access to medicines where it may be safe and desirable. Regulations in this area are likely to reduce confusion amongst health professionals. It recognises collective experience with changes in professions such as nurse practitioners, which have made significant progression in the last decade as a professional group. Appropriate levels of professional authority in the regulations, is likely to create flexibility and reduce regulatory burden. Expansion of the defined professional roles may reduce costs to consumers in some areas where a task may be undertaken by a different health practitioner group. It is expected to improve consumer access, timeliness of care or convenience.

For example:

Enrolled nurses suggested authority to access Schedule 8 medicines to administer these in hospitals would be a significant efficiency gain for WA health.



Providing increased clarity regarding professional authority is unlikely to provide any additional cost to consumers. There will be reduced cost to the Department regulating these health professionals or industry if there are clear definitions.

Consultation questions, Professional Authority:

- **Will the proposed regulations address the identified issues?**
- **Are there other impacts of the proposed regulations that should be considered?**

2.5 Structured Prescribing Arrangements

2.5.1 Background

Prescribing by health professionals other than doctors is an established practice both within Australia and the international health systems. In WA, dentists, nurse practitioners, and other allied health professionals holding varying authorisations to prescribe currently undertake prescribing of medications and poisons. Prescribing in this setting includes having the authority to decide to administer a medicine directly to a patient, supply medicines to a patient, or to instruct a pharmacist to supply medicines to a patient (i.e. issuing a prescription). The Act regulates this practice.

For the WA population the maldistribution of health workforce and shortage of health consumer access to prescribers of medications required is well documented. Evidence suggests that there are population pockets in regional and remote WA that are unable to access medicines in a timely manner. The vast majority of the WA landscape is considered to be regional or remote (nearly 2.5 million square kilometres), and approximately half a million people reside there¹².

This inability to easily access medicines when required, can be attributed to a combination of factors including isolation, a paucity of staff with prescribing and / or supply rights and 'specific health needs for certain subgroups often associated with harsh environments'¹³.

There is continued debate over how best to address these issues of geographic isolation and problems with access to, and shortages of, providers and services. It is widely accepted that the challenges cannot be overcome in isolation and "requires coordination across government, higher education, regulatory bodies, employers, industry, the professions, the private and the not-for-profit sector,"¹⁴

¹² WA Country Health Service. Annual Report - 2012-13.

https://www.health.wa.gov.au/publications/annual_reports_2013_WACHS.pdf

¹³ House of Representatives, Standing Committee on Regional Australia, 2013.

http://www.aph.gov.au/Parliamentary_Business/Committees/House_of_representatives_Committees?url=ra/fifodido/report/chapter6.htm

¹⁴ Health Workforce Australia. National Rural and Remote Health Workforce Innovation and Reform Strategy 2013.

http://www.hwa.gov.au/sites/uploads/HWA13WIR013_Rural-and-Remote-Workforce-Innovation-and-Reform-Strategy_v4-1.pdf



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Health Workforce Australia describes a model where prescribing (more accurately administration or supply) can occur via a “Structured Prescribing Arrangement” where a health worker with limited authorisation, to supply medicines by legislation, prescribes under a guideline, protocol or standing order.⁹ Structured Prescribing Arrangements provide a framework for the safe and effective governance of health care professionals who would be unable to supply required medicines without the supervision or guidance of an authorised prescriber.

The practice of administration and supply by health professionals has progressed in the absence of sufficient regulation documented in the 1965 Regulations. This has resulted in inconsistent approaches in the development of Structured Prescribing Arrangements.

A Structured Prescribing Arrangement is where very limited administration or supply might be undertaken by an authorised practitioner, in specified circumstances, when under written direction of an autonomous prescriber or other authority. This does not provide prescribing autonomy, but does mean the practitioner need not refer to an individual instruction from an authorised prescriber for each individual patient or circumstance. These types of arrangements are commonly termed standing orders and used to extend public access to medicines via health practitioners who are not otherwise authorised prescribers.

The fundamental prerequisites for prescribing are undertaking accredited / approved education or training to ensure competence and then obtaining recognition from the respective health practitioner National Board. The practitioner must then practice within any authority conferred by State legislation. This legislation requires that practitioners work within their lawful practice, and professional scope and competence.



Structured Prescribing Arrangements can be developed in the following areas:

1. **Departmental:** Structure Prescribing Arrangements issued by the Department of Health, under the authority of the CEO, for any class of person, for a list or class of medicines.

For example:

Aboriginal Health Worker approved to administer vaccinations in areas of public health need; or

In the event of a H1N1 pandemic the registered nurses at child health centres could be approved to provide vaccinations short-term to meet overwhelming public health need.

2. **Organisational:** Structured Prescribing Arrangements for health professionals (authorised to administer or supply medicines for public health and acute treatment) employed by a health organisation (hospital or health services) with an appropriate clinical governance structures.

For example:

An organisation, such as a hospital, through the Drugs and Therapeutic committee writes orders for registered nurses working in the Emergency Department to administer first doses of antibiotics to persons with febrile neutropaenia to start treatment more quickly; or

A Government contracted community-nursing program through an appropriate drug advisory (clinical governance) group writes directions for registered nurses to administer single doses of analgesia for the more timely treatment of pain.

3. **Medical Practitioner:** Structured Prescribing Arrangements for individual prescriber with an employee who is a recognised health professional.

For example:

A medical practitioner documents an arrangement with a practice nurse employed at the practice to be able to provide named childhood immunisations to any patient of the practice that meets established criteria, such as the standard childhood vaccination schedule.

2.5.2 Current Regulations and Issue Identification

The existing Regulations currently accommodates the autonomous, or traditional, prescribing model, whereby an individual sees a medical doctor or other authorised practitioner and receives a prescription, which provides instruction for supply of a medicine by a pharmacist

Where pressing public need exists, certain practitioners without a professional authority have been afforded access via regulations exempting use or supply of a named medicine from provisions of the Act in specified situations.



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Examples of these exemptions include:

- *Registered nurses in remote area nursing posts providing medicines as part of a standing order approved by the CEO;*
- *Registered nurses at regional or rural health services providing starter packs on the oral order of a medical practitioner;*
- *Registered nurses providing medicines for the treatment of chlamydia with a Code in the course of their employment by the Department of Health or a hospital;*
- *Registered nurses providing medicines for psychiatric emergencies on the oral order of a medical practitioner;*
- *Registered nurses administering H1N1 vaccine in their employment by the Department of Health or a hospital;*
- *Registered nurses administering other vaccines in accordance with a Code, in the course of their employment by the Department of Health, a hospital, aboriginal medical service, corrections facility or local government; and*
- *Pharmacists administering influenza vaccines in accordance with a Code.*

Due to the need to improve access to particular medicines, whilst still managing associated risk, specific exemption clauses have been added over time to the existing regulations to extend the reach of prescribers via nurses or other practitioners, to address some of these issues. Historically, a range of special authorisations have been made under the 1965 Regulations to permit various levels of authority to administer or supply medications, under a range of protocols, codes or direct order arrangements. These exemption clauses, although effective, have significant limitations in flexibility and from a regulatory / governing perspective are cumbersome and not responsive to need. To ease the regulatory burden the 2015 Regulations will set up a framework to incorporate different allowable types of Structure Prescribing Arrangements. This will provide clarity for prescribers and more effective governance for regulatory control.

Current issues relating to Structured Prescribing Arrangements can be summarised as:

- **No current framework to establish Structured Prescribing Arrangements; and**
- **Regulation currently achieved via various exemption processes, which are inconsistent, slow and difficult.**



2.5.3 Proposed Regulations

It is proposed that regulations be developed to support Structured Prescribing Arrangements in the following instances:

- Emergencies and resolution of an acute care issue: written orders to initiate administration can commence acute treatment.

For example:

A patient presents at a remote nursing post and is assessed as having a urinary tract infection; a registered nurse (such as employed by the Department) can supply a short course of antibiotics according to a written order. This leads to more timely treatment and prevents delays that could lead to health care complications.

- Public Health needs.

For example:

Aboriginal health care workers with appropriate training assist in the delivery of public health programs by administering vaccines or administration and supply of treatments for sexually transmittable diseases according to a written order. This leads to wider community protection and prevention of spread of communicable diseases in disadvantaged communities.

Structured Prescribing Arrangements must meet a minimum set of requirements / conditions, which need to be agreed upon and regulated. These requirements will include:

- Being outlined in a formal document signed by the authorising prescriber;
- That an original copy of that document is kept and is able to be produced as necessary, and is freely available for persons using the Structure Prescribing Arrangement when required to be able to safely administer or supply;
- Being uniquely identifiable such as by use of a number or appropriate code;
- Identifying the person issuing it and the authority it is issued under;
- Only applying to a specific registered health practitioner, or a defined health worker whose qualifications, employment or competencies can be defined;
- Clearly stating which persons it applies to and what actions it authorises;
- Having a defined relationship between the persons covered by the Structured Prescribing Arrangement. That is being employed by the authorising person or the organisation that employs the authorised person;
- Following conditions and rules outlined by the proposed regulations;
- In the case of an organisation, that all agreements are approved by an appropriate clinical governance body, for example a Drugs and Therapeutic Governance committee or similar;



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- Supplier administration is permanently recorded in the clinical notes, along with all other administration or supply details required by regulation.

It must be emphasised that Structured Prescribing Arrangements **are not** indicated if the usual autonomous prescribing mechanisms are readily available. Autonomous Prescribers currently include medical practitioners, veterinarians and dentists who provide the prescription directly to the health consumer.

Structured Prescribing Arrangements **are not** required where a prescriber undertakes administration or supply within their scope of practice under the normal supervision or direction of another authorised prescriber.

In the situation of a Structured Prescribing Arrangement a person is able to prescribe to authorise another person to administer or supply without individual patient authorisations based on the limits and conditions outlined in the written agreement, as outlined in Figure 1.

Figure 1. Prescribing under a Structured Prescribing Arrangement:



This includes either administration of a medicine to a person or supply of a medicine a person to self-administer.

For example:

An Aboriginal Health Care Worker at a remote nursing post injecting a vaccine; or

A nurse at a rural nursing post provides a patient with a urinary tract infection with a course of antibiotics.



An example of the minimum requirements for the written Structured Prescribing Arrangement

A registered nurse may administer an influenza vaccine in accordance with a Structured Prescribing Arrangement with a medical practitioner.

The registered nurse must be employed by that medical practitioner or within the same health provider organisation. The Arrangement may not extend beyond any terms of that employment. The Arrangement is only applicable to patients under the care of that medical practitioner.

The Agreement must be in writing. The original document must be retained at the medical practitioner's usual place of practice. Any registered nurse authorised and using the Agreement must be able to access a copy. The medical practitioner needs to be able to produce this document on demand.

An Agreement may cover a period of up to two years, after which a review by the authorising medical practitioner must take place. If intended to continue, a new Agreement must be written. Documents must be retained for two years after expiration.

The Agreement must contain the following particulars:

1. The name and address of the authorising medical practitioner;
2. Date of the Agreement;
3. Date of expiry (not more than 24 months);
4. A unique identification number (specific to the document);
5. Name and address of the authorised registered nurse(s);
6. Vaccine brand, route, form and any other specifics of the influenza vaccine(s) to be administered;
7. Patient criteria for inclusion, such as diagnosis and age;
8. Patient criteria for exclusion, such as comorbidities, allergies, age, interacting medicines;
9. Any conditions or limitations agreed by the parties as appropriate; and
10. Medical practitioner's signature.

Equivalent details would be required for any structured prescribing arrangement relevant to the practitioner and patient groups, and conditions and medicines involved.

If a Structured Prescribing Arrangement is provided by the Department for a class of practitioner, or a group of medicines it is likely to require additional information, and be supported by a Code of practice or an equivalent standard. The relevant education needs to be outlined and publicly available. It may also need to point to adherence to clinical guidelines or outline any specific practices required for the safe use of medicine including equipment, setting, method of administration, etc.



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The formalisation of Structured Prescribing Arrangements via regulation also allows for improved regulatory governance. The Department will have a role in ensuring compliance with the Structure Prescribing Arrangements. This is expected to be offset by the major benefits to the consumers and the efficiencies within the health workforce. The Department needs to be able to enforce regulations and to address any unsafe Structured Prescribing Arrangements based on misuse, inappropriate application or any other behaviour, which places the public at risk.

2.5.4 Summary

In summary, introduction of regulations regarding Structured Prescribing Arrangements:

- Bring together already established initiatives that allow administration or supply to people who are not able to follow usual prescribing practices;
- Increase compliance with the Act by providing a single regulatory framework so health professionals can clearly see their role and responsibilities;
- Provide health consumers with improved availability and safe access to prescription medicines (particularly in times of public health need);
- Optimise use of health professionals' skills and time, thereby reducing inefficient use of health resources;
- Provides more flexibility, allows extension into workplace reform;
- Ensures responsible and safe access to prescription medicines by making limited prescriber adhere to controls on patient safety and professional accountability; and

Provide regulations to allow the investigation of potential issues to safeguard and protect the public.

Proposed regulatory changes, for Structured Prescribing Arrangements, can be summarised as:

- **Providing a single regulatory framework so health professionals can clearly see their role and responsibilities;**
- **Supporting development of Structured Prescribing Arrangements from:**
 - **The Department;**
 - **For a health organisation;**
 - **For individual medical practitioners;**
- **Providing clear regulatory guidelines regarding minimum requirements of a Structured Prescribing Arrangements; and**

Ensuring safe application and use of Structured Prescribing Arrangements by medical other health practitioners.



2.5.5 Impact Analysis

Development of new regulations in this area will provide several advantages and likely cost benefits to the community. Workforce shortages in health care, particularly in rural and remote areas are well documented¹⁵. Provision of Structured Prescribing Arrangements can provide reform in areas of workforce shortage and make more effective use of health professionals such as paramedics and aboriginal health practitioners. It provides accountability and structure by dictating the quality and type of supervision and stipulating minimum requirements for Structured Prescribing Arrangements. It can provide structure and clear guidelines to support unregistered professionals when handling a medicine.

For example:

The health worker can ring the supervising medical practitioner to get medical advice and to regularly review activities, as part of their employment, which have taken place under the Structured Prescribing Arrangement. The supervising medical practitioner then must receive regular reports of what is being used.

Structured Prescribing Arrangements can allow more people to be reached for treatment with medicines for serious and widespread conditions. This has significant benefit for public health programs, specifically sexual health and vaccines.

In the event of an emergency or public health issue it is possible for the Department via the CEO to utilise a Structured Prescribing Arrangement to provide rapid and widespread care. Examples in which this may be enacted include:

- *Emergency provision of medication by police in event of a biohazard; or*
- *Provision of vaccinations by a health worker during an epidemic.*

Structured Prescribing Arrangements of this nature can have the benefit of increasing vaccination uptake for groups at risk. This has been demonstrated by use of registered nurses in WA public health vaccine administration programs. In the US a review of 22 studies from 1997-2008 assessed the impact of standing orders found immunisation increased by a median of 28 points¹⁶.

Consultation questions, Structure Prescribing Arrangements:

- **Will the proposed regulations address the identified issues?**
- **Are there other impacts of the proposed regulations that should be considered?**

¹⁵ Rural Health Workforce Australia. Annual Report 2014. http://www.rhwa.org.au/client_images/1740096.pdf

¹⁶ The Community Guide. Increasing Appropriate Vaccination: Standing Orders. 2009. <http://www.thecommunityguide.org/vaccines/RRstandingorders.html>



2.6 Electronic Prescribing

2.6.1 Background

A prescription medicine is any medicine that needs written authorisation by a doctor or other prescriber before a pharmacist can supply it. Prescriptions contain information about the dose and type of medicine the prescriber has advised an individual to take. The usual process for prescriptions is that the patient goes to the doctor who provides a paper based prescription, the person takes this piece of paper to the pharmacy, the piece of paper tells the pharmacy what to dispense. This process is illustrated in Figure 2. The authorising person is the doctor and the record of supply is held at the pharmacy.

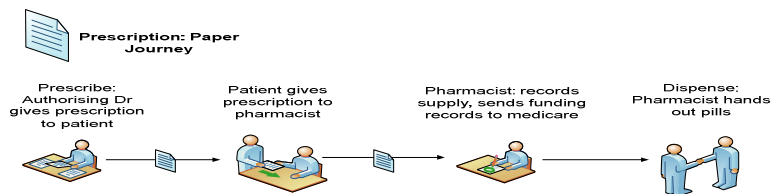


Figure 2: Illustrates the usual paper process for paper based authorisation of supply

The minimum information required to instruct a pharmacist or patient on the safe supply and use of a medicine is well established, highly consistent across all States and Territories and needs to remain as outlined in existing regulations. More recently the concept of paperless or electronic prescriptions as a way of transferring prescription information has become both technically feasible and accepted as important in modern health care. A prescription that is properly stored securely in electronic form could prevent issues of prescription forgery or altering prescriptions. The electronic communication of these instructions have the potential to reduce the risk of dispensing error, make the transmission of information faster, cheaper and more efficient, and provide greater security to prevent the unauthorised supply of medicines. Benefits are evident for health professionals such as the medical practitioner and pharmacist who will not need to deal with hard copy documents, which require handling, tracking and archiving. Consumers will benefit as their prescription will readily be available from any pharmacy and will not be lost or forgotten. From a regulatory point of view there is a lower risk of manipulation or alteration of the prescription.

2.6.2 Current Regulations and Issue Identification

In 2008 the current 1965 Regulations were amended to allow use of electronic prescriptions. It states approved systems must be secure and only allow an authorised person to prescribe or dispense a medicine or poison. Industry standards for passwords must be achieved. Information in the system must be protected and private, and unable to be erased. System access must be controlled and the system must have a human administrator. This view of a single electronic system is potentially out-dated and does not readily support the current work practice or full potential of electronic prescribing. The Regulations do not specify a need for an electronic signature, or state what this must be. Rather, it requires that access codes are used and the access code must establish the identity of the prescriber or dispenser. It is an offence to access the system unless



authorised, reveal access codes to another person, or allow unauthorised access. The system must record each person given an access code and access codes must be changed regularly. Each entry in the system is required to be uniquely numbered, include a time and date, and the access code of the person. Appropriate back up measures must be in place, administrator records are retained for seven years and the system must generate records of access and entries on demand. The overall principles, captured by these regulations, regarding supply and recording of medicines, are relatively consistent with expected future requirements, however need to be modernised to reflect current technology capabilities.

The new Act does not differentiate between additional requirements for hand written or electronic prescriptions, stating the prescription (regardless of form) must comply with requirements.

Current Issues regarding Electronic Prescribing can be summarised as:

- **Existing regulations are out-dated and do not support the current work practice or future potential of electronic prescribing; and**
- **Need to safeguard / protect from misuse or abuse of data (e.g. forgeries).**

2.6.3 Proposed Regulations

It is important that the proposed regulations support the ongoing development of electronic prescribing. This includes an explanation of electronic system requirements and digital signatures. For safe supply of a medicine, an electronic system would need to communicate the same information elements as contained in a paper-based prescription. Because the Act requires that all supply of medicine must comply with minimum requirements, the Regulations must detail what these specific prescription requirements are.

An electronic system:

- should only allow a prescription to be produce by an authorised prescribed;
- contain the minimum amount of instruction for safe supply;
- be the permanent record of instruction for a period of time;
- not be able to be deleted or altered;
- must allow the dispenser to mark that a supply has been made, keep records of supply and prevent repeated supply if not authorised;
- must not allow external tampering or alteration, copying or dissemination to multiple dispensers; and
- must allow reproduction of records on demand to allow administration of the Act.

The information in any system is sensitive and contains private personal health information. For these reasons systems must meet minimum privacy and security standards. It is important the systems in use are suitable and that any system that is not suitable can be



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excluded from use. It is also important to discourage poor practices in organisations or fraudulent behaviour by authorised and unauthorised individuals in accessing the systems to maintain the integrity of the information. This is supported by the National E Health Transition Authority (NEHTA) who has published minimum technical standards for these systems and published guidance for prescription exchanges.¹⁷ It is expected that these systems will be far more robust to prevent isolated forgeries, however they may instead present a new target for organised systemic attack (e.g. hacking).

Victorian Poisons Legislation has recently developed criteria for approval of e-Prescriptions¹⁸, which have been supported by NEHTA during consultations. The software issuing electronic prescriptions will have the relevant roles defined, with access rights, which will only allow authorised persons to generate electronic prescriptions for all medications.

The digital signature of the authorised prescriber must be included in the electronic prescription content. The generation of the digital signature for an electronic prescription must follow the following criteria:

- The prescriber must possess a credential (private key) that asserts the identity of the prescriber;
- The prescribing software must display the prescription and obtain a final approval from the prescriber prior to generating a prescription for electronic distribution; and
- The prescribing software must re-authenticate the prescriber's credentials at the point at which an electronic prescription for any medication, including drugs of dependence (which includes all Schedule 8 poisons and some Schedule 4 poisons), is generated.

Electronic prescriptions generated by the prescription software will produce the script information in an electronic format that is aligned with national medications messaging standards or related Australian Technical Specifications. The standards must include secure messaging (such as encryption), and application level acknowledgement, indicating positive or negative receipt of this information.

NEHTA has proposed that: "Healthcare organisations that operate electronic prescribing systems be responsible for identifying the prescribers that use those systems and for providing assurance to pharmacists of the origin of the electronic prescriptions that they generate"³. The electronic transfer of a prescription (e-prescribing) must use national standards for clinical information, terminology and medications in both prescribing and dispensing organisations. The exchange of electronic prescription detail should include the following capabilities:

- It will provide an indirect communication path between the prescriber and the dispenser(s) in which the individual (or their agent) can select the dispenser(s) at any time after the prescription is created;

¹⁷ National E Health Transition Authority. Electronic Transfer of Prescriptions. Technical Specifications Document NEHTA 1381:2013

¹⁸ Victorian Department of Health, Drugs and Poisons Regulation, Criteria for e-prescriptions. 2014. <http://www.health.vic.gov.au/dpcs/approve.htm>



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- It will provide a single point of control for each prescription that allows the prescriber to electronically cancel an electronic prescription. From the time of cancellation, the dispenser(s) system will inactivate the dispensing of any prescription items that have not been actioned;
- It will manage the security of the electronic prescription records that are distributed, including taking reasonable measures to apply current and future principles to:
 - Prevent the disclosure of information in the prescription record to unauthorised parties;
 - Ensure that the view of the prescription in both the prescribing and dispensing systems is consistent;
 - Protect against fraudulent electronic prescriptions;
 - The particulars of any electronic prescription issued will be included in the clinical or medication record of the person or animal for whom the electronic prescription was generated; and
 - The clinical or medication record of the person or animal for which the prescription was issued will be preserved for at least two years from the date on which the prescription was generated and will be capable of being produced when required.

Proposed regulatory changes, for electronic prescriptions can be summarised as:

- **Regulations will outline details regarding how the electronic systems can be used including: what information needs to be supplied, how it is supplied and when it is supplied; and**
- **Electronic prescriptions must meet existing details regarding prescription information requirements.**

2.6.4 Impact Analysis

Electronic script exchanges are already in use.^{19 20} This process of electronic prescription is illustrated in figure 3. In these models, a prescription is generated on prescribing software by a prescriber in their practice. The details of the prescription are transmitted to a “cloud” and stored in a secure electronic environment (script exchange) provided by commercial interests. The patient is provided with a printed prescription that includes a printed bar code, which acts as a document access key. When presented at the pharmacy the prescription is scanned by the dispensing software that links to the prescription exchange, and confirms all details of the prescription. In this arrangement the computer printed prescription is still the official prescription however, it is envisaged that eventually the electronically stored details would be the official prescription and no paper document may be involved at all. This model

¹⁹ <http://medisecure.com.au/>

²⁰ <http://www.erx.com.au/>



has significant potential to improve the validation of prescribing by a pharmacist and the Department is already aware of examples where use of the prescription bar code has been used to identify skilful forgeries and prevent unauthorised supply.

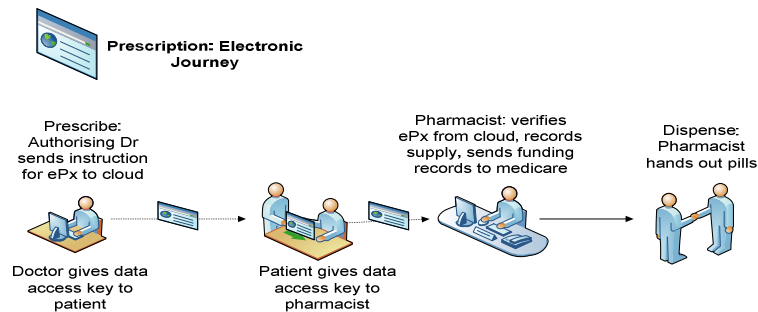


Figure 3: Illustrates the electronic prescription journey

There are a significant number of forgeries reported to the Department of Health each year and a variety of fraudulent methods used. Information extracted from the Department of Health WA Pharmacy Case Management system for 2014, reports over 152 incidents, which includes 32 incidents of known forgeries resulting from altered prescriptions²¹.

These range from simple modification of handwritten details or additions to sophisticated reproduction techniques of computer generated documents and medical practitioners' handwriting that are almost indistinguishable from legitimate prescriptions. Use of secure electronic prescribing could potentially decrease the number of reported forgeries and unauthorised access to medicines.

Consultation questions, Electronic Prescribing:

- **Will the proposed regulations address the identified issues?**
- **Are there other impacts of the proposed regulations that should be considered?**

2.7 Electronic Storage and Supply Units

2.7.1 Background

The 1964 Act did not allow use of Electronic Storage and Supply Units (ESSU) due to limitation to limitations of technology available at that time. Newer technologies are now sophisticated enough to limit access, identify and validate a person attempting access and keep comprehensive records of items supplied. In particular, such machines have been developed for use in medical settings. These machines have been in use overseas for some years and are available for purchase and use in Australia. As a result there is a large body of published evidence on the nature, capabilities and benefits of such machines. The

²¹ Department of Health, WA. Pharmacy Case Management Extract: 01.01.2014 to 31.12.2014.



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machines include such technologies as “robots” in hospital pharmacies, dose administration aid packing machines, anaesthetic trolleys, and automated medicines supply units on hospital wards. They are expensive but based on the efficiencies provided are often in routine use elsewhere in health services, hospitals and large-scale pharmacy supply chains. As the capabilities and potential uses increase and their cost decreases, application will become more widespread, extending into smaller health businesses where medicines are frequently supplied, such as pharmacies and nursing homes, veterinary surgeries and wholesale business practices.

Professional organisations support use of these technologies but not without regard for quality, minimum safeguards and patient protections.²² The expense and complexity means most will be purchased and run by organisations rather than individual health practitioners. They will be accessed by many health practitioners (potentially hundreds in a hospital). The upkeep, functioning, maintenance and responsibility must rest with appropriate and responsible individuals. On the basis of improved accountability, these machines should also be considered suitable for storage of Schedule 8 medicines. In fact, the machines offer even greater potential efficiency benefits for practitioners, when used to assist with recording and storage requirements for Schedule 8 medicines, due to the additional regulatory requirements involved. However, these medicines are a common target for theft, can enter the illicit market and can fetch high prices if illegally sold. The machines can build in protections for these substances, but cannot entirely replicate the storage conditions required from existing standards for large and heavy drug safes. It is therefore important that where used for Schedule 8 drugs, these machines should not compromise security or provide a lower level of public protection than existing expectations.

Minimum protections are then vital for these machines. Most legitimate and tested machines are expected to provide good security measures. Large organisations have quality procedures in place and systems of independent review²³ relating to medicines that may assist. There is also some guidance for practitioners to develop safe policies and procedures in using these machines²⁴. The Department is not aware of any legislation or enforceable industry standard that would prevent inferior machines being purchased and employed which may then allow unauthorised public access to medicines. The machines themselves vary greatly and are constantly being improved. It is then difficult to be prescriptive regarding necessary features, but principles around the minimum functions required to ensure medicines security are possible to devise.

To date there has been no request to utilise the machines for domestic poisons. These are generally low cost items, are frequently bulky or in liquid form and may not be suited to automated supply form these type of machines. Without a clear case of need it is not proposed that supply via these technologies be considered for these poisons. Schedule 7 poisons are highly dangerous and both their supply and use is heavily restricted. These should not be considered suitable for supply from an ESSU.

²² Society of Hospital Pharmacists of Australia. Position Statement - Automated medication systems. 2003. http://www.shpa.org.au/lib/pdf/positionstatement/amds_ps_aug03.pdf

²³ Australian Commission on Quality and Safety in Health Care. Safety and Quality Improvement Guide Standard 4 Medication Safety. 2012. http://www.safetyandquality.gov.au/wp-content/uploads/2012/10/Standard4_Oct_2012_WEB.pdf

²⁴ Institute for Safe Medicines Practices. Guidance for Interdisciplinary Safe Use of Automated Medicines Cabinets. 2008. http://www.ismp.org/Tools/guidelines/ADC_Guidelines_Final.pdf



2.7.2 Current Regulations and Issue Identification

The Poisons Act 1964 expressly forbids the use of an automated supply machine or ESSU for the supply of a poison. At the time of conception of this legislation, the available technology would not have allowed a machine to identify and distinguish between persons accessing the machine and receiving supply. Supply could then not be tracked and be assured that supply is only made to appropriate persons.

For example:

a child might access a machine in a public place and receive multiple and dangerous supplies of medicine.

Lack of human intervention would prevent any expert assessment of intended use and there would not be any certainty that the use was for a legitimate and correct purpose. This would allow the uncontrolled and potentially unsafe access of the public to both medicines and poisons.

The Act provides definition of a vending machine (considered synonymous with an automated supply machine or ESSU) capable of supply without attention or personal manipulation of the supplier. It allows for the use of these machines when complying with regulations.

Current issues relating to Electronic Storage and Supply Units can be summarised as:

- **Regulation is required in this area to ensure benefits realisation of automation and future proofing of regulations.**

2.7.3 Proposed Regulations

Existing regulations have provision for use of automated vending machines. Stakeholders support use of such machines and use will also meet the intent of the legislation to ensure there is access to medicines.

Allowing use when certain principles of safe supply would achieve aims of the legislation, limit public risk and is the preferred option. Based on the types of machines and use in other jurisdictions the following principles are proposed:

- machines are employed where a health practitioner provides professional oversight immediately prior to supply to an authorised patient, unless otherwise approved by the CEO;
- the machine may only be placed and/or used on the site or place of lawful business of the health practitioner or the authorised place of use on any poisons licence or permit the case of an organisation;



- A machine must meet recognised standard to ensure secure storage and supply and to prevent tampering or theft;
- the machine must store the medicines in such a way as to prevent public access;
- the machine must remain under the supervision and control of the authorised person or in the case of an organisation a suitable responsible person;
- the machine must be able to distinguish between persons accessing the machine and only allow access to medicines by an authorised person;
- the machine must keep a record of each occasion of supply. It should record the person making the supply, the date and time, the medicine and quantity supplied and be able to produce these records on demand for purpose of compliance with the Act; and
- for Schedule 8 medicines, a machine may be able to be approved and meet and any conditions deemed necessary to ensure security consistent with the risk posed.

2.7.4 Impact Analysis

These machines are justified on the basis of business efficiency, improved patient safety and accountability in health care.²⁵ For hospitals the machines can reduce stockholdings, reduce wastage and loss (such as to expired stock), and theft. They are well demonstrated to increase patient safety by reducing medicine selection errors.

For example:

a machine can match a product barcode to a prescription order to ensure that only the type, strength and quantity of the item ordered are correctly supplied.

They can improve security and governance when set to only provide a product to a person recognised and confirmed as having an appropriate authority.

For example:

in a hospital they could exclude general staff, but recognise and record individual nurses accessing medicines.

The machines can be made to ensure that no supply can be made without a record and that unauthorised access by an otherwise authorised person (i.e. theft and diversion) might be readily detected and prevented. It has been previously recommended that hospitals employ such machines to improve accountability²⁶.

²⁵ Australian Commission for Safety and Quality in Health Care. Evidence Briefings on Interventions to Improve Medicines Safety. Vol 1 Issue 2 July 2013. <http://www.safetyandquality.gov.au/wp-content/uploads/2013/12/Evidence-briefings-on-interventions-to-improve-medication-safety-Automated-dispensing-systems-PDF-832KB.pdf>

²⁶ Office of the Auditor General. Western Australian Auditor General's Report: Pharmaceuticals Purchase and Management of Pharmaceuticals in Public Hospitals. 2012. [http://www.parliament.wa.gov.au/publications/tabledpapers.nsf/displaypaper/3814893a80778ac5be8fa6c248257a1c001a6c15/\\$file/4893.pdf](http://www.parliament.wa.gov.au/publications/tabledpapers.nsf/displaypaper/3814893a80778ac5be8fa6c248257a1c001a6c15/$file/4893.pdf)



Inability to utilise these machines prevents realisation of the benefits described. It prevents technological, business efficiency and workplace improvements in the Western Australian acute health system. A primary driver is also improvements in patient safety and prevention of medication errors and adverse events. The allowable use of these technologies is important.

Consultation questions, Electronic Storage and Supply Units:

- **Will the proposed regulations address the identified issues?**
- **Are there other impacts of the proposed regulations that should be considered?**

2.8 Licensing and Permits

2.8.1 Background

The Department is responsible for issuing licences, permits and other authorisations in accordance with legislation.

A licence allows supply onwards; to give a medicine or poison to someone *e.g. a pharmacist dispenses a medication to patient on a prescription*. A licence may be granted to manufacture poisons, distribute or sell by wholesale or sell by retail.

A permit allows a person to use a poison *e.g. a school purchases bromine to use as part of experiments in science classes*. A permit may be granted to purchase poisons to use for industrial, educational, research purposes or to provide health services.

If an individual makes a medication or poison which they intend to sell they must have a wholesale licence. Wholesale can be defined as the sale of goods or merchandise to retailers; to industrial, commercial, institutional, or other professional business users; or to other wholesalers and related subordinated services.

Examples of wholesalers include:

- *Businesses who manufacture farm chemicals;*
- *Businesses who sell poisons to the mining industry; and*
- *Pharmaceuticals manufacturers*

Retail, in this context, can be defined as the sale of medications and poisons in small quantities directly to consumers, such as happens at a pharmacy.

A licence allows the holder to sell or supply by retail or wholesale those poisons listed in the licence. The types of poisons licences available under current regulations are as follows:



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- Wholesale/Manufacturer's licence – this authorises the holder to procure, manufacture and supply by wholesale dealing specified poisons at or from specified premises;
- Pharmacist licence – restricted to pharmacists registered in WA at or from a pharmacy registered under the *Pharmacy Act 2010*;
- Schedule 2 Retail licence – allows for the holder to procure and sell by retail poisons included in Schedule 2. These licences are made available to appropriate retail businesses located in regional areas at distances greater than 25km from the nearest community pharmacy; and
- Schedule 7 Retail licence – allows the holder to sell by retail to authorised persons, agricultural pesticides and herbicides included in Schedule 7.

A permit allows the holder to purchase those poisons listed in the permit for a specified use but not for resale. Poisons Permits are required by businesses, companies and Government Departments for poisons included in Schedule 2,3,4,7 and 8.

Permits may be for a single substance such as hydrofluoric acid in Schedule 7 for brick cleaning or they may be for a whole range of poisons such as for a public hospital pharmacy. Table 4 outlines who needs a poison licence or permit.

Table 4: Who needs a poisons licence or permit

Schedule	Licence required to sell by retail	Licence required to sell by wholesale	Permit required to purchase for businesses, companies or government Departments
2	Yes	Yes	Yes
3	Yes	Yes	Yes
4	Yes	Yes	Yes
5	No	No	No
6	No	Yes	No
7	Yes	Yes	Yes
8	Yes	Yes	Yes
9	Prohibited	Prohibited	Prohibited

The Department has a number of permit types available, which allow purchase of poisons and medicines according to individual requirements.

For example:

- *University researcher has a permit to access poisons for use in research;*



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- *An occupational health company has a permit to purchase medicines for use at remote mine sites;*
- *A stainless steel fabricator has a permit for purchase of poisons used for cleaning in the fabrication process; or*
- *Residential care facility has a permit to allow an imprest of medicine for urgent treatment of residents.*

2.8.2 Current Regulations

The Act outlines who is eligible to receive a licence, sets out how to apply for a licence and how the Department must manage licence requests. The Department cannot grant a licence unless minimum criteria are met and the holder of the licence has sufficient knowledge and capability to safely handle those medicines or poisons. The Act allows conditions to be placed on licences issued where necessary for public safety.

Rules regarding the issue of licences and permits ensure there are appropriate controls over access to medicines and poisons. The regulations support administrative rules to govern how the Department issues licence and permits. Stakeholder consultation has identified key areas of reform to ensure users have access to medicine and poisons as required. The framework for many of these reform areas are provided in the Act.

The Act has made provision for the following key changes:

- allows the issue of licences (to supply) and permits (to use) for a 12 month period from the date of issue;
- removal of Schedule 6 wholesale licences;
- removal of pharmacy licences;
- recognition of licences issued by other authorities, such as the TGA;
- provision for corporate licences with multiple sites;
- provision of a permit system for the access of Schedule 9s; and
- incorporation of a non-refundable application fee and fees for amendments to existing licence and permits.

It is essential that the proposed Regulations address these key changes to support the Act. The Regulations need to stipulate types of licences and permits, any further eligibility criteria, and fees and charges for their issue. The regulations will also stipulate any generic conditions that must apply to a specific licence type.

The types of licences and permits outlined in the existing 1965 Regulations are outlined in Table 5.



Table 5: Types of Licences and Permits

Licence / Permit	Authorises
Wholesale/Manufacturing	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, vet practices, 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
Stock feed manufacturers	Permit to obtain antibiotics to add to stock feed.

Whilst types of licences are clearly articulated, the 1965 Regulations do not adequately support the new licensing control requirements outlined in the Act. In drafting the Act consultation indicated the existing licensing area needed reform.

2.8.3 Current Regulatory Issues

Industry feedback has indicated that rolling expiry dates are more financially acceptable to business. This will facilitate timely process of renewals and avoid a licencing rush that only happens once a year. This will spread the workload associated with the renewals process, throughout the year. Rather than a peak in May-July, improving service delivery for licence, and permit holders.



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For example:

a manufacturer applies for a licence in March and pays the one-year fee. This licence would only be valid until the end of June, for three months, under the legislation. It is proposed that this licence be valid for 12 months and expire in March the following year.

Modifying the 1965 Regulations allows the Department to support the new provisions outlined in the Act including setting fees to support the different licence and permit types and adjust the types as required to reflect reciprocity and current practice. Comparison of licence requirements across jurisdictions has indicated that WA is the only state that requires a licence to wholesale Schedule 6 poisons. Client feedback would suggest that the current licence and permit structure does not fit the way some businesses perceive their role. Businesses have difficulty identifying which licences fit their requirements. Confusion is evident particularly related to the names of licences, the intended reason for requiring poisons and requiring a licence.

For example:

health services permit covers a wide range of activities involving use of medicines, such as standard medical practices, residential care facilities, veterinary surgery, ambulance services.

Businesses have also changed their patterns of usage and methods of supply and distribution.

For example:

the changing environment created by Internet sales means that some people who sell poisons do not actually store poisons or interact with purchasers in person.

Stakeholders have identified the need for alternative types of licences to allow for electronic commerce. The Regulations provide the opportunity to review the current licence and permit types.

Current issues regarding licencing includes:

- **Inflexible regulation;**
- **Duplication in licence requirements due to lack of reciprocity rules;**
- **National consistency with Schedule 7 permit requirements; and**
- **Gaps in meeting demands for certain types of trading.**



2.8.4 Proposed Regulations

The Department recognises that they are not the only regulatory body that may assess a person or organisation that may handle a poison. It is recognised that in relation to poisons, a licence or permit holder, may also need to comply with a range of other regulatory instruments or requirements that could provide adequate assessment and oversight to ensure public safety.

For example:

A mining site may have a dangerous goods site licence which covers use or transport of poisons at a specific site.

The Act has provisions for allowing recognition of licence and permits by a regulatory authorities other than the Department, so as to not require an additional licence. The regulations need to stipulate provisions regarding this recognition, including the proviso that there is a current licence governed by appropriate licensing or permit standards and an issuing authority. This would prevent businesses requiring multiple licences for essentially the same purpose.

If a person is an authorised professional they do not need a permit to authorise this same activity. However, a common business model for health practitioners is to, in partnerships or in professional groups at one location and purchase medicines on behalf of the practice as a whole. Where the medicines are being purchased and used on behalf of a business, rather than as an individual practitioner, a permit is required.

For example:

A medical practitioner does not need a permit to purchase medicines, but where the medicines are purchased by the practice, and used by all medical practitioners at the practice, a permit for poisons is needed.

The Regulations will have a role in identifying which standards or licencing authorities could be recognisable for reciprocity. Licensing standards and licensing authorities could be defined as:

- Licensing Standards - the standards identifying the requirements to obtain a Poisons licence. This implies the standards are fit for purpose; and
- Licensing Authority- the regulatory authority that determines the licensing standards or issues the poisons licence. This implies the authority is a reputable source.

In identifying appropriate standards and authority for licence it is expected that:

- the licence must be current;
- the licence comply with existing state legislation;
- the licensees are monitored to ensure compliance with licence requirements established by regulators; and
- the regulators have mechanism to enforce compliance.



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For example:

A mine site storing poisons has a Dangerous Goods Site Licence issued by the Department of Mines and Petroleum for cyanide. As they are licenced by another licensing authority the site should not require a permit from the Department; or

A person has a Therapeutic Goods Australia licence to manufacture, therefore does not require a wholesale licence from Department; or

A veterinary practice registered under the veterinary surgeons act, which employs multiple veterinary surgeons, would not require an additional permit from the Department. Any non-registered premises would still require a licence and permit from the Department.

Similarly removal of pharmacy licences is consistent with the fact that the Pharmacy Act already regulates pharmacy premises. The Pharmacy Premises Registration board stipulates that pharmaceutical licences be available via public register. The Department policy has been to only issue the current licence to the person who is nominated as the responsible pharmacist on the register. Pharmacists are already regulated by their professional standards and their provision of medicines is guided by the SUSMP and will continue to be subject to the Regulations.

Consultation will aim to identify other examples of duplication with potential for recognition of reciprocity. There is also potential to identify relevant industry codes of practice, which could support appropriate storage and handling of poisons.

Stakeholders have indicated difficulty determining when a wholesale licence is required. Wholesalers are further governed by the Australian Code of Good Wholesaling Practice for medicines in Schedule 2, 3, 4 & 8. This Code is concerned with ensuring that quality is maintained during wholesaling and sets out appropriate standards to be applied regarding handling, storage and distribution of medicines. It outlines specific storage facility requirements

Examples of activities requiring wholesale licences include:

- buying groups purchasing medicine or poisons in larger amounts for redistribution to the end user; or*
- or selling medicines to a medical treatment business, where the medicines are not for a known named patient, but intended to be supplied at a later point to a patient as determined by the medical treatment business.*

Wholesaling poses additional risks in terms of stock handling (including stringent temperature requirements) and stock control (including ability to deal with recalls). There are a significant number of drug recalls at wholesale level. A retailer operating, as a wholesaler may not adequately action recalls potentially leaving faulty goods in circulation. In current practice wholesalers can refer to codes to provide practical assistance. It is proposed that the wholesalers continue to apply the TGA Code of Good Wholesaling for Medicines in Schedules 2, 3, 4, and 8. Consultation may identify other codes/guidelines that may be applicable to other situations.



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At present there are no licence or permit requirements for the retail sale of Schedule 5 or Schedule 6 poisons. Under the current Poisons Regulations a wholesale licence is required for Schedule 6 poisons. This is not required for Schedule 5 poisons and not required in other States and Territories. The proposed controls over packaging, labelling, storage and disposal would apply equally to retailing and wholesaling and should be considered adequate in both circumstances. A wholesale licence for Schedule 6 poisons is suggested to provide little added benefit and is proposed to be removed as a requirement. This would be more consistent with other States and Territories and reduce costs for business, without any increase in public risk.

Schedule 7 licences and permits cover chemicals used widely in mining, heavy industry primary production or farming. Examples of Schedule 7 poisons include hydrofluoric acid, cyanide, mercury, agricultural pesticides and fox baits. The Department experience has shown larger organisations are likely to have multiple other levels of protection for safe handling, including Occupational Safety and Health compliance and dangerous good permits. For example, there are other regulatory regimes controlling large mining operations, which may provide adequate compliance. These other protections do not appear to be as robust for small-scale use or for individuals working as sole traders. There is likely to be continued risk, for poisons, which are stored on domestic premises, which requires regulation. It is proposed that these issues be addressed in the 2015 Regulations.

For example:

- *A large mining corporation, where use is clearly for industrial purposes, does not require a permit for mercury use; or*
- *A sole trader or individual gold prospector who wants to store mercury requires a permit.*

Consistent with the 1965 Regulations everyone who sells a Schedule 7 should be licenced. This is a consistent across Australia and provides clarity for highly dangerous substances like arsenic, mercury cyanide, hydrofluoric acid, and chlorine gas. Sellers must have access to appropriate storage facilities and skills to properly assess that the person they are selling to is authorised.

It is proposed that there is facility to accommodate indent trading. This would allow a new and specific type of licence, which could reduce regulatory burden. It is an additional category of wholesale licence to accommodate brokers and traders. An indent licence will require assessment of whether the licensee has knowledge to be able to access eligibility of purchase. They do not need to have knowledge of the chemicals themselves in terms of storage and physical handling. As regulators the Department does not need to assess a physical premises.

For example:

A broker sells Schedule 7 farm chemicals. The Department would expect the broker to have systems in place to ensure all clients are bone fide primary producers. There are no requirements for this broker to have facility to store dangerous poisons. They hence could operate the business from a home office.



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This type of licence still requires regulation, but can attract a lower fee because less assessment is required. Similar systems are in place in Victoria and have shown to contain business costs. Use of indent licensing is likely to be a more common phenomenon with electronic commerce. The introduction of indent licences will provide safer electronic commerce relating to supply of poisons and clarity regarding accountability.

The new Act will allow for permits for Schedule 9 poisons. The regulations need to outline specific criteria for Schedule 9 permits, which is likely to include:

- Use of the Schedule 9;
- Qualifications, history and experience of the permit holder; and
- Storage conditions.

Due to the inherent danger of Schedule 9 poisons these need to have strict criteria and the regulations need to identify governed uses. The permit will allow identification of the person with overall responsibility for Schedule 9 poisons at a named site. The permit may also list individuals, which require access. Regulations must prescribe the allowable uses for Schedule 9 poisons including bona fide academic research, analysis, treatment of exotic animals and training of drug detector dogs.

The Act, allows the Department to set fees for issuing and amending licences and permit schedule. The charges and fees are based on a cost recovery model. Permits and licences may differ in their fees based on the complexity of their issuance or amendment. Elements of these fees also include other activities associated with compliance monitoring.

Proposed regulatory changes, for licencing and permits, can be summarised as:

- **Licensees possessing a recognised licence or permit by a regulatory authority other than the Department would not require an additional licence:**
 - **Removal of Schedule 7 permit requirements for recognised industrial uses at clearly identifiable industrial locations;**
- **Removal of:**
 - **Schedule 6 Wholesale licences;**
 - **Pharmacy Licence; and**
- **Introduction of:**
 - **Indent licensing;**
 - **Permits for Schedule 9s; and**
- **Establishment of a schedule of fees; and**
- **Licences and Permits to be provided with expiry/renewal dates based on application dates.**



2.8.5 Impact Analysis

Changes in the area of licensing aim to provide improve cost efficiencies for businesses and improve capacity for the Department to monitor regulations. Additional clarity in the type and scope of licences and permits will improve stakeholder compliance with licence provisions. Acknowledgement of reciprocity of relevant licences and permits will have cost efficiencies created by the decrease in duplication of licences and associated costs for businesses and professionals with other relevant licences. Indent licences will have similar cost benefits to businesses and individuals in that they will save on the more expensive wholesale licence.

Consultation questions, Licensing:

- **Will the proposed regulations address the identified issues?**
- **Are there other impacts of the proposed regulations that should be considered?**

2.9 Poison Controls: Schedule 5, 6, 7 & 10 Controls

2.9.1 Background

National consistency to ensure that a poison is instantly recognisable and treated the same is important both for households purchasing poisons and industry manufacturing and supplying poisons. Most large-scale medicine and poison manufacturing does not originate from WA and these items are sold across Australia. For consumers the consistency across States is important, such that a poison made and transported from another state in Australia provides the same protection from spills, ingestion by a child, or other harm, no matter where it ends up.

In 2012 the former National Coordinating Committee on Therapeutic Goods undertook a national consultation process to look at consistency in relation to poisons controls²⁷. This process considered current controls across Australia, including those present in Poisons legislation in WA. The document *Strategies to implement a national approach to poisons chemical controls* Decision Regulation Impact Statement provided recommendations for adoption of a national standard. Through each State and Territory adopting these same controls, with the same wording, uniformity would be achieved in Regulation. This would provide industry certainty, reduce variation, reduce business costs in compliance and ensure that the public was afforded equal protection from poisons anywhere in Australia. A summary report of the impacts on WA regulations of the recommendations from this committee is contained in the discussion paper in Appendix 4.

²⁷ National Coordinating Committee on Therapeutic Goods. *Strategies to implement a national approach to poisonous chemical controls: Consultation Regulation Impact Statement*. 2012.
<http://www.health.qld.gov.au/ph/documents/ehu/ris-consult-paper.pdf>



During preliminary consultation there was limited comment relating to the matters raised in this document. The national consultation process was comprehensive and provided good opportunity for engagement and comment by all states, including WA. Specific comment was sought from industry groups. The recommendations of this document were endorsed. No significant WA related differences were identified. Stakeholders did comment on difference with licencing and permits between jurisdictions. This is covered in section 2.8

2.9.2 Current Regulations

Existing WA regulations regarding poisons include requirements over sale, purchase, storage, packaging, labelling, advertising, record keeping, disposal and hawking. Current labelling and packaging regulations include such issues as durability and breakage resistance of packaging, child resistance, inclusion of contents and concentration, and standard text for warnings and safety, size and location of warning. Regulations currently require poisons to be stored to preclude contamination of food and drug and prevent access by children, with increasing restrictions according to scheduling. There has been no suggestion by stakeholders that the specific controls outlined in existing regulations are ineffective or inadequate.

Schedule 7 Poisons may only be supplied by a person licenced to do so, in accordance with any Notice or Regulations and to a person authorised to use them. Current Regulations require that authorised users keep a register for Schedule 7 poisons. The register must record the date of sale of a Schedule 7 poison, the name and address of purchaser, name and quantity of poison sold, address the poison is delivered to and the intended place of use (if different), and the signature of the purchaser. The register may be kept in writing or electronically and readily available for inspection as required in compliance with Regulations.

Substances in Appendix C of the SUSMP are those that are of such risk to the public that they should be prohibited. They may be used in clinical trial settings and research settings. These substances are recognised in the Act as “strictly controlled substances”. In SUSMP 8, Appendix C has been replaced by Schedule 10. Schedule 10 will be adopted in the Regulations. The 1965 Regulations were constructed when the mechanism for listing as an Appendix C substance was via a different process. Within Schedule 10 there is a more robust process for poisons to be evaluated and listed, which is consistent across all medicines and poisons Schedules. Adoption of Schedule 10 ensures appropriate consultation, national consistency and less individual regulatory burden for WA.

Current issues related to Schedule 5, 6, 7 and 10 poisons are:

- **Lack of national consistency, which creates confusion for industry especially national companies; and**
- **Wholesale licensing requirements for Schedule 6 poisons out-dated (see licencing section for additional information).**



2.9.3 Proposed Regulations

The following table 6 summarizes the preferred regulatory controls as outlined in the *Strategies to implement a national approach to poisons chemical controls* Decision Regulation Impact Statement ²⁸ and the proposed regulations for WA.

Table 6: Preferred Regulatory Poison Controls Schedule 5, 6 and 7

Control	Schedule	Preferred National option	Proposed WA regulations
Storage	5	No explicit controls over retail storage	No explicit controls over retail storage
Storage	6	Outcome based control to limit retail storage.	Adoption of outcome based control to limit retail storage
Storage	7	Outcome based control, with "deemed to satisfy provisions" to limit retail storage	Adoption of outcome based control with provisions to limit retail storage
Disposal	5, 6, 7	Outcome based control to prevent public harm from unsafe disposal	Maintain existing regulatory control
Labelling	5, 6, 7	Labelling provisions of the SUSMP as is	Maintain adoption of SUSMP Labelling Provisions
Packaging	5, 6, 7	Packaging provisions of the SUSMP as is	Maintain adoption of Packaging provisions
Record Keeping	7	Adopt a prescriptive control for keeping of records for supply of Schedule 7 poisons	Maintain existing regulatory controls, and include requirement for record keeping storage for 5 years
Advertising	7	Remove controls	No controls required
Hawking	5, 6, 7	Adopt a prescriptive control	Maintain existing regulatory controls
SUSMP Appendix C	10	Adopt a prescriptive control by removing prohibited substances from Appendix and including in a new schedule	Adoption of Schedule 10 - further information outlined below
SUSMP Appendix I: Uniform Paint Standard		Implement provisions of the SUSMP Schedule as written	Maintain existing regulatory consistent with national
SUSMP Appendix J: conditions for availability		Adopt a prescriptive standard once appendix J has been subject to review and update	Maintain existing regulatory control consistent with national

²⁸ National Coordinating Committee on Therapeutic Goods. *Strategies to implement a national approach to poisonous chemical controls: Consultation Regulation Impact Statement*. 2012. <http://www.health.qld.gov.au/ph/documents/ehu/ris-consult-paper.pdf>



The Regulations need to outline specific criteria for Schedule 10 poisons, which is likely to include:

- Allowable uses of the Schedule 10, if any;
- Records of use; and
- Storage conditions.

2.9.4 Impact Analysis

The need for continued controls is evident in the number of poisonings seen annually in Australia. The number of calls taken by poison information centres each year, suggests that exposure to poisons and poisoning is still a frequent event in our society. The rate is relatively constant suggesting a residual risk associated with access to these substances.

Modifications in this area aim to achieve national consistency by complying with the SUSMP. This has the benefits of:

- Providing a consistent practice thereby decreasing confusion for stakeholders operating nationally;
- Providing a consistent stakeholder experience across States and Territories based on best practice, which is particularly relevant given the national business interests of stakeholders; and
- Reduced red tape to businesses having to accommodate mixed regulations for example: height of storage snail pellet product for retail sale can be uniform for organisation regardless of locality.

For industry, variations in packaging by State or Territory would be difficult to meet without financial penalty. National consistency of regulatory requirements is the most cost effective if all States and Territories adopt SUSMP labelling requirements without modification.

The proposed record keeping duration for Schedule 7 poisons is for a longer time period than is currently required. This time period for keeping this business information may already be required for other purposes, e.g. tax and hence the impact is expected to be limited.

Development of Regulations for Schedule 10 medicines is fundamental to support the Act. It will assist in ensuring that rules applying to substances which require strict control regarding supply and use are enforced so as to protect the health, safety and welfare of the public. Proposed regulation in this area will allow for national consistency via appropriate adoption of the former Appendix C of the SUSMP. Adoption of the Schedule 10 substances via the Schedule listing process will decrease regulatory burden in that there is a robust national platform for evaluation of these poisons. It also provides better clarity regarding the restrictions of use of these substances.



Consultation questions, Poisons Controls:

- **Will the proposed regulations address the identified issues?**
- **Are there other impacts of the proposed regulations that should be considered?**

2.10 Medicine Controls

2.10.1 Background

The legislative controls over these substances are intended to minimise the incidence of:

- Accidental and deliberate poisoning;
- Medicinal misadventure; and
- Diversion for abuse or manufacture of substances of abuse.

The regulatory controls for Schedule 2 and 3 pharmacy medications define retail sale requirements and are primarily concerned with supply of medication in terms of retail sale at a pharmacy. An authorised practitioner, as part of a consultation, may also provide these medications.

For example:

People entering a pharmacy to purchase a Schedule 3 “pharmacist only medicine” such as an analgesic containing codeine; or

An optometrist might provide Schedule 2 “pharmacy medicine” eye drops as part of a consultation but cannot offer retail sale of eye drops outside a professional consultation.

Certain information must appear on the labels of medicines, such as the product name, ingredients and relevant warnings. These are adopted around Australia from the SUSMP. There are also requirements on how these items are packaged, for example tamper evident and child resistant packaging. Regulations regarding labelling provide a consistency in terms of best practice, consumer experience and reducing red tape to businesses.

The acquisition, use, storage and disposal of Schedule 4 and Schedule 8 medicines are subject to jurisdictional legislative requirements. The primary mechanism for consumer access is for the authorised prescriber to write a prescription and for that prescription to be dispensed by a pharmacist. Anyone who supplies Schedule 4 reportable or Schedule 8 medication must notify the Department that this medication is supplied.



Anyone supplying or prescribing should follow the same general principles:

1. Assessment of therapeutic need;
2. Reasonable steps to prevent abuse; and
3. Provide medications within scope of practice.

Additional issues in relation to Schedule 8 medications are related to:

- Prescribing Codes for the prescription of drugs of addiction;
- Reporting requirements; and
- Identification of persons with drug dependency.

2.10.2 Current Regulations & Proposed Regulations Schedule 2, 3 and 4

Controls increase from Schedule 2-4 as outlined in figure 4 below. The existing regulations are guided by the SUSMP Schedules and provide rules for consumers regarding access to medicines.

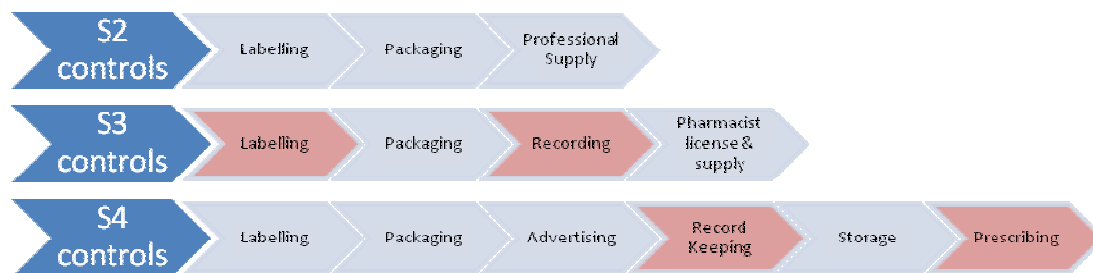


Figure 4: Regulatory Controls Schedule 2, 3 and 4

Areas, which are recommended for change, are illustrated in red.

2.10.2.1 Schedule 2 Medicines

No alteration is recommended in existing Schedule 2 labelling, packaging and supply. The regulations support that a registered health practitioner (as defined by professional authority) can supply, as part of their regular practice.

For example:

Schedule 2 cough and cold remedies can be purchased as part of retail supply from a pharmacy. It is acceptable for other practitioners to provide, as part of a consultation with a patient, within their professional scope.



2.10.2.2 Schedule 3 Medicines

Part 3 of the SUSMP recommends labelling and recording of all Schedule 3 medicines in requirement for assessment of therapeutic need. This is regular practice in some States such as Queensland. In WA this is a current requirement for some Schedule 3 medicines including pseudoephedrine. At present, a pharmacist must personally supervise the retail sale of a Schedule 3 substance. It is proposed that WA regulations adopt the recommendation that all Schedule 3 medication should be labelled and recorded. This should apply to anyone supplying a Schedule 3 medicine as part of usual professional practice.

For example:

For practitioners providing as part of a consultation with a patient a Schedule 3 medicine, the supply should be recorded and the product labelled with a patient name.

It is anticipated that labelling of medicines would also assist with making clinically appropriate decisions regarding prior supply. This offers benefit to regular customers in terms of ensuring quality use of medicines and supports the requirement of identification of therapeutic need prior to dispensing.

There needs to be facility for the emergency treatment of persons with Schedule 3 medicines for anaphylaxis and acute asthma at places like schools or child care centres.

2.10.2.3 Schedule 4 Medicines

For Schedule 4 medicines, changes are recommended in terms of record keeping, reporting and supply. The following regulatory rules should continue to apply:

- Storage of prescription medicine needs to be explicit in the regulations; out of public access does not guarantee adequate consumer protection;
- Distinction between animal and human treatment;

For example: labelled animal treatment only, so it is clear a medicine is not for human consumption;

- Provisions for emergency supply; and
- More detailed provisions to guide the appropriate authorisation of administration to a patient in a hospital setting. Administration in a hospital may be via an order, which must contain specific information and must be signed by an authorised prescriber. Regulations support the verbal approval of administration, so that a medication can be administered under the direction of an authorised prescriber.



Appendix D of the SUSMP makes recommendations for additional controls over Schedule 4 medicines where an additional risk has been identified, e.g. birth defects. Additional prescribing requirements include limitation of prescribing to specialist practitioners. The Appendix D regulations have been implemented through individual regulations in the 1965 Regulations. In order to clarify prescribing restriction, the 1965 Regulations outline the authorised providers:

For example:

Thalidomide may only be prescribed by a specialist physician or dermatologist and must be labelled with warning causes birth defects.

Whilst there may be a need to restrict other medications in this way, it is considered that there are often other mechanisms and regulatory systems in place that mean these restrictions are not always required. Such mechanisms might include:

- Improved access to drug information by health practitioners and consumers;
- Restrictions through funding schemes such as the Pharmaceutical Benefits Scheme;
or
- Risk Management programs mandated by the TGA.

2.10.2.4 Schedule 4 Reportable Medicines

Some Schedule 4 medicines have a potential for misuse and or dependency but the risk is assessed as lower than a Schedule 8 medicine. The Act allows for some Schedule 4 medicines to be named as “Schedule 4 reportable”. Being named as reportable allows the department to keep a record of supply and prescription of these medications.

For example:

It has been suggested that classes of medications such as benzodiazepines are of such risk that they should be tracked and monitored by the department.

Conditions regarding Schedule 4 reportable medicines would include:

1. Treatment as a Schedule 8 drug of addiction by the Act;
2. Reporting of dependence or oversupply;
3. Keeping of a record of prescribing and supply, such as in an electronic recording system for medical practitioner use; and
4. Restrictions on prescribing for dependent or oversupplied persons.

The storage packaging and labelling and other controls for this reportable medicine would remain as per usual Schedule 4 requirements.



2.11 Drugs of Addiction

2.11.1 Background

The Act defines drugs of addiction as those substances listed as Schedule 8 and 9 or a Schedule 4 reportable medicine. Substances included in Schedule 8 are used for therapeutic purposes and have been recognised in the SUSMP as having a potential for dependency. Schedule 9 substances are illicit substances without defined medicinal value. The major controls around illicit possession or supply of these medicines are covered by the Misuse of Drugs Act. The Act is primarily controlling the legitimate medicinal use of Schedule 8 substances whilst at the same time preventing dependency, diversion and misuse.

Historically, prescribers, lawmakers and the public have had concerns about the addiction potential of Schedule 8 substances and the potential for diversion or abuse to occur. The legislation relating to regulation of Schedule 8 substances in Western Australia was introduced over 30 years ago. Since then, drugs listed in Schedule 8 have become much more widely used in the treatment of chronic pain and are more frequently prescribed by medical practitioners in the course of treatment. Also, new dosage forms, such as the long-acting preparations, which may be less likely to cause addiction, have been developed.

Evidence suggests prescription medicine misuse is an increasing problem across the community, which is a major public health concern²⁹. There is a clear need for strict regulation, whilst still allowing legitimate access to these medicines.

2.11.2 Current Regulations

The 1965 Regulations provide a range of controls intended to allow consumer's access to Schedule 8 poisons for legitimate medical needs, while still protecting against diversion, misuse or abuse. These rules are very similar in most States and Territories of Australia. In each case, this has the effect of limiting one patient, to one prescriber (or practice), at any one time. Authorisation to prescribe is only issued to one prescriber (or practice) at a time. If a patient moves to a new prescriber, then a new authorisation is required. If a new authorisation is issued, this cancels any prior authorisation.

The 1965 Regulations state that a doctor cannot provide a Schedule 8 medication for periods of longer than 60 days or to someone with documented prior drug dependency, without getting permission from the Department. This is in recognition that longer-term treatment may be associated with dependence but provides for short-term treatment without unnecessary impact on clinical autonomy. Due to this risk of dependence permission may be subject to conditions.

²⁹ National Pharmaceutical Drug Misuse Framework for Action (2105-2015). A Matter of Balance.
[http://www.nationaldrugstrategy.gov.au/internet/drugstrategy/Publishing.nsf/content/9C52D7D6E2C14A72CA257C3F001F009D/\\$File/National%20PDM%20Framework.pdf](http://www.nationaldrugstrategy.gov.au/internet/drugstrategy/Publishing.nsf/content/9C52D7D6E2C14A72CA257C3F001F009D/$File/National%20PDM%20Framework.pdf)



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The 1965 Regulations limit patients to supply of a Schedule 8 from one pharmacy for the life of that prescription. In addition, Schedule 8 dispensing information is provided to the Department of Health. At present this information is collected retrospectively and is only accessible by the Department.

For example:

For a person with a history of drug abuse, opiates may be medically indicated for treatment of pain. A doctor can apply to the Department for permission to prescribe. The Department's authorisation restricts prescribing to one doctor, or practice. The Department monitors dispensing to ensure the prescribing continues to be linked to the authorised prescriber.

Regulations governing the use, sale and supply of Schedule 8 drugs are currently provided for in the 1965 Regulations. The Act provides a framework for regulating the prescribing of substances in Schedule 8, while the mechanics of the controls continue to be retained in the Regulations. Regulations need to cover any rules relating to prescribing and dispensing of Schedule 8 drugs to patients, particularly to patients who are drug dependent. The Act states that only an authorised prescriber can prescribe a Schedule 8 medication to a drug dependent or over supplied person.

The 1965 Regulations requires every pharmacy to complete a report at the end of each month with details of Schedule 8 drugs dispensed. The Department has developed a code to help the safe prescribing of Schedule 8 medicines and assist practitioners in the navigation of the Department's authorisation process³⁰.

A specific area of the Regulations is restrictions on the prescribing of Schedule 8 drugs. A comprehensive discussion paper was developed to support consultation in this particular area and is contained in the Appendix 2. This paper details the specific regulations regarding prescribing and dispensing. Although the Regulations apply to all Schedule 8 prescribing, the consultation to date has been predominantly concerned with prescribing of opioids, such as morphine or oxycodone. Any outcomes may also inform legislation for other drugs including benzodiazepines and related medicines.

In addition to the Schedule 8 prescribing code the regulations outline requirements related to specific Schedule 8 use including:

- Community Program for Opioid Pharmacotherapy (CPOP); and
- Stimulant Regulatory Scheme.

The Regulations must include reference to the code or policies applicable to each program area.

³⁰ WA Department of Health. Schedule 8 Prescribing Code. 2014.
<http://ww2.health.wa.gov.au/~media/Files/Corporate/general%20documents/medicines%20and%20poisons/Word/schedule-8-medicines-prescribing-code.ashx>



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The Pharmaceutical Services Branch administers the regulatory controls for the Community Program for Opioid Pharmacotherapy (CPOP) in Western Australia as set out in the Regulations. Regulation in this area is guided by published policy and procedures³¹.

The CPOP provides opioid replacement treatment in primary health care settings for patients who have been identified as opioid dependent and wish to engage in treatment. Current pharmacotherapies available are methadone as a syrup or solution, and buprenorphine as Subutex® or with naloxone as Suboxone®. Medical practitioners and pharmacies require approval to participate in the CPOP.

The Stimulant Regulatory Scheme commenced in August 2003 in response to the paper, "Attentional Problems in Children: diagnosis and management of Attention Deficit Hyperactivity Disorder (ADHD) and associated disorders"³². The Stimulant Prescribing Code sets the criteria for the prescribing and dispensing of stimulant medicines (dexamphetamine, Lis dexamphetamine and methylphenidate) in Western Australia. The existing system is well-established and meeting client's needs³³.

The Stimulant Prescribing Code sets out the criteria for the prescribing of stimulant medicines in WA. This Code is referenced by the 1965 Regulations. The Code states that treatment with stimulant medicines may only be initiated by an authorised prescriber, with specialist qualifications in psychiatry, paediatrics, neurology, or other approved qualifications, and has obtained a Stimulant Prescriber Number from the Department of Health.

Stimulant medicines may only be prescribed for the treatment of ADHD, depression, brain damage, narcolepsy, and other conditions as approved by the Chief Executive Officer (CEO) of Health.

It is important that the Regulations and Stimulant Prescribing Code were believed to be largely appropriate by stakeholders. No regulatory modification is required apart from consideration of minor flexibility issues relating to reporting requirements.

It is not acceptable for someone to supply or dispense to further someone's addiction. Medical practitioners must notify the Department if a person they treat is identified as drug dependent. The Department uses a standard format to guide practitioners when notifying of a drug dependent person.

³¹ Drug and Alcohol Office. Clinical Policies and Procedures for the Use of Methadone and Buprenorphine in the Treatment of Opioid Dependence. 2014.

http://www.dao.health.wa.gov.au/DesktopModules/Bring2mind/DMX/Download.aspx?Command=Core_Download&EntryId=166&PortalId=0&TabId=211

³² Office of Mental Health. Attentional Problems in Children. 2002

http://ww2.health.wa.gov.au/~media/Files/Corporate/general%20documents/medicines%20and%20poisons/PDF/Attentional_problems_in_children_Mgmt%20of%20ADHD.ashx

³³ WA Department of Health. Stimulant Prescribing Code: Clinical criteria for the prescribing of stimulant medicines in

Western Australia. 2014 <http://www.public.health.wa.gov.au/cproot/3591/3/stimulant-prescribing-code-march-2014.doc>



2.11.3 Current Regulatory Issues

The number of patients receiving Schedule 8 opioid medications is increasing³⁴. The number of opioid medications and formulations available is also expanding³⁵. More professional groups are now prescribing and some of these can prescribe opioid medicines. With an aging population, the prescription of use of opioids for palliative care and pain associated with malignancies is likely to remain an important treatment modality. There is mounting evidence that prescribed opioids are increasingly diverted into illicit use and responsible for harm from overdose and other misuse. The overall risk to the public may then be increasing.

With increasing use there is an administrative burden for health practitioners in prescribing and dispensing, and for Government in administering the regulations. The Act allows for the record of prescribing and dispensing to be visible to practitioners and it is the intention that this would be done through a secure electronic system. When the prescriber or dispenser is able to see the prior supply, they will be able to take this information into account when making clinical decisions to prescribe or dispense.

In general, the current Departmental authorisation system is not sustainable indefinitely. The current system is also paper based and labour intensive for prescribers. Authorisations represent an administrative burden for prescribers that add time and cost to treatment as well as potential delays for patients. Improved flexibility in this area could vastly reduce the time taken for the authorisation of Schedule 8 medicine.

The existing approach regulating the use of Schedule 8 drugs is not sustainable with the current growth rate in the use of Schedule 8 drugs.

Departmental records indicate growth of Schedule 8 Medicine prescriptions:

- in WA in 2003, 323,862 prescriptions were dispensed;
- shows an increase of approximately 8% each year;
- authorisations for Schedule 8 medicines is increasing at a growth rate of 16%; and
- authorisations for Schedule 8 medicines, for people with drug dependency, shows a growth rate of 19%.

³⁴ Nicholas R, Lee N, Roche A. Pharmaceutical Drug Misuse Problems in Australia: Complex Issues, Balanced Responses [pdf]. *Adelaide (AUST): Flinders University, National Centre for Education and Training on Addiction*; 2011. http://nceta.flinders.edu.au/files/6113/2823/3742/EN448_Nicholas_2011.pdf.

³⁵ Harrison CM, Charles J, Henderson J, Britt H. Opioid prescribing in Australian general practice. *Med J Aust*. 2012; 196(6): 380-1. <https://www.mja.com.au/journal/2012/196/6/opioid-prescribing-australian-general-practice>



Detoxification should be considered separate to long term pharmacotherapy. Opiate detoxification is defined as the medically supervised, rapid withdrawal from opioids, where opioid agents may be used to reduce symptoms and improve patient safety during this period. Detoxification might be considered to be limited to a short acute treatment period, such as 72 to 96 hours. Supply or administration outside this period should not be considered detoxification and should be subject to the usual rules for opioid pharmacotherapy.

Detoxification is currently undertaken in WA in a limited number of settings. The current regulations do not allow for detoxification in community-based settings.

Current issues regarding drugs of addiction:

- **Increasing illegitimate use of Schedule 8s is becoming an administrative burden to practitioners;**
- **Evidence of increasing misuse of Schedule 8 drugs;**
- **Requirement to determine which medicines should be named as Schedule 4 reportable;**
- **Rules regarding detoxification in approved settings are undefined.**

2.11.4 Proposed Regulations

The review of the 1965 Regulations provides an opportunity to review the current Schedule 8 framework. New legislation must still ensure that both patients and public are protected from risks associated with use of Schedule 8 drugs. The availability of real time reporting as outlined in Section 2.12 will assist in this area. It is proposed that the regulations will be amended to provide that authorised health professionals will only be able to prescribe Schedule 8 drugs in accordance with the requirements specified in published guidelines such as the regulatory code.

It is proposed that a supportive regulatory code is published which defines the broad parameters for prescribers to work within that represent safe practice for Schedule 8 medicines. This sort of code is used extensively already within the current Regulations and would be readily adaptable for this situation. When prescribing outside the parameters of the code, this might be considered a higher risk activity and therefore require higher scrutiny by the Department.

A practitioner prescribing a Schedule 8 medicine will be required to make a judgement based on the clinical assessment of the patient's condition and other information available such as the patient's prescription history. This history would be available from the system database of dispensed medicines. It is envisaged that this will encourage appropriate and timely treatment of all patients based on the medical practitioner's assessment.

There are major benefits for oversupplied or drug dependent users, as the prescribing of these should be subject to conditions. Prescription for non-dependent users can be



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facilitated via a prescribing Code. Reporting, prescribing and dispensing, of these drugs is the same, however in low risk users, an authorisation would not be required.

The criteria for low risk and high risk prescribing will not be outlined in the Regulations but will be included in a Code. Within the low risk criteria practitioners could self-manage without needing prior authorisation to prescribe. This could also capture the requirements for Schedule 4 reportable medicines.

For high risk prescribing, such as very high doses, prior authorisation would be required. It is expected an approval would be contingent on medical specialist support or some other similar higher-level control. This option would only focus on high risk prescribing. It assumes that the majority of risk from opioid prescribing is manageable by individual practitioners and does not require approval by the Department.

The Department publishes a Schedule 8 Prescribing Code with the intention of assisting prescribers when complying with prescribing of Schedule 8 Medicines. It is expected that under new Regulation the supporting code setting out criteria might be modelled on this existing tool. This will allow much of the lower risk Schedule 8 prescribing to be managed without direct intervention from the Department. This Code will need to be referenced in regulations. The Code will need to set out the criteria for prescribing, where Department interaction is required and when additional regulatory controls are to be exercised.

It is proposed that Regulations be amended to allow the prescribing of Schedule 8 drugs for the treatment of a drug dependent person for the purpose for detoxification. This would be separate but maybe complementary to the current pharmacotherapy interventions. Given the nature of these patients and the potential public risk the Regulations should be specific about who may receive the medication and who may prescribe or supply the medication. Similar to current pharmacotherapy regulations it should stipulate who is authorised such as a practitioner who has appropriate qualifications and has completed an approved course. Approved prescribers may administer approved Schedule 8 drugs for opioid detoxification. Approval will involve specific rules for patient assessment including appropriate systems, policies and procedures. The Department must be notified regarding individual patient details and medication protocols, at the time of detoxification. Compliance with the authorisation and notification would support detoxification in non-hospital settings. Records will need to be kept regarding administration of Schedule 8 drugs over the detoxification period per Schedule 8 requirements.

The rules underpinning the Schedule 8 programs are outlined in table 7.



Table 7: Demonstrates rules underpinning the programs for Schedule 8 Supply

Program	Who can prescribe?	Who can receive?	Who can Supply from?	According to what rules?
Schedule 8 Medicines	Any Medical or nurse practitioner *	Anyone meeting criteria of code	Any pharmacy	Published Schedule 8 Code
		Patients requiring individual authorisation	Any Pharmacy	According to conditions of authorisation criteria
CPOP	Authorised provider	Authorised patient (on drug dependent record)	Authorised pharmacy	Published CPOP Code
Stimulants	Approved specialists and Nominated Co-prescribers	Patients meeting criteria e.g. patients with ADHD	Any pharmacy	Published Stimulant Prescribing Code
Schedule 4 Reportable Medicine	Any Medical and Nurse Practitioner *	Any person	Any pharmacy	No rules
		Patients with a record of oversupply or drug dependence requiring individual authorisation	Any pharmacy	Proposed Code as per Schedule 8 Medicines
Detoxification	Authorised prescriber	Patients meets criteria	Authorised prescriber	Published Code

*Other Authorised Health Professional Groups may also be able to prescribe a limited amount of Schedule 8 or Schedule 4 Reportable Medicines.

These models support prescribing according to best practice and basic principles of authorisation based on risk. Depending on the program, the clinician will need to ask for permission and may have to meet more stringent criteria in the interest of serving multiple patient needs. In particular, for certain groups, prescribers must always seek authorisation: e.g. very young children, prescription to people who have previously had a drug dependency issue. Consistent with the long established approach with existing authorisations, prescribing will be limited to one practitioner at a time. If a patient transfers to a new treatment provider the previous authorisation would be terminated and a new authorisation will be required. This approach does not apply to animal treatment.

Nurse practitioners are already able to prescribe Schedule 8 medications in WA. At present a nurse practitioner must be designated and provide clinical protocols to the Department of Health. These restrictions are not likely to transition in to new Regulations. To date



Schedule 8 prescribing by this group appears to be part of collaborative care, is generally continuation of that commenced by a medical practitioner, or restricted to specialised areas such as palliative care. This may not be the case in the future. Developments will like be addressed by discipline specific regulation.

Proposed regulations for drugs of addiction can be summarised as:

- **Use of published codes to reduce regulatory burden.**

2.11.5 Impact Analysis

The key objectives of the reform in this area are to develop a system that:

- ensures appropriate, effective and timely treatment with schedule 8 drugs;
- is open and transparent;
- minimises the potential of abuse and diversion of schedule 8 drugs.

Realisation of full potential to ensure legitimate access, while adequately protecting patients in this area will be facilitated by the introduction of real time reporting. Introduction of modifications to the Schedule 8 prescribing code could reduce administrative burden on prescribers. This is expected to reduce unnecessary Department interaction, decrease authorisation-waiting times and inconvenience to the patient.

These proposed changes would continue to provide public protection, however this will be targeted at specific predetermined risk areas. The regulatory burden on the Department would be reduced as monitoring could be targeted towards compliance with high-risk authorisation requirements, and identifying patients or prescribing patterns indicating high risk.

For example:

Low risk: patient presents for a need for prescription of oxycodone for treatment of cancer pain. Medical practitioner takes reasonable steps to check for prior drug dependency and clinical need, and prescribes according to the published Code (e.g. within dose limit, no need for authorisation); or

High risk: person with recent history of illicit substance use presents at medical practice. The medical practitioner identifies need for opiate treatment and applies to the Department for authorisation to prescribe. The Department provides authorisations, inclusive of any stated conditions (e.g. weekly dispensing of medicine).

Inclusions of rules at a Code level will enable the use of language, which is less legal in nature and more usable in clinical practice. It is anticipated that this will facilitate increased compliance and flexibility, whilst still maintaining the level of public safety required.



Consultation questions, Drugs of Addiction:

- **Will the proposed regulations address the identified issues?**
- **Are there other impacts of the proposed regulations that should be considered?**

2.12 Register of Notified Drug Dependent Persons

2.12.1 Current Regulations

The 1965 Regulations require a medical practitioner to obtain permission prior to prescription of a Schedule 8 medicine if a person has a dependency or if treatment is required for a period longer than 60 days. The *Drugs of Addiction Notification Regulations 1980* (the Notification Regulations) require a medical practitioner who in the course of his / her practice becomes aware of, or suspects a person of having a drug dependency, to inform the Department. A register of Notified Drug Dependent Persons (the Register) is required to be maintained by the Department.

A person may be added to the Register in two ways:

1. A medical practitioner is required to notify the Department of Health if they become aware or suspect that an individual has a dependency on medicine; or
2. To receive treatment for drug dependence under the Community Program for Opioid Pharmacotherapy (CPOP) clients need to sign a statement. This statement acknowledges that the clients are aware that their name will be included on the Register.

The Register is for the purposes of guiding medical treatment only. If a person on the register requires treatment with a Schedule 8 medicine (opioid analgesic) then their doctor is required to make an application to the Department of Health before prescribing. Emergency administration is excluded from this requirement, e.g. patient treatment after cardiac arrest or treatment in hospital after surgery. Information about people on the register is only provided to prescribers who are involved in a person's treatment, when needed to make decisions about the persons care. Information from the Register is not available to employers, police or other Government agencies.

The Drugs of Addiction Notification Regulations 1980³⁶ describes how a name may be removed from the Register.

The criteria are:

- the person referred to in the register has died;
- the entry was, for any reason, false or incorrect;
- after the person has been drug-free for 2 years, the Director, Alcohol and Drug

³⁶ Drugs of Addiction Notification Regulations 1980.
https://www.slp.wa.gov.au/legislation/statutes.nsf/main_mrtitle_1327_homepage.html



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Authority has advised that the person referred to in the register has ceased to use drugs; or

- there has been no contact with the Department for 5 years.

The Department periodically assesses those persons believed to have died or where there has been no contact for a period of at least 5 years validates this information and removes these persons from the register, on an ongoing basis.

The Department also has a process for people to apply for information about their status on the register and provides advice for those people wishing to seek removal.

2.12.2 Current Regulatory Issues

These regulations covering the register of Drug Dependent persons currently sit under the Health Act of 1911. The replacement Public Health Bill 2015 is currently before the WA Parliament. In development of the Bill, it was considered appropriate for notification regulations to be included in the Medicine and Poisons legislation. The Act has made provision for the drug dependent persons to be considered within it. It is therefore important that the details regarding notifications are adequately supported by the subsidiary legislation.

The Department needs to maintain a record of people reported as drug dependent. It is important that such records are accurate. The Department understands some medical practitioners may be reluctant to notify about patients whom they suspect may have a drug dependency. This reluctance may stem from concerns about patients not seeking care. The present system may also act as a perceived barrier to the legitimate use of Schedule 8 drugs for a person on the register.

The current system does not recognise the difference between people using drugs and people seeking them with the intention selling them for illegal use. There are limited provisions to deal with people who are not on the record but are clearly obtaining excessive quantities. Drug dependence has the connotation that an individual is taking drugs. The term doctor shopper tends to be more related to people selling medication.

Under the existing system, patients can be 'notified' without their knowledge. Inaccurate information, the stigma attached to the label of a 'drug addict', and the lack of any appeal provisions when a name is added to the record, all contributes to a lack of confidence in the use and maintenance of the record. The growing awareness of consumer rights associated with privacy of information need to be addressed in the legislative framework.

The Regulations need to allow a person to apply to the Department and have the information amended or removed when appropriate. This would include if a person can prove that it was not them, or the notification was vindictive or erroneous or if there has been no Schedule 8 use for over 5 years.



Current Issues regarding the Register of Notified Drug Addicts:

- **Ensuring the process for addition and removal are transparent;**
- **Ensuring drug dependent people and doctor shoppers can be identified; and**
- **Perception that the register is a barrier to treatment.**

2.12.3 Proposed Regulations

The Act proposes that drug dependent persons are being reported and that prescribing restrictions for this group are applied. The notification of a drug dependent person will remain the responsibility of the treating medical practitioner based on their professional assessment of dependency. Guidance over who is drug dependent needs to be based on input from medical practitioners. It is recommended that the Department endorse the DSM criteria for drug dependency in supporting practitioners when making reporting decisions.

The Act does allow the Department to form a view that a patient may be oversupplied based on prescription records. Pharmacists, a medical practitioner or a nurse practitioner or the Department may identify oversupplied or doctor shopping patients. This might for example, apply to persons attending multiple practitioners concurrently or receiving amounts over time that are well in excess of personal needs based on the prescribed dosage. An oversupplied person may be subject to controls, such as an authorisation system, similar to that of a drug dependent person.

The Department must have clear criteria to definitions for what constitutes possible oversupply. Currently the Department reviews information regarding the numbers of doctors seen, frequency and quantity of the access to medication. In these instances the Department will investigate the reasons for occurrence, which may be valid medical need such as increased supply due to scheduled holidays, before considering a person may be oversupplied. It is proposed that if a person is oversupplied they will be subject to similar provisions to drug dependent persons and permission will need to be sort prior to Schedule 8 prescribing.

Two years is considered the minimum risk period during which a person's name needs to be flagged on the record for their protection. At the moment a person's details may be removed from the record in certain instances, when defined conditions are met. Ongoing stakeholder feedback indicates that the Regulations need to clearly stipulate what these conditions should be. Consultation has suggested that if someone has legitimately been included on the record, after 2 years, if they are drug free and if this is properly validated by a medical practitioner, it should be acceptable to be removed from this record.

Under prior Regulations one pathway for removal was with the recommendation of the Drug and Alcohol Office (DAO) after a two-year period. With the current community pharmacotherapy program many patients are not managed directly by DAO and it is proposed that other medical practitioners could safely determine people eligible to be taken off the record. To be considered for removal, the person should have a history of treatment with a medical practitioner over a reasonable period of time, so that the practitioner has a good knowledge of their medical situation. This should also be confirmed through other methods such as clinical examination plus independent objective assessment such as urine



tests. If there are no interactions with the Department, a person will automatically be removed after 5 years, without requiring confirmation by DAO or another medical practitioner.

2.12.4 Impact Analysis

It is expected under the new Act that medical practitioners may report people who would previously been on the register of drug addicts. There are currently 7961 people on the record at present. This presents approximately 0.3% of the total WA population. There are several hundred notifications each year. As the scope of reporting is relatively similar under the Act, it is not anticipated that there will be significant change to the number of people reported. It is expected that a number of people will be newly identified as oversupplied, however there may be significant overlap between the two groups. Inclusion of Schedule 4 reportable medicines such as benzodiazepines may identify additional persons, however some may have already been notified. Capture of this information on the electronic reporting system outlined in section 2.13 will assist in identification of doctor shoppers and drug dependent persons.

If a person were previously on the Register of Drug Addicts, they would now be notified as drug dependent. The Regulations are designed to capture the same people and provide the same protection afforded by the Drugs of Addiction Notification Regulations. The only difference is that individuals will have the opportunity to refute any erroneous claims and fully understand the implication of being reported. Clear guidance on removal from the record and flexibility for removal criteria will meet stakeholder concerns generated during consultation.

Consultation questions, Register of Notified Drug Addicts:

- **Will the proposed regulations address the identified issues?**
- **Are there other impacts of the proposed regulations that should be considered?**

2.13 Electronic Real Time Controlled Drug Reporting

2.13.1 Background

The Commonwealth Government has proposed a national system called the Electronic Reporting and Recording Controlled Drug (ERRCD) system. Such a system could potentially provide real time access to the prescriber of a patient's history of Schedule 8 dispensing at the time of prescribing. The Act contains provisions to allow the collection and sharing of data via ERRCD reporting.



2.13.2 Current Regulations and Issue Identification

The Regulations require that all pharmacies send their Schedule 8 dispensing information to the Department within 7 days of the end of the month. The information is collected and stored by the Department in a database and forms the basis of a prescription monitoring program. This system is used to plan, monitor and evaluate services for the control of the supply of prescription of Schedule 8 medicine in WA. This system allows:

- identification of who has received prescriptions for more than 60 days and requires authorisation;
- monitoring of items which have been prescribed to people who are recorded as dependent;
- identification of people seeing more than one prescriber at a time e.g. doctor shopping; or
- identification of medical practitioners prescribing beyond their authorisation.

There now exists technology that would support the secure collection and transmission of this information in real time. This would provide the ability to respond instantly to any potential oversupply. In addition to the Department monitoring this information, it can also be provided securely to health practitioners in real time, to use in clinical decision-making. By providing this information to the prescriber or dispenser, practitioners will see an up to date history of medication use, and be better prepared when making therapeutic judgements about legitimate supply. This would also assist practitioners with compliance around controls for Schedule 8 medicines.

For example:

At present if a medical practitioner wishes to obtain a prescription history they must ring the Department telephone advice line during normal business hours. When faced with a new patient outside these hours there is no ability to obtain the same information.

If this information were provided in real time, the medical practitioner would be able to identify that the medication had been prescribed by another practitioner and the pharmacist may be able to identify medication had been previously dispensed.

2.13.3 Proposed Regulations

The Act requires the Department to keep a record of information relating to the supply and prescription of drugs of addiction. The Regulations will need to outline the details of how this information will be obtained including: what information needs to be supplied, how it is supplied and when it is supplied. Regulatory control will ensure that as far as practicable, patients are identified prior to prescribing in an attempt to identify oversupplied or drug dependent persons. If a real time system is implemented the expectation will be that the clinician access this system to utilise information to ensure that prescribing and dispensing of medicine is in compliance with the legislation.



It is proposed that the same information is provided from community pharmacies however this information should be provided in real time in an electronic format.

2.13.4 Impact Analysis

All Australian jurisdictions have adopted some form of monitoring of prescription of drugs of dependence. Of note, Tasmania has implemented a clinical regulatory interface to allow real time monitoring. The evidence from Tasmania suggests that this approach has contained the harms arising from the increasing prescribing of opioid analgesics.³⁷

The increase transparency afforded to prescribers provides assistance with clinical decision-making and direct benefits to patient care. There is no impact on the person who is taking medicine as prescribed. For the person that is seeing multiple practitioners it allows identification early to assist in prevention of dependency. Stakeholders are supportive of the role of ERRCD systems to assist in monitoring and regulating the supply of medicines. Stakeholders including peak medical groups are supportive of rollout of a real time prescription drug database to reduce the number of people dying from prescription drug related overdoses³⁸.

Consultation questions, Electronic Real Time Controlled Drug Reporting:

- **Will the proposed regulations address the identified issues?**
- **Are there other impacts of the proposed regulations that should be considered?**

2.14 Destroying Drugs of Addiction

2.14.1 Background and Current Regulations

Regulations currently require that poisons not be disposed of in any place or manner likely to constitute a risk to the public. There is risk that upon completion of use of a medicine or poison that it may be discarded in a way that allows access by another person and results in harm.

Destroy, in the context of drugs of addiction means to make it unusable by any other person. This means it would not be able to be reused by an unauthorised person. The Department recommends that all pharmaceuticals be ultimately disposed of by incineration.

³⁷National Drug and Alcohol Research Centre. A Review of Opioid Prescribing in Tasmania: A Blueprint for the Future 2012. http://www.dhhs.tas.gov.au/__data/assets/pdf_file/0019/137062/A_Review_of_Opioid_Prescribing_in_Tasmania_A_Blueprint_for_the_Future_NDARC_2012.pdf

³⁸Royal Australian College of General Practitioners. GPs call for real time prescription drug database in bid to save lives. 2015 <http://www.racgp.org.au/yourracgp/news/media-releases/prescription-drug-database/>



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Only an authorised person can destroy, with a valid reason such as not suitable for use, out of date or damaged. Records of destruction must be made and must include: who destroyed the drug, why they destroyed it and a witness to confirm this. The concept is that an authorised person can destroy a Schedule 8 medicine, but they must have a second authorised person to act as a witness to confirm that this took place as stated. A person authorised to possess is also authorised to destroy.

The presence of an authorised witness ensures that Schedule 8 medicine cannot be diverted through the destruction process. Disposal in this manner ensures that Schedule 8 medicines cannot enter the illicit market. Stakeholder feedback indicates that destroying and witnessing requirements for Schedule 8 medicine are at times too restrictive to allow practical achievement in many practice settings.

For example:

- *A veterinary practice may have to contact a policeman to witness destruction of medication; or*
- *A residential care facility does not have pharmacists available to witness destruction and a nurse is not sufficient.*

2.14.2 Proposed Regulations and Impact Analysis

To facilitate appropriate destruction it is recommended that witness requirements for Schedule 8 and 9 medicines be decreased to enable staff working directly with authorised persons to witness destruction. It is anticipated that this would create greater efficiency in workplaces by reducing unnecessary use of public resources, such as police to witness destruction. This will prevent stockpiling and result in the more frequent destruction of small quantities of medicine in a more timely manner. The proposed regulations will state that the authorised person must destroy and create the record, in front of an appropriate witness.

For example:

- *In a veterinary practice destruction of a Schedule 8 could be done by a veterinarian and witnessed by another veterinarian; and*
- *In a residential care facility a registered nurse could dispose of a Schedule 8 and be witnessed by another registered nurse or enrolled nurse.*

This should ensure greater compliance with regulatory requirements. In the event that there is an offence committed destruction records should provide ability to investigate for evidence of collusion (destroyer and witness acting together) or wrongful doing by the destroyer.



Consultation questions, Destroying Drugs of Addiction:

- **Will the proposed regulations address the identified issues?**
- **Are there other impacts of the proposed regulations that should be considered?**

2.15 Storage and Transport of Drugs of Addiction

2.15.1 Background

The current community concerns with prescription medicine misuse related to Schedule 8 medicines are well documented. Inadequate security measures surrounding these medications can lead to diversion to the illicit market and contribute to this misuse.

Since the time of the writing of the previous Act in 1964 the range of Schedule 8 medicines, the quantities stored, the types of practitioners handling them and the range of practice settings they are used in have all increased. The result is that there are more Schedule 8 medicines in circulation that require adequate protections from theft or misuse.

There are already stringent storage and handling requirements for Schedule 8 medicines to ensure there is no opportunity for their diversion into illicit use. These requirements are important, need to remain and should be appropriate for the current practice use settings.

Storage safe, transport and handling requirements can vary greatly between an institution such as a very large teaching hospital with thousands of staff, a wholesaler with very large quantities of drug or a small surgery with a single practitioner. Under the 2015 Regulations there are expected to be more health practitioners seeking to store scheduled medicines, which they are authorised to use in the practice of their profession.

2.15.2 Current Regulations

The storage requirements for Schedule 8 medicines require use of a large safe that weighs 500 kilogram or more. There is a process for exemption from these requirements, but this must be applied for individually and assessed by the Department. In addition the following controls apply to safe regulations:

- Any safe access device (key) must be kept by or only known by an authorised person;
- Safes must be kept locked;
- Safes must not be located in public areas of a premises;
- Above a certain specified quantity of Schedule 8 medicine additional security requirements apply e.g. monitored alarm systems; and
- A safe must always be under control of an authorised person.



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There are some exceptions, as to when Schedule 8 medicines are not required to be stored in a safe. In these instances authorised persons must still take all reasonable steps to keep the Schedule 8 medicines secure.

For example:

- *A small quantity of morphine stored in a Doctor's Bag for emergency use.*

The objectives regarding regulation of transport requirements are to:

- Make sure that items do not get diverted or lost in transport by taking reasonable steps to ensure delivery and receipt; and
- Report anything that is lost or stolen in transit.

Current regulations stipulate Schedule 8 medicines to be transported without visible identifiers and receipted on arrival. The 1965 Regulations refer to a “common courier”.

2.15.3 Current Issues

Stakeholders have identified the current ‘one size fits all’ approach to handling of Schedule 8 medicines in the 1965 Regulations is neither always achievable nor practical to accommodate within the increasing variety of settings where these medicines are stored, handled or transported. Stakeholders accept that reasonable measures need to be in place to prevent theft or loss and that authorised persons must be accountable for the storage of the medicines. The existing 1965 Regulations do not take into account into factors such as health and safety risk posed at a specific setting, practical issues and current industry standards, and the overall and specific public health risk.

For example:

Many veterinary practices hold small quantities of Schedule 8 medicines and the Department must issue an exemption from the large safe requirements prescribed in the Regulations for each individual practice.

Regulations support making of an inventory at regular intervals to monitor Schedule 8 medicine stock levels. Currently all records of Schedule 8 medicine including inventory registers need to be kept for 7 years. Additional inventories are required when the control of the drugs are handed over to another authorised person.

For example:

An inventory once a month at a busy hospital where multiple transactions take place daily is not sufficient.

Current regulations provide limited guidance for or regulatory oversight of secure transport requirements. There is confusion over obligations of an authorised person with regard to reporting of losses or theft of a Schedule 8 medicine.



Current Issues regarding storage and transport requirements:

- **Safe/storage requirements for Schedule 8 medicines are inflexible**
- **Duration of record keeping is excessive**
- **Lack of clarity regarding transport recording and inventory loss reporting requirements**

2.15.4 Proposed Regulations

It is proposed that storage of records be maintained for five years. Although shorter than the current seven year time period, it is in alignment with other industry norms and similar to other business requirements such as taxation records. This is consistent with Schedule 7 requirements and although longer than existing requirements for Schedule 4s proposed, is considered necessary due to the higher risk associated with these medicines. It should be acceptable to keep these records electronically as long as they are a true and accurate copy.

New legislation regarding transportation of Schedule 8 medication mandates the reporting of medicines, which do not arrive at their intended destination after transportation. It is proposed that there is an adequate audit trail to ensure that medicines lost or stolen are rapidly identified. The tracking of high value goods in transit is now routine and should place no additional burden on businesses. It is in the best interest of the general public to ensure Schedule 8 poisons cannot be diverted during their distribution to points of supply.

For example:

If a shipment is lost in transit, the Department must be informed.

Storage requirements are another regulation to prevent public exposure to medications. Safe requirements are proposed to be more flexible based on the level of requirements in different settings. Where there are other security measures in place or a higher level of supervision, the risk may be considered lower. The suggested approach is outlined in more detail in Table 8, which suggests storage requirements for Schedule 8 & 9 substances. Table 9 further defines specific safe requirements.



Table 8 Suggested requirements for storage of Schedule 8 and 9 substances

Setting		Quantity	Reasonable steps	Hardwood cupboard or drawer	Small safe	Large safe	Strongroom or safe	Conditions	Additional security
		number of individual dose units [#]		Securely fixed, lockable	AS/NZS 3809:1998 Resistance Grade I / Table 2, Level 1	AS/NZS 3809:1998 Resistance Grade II / Table 2, Level 2	AS/NZS 3809:1998 Resistance Grade VII		Monitored alarm system + movement detectors
During mobile patient treatment	“Doctor’s bag”	Minimum required	✓					Authorised person responsible	
	Veterinarian	Minimum required for one day	✓						
	Ambulance	Minimum required	✓						
Patient Care Area: Hospital / Health care facility	Supervised* 24/7	Any		✓					
	Not supervised 24/7	≤ 250			✓				
		> 250			✓				✓
Health Practitioner: Doctor’s surgery / Dental surgery / Veterinary practice		≤ 250			✓				
		250 to 500			✓				✓
		> 500					✓		
Schedule 8/Schedule 9 Medicines Permit (researcher, analyst)		≤ 250			✓				
		250 to 500			✓				✓
		> 500					✓		



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Pharmacy / Hospital Pharmacy	Any		Securely fixed, lockable				opening hours only / authorised person on site	
	Any				✓			✓
Manufacturer or wholesaler	Any					✓		✓
Electronic Supply Unit: Hospital / Health Care Facility	≤ 250		Equivalent protection to					
	250 – 500			Equivalent protection to				
	> 500			Equivalent protection to				Equivalent protections to

Dose means usual human (or animal for an animal product) therapeutic dose. For example, a 50 mL multidisc vial of ketamine (as used by vets) would be considered to constitute 50 doses of 100 mg and a 10 mL multidisc vial of 10mg/mL butorphanol would be considered to represent 50 doses of 2mg.

*Supervised means that an authorised person is physically on the premises near where the Schedule 8 medicines are stored, and in control of the safe, 24 hours a day, 7 days a week. All receptacles to be kept locked when not in immediate use for accessing the medicine.



Table 9: Safe specifications

	Level 1	Level 2
Cabinet/Body	Made from solid steel plate at least 10mm thick or a steel skin with concrete fill 50mm thick Continuous welding of all joints	<ul style="list-style-type: none"> • Made from solid steel plate at least 10mm thick or steel skin with concrete fill 50mm thick • Continuous welding of all joints
Door	<ul style="list-style-type: none"> • Made from steel plate at least 10mm thick or a steel skin with concrete fill 50mm thick • Flush fit • Maximum clearance of 1.5mm when closed • Hinge system such that hinge removal would not allow the door to be opened. 	<ul style="list-style-type: none"> • Made from steel plate at least 10mm thick or a steel skin with concrete fill 50mm thick • Flush fit • Maximum clearance of 1.5mm when closed • Secured with at least 2 locking bolts of 32mm diameter • Hinge system such that hinge removal would not allow the door to be opened.
Lock	<ul style="list-style-type: none"> • 6 lever key, type 2 UL rated, or • 4 wheel combination or electronic (digital), group 2 UL rated 	<ul style="list-style-type: none"> • 6 lever key, type 2 UL rated, or • 4 wheel combination or electronic (digital), group 2 UL rated
Mounting	To brick or concrete wall and/or floor with at least four bolts of at least 12 mm in diameter. If mounting to brick or concrete wall and/or floor is not possible, safe must be securely mounted to structural elements of the building such as studs or floor joists.	Directly to concrete floor with a 16mm diameter expanding bolt, installed by a person licenced under the <i>Security and Related Activities (Control) Act 1996</i> to install safes. Safes weighing over 1 tonne are not required to be bolted.
Weight	No minimum weight	Minimum weight 250kg

2.15.5 Impact Analysis

The flexible approach to storage requirements will provide increased clarity for stakeholders. They will be able to identify their own personal situation and readily identify the minimum requirements to achieve. The inclusion of an increased number of storage options will allow a reasonable and appropriate solution for the risk posed by an individual practice setting. The options will be more achievable for most settings. In many cases they will be cheaper. They will still ensure that there are minimum standards to be met and that storage is adequate to prevent authorised access and diversion.

Use of 'number of doses' as the cut-off for specific controls, rather than total weight as currently used will better assist practitioners to identify which requirements they must personally meet. The number of doses more accurately reflects risk of diversion than total weight for high potency drugs like fentanyl or high volume veterinary drugs like ketamine.

For example:

a veterinary practice could use a 'small safe' where they hold less than the equivalent of 250 human doses. This could include a relatively standard inventory of 2 x 50mL multidose vials of ketamine 100mg/mL (100 doses), 1 x 10 mL multidose vial of butorphanol 10 mg/mL (50 doses), 20 x buprenorphine 300 mcg/mL ampoules (20 doses), 10 x morphine 10 mg/mL ampoules (10 doses) and 10 x morphine 5 mg/mL ampoules (10 doses).

Requirements for pharmacies are proposed to be higher than other health related practices. Pharmacies generally maintain larger stocks and frequently supply Schedule 8 medicines. Pharmacies as an open retail store have potentially less control over who is on the premises at any one time. Other health practitioners (vets, medical, dental) generally use appointment systems and medicines are stored in areas separated from publicly accessible areas. Very few pharmacies have completely closed dispensary areas where the Schedule 8 safe may be located. Due to the nature of their business, pharmacies appear to be known targets for burglaries and hold-ups compared to other practitioner groups.

As all pharmacies should already be compliant with existing legislation there is no new cost of compliance. The proposed requirements for pharmacies maintain the status quo with the exception that the minimum safe weight is reduced to 250 kg to make this comparable with standards outlined by other jurisdictions. This reduction is not believed to make a discernible difference to the risk of the entire safe being stolen but can potentially reduce costs for business. However, in practice many pharmacies may require a heavier safe simply to provide adequate internal volume to hold the quantity of Schedule 8 medicines they keep to meet prescription demand.

Hospital inpatient wards can use a cupboard but other patient care areas that are not operational 24/7 needs to use a safe. Health care facilities with inpatients (or residents) will usually have staff on site 24/7. However, unless there are authorised staff in the vicinity of the storage area for the Schedule 8 medicines (such as will be the case with a standard inpatient 24/7 ward), a safe rather than a cupboard is required to reduce the risk of theft when there are no staff in the area. This means a ward set up for day cases only which is closed for a period overnight will require a safe rather than a cupboard.

Benefits to business of the introduction of these proposed regulations are that they are easier to understand, which should aid in compliance. They also have cost benefits in that the cheapest safe that will meet the Department requirements can be utilised by business.

Consultation questions, Storage, Transport and Inventory of Drugs of Addiction:

- **Will the proposed regulations address the identified issues?**
- **Are there other impacts of the proposed regulations that should be considered?**

2.16 Shipping and Vessels

2.16.1 Background

Ships and vessels have an established need to possess and use medicines including some Schedule 8 medicines, for the treatment of medical conditions and emergencies when at sea. The existing poisons legislation has historically provided the ability for ships and vessels to lawfully obtain and use medicines.

There have been several recent laws enacted federally which influence the regulatory requirements in this area. The *Marine Safety (Domestic Commercial Vessel) National Law Act 2012* (Commonwealth) was passed in August 2012 and implemented on the 1 July 2013.

The 1965 Poison Regulations define a Certified Commercial Vessel as one registered under WA Marine Act 1982. In 2011, the Commonwealth, State and Territorial governments signed the Intergovernmental Agreement for Commercial Vessel Safety Reform to transfer responsibility for the regulation of all commercial shipping to the Federal Government, including design, construction, survey, operations, manning and crew qualifications.

The new regulatory framework is known as the National System for Commercial Vessel Safety and will be administered by the Australian Maritime Safety Authority (AMSA). It consists of regulations and marine orders to adopt:

- National Standard for Commercial Vessels (NSCV); and
- Regulatory Plan (for vessel and crew treatment).

This will mean that the Western Australian Government will no longer regulate commercial shipping in the State. Newly built vessels will be regulated by the AMSA, while existing vessels will be 'grandfathered' into the National System.

The Maritime Labour Convention, 2006 (MLC, 2006) establishes standards for medical care on board ship and ashore. Regulated Australian vessel must be provided with medicine chests with at least minimum medicines, medical and surgical stores, appliances and antiscorbutic treatments stored according to Medical carriage requirements outlined by AMSA.

2.16.2 Current Regulatory Issues

To meet medical needs aboard ships and yachts, pharmacists and other pharmaceutical suppliers may be requested to supply medicines to complete the required safety equipment for these vessels. The Department commonly fields requests and questions from poisons licence holders and personnel from ships querying the supply to these vessels as outlined in the Regulations. This suggests that there is generally poor understanding of the current legislative requirements

Whilst the ships and vessels are a generally highly regulated area, the Poisons Regulations are the only legislative tool, which governs the supply and management of poisons to and on ships. The Regulations will need to reflect the new medical equipment scales outlined in the national standards for registered vessels. The 1965 Regulations refer to Section 125 of Navigation Act. Since this time there have been a number of amendments to the Navigation Act.

The current Act refers to Marine Orders 10; however this now appears to be covered by Marine Orders 11, Division 8. These orders refer to the Medical Carriage requirements on regulations Australian vessels, published by AMSA and the International Medical Guide for Ships by the World Health Organisation.

There is a long-standing and accepted need for ships and yachts to carry basic medicines for medical emergencies when away from land. These vessels and their staff may not be health practitioners, nor be suitable to apply for poisons permits due to their place of origin and mobility. However as they should still be authorised to obtain and use poisons for medical treatment purposes, the Regulations need to outline how they may purchase medicines. In particular the Regulations need to clearly describe under what circumstances a pharmacy or pharmaceutical supplier may supply to these persons.

The current regulatory issues with Ships and Vessels can be summarised as:

- **The current regulations refer to out dated legislation and are difficult for users to understand and apply.**

2.16.3 Proposed Regulations

It is proposed that Regulations be modified to compliment the requirements of the new maritime legislation and provide improved clarity for pharmacists and wholesalers when supplying to vessels. Consistent with the current approach, it is not practical for a poisons permit to be required of the purchaser of the medicines to equip these vessels. Similarly, there should be no need for a medical practitioner to write prescriptions to authorise supply to the types of vessels covered by the Regulations.

The 2015 Regulations need to have a mechanism to include definitions of the types and general allowable quantities of drugs which domestic and commercial vessels should be permitted to obtain. In addition the regulations must outline the storage and recording requirements for supply by pharmacists and use by ships.

As for any other instance of supply, there must be a valid order stating outlining the authority to supply to the supplier. Pharmacists and wholesalers should receive a written requisition, signed and dated by the master of the vessel, which includes the following information necessary for supply:

- name of the domestic commercial vessel;
- machinery and hull number (M & H number) of the vessel;
- name and address of the master of the vessel; and
- medicines required including strength, dosage form and quantity

Schedule 8 transactions involving vessels should be part of collected information on the supply of drugs of addiction and include:

- date of supply;
- name of the vessel;
- name of the ordering person;
- drug supplied including strength and dosage form; and
- quantity supplied.

Proposed regulatory changes, for shipping and vessels, can be summarised as:

- **Update the existing regulations to reflect current maritime legislation; and**
- **Outline pharmacists and wholesaler recording requirements.**

2.16.4 Impact Analysis

It is essential that requirements in this area be updated as part of maintenance of existing regulations. Removing regulation in this area will not support the maritime legislation and meet the needs of vessels that need to obtain and use medicines.

Regulations must allow pharmacists and wholesalers to supply medicines to three types of vessels:

- registered ships;
- domestic commercial vessels; and
- yachts participating in offshore races departing from Western Australia.

As pharmacists and wholesalers already have to meet recording requirements for this type of supply there is not expected to be any additional impact.

Stakeholder feedback has indicated a lack of clarity regarding requirements in this area. Introduction of new Regulations have the benefits of supporting existing regulatory programs for vessels as well as improving the supply to vessels and hence their access for medicines to use for medical purposes. There are not expected to be any additional costs to compliance with these regulations due to improved regulatory certainty for suppliers. Overall, improved understanding is likely to improve compliance with regulation and decrease regulatory burden.

Consultation questions, Shipping and Vessels?

- **Will the proposed regulations address the identified issues?**
- **Are there other impacts of the proposed regulations that should be considered?**

2.17 Summary of Regulatory Recommendations

This consultation paper has been compiled based on feedback from discussion papers, an online survey and various stakeholder interviews and forums. It presents options for the new regulatory framework and poses questions to identify further issues to be incorporated in the Decision RIS. In Sections 2.4 through 2.9 & section 2.16 it proposes regulations to address issues identified regarding: Professional Authority, Structured Prescribing Arrangements, Electronic Prescribing, Electronic Storage and Supply Units, Licensing, and Shipping and Vessels. The proposed Regulations recommendations for these sections are summarised in Table 10.

The regulatory requirements related to Medicine and Poisons Schedules were also examined. In assessing required regulatory control the schedules provide a framework for the level of control in the following areas: labelling, packaging, advertising, storage, record keeping, transport and hawking. The SUSMP guidelines regarding level of control was considered in identifying regulatory issues to be incorporated in the subsidiary legislation. Proposed changes in regulatory control according to the schedule requirements are summarised in Table 11.

Table 10: Summary of Regulatory Issues and Proposed Regulations

Area	Regulatory Issues	Proposed Regulations
Professional Authority	<ul style="list-style-type: none"> • Lack of alignment with national registration standards outlined by AHPRA. • Certain professions are not named and therefore it is difficult to identify restrictions; • Current regulations are out dated in terms of current practice; • Current authority system does not allow changes in response in professional scope therefore there is inflexibility to changing workforce needs. 	<ul style="list-style-type: none"> • Defining individual professions that need access to medicines and what includes or excludes a person as part of that practitioner group. • Outlines conditions or limitations for any specific authority or group and define what legitimate practice may be for this group. • Define appropriate level of authority in terms of each professions ability to obtain, possess, administer, supply, prescribe, dispense and manufacture medicine and poisons.
Structured Prescribing Arrangements	<ul style="list-style-type: none"> • No current framework to establish Structured Prescribing Arrangements (SPAs). • Regulation currently achieved via various exemption processes, which are inconsistent, slow and difficult. 	<ul style="list-style-type: none"> • Providing a single regulatory framework so health professionals can clearly see their role and responsibilities. • Support development of SPAs from: <ul style="list-style-type: none"> • The Department of Health • For a health organisation • For individual medical practitioners • Provide clear regulatory guidelines regarding minimum requirements of a SPA. • Ensure safe application and use of SPAs by medical practitioners and other health practitioners.

Electronic Prescribing	<ul style="list-style-type: none"> Existing regulations are out-dated and do not support the current work practice or future potential of electronic prescribing. Need to protect or safe guard from misuse or abuse of data e.g. forgeries 	<ul style="list-style-type: none"> Regulations will outline details regarding how the electronic systems can be used including: what information needs to be supplied, how it is supplied and when it is supplied. Electronic prescriptions must meet existing principles of prescription regulations
Electronic Storage and Supply Units	<ul style="list-style-type: none"> Regulation is required in this area to ensure benefits realisation of automation and future proofing of regulations. 	<ul style="list-style-type: none"> Support the requirements set out in the Act regarding vending machines.
Licensing and Permits	<ul style="list-style-type: none"> Licensees possessing a poison licence or permit may require duplicate registration by a regulatory authority other than the Department. Inconsistent with national requirements for: <ul style="list-style-type: none"> Schedule 6 Wholesale licences Pharmacy Licence No facility to provide an appropriate licence or permit for: <ul style="list-style-type: none"> Indent trading Use of Schedule 9s Need to establish new schedule of fees The Act requires Licences and Permits to be provided with expiry/renewal dates based on the date of application rather than the same day each year. 	<ul style="list-style-type: none"> Licensees possessing a recognised licence or permit by a regulatory authority other than the Department would not require an additional licence: <ul style="list-style-type: none"> Removal of Schedule 7 permit requirements for recognised industrial uses at clearly identifiable industrial locations; Removal of: <ul style="list-style-type: none"> Schedule 6 Wholesale licences; Pharmacy Licence; and Introduction of: <ul style="list-style-type: none"> Indent licensing; Permits for Schedule 9s; and Establishment of a schedule of fees; and Licences and Permits to be provided with expiry/renewal dates based on application dates.
Shipping and Vessels	<ul style="list-style-type: none"> The current regulations refer to out dated legislation and are difficult for users to understand and apply. 	<ul style="list-style-type: none"> Update the existing regulations to reflect current maritime legislation. Outline pharmacists and wholesaler recording requirements.

Table 11: Schedules as outlined in the SUSMP and proposed areas of change in Regulations

Schedule #	Classification	Controls: Key: Tick if changes are recommended, X indicates no change.								Summary of proposed changes
		Licensing	Advertising	Labelling & Packaging	Prescribing	Supply	Storage	Recording	Disposal & Transport	
Schedule 1	Not currently in use	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Schedule 2	Pharmacy Medicine	X	X	X	N/A	X	X	X	X	No changes proposed
Schedule 3	Pharmacist Only Medicine	X	X	√	N/A	X	X	√	X	Pharmacy recording requirements Labelling changes
Schedule 4	Prescription Only Medicine OR Prescription Animal Remedy	X	X	X	√	X	X	√	X	SPAs Specialist authority prescription restrictions Schedule 4 Reportable e.g. Specified drugs such as benzodiazepines.
Schedule 5	Caution	N/A	X	X	N/A	X	√	X	X	Adoption of national controls regarding Storage
Schedule 6	Poison	√	X	X	N/A	X	√	X	X	Adoption of national controls regarding Storage Removal of wholesale licensing requirements
Schedule 7	Dangerous Poison	√	X	X	N/A	X	X	√	X	Licence changes Duration of record keeping

Schedule #	Classification	Licensing	Advertising	Labelling & Packaging	Prescribing	Supply	Storage	Recording	Disposal & Transport	Summary of proposed changes
Schedule 8	Controlled Drug	X	X	X	√	√	√	√	√	Revised Schedule 8 prescribing authorities Revised professional authorities Detoxification clinics Real time electronic recording Changes to oversupplied and drug dependent persons Safes Destruction
Schedule 9	Prohibited Substance	√	X	N/A	X	N/A	√	√	√	Supply and access changes - permits.
Schedule 10	Strictly Controlled Substances	√	X	N/A	N/A	√	√	√	√	Regulations proposed as new to Schedule.

2.18 Implementation and Transition

The recommendations of this CRIS will be implemented via multiple strategies including:

- development of regulatory guides and teaching materials;
- education sessions via peak bodies and stakeholder forums;
- updating and renewing guidance materials available online;
- letters to people affected by regulations;
- development of Departmental policies and information circulars;
- development of published Codes where required by Regulation; and
- issue of Notices where required under the Act.

Where ever possible provision of previous regulatory rules will main in effect. Where authority is time limited, *e.g. licences*, these will apply for the previously approved time period. Specific transition provisions are outlined in the 2014 Act and will be in alignment with the transition provisions written into the new Regulations.

For example:

- *A Licence which has been issued for 3 years will not expire till the 3 years is complete, at that time the licensee will be provided with an option to renew or transition to the most appropriate licence type; or*
- *A health practitioner who has had any authority revoked to prescribe or access medications will also have no authority under the power of the new Regulations.*

To enable continuity of patient care, Regulations may provide that any existing authorisation apply till the completion of the expiration date given under prior Regulations. Any authorisation written or prescription for a patient remains valid till the natural duration of the existing prescription.

For example:

- *An approved medication order will be honoured;*
- *A CPOP authority will remain valid under the new Regulations; and*
- *A prescription written under the old Regulations will still remain valid.*

Any authority or approval issued under the power of previous Regulations will be subject to new Regulations on renewal. Where there are modifications to existing Regulations a transition plan will be adopted.

For example:

- *Any exemption will remain in effect until such time as the business changes hands, e.g. approval of a small safe at a veterinary practice.*

Exemption for labelling a medicine this would be allowed to continue under the new legislation.

For example:

- *Poisons supplied need to comply with SUSMP packaging which includes adherence to standards to poisons bottles, there are instances where exemptions have been granted to manufacturers who are using safety features which have been deemed as being equivalent. It would be expensive for the manufacturer and unnecessary, if there are no public health issues, to enforce a change to this and therefore, these exemptions should continue.*

The Department will endeavour to inform all identified stakeholders regarding implementation of the new Regulations.

Consultation question, Implementation?

Is there a particular method or preferred manner of implementation, which you would like to see completed?

2.19 Review and Evaluation

The Department is aware that this legislation complements many other pieces of state and federal legislation. It is likely that some ongoing amendment will be required to ensure alignment with complimentary legislation. Any amendments will follow the standard regulatory gatekeeping process.

In addition it is proposed that the Department complete a formal review of the Regulations after 5 years. This review will be required, among other reasons, to assess the impact of the Regulations on industry and to consider whether further regulation is required to ensure public health and safety.

Part 3: Consultation

A comprehensive stakeholder assessment process is already underway and has been guided by the following: Public health consultation: A guide for developers³⁹. The aim of this consultation process is to facilitate appropriate stakeholder engagement to encourage contribution to discussions and influence of decisions and actions, which affect that. Stakeholders have had an opportunity to influence decisions and actions via a range of methodology. The consultation process generated from this document will be used to collect more detailed views about the proposed changes and inform the identification of the preferred changes.

Consultation to date has occurred in three phases:

- Phase 1 – Online survey;
- Phase 2 – Stakeholder interviews and forums; and
- Phase 3 – Consultation paper.

Phases 1 and 2 are complete. The Poisons Regulations Discussion Paper was developed to consider options in regulatory modification and was publicly circulated for comment. The discussion paper was sent out with survey the results collated and anyone was allowed to ask for an individual interview. Targeted stakeholder interviews have also been conducted as outlined in section 1. Group forums were held on particular topics of regulatory failure including, Schedule 8 opiate forum, rural and remote health, public health, veterinary medicine and stimulant control.

This consultation paper has incorporated feedback from phases 1 and 2 and presented options for the new regulatory framework. Preferred options, costs and benefits will be further refined and identified for Government approval and legislative drafting based on this consultation paper.

This consultation RIS considers options to improve consistency of the medicines and poisons regulations to support the Medications and Poisons Act. Software purchased to support public health consultation processes will be utilised to collate stakeholder feedback. Consultation via will be facilitated online on <https://consultation.health.wa.gov.au/>.

Feedback from stakeholders is sought on options for reform in each of the areas of regulation. Preferred options, costs and benefits will be further refined and identified for Government approval and legislative drafting based on this consultation paper. Feedback will be compiled by the Pharmaceutical Service Branch. The completed Decision Regulation Impact Statement, Medicine and Poisons Regulations 2015, will be completed by October 2015. Once approved this document will be put on website, emailed to stakeholders and distributed via public health network.

³⁹ WA Department of Health. Public health consultation: A guide for developers. 2006.
http://www.public.health.wa.gov.au/cproot/1503/2/Public_Health_Consultation_Guide.pdf

Appendices

Appendix 1: Stakeholders

Appendix 2: Discussion Paper: Poisons Regulations 1965

Appendix 3: Discussion Paper: Schedule 8 Opioid Regulations

Appendix 4: Discussion Paper: Poisons Schedules