Consultation Draft

8 December 2015

Proposed draft regulations to replace the Drugs, Poisons and Controlled Substances Regulations 2006

NOTE – This is not a legal document. It is provided for the purposes of consultation only. The wording used in this document and the proposed changes for the proposed Drugs, Poisons and Controlled Substances Regulations 2016 are not final. They may be subject to change following the preparation of the regulatory impact statement, responses as a result of consultation and the legal drafting process.

Introduction

The *Subordinate Legislation Act 1994* revokes statutory rules, such as regulations, ten years after the day on which they are made. The Drugs, Poisons and Controlled Substances Regulations 2006 (2006 Regulations) are due to be revoked on 25 May 2016.

This document indicates how the proposed draft Drugs, Poisons and Controlled Substances Regulations 2016 (proposed draft regulations) may differ from the 2006 Regulations. Proposed changes are based on the Department of Health and Human Services' experience in administering the 2006 Regulations and initial stakeholder feedback.

Proposed changes are discussed in the appropriate Commentary and identified in *red italicised* text.

You are invited to provide comment on any aspect of the proposed draft regulations.

The consultation process

For the purpose of consultation with stakeholders the proposed process is as follows:

- the Consultation Draft will be released to a broad range of stakeholders for comment;
- comments will be assessed and used in the preparation of the regulatory impact statement and the new regulations.
- Once the regulatory impact statement is assessed as adequate by the Commissioner for Better Regulation, together with the settled regulations, will be advertised in the press and released for the mandatory 28 day public comment period;
- any further comments will be assessed; and
- once all the formal processes are complete, the new regulations will be made.

NOTE - Other public consultation relating to drugs, poisons and controlled substances may be occurring at or around the same time but separate to the consultation on the review of the 2006 Regulations. This may include consultation on real-time prescription monitoring and medicinal cannabis.

This document is based on Version No. 016 of the 2006 Regulations, dated 29 September 2015.

Drugs, Poisons and Controlled Substances Act

The *Drugs, Poisons and Controlled Substances Act 1981* (the Act) provides a framework for the protection of the public from harm that could follow from the misuse or abuse of drugs, poisons and controlled substances that fall under the control of the Act.

It regulates the availability of drugs, poisons and controlled substances by:

- Adopting by reference the national standard for listing medicines and poisons into schedules, known as the Poisons Standard (or the Standard for the Uniform Scheduling of Medicines and Poisons) a Commonwealth legislative instrument.
- Regulating access to drugs, poisons and controlled substances in accordance with their listing within the Poisons Standard that reflects the risk to the public.
- Establishing a framework of authorising, licensing and permitting access to drugs, poisons and controlled substances according to health profession or activity, for example:
    - Authorising medical practitioners, pharmacists, dentists, veterinary practitioners, nurse practitioners, optometrists, podiatrists, midwives and nurses to possess, use and supply;
    - Licensing persons to manufacture and supply or supply;
    - Permitting persons to possess for use for particular purposes, for example industrial, educational, research purposes or for the provision of health services; and
    - Creating offence provisions relating to possession, sale or supply without authorisation.

The regulation-making process

The regulations will be made in accordance with the Department of Treasury and Finance *Victorian Guide to Regulation 2014* (the guide). The purpose of the guide in general is to ensure that regulations are developed that impose the lowest possible burden on Victorian business, not-for-profit and government sector organisations and the community as a whole.

The guide includes the process for preparing a regulatory impact statement. The purpose of the process is to ensure that regulation is only implemented when there is a justified need, only the most efficient forms of regulation are adopted and there is an adequate level of public consultation in the development of regulatory measures. The Commissioner for Better Regulation provides advice on the adequacy of the consultation and analysis included in the regulatory impact statement.

Characteristics identified in the guide that assist in the development of good regulation include that regulation should be focussed on the problem and achieve its intended objectives with minimal side effects; be open to innovation and market efficiency; introduce compliance and penalties proportional to the problem; not unnecessarily constrain future developments; be transparent to stakeholders; be consistent with other laws affecting the regulated parties including interstate laws where appropriate and provide a stable and predictable regulatory environment.

New regulations should be outcome based and reduce regulatory burden where possible.

New regulations can only cover matters that are consistent with the purpose of the Act and permitted under its regulation-making powers.

Any proposed offences or new penalty provisions in the new regulations are required to be reviewed in consultation with the Department of Justice and Regulation.

Proposed draft regulations

In order for the proposed draft regulations to be within scope and consistent with good regulation, not all stakeholder suggestions received to date are included in this document. The principle reasons are:

- The matter is an issue for consideration under the Act.
- The matter is not permitted by the provisions of the Act.
- Provisions already exist within the Act and regulations to accommodate the request.
- The requirements go beyond the provisions in the regulations.
- The matter would be better assisted by guidance documents developed by the department after the proposed regulations are made.

Other initiatives being considered by the Department of Health and Human Services are insufficiently developed to be included in these proposed draft regulations. These initiatives include new or expanded authorisations for certain health practitioners such as physiotherapists and paramedics, incorporation of real-time prescription monitoring and regulation of medicinal cannabis.

The objectives, structure and intent of the proposed draft regulations do not differ substantially from the 2006 Regulations. There may be some streamlining of references to the ever-expanding list of authorised health professionals who can prescribe, clarification of more complex regulations and other corrections as needed.

Consistent with the 2006 Regulations, the intent of the proposed draft regulations is to define the limits of professional practice but not to encroach on what is the appropriate clinical practice. Regulating professional practice is the responsibility of professional registration boards.

Where practical, amendments are consistent with controls in the majority of States and Territories. While national uniformity is a worthwhile aim, it requires a national approach and it is beyond the scope of this review process to compare and contrast the regulations in all of the States and Territories and the terminology used.

Comments on the proposed draft regulations should be emailed (for preference) or sent to:

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Drugs, Poisons and Controlled Substances Regulation Review
Drugs and Poisons Regulation
Department of Health & Human Services
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Comments should be received by **31 January 2016**

PART 1—PRELIMINARY

1 Objectives

Commentary

No changes are proposed.

Objective (b) The Department of Health and Human Services will set out a new fee structure in the regulatory impact statement based on inputs and current costs.

The objectives of these Regulations are to—

(a) facilitate and enhance the orderly sale, supply, prescribing, administration and use of drugs, poisons and controlled substances by health professionals, authorised persons, licensed or permitted persons and the general public; and

(b) prescribe fees relating to the provision of licences and permits issued under the **Drugs, Poisons and Controlled Substances Act 1981**; and

(c) prescribe forms and other matters necessary to be prescribed for the purposes of the **Drugs, Poisons and Controlled Substances Act 1981**.

4 Definitions

Commentary

A definition of 'authorised prescriber' is added, with a view to streamline references to health practitioners who are authorised to prescribe, currently listed individually within the regulations and to accommodate future additions. At this time, the existing definitions of individual health practitioners are not removed from the regulations.

Regulation 5 is amended as an example of how the streamlining could occur. The other regulations where streamlining could occur are not amended in this document. We will appreciate comment on whether the grouped or individual health practitioner regulations are preferred.

As a consequence of the new definition of 'authorised prescriber', a definition of 'registered health practitioner' is inserted.

A definition of 'care' is included to make it clear that care includes care provided by a person who is engaged or employed for that purpose.

A definition of 'form' of stock food is included to provide clarity.

The definition of 'high level of residential care' is removed as this definition is no longer referable in the *Aged Care Act 1997* of the Commonwealth.

The definition of National Health (Residential Medication Chart) Determination 2012 is removed as the determination was repealed in 2015 and was replaced by an amendment to the Commonwealth National Health (Pharmaceutical Benefits) Regulations 1960.

A consequential amendment is made to the definition of residential medication chart, which is also broadened to relate to an authorised prescriber.

A definition of 'prescription' is included to avoid confusion between a prescription, which is a written instruction from a prescriber to a pharmacist to supply a medication to a patient and an order, which is a broader term that includes a request from an authorised person to a supplier to supply back to that authorised person.

A definition of 'type' of stock food included to provide clarity.

In these Regulations—

aged care service has the same meaning as it has in the *Aged Care Act 1997* of the Commonwealth;

animal includes any bird, fish or insect;

approved means approved in writing by the Secretary;

approved provider has the same meaning as it has in the *Aged Care Act 1997* of the Commonwealth;

Australian Orthoptic Board means a committee constituted of the directors of the Australian Orthoptists Registration Body Pty Ltd;

authorised optometrist means a registered optometrist whose registration is endorsed under section 94 of the Health Practitioner Regulation National Law;

authorised podiatrist means a registered podiatrist whose registration is endorsed under section 94 of the Health Practitioner Regulation National Law;

authorised prescriber *means a registered health practitioner authorised under section 13(1) of the Drugs Poisons and Controlled Substances Act 1981, who is authorised to prescribe within the lawful practice of the registered health practitioner's profession and where applicable, authorisation is noted on the registered health practitioner's endorsement of registration.*

authorised registered midwife means a registered midwife whose registration is endorsed under section 94 of the Health Practitioner Regulation National Law;

authorised registered nurse means a registered nurse (Division 1) whose registration is endorsed under section 94 of the Health Practitioner Regulation National Law;

care *includes but is not limited to, care given by a person who provides care in the course of their employment, under a contract of service or a contract for the provision of services;*

enrolled nurse means a person registered under the Health Practitioner Regulation National Law—

(a) to practise in the nursing and midwifery profession as a nurse (other than as a student); and

(b) in the enrolled nurses division of the Register of Nurses;

form (of stock food) includes pellets, mash;

listed regulated poison means a Schedule 7 poison that is included in Part 2 of Chapter 1 of the Poisons Code in the list of substances that are not for general sale by retail;

* * * * *

National Health (Continued Dispensing) Determination 2012 means the legislative instrument made under section 89A(3) of the *National Health Act 1953* of the Commonwealth as formulated or published from time to time;

nurse means—

(a) a registered nurse;

(b) an enrolled nurse other than an enrolled nurse who has a notation on his or her registration indicating that he or she is not qualified to administer medication;

orthoptist means a person who is registered as an orthoptist with the Australian Orthoptic Board; *ovulatory stimulant* means a substance listed as an ovulatory stimulant in Part 2 of Chapter 1 of the Poisons Code;

palliative care service means a service which provides medical and nursing care to persons who are terminally ill;

pharmacy has the same meaning as it has in the *Pharmacy Regulation Act 2010*;

pharmacy business has the same meaning as it has in the *Pharmacy Regulation Act 2010*;

pharmacy department has the same meaning as it has in the *Pharmacy Regulation Act 2010*;

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prescription means a written instruction issued by an authorised prescriber to authorise a pharmacist in a pharmacy to supply the specified substances for the treatment of the person or animal named on the document.

prostaglandin means a substance listed as a prostaglandin in Part 2 of Chapter 1 of the Poisons Code;

registered dental hygienist means a person registered under the Health Practitioner Regulation National Law—

(a) to practise in the dental profession as a dental hygienist (other than as a student); and

(b) in the dental hygienists division of the Register of Dental Practitioners;

registered health practitioner means a registered medical practitioner, veterinary practitioner, dentist, nurse practitioner, authorised registered optometrist, authorised registered podiatrist and authorised registered midwife

registered dental therapist means a person registered under the Health Practitioner Regulation National Law—

(a) to practise in the dental profession as a dental therapist (other than as a student); and

(b) in the dental therapists division of the Register of Dental Practitioners;

registered oral health therapist means a person registered under the Health Practitioner Regulation National Law—

(a) to practice in the dental profession as an oral health therapist (other than as a student); and

(b) in the oral health therapists division of the Register of Dental Practitioners;

resident means a person who receives residential care in a residential facility;

residential care service has the meaning given by Schedule 1 to the *Aged Care Act 1997* of the Commonwealth;

residential medication chart means a written instruction, other than a prescription, given by an authorised prescriber to a pharmacist to supply a Schedule 4 poison to the resident named on the residential medication chart, in accordance with the National Health (Pharmaceutical Benefits) Regulations 1960;

retinoid means a substance listed as a retinoid in Part 2 of Chapter 1 of the Poisons Code;

special Schedule 7 substance means a substance listed as a special Schedule 7 substance in Part 2 of Chapter 1 of the Poisons Code;

storage facility includes a cabinet, receptacle, cupboard, refrigerator or room;

thalidomide means—

(a) thalidomide for human use; or

(b) a substance listed as a thalidomide-like substance in Part 2 of Chapter 1 of the Poisons Code;

the Act means the *Drugs, Poisons and Controlled Substances Act 1981*;

type (of stock food) includes broiler starter, porker.

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PART 2—DRUGS OF DEPENDENCE, SCHEDULE 4 POISONS, SCHEDULE 8 POISONS AND SCHEDULE 9 POISONS

Commentary

A Note to explain drugs of dependence is to be inserted:

Note Drugs of dependence are substances included in Schedule 11 to the *Drugs, Poisons and Controlled Substances Act 1981*. Drugs of dependence are those substances subject to misuse and abuse. Some medicines are also drugs of dependence. Their regulatory requirements relate to whether the substance is in Schedule 3, Schedule 4, Schedule 8 or Schedule 9 of the Poisons Standard.

Note

Drugs of dependence are substances included in Schedule 11 to the Drugs, Poisons and Controlled Substances Act 1981. Drugs of dependence are those substances subject to misuse and abuse. Some medicines are also drugs of dependence. Their regulatory requirements relate to whether the substance is in Schedule 3, Schedule 4, Schedule 8 or Schedule 9 of the Poisons Standard.

Division 1—Possession

Commentary

A NOTE to explain regulation 5 is to be inserted:

Note It is possible for a person to be authorised in accordance with multiple aspects of regulation 5 depending on the circumstances. For example a nurse may administer a Schedule 4 poison in accordance with regulation 47 and in other circumstances may act as a carer and assist a person with the administration of their own medication.

Regulation 5 now includes a reference to Schedule 2 poisons to accommodate new Item 22.

Regulations 5(1) TABLE PART 1 Items 2 and 3 are amended to include the reference to 'authorised prescriber'. As a consequence, Items 4, 5, 6 and 6A are deleted.

Regulation 5(1) Item 19 is amended to replace the *Health Act 1958* with the replacement *Public Health and Wellbeing Act 2008*.

Regulation 5(1) Item 21 is amended such that the Schedule 4 poisons available to orthoptists are approved by the Secretary instead of listed in the regulation, to facilitate any future changes and to be consistent with other approvals in regulation 5.

Regulation 5(1) Item 22 is added to authorise those persons required to have a liferaft with medical equipment under Victorian maritime law, to possess those medicines (seasickness pills) that are within Schedule 2. This will remove the need for those persons to hold a permit to purchase or otherwise obtain those medicines.

Regulation 5(1) Item 23 is added to authorise emergency response workers trained in Advanced First Aid to possess certain approved Schedule 4 poisons to provide pain relief to injured workers in inaccessible locations at mine sites, power stations and large industrial operations until the ambulance service arrives. How would the 'large industrial operations' be defined?

Regulation 5(2) is amended to include the reference to 'authorised prescriber'.

Regulation 5(3) is amended to enable a Secretary Approval where direct or indirect supervision may not be possible, for example for nurses or midwives providing Advanced Life Support in the event of cardiac arrest.

Note

It is possible for a person to be authorised in accordance with multiple aspects of regulation 5 depending on the circumstances. For example a nurse may administer a Schedule 4 poison in accordance with regulation 47 and in other circumstances may act as a carer and assist a person with the administration of their own medication.

5 Possession of Schedule 2 poisons, Schedule 4 poisons, Schedule 8 poisons and Schedule 9 poisons

(1) A person or class of persons shown in an item in Column 1 of the following table is authorised to have in his or her possession a Schedule 2 poison, Schedule 4 poison, Schedule 8 poison or Schedule 9 poison to the extent shown in Column 2.

TABLE

Column 1		Column 2
PART 1		
1.	A person who holds or who is the agent of a person who holds a licence, permit or warrant issued under the Act or these Regulations.	Those Schedule 4 poisons, Schedule 8 poisons or Schedule 9 poisons named on the licence, permit or warrant to the extent and for the purpose specified in the licence, permit or warrant.
2.	A person who is a carrier, a carrier's employee or a messenger.	For the purposes of delivery to the person to whom the consignment is addressed, those Schedule 4 poisons, Schedule 8 poisons or Schedule 9 poisons consigned by— (a) a person holding a licence or permit under the Act or these Regulations; or
Column 1		Column 2
		(b) an *authorised prescriber* or pharmacist.
3.	A person for whom a Schedule 4 poison, Schedule 8 poison, or Schedule 9 poison has been supplied by an *authorised prescriber* or pharmacist in accordance with the Act and these Regulations.	That Schedule 4 poison, Schedule 8 poison, or Schedule 9 poison to the extent and for the purpose for which it is supplied.
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7.	The agent or a person who has the care of, or who is assisting in the care of, a person referred to in item 3.	That Schedule 4 poison, Schedule 8 poison, or Schedule 9 poison to the extent and for the purpose for which it is supplied.
8.	An owner of, or a person having custody or care of, an animal for which a Schedule 4 poison or Schedule 8 poison has been	That Schedule 4 poison or Schedule 8 poison to the extent and for the purpose for which it is supplied.

	supplied by a veterinary practitioner or pharmacist in accordance with the Act and these Regulations.	
9.	An owner or person having custody or care of a flock or herd of animals for which a Schedule 4 poison has been supplied by wholesale in a stock food on the order of a veterinary practitioner for the treatment of that flock or herd of animals in accordance with the Act or these Regulations.	That Schedule 4 poison to the extent and for the purpose for which it is supplied.

Column 1		Column 2
PART 2		
10.	An operational staff member within the meaning of the *Ambulance Services Act 1986*.	Those Schedule 4 poisons or Schedule 8 poisons listed in the health services permit held by that ambulance service within the meaning of the *Ambulance Services Act 1986*.
11.	A member of St John Ambulance Australia (Vic.) recognised by that organisation as qualified to Advanced First Aid level.	Those Schedule 4 poisons listed in the health services permit held by St John Ambulance Australia (Vic.).
12.	A master or chief officer of a ship in port in Victoria.	Those Schedule 4 poisons or Schedule 8 poisons that are required by State, Commonwealth or international law to complete the equipment of that ship.
13.	A yacht owner or crew member who is a member of Yachting Australia and whose yacht is entered in a race conducted under the rules of Yachting Australia.	Those Schedule 4 poisons or Schedule 8 poisons contained in the Medical Kit for the Yachting Australia Race Category in which the yacht is entered.
14.	A registered optometrist carrying on the lawful practice of his or her profession.	Those Schedule 4 poisons approved by the Secretary that are required in the practice of his or her profession for use in the eyes of patients.
15.	A registered podiatrist carrying on the lawful practice of his or her profession.	Those Schedule 4 poisons approved by the Secretary that are required in the practice of his or her profession for the treatment of conditions of the human foot.
16.	A person who holds a permit to use etorphine in accordance with the Act and these Regulations or a person assisting that permit holder.	Those morphine antagonists that are necessary for administration as an antidote to etorphine.

17.	An Australian Ski Patrol Association Inc. qualified ski patroller.	Those Schedule 4 poisons approved by the Secretary that are required in the performance of a ski patroller's duties for the treatment of emergencies.
18.	A Director of State Emergency Services.	Those Schedule 4 poisons or Schedule 8 poisons that are required in the performance of his or her duties in an emergency coming within his or her jurisdiction.
19.	A municipal council, an environmental health officer or a nurse or midwife employed or appointed by a municipal council.	Those Schedule 4 poisons that are necessary for immunisation programs coordinated by a municipal council in accordance with its functions under the *Public Health and Wellbeing Act 2008*.
20	A registered dental hygienist, registered dental therapist or registered oral health therapist.	Those Schedule 4 poisons approved by the Secretary that are required for the provision of dental care by the registered dental hygienist, registered dental therapist or registered oral health therapist.
21.	An orthoptist practising under the direction of a registered medical practitioner or an authorised optometrist.	Those Schedule 4 poisons *approved by the Secretary* in topical ophthalmic preparations for the use in the eyes of patients.
22.	*A captain operating a boat required to have a liferaft in Victoria.*	*Those Schedule 2 poisons that are required by State law to complete the medical equipment of that liferaft.*
23.	*Emergency response workers trained in Advanced First Aid at mine sites, power stations and large industrial operations.*	*Those Schedule 4 poisons approved by the Secretary that are* required in the performance of an emergency response worker's duties for the treatment of emergencies.

(2) A nurse or registered midwife is authorised to possess those Schedule 4 poisons, Schedule 8 poisons or Schedule 9 poisons that are necessary for administration to a patient under the care of that nurse or registered midwife in accordance with—

(a) the instructions of and upon the authorisation for that patient by an *authorised prescriber*; or

(b) the conditions of a permit to purchase or obtain and use a poison or controlled substance for the provision of health services; or

(c) the approval of the Secretary under subregulation (3).

(3) Subject to subregulation (4), the Secretary may approve the possession of a Schedule 4 poison, Schedule 8 poison or Schedule 9 poison by a nurse, class of nurses, registered midwife or class of registered midwife without the *supervision* of *an authorised prescriber*.

(4) The Secretary must not grant an approval referred to in subregulation (3) unless the Secretary considers that the approval—

(a) is necessary for the provision of health services; and

(b) is within the competence of a nurse or registered midwife without the *supervision* of *an authorised prescriber* (as the case requires).

6 Approval of Schedule 4 poisons and Schedule 8 poisons

The Secretary may approve Schedule 4 poisons or Schedule 8 poisons or classes of Schedule 4 poisons or Schedule 8 poisons for possession and use by a person or class of persons specified in an item in Column 1 of Part 2 of the table in regulation 5 to the extent specified in column 2 of the item applicable to that person or class of person.

7 Permit required for Schedule 9 poisons

A registered medical practitioner, pharmacist, veterinary practitioner or dentist must not manufacture, sell, supply, purchase or otherwise obtain, possess, administer, use or prescribe a Schedule 9 poison unless he or she holds a permit issued under the Act or these Regulations to do so.

100 penalty units.

Division 2—Treatment

Commentary

Regulations 8 to 13 are examples of regulations that put limits on professional practice. It is not the role of the regulations to determine what constitutes professional practice.

Regulation 15(1) is amended to enable an authorised prescriber to provide the instruction to supply a Schedule 4 poison on a residential medication chart.

Regulation 15(4) is added to allow for a pharmacist at a pharmacy department to make a limited supply of discharge medication to an inpatient on the basis of an inpatient medication chart. We have suggested a 7 day limit. Is this amendment needed? If so, should there be a limit on treatment days? If so, what should it be?

Regulation 17 is removed as registration under the *Veterinary Practice Act 1997* (s 3A) deems interstate registered veterinary practitioners as registered for the purposes of that Act.

Regulations 21, 21A, 21B and 22 are not amended here. However, we are considering an amendment such that substances could be approved and gazetted, rather than being listed in the body of the regulations. This change would remove the need to amend the regulations each time a new medicine is added and enable controls on new of existing medicines to be introduced more quickly if needed. Would this approach be preferred or not?

8 Patient identity and therapeutic need to be determined—registered medical practitioners

(1) A registered medical practitioner must not administer, prescribe, sell or supply a drug of dependence or Schedule 8 poison unless—

(a) that drug or poison is for the medical treatment of a person under his or her care; and

(b) he or she has taken all reasonable steps to ascertain the identity of that person; and

(c) he or she has taken all reasonable steps to ensure a therapeutic need exists for that drug or poison.

100 penalty units.

(2) A registered medical practitioner must not administer, prescribe, sell or supply a Schedule 4 poison unless—

(a) that poison is for the medical treatment of a person under his or her care; and

(b) he or she has taken all reasonable steps to ensure a therapeutic need exists for that poison.

100 penalty units.

9 Patient identity and therapeutic need to be determined—nurse practitioners

(1) A nurse practitioner must not administer, prescribe, sell or supply a Schedule 8 poison unless—

(a) that poison is for the treatment of a person under his or her care; and

(b) he or she has taken all reasonable steps to ascertain the identity of that person; and

(c) he or she has taken all reasonable steps to ensure a therapeutic need exists for that poison.

100 penalty units.

(1A) Nothing in subregulation (1) prohibits a nurse practitioner from administering a Schedule 8 poison in accordance with regulation 47(2).

Note

Regulation 47(2) describes circumstances in which a nurse may administer a Schedule 8 poison. For example, regulation 47(2)(b) allows a nurse to administer a Schedule 8 poison on the written instruction of a registered medical practitioner.

(2) A nurse practitioner must not administer, prescribe, sell or supply a Schedule 4 poison unless—

(a) that poison is for the treatment of a person under his or her care; and

(b) he or she has taken all reasonable steps to ensure a therapeutic need exists for that poison.

100 penalty units.

(3) Nothing in subregulation (2) prohibits a nurse practitioner from administering a Schedule 4 poison in accordance with regulation 47(3).

Note

Regulation 47(3) describes circumstances in which a nurse may administer a Schedule 4 poison. For example, regulation 47(3)(b) allows a nurse to administer a Schedule 4 poison on the written instruction of a registered medical practitioner.

9A Patient identity and therapeutic need to be determined—authorised registered nurse

(1) An authorised registered nurse must not administer or supply a Schedule 8 poison unless—

(a) that poison is for the treatment of a person under his or her care; and

(b) he or she has taken all reasonable steps to ascertain the identity of that person; and

(c) he or she has taken all reasonable steps to ensure a therapeutic need exists for that poison.

100 penalty units.

(1A) Nothing in subregulation (1) prohibits an authorised registered nurse from administering a Schedule 8 poison in accordance with regulation 47(2).

Note

Regulation 47(2) describes circumstances in which a nurse may administer a Schedule 8 poison. For example, regulation 47(2)(b) allows a nurse to administer a Schedule 8 poison on the written instruction of a registered medical practitioner.

(2) An authorised registered nurse must not administer or supply a Schedule 4 poison unless—

(a) that poison is for the treatment of a person under his or her care; and

(b) he or she has taken all reasonable steps to ensure a therapeutic need exists for that poison.

100 penalty units.

(3) Nothing in subregulation (2) prohibits an authorised registered nurse from administering a Schedule 4 poison in accordance with regulation 47(3).

Note

Regulation 47(3) describes circumstances in which a nurse may administer a Schedule 4 poison. For example, regulation 47(3)(b) allows a nurse to administer a Schedule 4 poison on the written instruction of a registered medical practitioner.

9B Patient identity and therapeutic need to be determined—authorised registered midwife

(1) An authorised registered midwife must not administer, prescribe, sell or supply a Schedule 8 poison unless—

(a) that poison is for the midwifery treatment of a person under his or her care; and

(b) he or she has taken all reasonable steps to ascertain the identity of that person; and

(c) he or she has taken all reasonable steps to ensure a therapeutic need exists for that poison.

Penalty: 100 penalty units.

(2) Nothing in subregulation (1) prohibits an authorised registered midwife from administering a Schedule 8 poison in accordance with regulation 47(2).

Note

Regulation 47(2) describes circumstances in which a registered midwife may administer a Schedule 8 poison. For example, regulation 47(2)(b) allows a registered midwife to administer a Schedule 8 poison on the written instruction of a registered medical practitioner.

(3) An authorised registered midwife must not administer, prescribe, sell or supply a Schedule 4 poison unless—

(a) that poison is for the midwifery treatment of a person under his or her care; and

(b) he or she has taken all reasonable steps to ensure a therapeutic need exists for that poison.

Penalty: 100 penalty units.

(4) Nothing in subregulation (3) prohibits an authorised registered midwife from administering a Schedule 4 poison in accordance with regulation 47(3).

Note

Regulation 47(3) describes circumstances in which a registered midwife may administer a Schedule 4 poison. For example, regulation 47(3)(b) allows a registered midwife to administer a Schedule 4 poison on the written instruction of a registered medical practitioner.

10 Patient identity and therapeutic need to be determined—dentists

(1) A dentist must not administer, prescribe, sell or supply a drug of dependence or Schedule 8 poison unless—

(a) that drug or poison is for the dental treatment of a person under his or her care; and

(b) he or she has taken all reasonable steps to ascertain the identity of that person; and

(c) he or she has taken all reasonable steps to ensure a therapeutic need exists for that drug or poison.

100 penalty units.

(2) A dentist must not administer, prescribe, sell or supply a Schedule 4 poison unless—

(a) that poison is for the dental treatment of a person under his or her care; and

(b) he or she has taken all reasonable steps to ensure a therapeutic need exists for that poison.

100 penalty units.

11 Therapeutic need to be determined—authorised optometrists

An authorised optometrist must not administer, prescribe, sell or supply a Schedule 4 poison unless—

(a) that poison is for the ocular treatment of a person under his or her care; and

(b) the optometrist has taken all reasonable steps to ensure a therapeutic need exists for that poison.

100 penalty units.

11A Therapeutic need to be determined—authorised podiatrists

An authorised podiatrist must not administer, prescribe, sell or supply a Schedule 4 poison unless—

(a) that poison is for the podiatric treatment of a person under his or her care; and

(b) the podiatrist has taken all reasonable steps to ensure a therapeutic need exists for that poison.

100 penalty units.

12 Patient identity and therapeutic need to be determined for drugs of dependence—pharmacists

(1) A pharmacist who supplies a drug of dependence to or for a person other than by wholesale or on the prescription of a registered medical practitioner, dentist, nurse practitioner or an authorised registered midwife or on a residential medication chart completed by a registered medical practitioner for a drug of dependence must—

(a) take all reasonable steps to ascertain the identity of the person to or for whom it is proposed to supply the drug of dependence; and

(b) do so only for the therapeutic use of the person after having taken all reasonable steps to ensure a therapeutic need for the drug of dependence exists.

100 penalty units.

(2) A pharmacist who supplies a drug of dependence to a person for an animal other than by wholesale or on the prescription of a veterinary practitioner must do so only for the therapeutic use of the animal after having taken all reasonable steps to ensure a therapeutic need for the drug of dependence exists.

100 penalty units.

13 Therapeutic need to be determined—veterinary practitioners

A veterinary practitioner must not administer, prescribe, sell or supply a drug of dependence, Schedule 8 poison or Schedule 4 poison unless—

(a) that drug or poison is for the treatment of an animal under his or her care; and

(b) he or she has taken all reasonable steps to ensure a therapeutic need exists for that drug or poison.

100 penalty units.

14 Notification of fraudulent obtaining of drugs or poisons

(1) A registered medical practitioner, pharmacist, veterinary practitioner or dentist who suspects or has reason to believe that a person has obtained from him or her by means of a false pretence—

(a) a drug of dependence, Schedule 9 poison, Schedule 8 poison or Schedule 4 poison; or

(b) an order or prescription for a drug of dependence, Schedule 9 poison, Schedule 8 poison or Schedule 4 poison—

must immediately inform the Secretary and a member of the Victoria Police of that suspicion or belief.

50 penalty units.

(2) A nurse practitioner or an authorised registered midwife who suspects or has reason to believe that a person has obtained from him or her by means of a false pretence—

(a) a Schedule 8 poison or Schedule 4 poison; or

(b) an order or prescription for a Schedule 8 poison or Schedule 4 poison—

must immediately inform the Secretary and a member of the Victoria Police of that suspicion or belief.

50 penalty units.

(3) An authorised optometrist who suspects or has reason to believe that a person has obtained from him or her by means of a false pretence, a Schedule 4 poison or an order or prescription for a Schedule 4 poison, must immediately inform the Secretary and a member of the Victoria Police of that suspicion or belief.

50 penalty units.

(4) An authorised podiatrist who suspects or has reason to believe that a person has obtained from him or her by means of a false pretence, a Schedule 4 poison or an order or prescription for a Schedule 4 poison, must immediately inform the Secretary and a member of the Victoria Police of that suspicion or belief.

50 penalty units.

(5) An authorised registered nurse who suspects or has reason to believe that a person has obtained from him or her by means of a false pretence a Schedule 8 poison or Schedule 4 poison must immediately inform the Secretary and a member of the Victoria Police of that suspicion or belief.

50 penalty units.

15 Pharmacist administration, sale or supply authorised from within Victoria

(1) A pharmacist must not administer, sell or supply a Schedule 4 poison or Schedule 8 poison except—

(a) in accordance with section 13(3) of the Act; or

(b) subject to regulation 16, on the original prescription of—

(i) in the case of a Schedule 8 poison, a registered medical practitioner, veterinary practitioner, dentist, nurse practitioner or an authorised registered midwife;

(ii) in the case of a Schedule 4 poison, a registered medical practitioner, veterinary practitioner, dentist, nurse practitioner or an authorised registered midwife;

(iii) in the case of a Schedule 4 poison specified in his or her endorsement of registration, an authorised optometrist or an authorised podiatrist; or

(c) in accordance with regulation 27; or

(d) in the case of a Schedule 8 poison, on the order of a registered medical practitioner, veterinary practitioner, dentist, nurse practitioner or an authorised registered midwife; or

(e) in the case of a Schedule 4 poison, on the order of—

(i) a registered medical practitioner, veterinary practitioner, dentist, nurse practitioner or an authorised registered midwife; or

(ii) an authorised optometrist or an authorised podiatrist, in accordance with his or her endorsement of registration; or

(ea) in the case of a Schedule 4 poison for a resident, on a residential medication chart completed by an authorised prescriber which—

(i) is signed by the authorised prescriber; and

(ii) includes a copy of the page of the residential medication chart identifying the resident and the authorised prescriber, the name of the pharmacy and the complete contact details of the pharmacy;

or

(f) on the order of a person holding a permit for that Schedule 4 poison or Schedule 8 poison; or

(g) to a person referred to in Column 1 of Part 2 of the table in regulation 5 to the extent referred to in Column 2 of that Part of that Table.

100 penalty units.

(2) Despite subregulation (1), in an emergency, a pharmacist may, if he or she considers it necessary to ensure continuity of treatment, supply once only a Schedule 4 poison without the prescription of a registered medical practitioner, nurse practitioner or an authorised registered midwife if—

(a) the pharmacist is satisfied that—

(i) there is an immediate need for the Schedule 4 poison and it is impracticable for the patient to obtain a prescription in time to meet that need; and

(ii) treatment with that Schedule 4 poison has been previously prescribed for the patient by a registered medical practitioner, nurse practitioner or an authorised registered midwife; and

(iii) the patient, or the agent of the patient, or a person who has the care of, or is assisting in the care of, the patient, is aware of the appropriate dose of that Schedule 4 poison for that patient; and

(b) the quantity supplied does not exceed—

(i) 3 days' supply; or

(ii) if it is not practical to supply a quantity required for 3 days, the smallest commercially available pack.

(3) Despite subregulation (1), if a pharmacist considers it necessary to ensure continuity of treatment of a person, he or she may supply a Schedule 4 poison to a person without a prescription once within a 12 month period if the pharmacist is satisfied that—

(a) the Schedule 4 poison is listed in the National Health (Continued Dispensing) Determination 2012; and

(b) the conditions in Part 2 of the National Health (Continued Dispensing) Determination 2012 are met; and

(c) the Minister has approved the Schedule 4 poison as suitable for supply under regulation 15A.

(4) Despite subregulation (1), a pharmacist in a pharmacy department may supply a Schedule 4 poison to an inpatient at the health service where the pharmacy department is located if—

(a) the Schedule 4 poison is for discharge medication;

(b) the inpatient medication chart is signed by an authorised prescriber; and

(c) the supply provides not more than 7 days treatment.

15A Minister may approve supply without prescription

(1) For the purposes of regulation 15(3) the Minister may, by notice published in the Government Gazette, approve a Schedule 4 poison as suitable for supply.

(2) An approval notice under subregulation (1) takes effect—

(a) on the date of publication of the approval notice in the Government Gazette; or

(b) on a later date specified in the notice.

16 Supply on copy of prescription permitted in certain circumstances

(1) Subject to subregulation (2), a pharmacist may supply a Schedule 4 poison or a Schedule 8 poison on the copy of an original prescription if the original prescription is required to be submitted to a public authority by any Act of a State or Territory or the Commonwealth.

(2) A pharmacist must not supply a Schedule 4 poison or a Schedule 8 poison on the copy of an original prescription unless the copy of the original prescription is certified by or accompanied by a certification from—

(a) the pharmacist who received the original prescription but did not supply all of the items on that prescription; or

(b) a pharmacist who has previously supplied the Schedule 4 poison or Schedule 8 poison on that original prescription.

100 penalty units.

18 Form of notification of a drug-dependent person

For the purposes of section 33(5) of the Act, the prescribed form is the form of DP1 in Schedule 2.

19 Form of application for Schedule 9 permit or Schedule 8 permit

(1) For the purposes of section 33A(2) of the Act, the prescribed form of application for a Schedule 9 permit is the form of DP2 in Schedule 2.

(2) For the purposes of sections 34(4) of the Act, the prescribed form of application for a Schedule 8 permit is the form of DP2A in Schedule 2.

20 Form of Schedule 9 permit and Schedule 8 permit

(1) For the purposes of section 33B(2) of the Act, the prescribed form of a Schedule 9 permit is the form of DP3 in Schedule 2.

(2) For the purposes of section 34A(2) of the Act, the prescribed form of a Schedule 8 permit is the form of DP3 in Schedule 2.

21 Permit required in particular circumstances for supply of methadone

(1) For the purposes of preventing the improper use of methadone, a registered medical practitioner or nurse practitioner must not administer, supply or prescribe methadone in circumstances where the registered medical practitioner or nurse practitioner is not required to hold a Schedule 8 permit unless he or she—

(a) has a permit from the Secretary authorising that registered medical practitioner or nurse practitioner to administer, supply or prescribe methadone; or

(b) is authorised by section 34D, 34E or 34F of the Act to administer, supply or prescribe methadone.

100 penalty units.

(2) Despite subregulation (1), a registered medical practitioner or nurse practitioner is not required to have a permit under this regulation if—

(a) he or she is treating a patient at an oncology clinic or a pain clinic at a hospital; or

(b) he or she is treating a patient who is under the care of a palliative care service.

21A Permit required in particular circumstances for supply of nabiximols

For the purposes of preventing the improper use of nabiximols, a registered medical practitioner or nurse practitioner must not administer, supply or prescribe nabiximols in circumstances where the registered medical practitioner or nurse practitioner is not required to hold a Schedule 8 permit unless he or she—

(a) has a permit from the Secretary authorising that registered medical practitioner or nurse practitioner to administer, supply or prescribe nabiximols; or

(b) is authorised by section 34D, 34E or 34F of the Act to administer, supply or prescribe nabiximols.

Penalty: 100 penalty units.

21B Permit required in particular circumstances for supply of sodium oxybate

For the purposes of preventing the improper use of sodium oxybate, a registered medical practitioner or nurse practitioner must not administer, supply or prescribe sodium oxybate in circumstances where the registered medical practitioner or nurse practitioner is not required to hold a Schedule 8 permit unless the registered medical practitioner or nurse practitioner—

(a) has a permit from the Secretary authorising that registered medical practitioner or nurse practitioner to administer, supply or prescribe sodium oxybate; or

(b) is authorised by section 34D, 34E or 34F of the Act to administer, supply or prescribe sodium oxybate.

Penalty: 100 penalty units.

22 Permit required in particular circumstances for supply of amphetamine, dexamphetamine, lisdexamfetamine, methylamphetamine and methylphenidate

(1) For the purposes of preventing the improper use of amphetamine, dexamphetamine, lisdexamfetamine, methylamphetamine or methylphenidate, a registered medical practitioner or nurse practitioner must not administer, supply or prescribe any one or more of those substances in circumstances where the registered medical practitioner or nurse practitioner is not required to hold a Schedule 8 permit unless he or she—

(a) has a permit from the Secretary authorising that registered medical practitioner or nurse practitioner to administer, supply or prescribe one or more of those substances; or

(b) is authorised by section 34D, 34E or 34F of the Act to administer, supply or prescribe any one or more of those substances.

100 penalty units.

(2) Despite subregulation (1), a registered medical practitioner is not required to have a permit under this regulation if he or she is—

(a) a paediatrician who is treating a person for attention deficit disorder; or

(b) a psychiatrist who is treating a person for attention deficit disorder.

22A Applications for permits under regulations 21, 21A, 21B or 22

(1) The prescribed form of an application for a permit required under regulation 21 authorising the administration, supply or prescription of methadone is the form of DP2A in Schedule 2.

(2) The prescribed form of an application for a permit required under regulation 21A authorising the administration, supply or prescription of nabiximols is the form of DP2A in Schedule 2.

(2A) The prescribed form of an application for a permit required under regulation 21B authorising the administration, supply or prescription of sodium oxybate is the form of DP2A in Schedule 2.

(3) The prescribed form of an application for a permit required under regulation 22 authorising the administration, supply or prescription of amphetamine, dexamphetamine, lisdexamfetamine, methylamphetamine or methylphenidate is the form of DP2A in Schedule 2.

22B Secretary may issue a Schedule 8 permit

(1) On receiving an application for a permit under regulation 21, the Secretary may issue a Schedule 8 permit to a registered medical practitioner or nurse practitioner authorising the practitioner to administer, supply or prescribe methadone to or for a person who is not a drug dependent person.

(2) On receiving an application for a permit under regulation 21A, the Secretary may issue a Schedule 8 permit to a registered medical practitioner or nurse practitioner authorising the practitioner to administer, supply or prescribe nabiximols to or for a person who is not a drug-dependent person.

(2A) On receiving an application for a permit under regulation 21B, the Secretary may issue a Schedule 8 permit to a registered medical practitioner or nurse practitioner authorising the practitioner to administer, supply or prescribe sodium oxybate to or for a person who is not a drug-dependent person.

(3) On receiving an application for a permit under regulation 22, the Secretary may issue a Schedule 8 permit to a registered medical practitioner or a nurse practitioner authorising the practitioner to administer, supply or prescribe amphetamine, dexamphetamine, lisdexamfetamine, methylamphetamine or methylphenidate to or for a person who is not a drug-dependent person.

(4) A Schedule 8 permit issued under subregulation (1), (2), (2A) or (3) must be in the form of DP3 in Schedule 2.

(5) The Secretary may at any time amend, suspend or revoke a Schedule 8 permit issued under subregulation (1), (2), (2A) or (3) and any permit which is suspended or revoked ceases to have effect.

23 Dentists not able to obtain permit for specialised supply

A dentist must not possess, administer, supply or prescribe methadone.

100 penalty units.

24 Disclosure of drug use within previous 8 weeks required

(1) A person who in the previous 8 weeks has been treated with a drug of dependence must not, without disclosing that fact at the time, procure or attempt to procure from a registered medical practitioner, veterinary practitioner, dentist, nurse practitioner, an authorised registered nurse or an authorised registered midwife—

(a) the same or a similar drug of dependence; or

(b) a drug of dependence for the same or a similar purpose.

100 penalty units.

(2) A person who in the previous 8 weeks has been treated with a drug of dependence must not, without disclosing that fact at the time, procure or attempt to procure from a pharmacist, other than on a prescription or order of a person authorised in relation to that drug of dependence under section 13(1) of the Act—

(a) the same or a similar drug of dependence; or

(b) a drug of dependence for the same or a similar purpose.

100 penalty units.

Division 3—Supply

Commentary

Regulation 26(3)(b) and Regulation 29(1)(a) are amended to clarify the prescription may apply to more than one animal.

Regulation 26 is amended to require a written prescription for a Schedule 8 or Schedule 9 poison to specify where applicable that no repeats are to be issued.

Regulation 26 is amended to require the date of birth of the person named on the prescription for a Schedule 8 or Schedule 9 poison as this is consistent with regulations in other States and Territories.

Regulation 29 is amended to require the name of the poison or controlled substance to be in primary position on the label with the trade name in a secondary position. This is a safety measure to reduce confusion for patients receiving multiple package changes with generic medicines.

Regulation 29 is amended to make it consistent with the labelling requirements for containers of Schedule 4, Schedule 8 and Schedule 9 poisons Appendix L of the Poisons Standard.

It has been suggested that Regulation 29(7) be amended to remove the capacity for a veterinary practitioner to supply Schedule 4 poisons in unlabelled containers . The change would facilitate compliance action regarding potential illegal supply and misuse. The change is not made in this consultation draft and we would appreciate comment on the benefit or impact of such a change.

Regulation 31 is to have a Note inserted to explain that regulation 31(1)(a) also applies to multiple supplies or

repeats of the prescribed quantity unless authorised by the prescriber or so directed by the prescriber's endorsement on the prescription.

Regulation 33 is amended to require a pharmacist to retain a prescription for a Schedule 4 poison that is a drug of dependence for a period of 2 years to assist in compliance investigations. A 2 year period is consistent with recent changes to regulation 32 of the Commonwealth *National Health (Pharmaceutical Benefits) Regulations 1960* and is adopted by some other States and Territories. Should a new regulation be limited to drugs of dependence?

A new regulation is proposed to require that an order issued to a stock food manufacturer by a veterinary practitioner for the supply of a Schedule 4 poison is to be in writing and contain specified details. This is to assist in controlling and tracking supplies of medicated stock food. The veterinary practitioner is to keep a record of the issued order for three years.

25 Persons authorised to write prescriptions

(1) A person other than a registered medical practitioner, veterinary practitioner or dentist must not write a prescription for a Schedule 9 poison.

100 penalty units.

(2) A person other than a registered medical practitioner, veterinary practitioner, dentist, nurse practitioner or an authorised registered midwife must not write a prescription for a Schedule 8 poison.

100 penalty units.

(3) A person other than a registered medical practitioner, veterinary practitioner, dentist, nurse practitioner, an authorised registered midwife, an authorised optometrist or an authorised podiatrist must not write a prescription for a Schedule 4 poison.

100 penalty units.

(4) A registered medical practitioner or dentist must not write a prescription for a Schedule 4 poison, Schedule 8 poison or Schedule 9 poison other than for the treatment of a person named on the prescription.

100 penalty units.

(5) A nurse practitioner or an authorised registered midwife must not write a prescription for a Schedule 4 poison or Schedule 8 poison other than for the treatment of a person named on the prescription.

100 penalty units.

(6) An authorised optometrist or an authorised podiatrist must not write a prescription for a Schedule 4 poison other than for the treatment of a person named on the prescription.

100 penalty units.

(7) A veterinary practitioner must not write a prescription for a Schedule 4 poison, Schedule 8 poison or Schedule 9 poison other than for the treatment of an animal named or described on the prescription.

100 penalty units.

26 Style and required particulars for prescriptions

(1) A person authorised to write a prescription under regulation 25 must write a prescription for a Schedule 4 poison, Schedule 8 poison or Schedule 9 poison (as the case requires)—

(a) in his or her own handwriting; or

(b) in a manner of writing approved by the Secretary.

50 penalty units.

(2) In approving another manner of writing a prescription under subregulation (1)(b), the Secretary—

(a) must have regard to security; and

(b) must have regard to legibility; and

(c) may have regard to any other factors the Secretary considers relevant in the circumstances.

(3) A person authorised to write a prescription under regulation 25 must ensure that any prescription written by the person for a Schedule 4 poison, Schedule 8 poison or Schedule 9 poison (as the case requires) is legible and durable and includes—

(a) the name, address and telephone number of the prescriber; and

(b) the name and address of the patient for whom the prescription is intended, or if a prescription is written by a veterinary practitioner, the name or species of animal and the name and address of the owner or the person having the custody of the animal *or animals*; and

(c) the date on which the prescription was written; and

(d) the signature of the prescriber; and

(e) full particulars of the poison or controlled substance to be supplied including a statement of the quantity to be supplied; and

(f) in the case of a Schedule 8 poison or Schedule 9 poison, the statement of the quantity to be supplied written in words and figures; and

(g) directions for the precise dose or use and frequency of administration except in cases where—

(i) because of the complexity of the dosage regimen or use it is impracticable to do so and the prescriber has separately supplied the patient with written instruction; or

(ii) the administration of the poison or controlled substance is to be carried out by a registered medical practitioner, veterinary practitioner, pharmacist, dentist, authorised optometrist, authorised podiatrist, nurse or registered midwife as the case requires; and

(h) the maximum number of times the prescription may be supplied if more than once; and

(i) in the case of a Schedule 8 poison or Schedule 9 poison, the maximum number of times the prescription may be supplied written in words and figures; and

(j) in the case of a Schedule 8 poison or Schedule 9 poison where the prescription may be supplied a maximum of once, that there is no repeat supply; and

(k) in the case of a Schedule 8 poison or Schedule 9 poison, the date of birth of the person named on the prescription.

50 penalty units.

(4) A prescription for a Schedule 4 poison, Schedule 8 poison or Schedule 9 poison must not be written in a secret code or cipher.

50 penalty units.

(5) A prescriber must not knowingly include on a prescription for a Schedule 4 poison, Schedule 8 poison or Schedule 9 poison any particular which is false or misleading.

100 penalty units.

(6) A dentist must not direct that a prescription for a Schedule 4 poison, Schedule 8 poison or Schedule 9 poison be supplied more than once.

50 penalty units.

27 Emergency directions to pharmacists regarding supply

(1) Despite anything in this Division to the contrary, a registered medical practitioner, veterinary practitioner or dentist may issue oral instructions to a pharmacist to supply a Schedule 4 poison, Schedule 8 poison or Schedule 9 poison if in the opinion of the registered medical practitioner, veterinary practitioner or dentist, an emergency exists.

(2) Despite anything in this Division to the contrary, a nurse practitioner or an authorised registered midwife may issue oral instructions to a pharmacist to supply a Schedule 4 poison or Schedule 8 poison if, in the opinion of the nurse practitioner or authorised registered midwife, an emergency exists.

(3) Despite anything in this Division to the contrary, an authorised optometrist or an authorised podiatrist may issue oral instructions to a pharmacist to supply a Schedule 4 poison if, in the opinion of the authorised optometrist or the authorised podiatrist, an emergency exists.

(4) A registered medical practitioner, veterinary practitioner, dentist, nurse practitioner, an authorised registered midwife, an authorised optometrist or an authorised podiatrist who issues oral instructions pursuant to subregulation (1), (2) or (3), as the case requires, must as soon as practicable write a prescription—

(a) indicating that it is in confirmation of the oral instructions; and

(b) deliver or forward that prescription to the pharmacist.

50 penalty units.

28 Particular prescription details to be verified prior to supply

(1) A pharmacist must not supply a Schedule 8 poison or Schedule 9 poison on a prescription unless he or she—

(a) if the prescription is handwritten, is familiar with the purported prescriber's handwriting and the writing is comparable with the usual writing of the purported prescriber; or

(b) has taken reasonable steps to verify that the prescription was written by the purported prescriber.

100 penalty units.

(2) Despite subregulation (1), a pharmacist may supply a quantity of a Schedule 8 poison sufficient for no more than 2 days' treatment.

(3) A pharmacist who supplies a Schedule 8 poison in accordance with subregulation (2) must retain the prescription despite the full quantity ordered not having been supplied.

100 penalty units.

29 Containers of drugs to be labelled with certain details

(1) A registered medical practitioner, pharmacist, veterinary practitioner or dentist who supplies a Schedule 4 poison, Schedule 8 poison or Schedule 9 poison for the treatment of a specific person, or the

veterinary treatment of a specific animal, must ensure that the container in which it is packed is labelled with the following information—

(a) the name of the patient or name or species of animal and the name of the owner or person having custody of the animal *or animals*; and

(b) the date of recording as required by Division 5; and

(c) the name, address and telephone number of the place of supply; and

(d) the name of the poison or controlled substance in primary position followed by the trade name in secondary position, which unambiguously identifies the poison or controlled substance and its strength, form and quantity; and

(e) subject to subregulation (2), the directions for use; and

. (f) in accordance with Appendix L of the Poisons Standard.

50 penalty units.

(2) A registered medical practitioner, pharmacist, veterinary practitioner or dentist who supplies a Schedule 4 poison, Schedule 8 poison or Schedule 9 poison in accordance with subregulation (1) is not required to include directions for use of the poison on a label on the container if—

(a) in the case of a pharmacist—

(i) directions for use have not been included by the prescriber on the prescription for that poison; or

(ii) the dosage regimen or use is so complex that the prescriber has supplied the patient with separate written instruction; or

(b) the dosage regimen or use is so complex that the registered medical practitioner, veterinary practitioner or dentist has supplied the patient with separate written instruction; or

(c) the administration of the poison is to be carried out by a registered medical practitioner, pharmacist, veterinary practitioner, dentist, authorised optometrist, authorised podiatrist, nurse or registered midwife.

(3) A nurse practitioner, an authorised registered nurse or authorised registered midwife who supplies a Schedule 4 poison or Schedule 8 poison for the treatment of a specific person must ensure that the container in which it is packed is labelled with the following information—

(a) the name of the patient; and

(b) the date of recording as required by Division 5; and

(c) the name, address and telephone number of the place of supply; and

(d) the name of the poison or controlled substance or a trade name which unambiguously identifies the poison or controlled substance and its strength, form and quantity; and

(e) subject to subregulation (4), the directions for use.

50 penalty units.

(4) A nurse practitioner, an authorised registered nurse or an authorised registered midwife who supplies a Schedule 4 poison or Schedule 8 poison in accordance with subregulation (3) is not required to include directions for use of the poison on a label on the container if—

(a) the dosage regimen or use is so complex that the nurse practitioner, authorised registered nurse or authorised registered midwife has supplied the patient with separate written instruction; or

(b) the administration of the poison is to be carried out by a registered medical practitioner, pharmacist, dentist, authorised optometrist, authorised podiatrist, nurse or registered midwife.

(5) An authorised optometrist or an authorised podiatrist who supplies a Schedule 4 poison for the treatment of a specific person must ensure that the container in which it is packed is labelled with the following information—

(a) the name of the patient; and

(b) the date of recording as required by Division 5; and

(c) the name, address and telephone number of the place of supply; and

(d) the name of the poison or controlled substance or a trade name which unambiguously identifies the poison or controlled substance and its strength, form and quantity; and

(e) subject to subregulation (6), the directions for use.

50 penalty units.

(6) An authorised optometrist or an authorised podiatrist who supplies a Schedule 4 poison in accordance with subregulation (5) is not required to include directions for use of the poison on a label on the container if—

(a) the dosage regimen or use is so complex that the authorised optometrist or authorised podiatrist has supplied the patient with separate written instruction; or

(b) the administration of the poison is to be carried out by a registered medical practitioner, pharmacist, dentist, an authorised optometrist, an authorised podiatrist, nurse or registered midwife.

(7) A veterinary practitioner is not required to comply with subregulation (1) if a Schedule 4 poison is supplied in bulk for treatment of flocks or herds of animals provided that—

(a) each container of the poison retains the manufacturer's original label; and

(b) the veterinary practitioner provides written instructions containing the information specified in subregulation (1) to the owner of, or the person having custody of, the animals.

30 Duration of prescriptions

(1) A pharmacist who supplies a Schedule 4 poison, Schedule 8 poison or Schedule 9 poison on a prescription must ensure that the prescription is marked in a way that indicates durably—

(a) that the poison or controlled substance has been supplied; and

(b) the date of recording as required by Division 5; and

(c) the premises from which the poison or controlled substance was supplied.

50 penalty units.

(2) A pharmacist must not supply a Schedule 4 poison, Schedule 8 poison or Schedule 9 poison on a prescription if it is more than—

(a) 12 months after the date written on the prescription in the case of a prescription for a Schedule 4 poison; or

(b) 6 months after the date written on the prescription in the case of a prescription for a Schedule 8 poison or Schedule 9 poison.

50 penalty units.

30A Requirements when supply of Schedule 4 poison is made on a residential medication chart

A pharmacist who supplies a Schedule 4 poison on a residential medication chart for a resident must ensure that the residential medication chart is marked in a durable form in a way that indicates—

(a) that the Schedule 4 poison has been supplied; and

(b) the date of recording as required by Division 5 of this Part; and

(c) the premises from which the Schedule 4 poison was supplied.

Penalty: 50 penalty units.

31 Circumstances where prescriptions are not to be filled

(1) A pharmacist must not supply a Schedule 4 poison, Schedule 8 poison or Schedule 9 poison on a prescription—

(a) in excess of the quantities authorised; or

(b) which he or she has reason to believe has been forged or is fraudulent in any way; or

(c) which he or she has reason to believe has been altered in any way other than by or on the instruction of the prescriber; or

(d) which is illegible or defaced; or

(e) when the quantity authorised has already been supplied.

100 penalty units.

Note

Regulation 31(1)(a) also applies to multiple supplies or repeats of the prescribed quantity unless authorised by the prescriber or so directed by the prescriber's endorsement on the prescription.

(2) A pharmacist to whom a prescription referred to in subregulation (1)(b) or (c) is presented must without delay notify a member of the Victoria Police and the Secretary of the circumstances concerning the presentation of the prescription.

50 penalty units.

32 Duty of pharmacist to notify different prescribers of similar supply

A pharmacist who is presented with a prescription for a drug of dependence or a Schedule 8 poison or Schedule 9 poison for a person whom the pharmacist has reason to believe was supplied in the previous 8 weeks with the same or a similar drug of dependence, Schedule 8 poison or Schedule 9 poison on a prescription written by a different prescriber must take all reasonable steps prior to supply or, if unable to do so, as soon as practicable after the supply has occurred, to inform the prescriber that the previous supply has occurred unless the pharmacist has reason to believe the prescriber is already aware of the previous supply or prescription.

50 penalty units.

33 Retention of original prescriptions or orders once supply completed

(1) A pharmacist who supplies a Schedule 8 poison or Schedule 9 poison on a prescription or order of a registered medical practitioner, veterinary practitioner or dentist or a Schedule 8 poison on the prescription or order of a nurse practitioner or an authorised registered midwife must on the last occasion the supply is made—

(a) retain that prescription or order in a manner that maintains the integrity of the prescription or order; or

(b) in the case of a prescription or order on which other poisons or controlled substances may still be legally supplied, ensure that the prescription or order is durably marked in such a way that it can be seen clearly that further supplies of that Schedule 8 poison or Schedule 9 poison are not allowed.

50 penalty units.

(2) A pharmacist who retains a prescription or order pursuant to subregulation (1)(a) must retain that prescription or order on a file kept solely for the purpose of retaining such prescriptions or orders for a period of 3 years from the date the Schedule 8 poison or Schedule 9 poison (as the case requires) was last supplied.

(3) A pharmacist must produce a prescription or order referred to in subregulation (2) on demand to an authorised officer.

(4) It is sufficient compliance with subregulation (1) if a pharmacist retains a legible copy of the prescription or order if he or she is required to submit the original to a public authority by any Act of a State, a Territory or the Commonwealth.

(5) A pharmacist who supplies a Schedule 4 poison that is a drug of dependence on a prescription or order of a registered medical practitioner, veterinary practitioner, dentist, nurse practitioner, authorised registered midwife, authorised optometrist or authorised podiatrist must on the last occasion the supply is made—

(a) retain that prescription or order in a manner that maintains the integrity of the prescription or order; or

(b) in the case of a prescription or order on which other poisons or controlled substances may still be legally supplied, ensure that the prescription or order is durably marked in such a way that it can be seen clearly that further supplies of that Schedule 4 poison is not allowed.

50 penalty units.

(6) A pharmacist who retains a prescription or order pursuant to subregulation (5)(a) must retain that prescription or order on a file kept solely for the purpose of retaining such prescriptions or orders for a period of 2 years from the date the Schedule 4 poison was last supplied.

(7) A pharmacist must produce a prescription or order referred to in subregulation (6) on demand to an authorised officer.

(8) It is sufficient compliance with subregulation (5) if a pharmacist retains a legible copy of the prescription or order if he or she is required to submit the original to a public authority by any Act of a State, a Territory or the Commonwealth.

New regulation Veterinary practitioner order to supply stock food containing a Schedule 4 poison

(1) A veterinary practitioner who issues an order to a stock food manufacturer to supply a stock food containing a Schedule 4 poison must ensure that the order is in writing and is legible and durable and includes—

(a) the name, address and telephone number of the veterinary practitioner issuing the order; and

(b) the name and address of the owner or the person having the custody of the animals; and if different, the consignment address;

(c) the species of the animals; and

(d) the date on which the order was written; and

(e) the signature of the veterinary practitioner issuing the order; and

(f) the name and address of the stock food manufacturer; and

(g) full particulars of the Schedule 4 poison to be supplied including the type, form, strength, trade name and quantity of prepared stock food to be supplied; and

(h) directions for use, including mandatory withholding periods; and

(i) time(s) of supply.

xx penalty units.

(2) A veterinary practitioner who issues a written order pursuant to subregulation (1) must keep a record of the order for a period of three years and produce it on demand to an authorised officer.

xx penalty units.

Division 4—Storage

Commentary

Regulation 35 is amended to enable the use of new and emerging technology in automated storage and recording facilities for Schedule 8 and Schedule 9 poisons. We ask for further comment on the proposed security features and what if any restrictions on the types of setting (for example health services, pharmacy departments, community pharmacies, pharmacies, veterinary clinics and the like) should be included to support it.

Regulations 34, 35 and 36 are amended to clarify that an unauthorised person is a person not authorised under the Act or Regulations.

Regulation 36 is amended to remove the reference to high level residential care as this term is no longer referenced by Commonwealth *Aged Care Act 1997* and has not been replaced with another definition. The regulation is to apply to all approved providers on the basis that most approved providers are likely to already be applying storage security for prescribed medication that complies with the regulation.

34 General security requirement—Schedule 4 poisons

(1) A person to whom this regulation applies must store any Schedule 4 poisons in the person's possession in a lockable storage facility.

100 penalty units.

(2) A person to whom this regulation applies must take all reasonable steps to ensure that the storage facility referred to in subregulation (1) remains locked and secured to prevent access by a *person not authorised by the Act or these Regulations* at all times, except—

(a) when it is necessary to open it to carry out an essential operation in connection with the poisons stored in it; or

(b) in the case of poisons stored in accordance with subregulation (3)(a) or (b), when a registered medical practitioner, pharmacist, veterinary practitioner, dentist, nurse practitioner, an authorised registered midwife, an authorised optometrist, an authorised podiatrist, nurse or registered midwife authorised under regulation 5(2)(a) is present.

100 penalty units.

(3) Despite subregulations (1) and (2), a registered medical practitioner, pharmacist, veterinary practitioner, dentist, nurse practitioner, an authorised registered midwife, an authorised optometrist or an authorised podiatrist may store Schedule 4 poisons at the premises in which he or she carries out the lawful practice of his or her profession in—

(a) the dispensing area or pharmacy department of the premises; or

(b) the treatment room of the premises; or

(c) in an area separated from the remainder of the premises and to which only a registered medical practitioner, pharmacist, veterinary practitioner, dentist, nurse practitioner, an authorised registered midwife, an authorised optometrist or an authorised podiatrist has access.

(4) This regulation applies to—

(a) a registered medical practitioner, pharmacist, veterinary practitioner, dentist, nurse practitioner, an authorised registered midwife, an authorised optometrist and an authorised podiatrist; and

(b) a person holding a licence, permit or warrant to manufacture, sell, supply, purchase or otherwise obtain, possess, administer or use a Schedule 4 poison; and

(c) a nurse or registered midwife approved under regulation 5(3) to be in possession of a Schedule 4 poison.

35 Storage of Schedule 8 and Schedule 9 poisons

(1) A person to whom this regulation applies must store any Schedule 8 poisons or Schedule 9 poisons in that person's possession in a lockable storage facility that provides not less security than a storage facility that is—

(a) constructed of mild steel plate of 10 millimetres thickness; and

(b) constructed with continuous welding of all edges; and

(c) fitted with a door constructed of mild steel plate of 10 millimetres thickness, swung on hinges welded to the door and body of the cabinet, the door being flush fitting with a clearance around the door of not more than 1·5 millimetres; and

(d) fitted with a fixed locking bar, welded to the inside face of the door near the hinge edge, which engages in a rebate when the door is closed; and

(e) fitted with a 6 lever lock securely affixed to the rear face of the door; and

(f) securely attached to a wall or floor in such a manner that it will resist attack by hand tools for 30 minutes or power tools for 5 minutes.

100 penalty units.

(2) Not less security might include the use of electronic storage and recording equipment where-

(a) access is restricted to persons who are authorised by the Act or these Regulations and are permitted to have access; and

(b) access is restricted to the Schedule 8 or Schedule 9 poisons specified by the person permitted to have access; and

(c) security features to record and report access, attempted access, tampering and movement of the unit are engaged; and

(d) an alarm sounds if security features are breached; and

(e) a message alert is sent to the security service in real-time if security features are breached.

(3) A person to whom this regulation applies must take all reasonable steps to ensure that the storage facility remains locked and secured to prevent access by a *person not authorised by the Act or these Regulations* at all times, except when it is necessary to open it to carry out an essential operation in connection with the poisons stored in it.

100 penalty units.

(4) A person to whom this regulation applies must take all reasonable steps to ensure that the storage facility referred to in subregulation (1) is used only for the storage of Schedule 8 poisons, Schedule 9 poisons and drugs of dependence.

100 penalty units.

(5) A person to whom this regulation applies must keep any Schedule 8 poisons or Schedule 9 poisons in the person's possession which are being transported for use in another place in a locked storage facility which is secured to prevent unauthorised access to those poisons.

100 penalty units.

(5) Despite subregulations (1) and (3), a person to whom this regulation applies may keep up to 6 divided doses of a Schedule 8 poison in a lockable storage facility for use in an emergency.

(6) This regulation applies to—

(a) a registered medical practitioner, pharmacist, veterinary practitioner, dentist, nurse practitioner and an authorised registered midwife; and

(b) a person holding a licence, permit or warrant to manufacture, sell, supply, purchase or otherwise obtain, possess, administer or use a Schedule 8 poison or a Schedule 9 poison; and

(c) a nurse or registered midwife approved under regulation 5(3) to be in possession of a Schedule 8 poison or a Schedule 9 poison.

36 Storage requirements

(1) A person to whom this regulation applies must—

(a) store any Schedule 4 poison in the person's possession in a lockable storage facility; and

(b) store any Schedule 8 poison or Schedule 9 poison in the person's possession in a lockable room or in a lockable storage facility which is firmly fixed to a floor or wall; and

(c) take all reasonable steps to ensure that the storage facilities for Schedule 4 poisons, Schedule 8 poisons and Schedule 9 poisons remain locked and secured to prevent access by a *person not authorised by the Act or these Regulations* at all times, except when it is necessary to open them to carry out an essential operation in connection with the poisons stored in them.

100 penalty units.

(2) This regulation applies to—

(a) a person referred to in Column 1 of Part 2 of the table in regulation 5 as authorised to have in his or her possession a Schedule 4 poison or Schedule 8 poison; and

(b) an approved provider of an aged care service if—

(i) in that service there is a *resident who has been supplied*—

(A) on a prescription or on a residential medication chart with a Schedule 4 poison; or

(B) on a prescription with a Schedule 8 poison or a Schedule 9 poison.

37 Additional security provisions required in certain circumstances

(1) Subject to subregulation (2), the Secretary may—

(a) direct a person to whom regulation 34, 35 or 36 applies to provide more secure storage for Schedule 4 poisons, Schedule 8 poisons or Schedule 9 poisons than that described in regulations 34, 35 and 36; or

(b) grant approval for a person to store substances other than Schedule 8 poisons or Schedule 9 poisons in the same storage facility as Schedule 8 poisons or Schedule 9 poisons.

(2) Before giving a direction or granting approval under subregulation (1) the Secretary—

(a) must have regard to—

(i) the nature and quantity of the poisons or controlled substances being stored; and

(ii) the location, layout and construction of the storage facility and the premises; and

(iii) the warning devices and detectors with which the storage facility and premises are equipped; and

(iv) the number and frequency of transactions; and

(v) the number of persons requiring access; and

(b) may have regard to any other factors the Secretary considers relevant in the circumstances.

(3) A person who is directed by the Secretary to provide more secure storage under subregulation (1)(a) must provide that secure storage.

100 penalty units.

Division 5—Records

Commentary

Regulation 39 is amended to remove the reference to high level of residential care as this term is no longer referenced by Commonwealth *Aged Care Act 1997* and has not been replaced with another definition. The regulation is to apply to all approved providers on the basis that most approved providers are likely to already be applying record keeping standards for prescribed medication that comply with the regulation.

Regulation 41 is amended such that the balance for a transaction involving Schedule 8 poison opioid replacement therapy must be recorded after each transaction or at least daily, to reflect long-standing practice.

Regulation 41 is amended to require a person with an access code used to create an electronic record of a transaction for Schedule 8 or Schedule 9 poisons to take all reasonable steps to keep that access code secure. The access code will therefore be not able to be used by another person to create a false record.

Regulation 41 is amended to remove the reference to high level of residential care as this term is no longer referenced by Commonwealth *Aged Care Act 1997* and has not been replaced with another definition. The amendment maintains the exemption for approved providers to keep a Schedule 8 or Schedule 9 poison register for residents receiving prescribed medication in tamper-evident dose administration containers.

A Note is to be inserted at Regulation 42 to explain that the practice of a pharmacist supplying a Schedule 4,

Schedule 8 or Schedule 9 poison on an oral instruction in accordance with Regulation 27, i.e. in advance of receiving a prescription, then deleting the record and recreating it at a later date (i.e. when the prescription is received) would represent a contravention of Regulation 42 unless the record includes a clear reference to the original record.

38 Definition of transaction

In this Division transaction means the manufacture, preparation, use, transfer within and between premises, administration, sale, supply, disposal or destruction of a Schedule 4 poison, Schedule 8 poison or Schedule 9 poison.

39 Persons required to keep records

The following persons are required to keep records under this Division—

(a) a registered medical practitioner, pharmacist, veterinary practitioner, dentist, nurse practitioner, an authorised registered midwife, an authorised optometrist and an authorised podiatrist; and

(b) a person holding a licence, permit or warrant to manufacture, sell, supply, purchase or otherwise obtain, possess, administer or use a Schedule 4 poison, Schedule 8 poison or Schedule 9 poison; and

(c) a nurse or registered midwife authorised under regulation 5(2) to be in possession of a Schedule 4 poison, Schedule 8 poison or Schedule 9 poison; and

(d) an approved provider of an aged care service if—

(i) in that service there is a resident who is receiving *residential* care; and

(ii) that resident has been supplied—

(A) on a prescription or on a residential medication chart with a Schedule 4 poison; or

(B) on a prescription with a Schedule 8 poison or a Schedule 9 poison; and

(e) a person referred to in Column 1 of Part 2 of the table in regulation 5 as authorised to have in his or her possession a Schedule 4 poison or Schedule 8 poison.

40 Details to be contained in records

(1) A person required to keep records under this Division must, as soon as practicable after completing a transaction, record—

(a) the date of each transaction; and

(b) the name, form, strength and quantity of the poison or controlled substance; and

(c) in the case of a transaction involving supply on a prescription—

(i) the name of the prescriber; and

(ii) the directions for use as set out on the prescription; and

(ca) in the case of a transaction involving supply on a residential medication chart—

(i) the name of the registered medical practitioner; and

(ii) the directions for use as set out in the residential medication chart; and

(d) the name and address or location of persons to whom the poison or controlled substance is transferred, supplied, administered or otherwise disposed of; and

(e) in the case of a Schedule 8 poison or Schedule 9 poison purchased or obtained, the name and address of the person from whom the poison was purchased or obtained; and

(f) in the case of a Schedule 8 poison or Schedule 9 poison which has been destroyed by a registered medical practitioner, pharmacist, veterinary practitioner or dentist in accordance with regulation 51(3)(a), the details set out in regulation 51(3)(b); and

(g) in the case of a Schedule 8 poison which has been destroyed by a nurse practitioner or an authorised registered midwife in accordance with regulation 51(2)(a), the details set out in regulation 51(2)(b); and

(ga) in the case of a Schedule 8 poison listed in the health services permit held by an ambulance service within the meaning of the Ambulance Services Act 1986 which has been destroyed by an operational staff member within the meaning of that Act in accordance with regulation 51(4A)(a), the matters set out in regulation 51(4A)(b); and

(h) in the case of the unused contents of a previously sterile container containing a Schedule 8 poison or a Schedule 9 poison that are not required for administration to a patient which has been destroyed by a registered medical practitioner, pharmacist, veterinary practitioner, dentist, nurse or registered midwife in accordance with regulation 51(4)(a), the details set out in regulation 51(4)(b); and

(i) in the case of a transaction involving supply or administration to a specific person, the name of the person carrying out the transaction.

50 penalty units.

(2) Despite subregulation (1), a registered medical practitioner, pharmacist, veterinary practitioner, dentist, nurse practitioner, an authorised registered midwife, an authorised optometrist or an authorised podiatrist is not required to keep a record of the destruction of Schedule 4 poisons.

41 Methods by which records are to be retained and retrieved

(1) A person required to keep records under this Division must ensure that the records of all transactions in Schedule 8 poisons or Schedule 9 poisons kept by the person—

(a) are able to be readily sorted by poison or controlled substance; and

(b) show the true and accurate balance of each Schedule 8 poison and Schedule 9 poison remaining in the person's possession after each transaction or *for Schedule 8 poisons that are lawfully prescribed for opioid replacement therapy after each transaction or at least daily*; and

(c) show the name of the person carrying out the transaction.

50 penalty units.

(2) A person required to keep records under this Division must keep records made by the person readily retrievable in English.

50 penalty units.

(3) A person required to keep records under this Division must retain a record of each transaction in a Schedule 4 poison, Schedule 8 poison or Schedule 9 poison in a readily retrievable form for 3 years from the date of the transaction.

50 penalty units.

(4) A person required to keep records under this Division must produce on demand to an authorised officer all records required to be kept under this Division.

50 penalty units.

(5) A person required to keep records under this Division must maintain the records made by him or her of transactions in Schedule 8 poisons or Schedule 9 poisons in a manner that ensures that the records cannot be altered, obliterated, deleted or removed without detection.

50 penalty units.

(5a) A person required to keep records under this Division must take all reasonable steps to ensure their access code for making an electronic transaction record for Schedule 8 or Schedule 9 poisons is not known or used by another person.

(6) An approved provider of an aged care service where *there is a resident who* has been supplied with a Schedule 4 poison on prescription or a residential medication chart or supplied on prescription with a Schedule 8 poison or Schedule 9 poison need not comply with subregulation (1) in relation to Schedule 8 poisons or Schedule 9 poisons that are—

(a) supplied on prescription for a specific person; and

(b) supplied in tamper-evident compartments of dose administration containers; and

(c) labelled by a registered medical practitioner, pharmacist, dentist or nurse practitioner for administration at times specified on the label.

42 Accurate records to be kept

A person required to keep records under this Division must not knowingly make or cause to be made an entry which is false or misleading in any records in respect of a Schedule 4 poison, Schedule 8 poison or Schedule 9 poison.

50 penalty units.

Note

The practice of a pharmacist supplying a Schedule 4, Schedule 8 or Schedule 9 poison in accordance with Regulation 27, i.e. in advance of receiving a prescription, then deleting the record and recreating it at a later date (i.e. when the prescription is received) would represent a contravention of Regulation 42 unless the record includes a clear reference to the original record.

43 Discrepancies in records to be investigated

A person required to keep records under this Division must—

(a) investigate without delay any discrepancies found in the transaction records kept by that person; and

(b) after that investigation, notify the Secretary without delay of any discrepancy which remains.

50 penalty units.

44 Lost or stolen records to be reported

A person required to keep records under this Division must notify the Secretary without delay of the circumstances of any loss, destruction or theft of records kept by the person relating to Schedule 4 poisons, Schedule 8 poisons or Schedule 9 poisons.

50 penalty units.

Division 6—Administration

Commentary

Regulation 46 is amended to require the instruction from the registered medical practitioner, dentist, nurse practitioner, authorised midwife, authorised optometrist or authorised podiatrist to include the dose to be administered and the frequency of administration. This amendment is intended to address situations where practitioners' instructions are not clear and are interpreted by others, to the potential detriment of the person being treated.

45 Use of drugs and poisons restricted to person or animal for whom they were supplied

(1) A person must not administer or use a Schedule 4 poison, Schedule 8 poison or Schedule 9 poison supplied by a registered medical practitioner, pharmacist, veterinary practitioner or dentist for the treatment of a specific person or animal other than for the treatment of that person or animal.

100 penalty units.

(2) A person must not administer or use a Schedule 4 poison or Schedule 8 poison supplied by a nurse practitioner, an authorised registered midwife or authorised registered nurse for the treatment of a specific person other than for the treatment of that person.

100 penalty units.

(3) A person must not administer or use a Schedule 4 poison supplied by an authorised optometrist or an authorised podiatrist for the treatment of a specific person other than for the treatment of that person.

100 penalty units.

46 Administration of drugs and poisons to be authorised

(1) A registered medical practitioner or dentist who orders the administration of a Schedule 4 poison, Schedule 8 poison or Schedule 9 poison to a person—

(a) must provide that instruction in writing in a legible and durable form;

(xx) must include the dose and frequency of administration; and

(b) must date and confirm that order with his or her signature;

100 penalty units.

(2) A nurse practitioner or an authorised registered midwife who orders the administration of a Schedule 4 poison or Schedule 8 poison to a person—

(a) must provide that instruction in writing in a legible and durable form;

(xx) must include the dose and frequency of administration; and

(b) must date and confirm that order with his or her signature.

100 penalty units.

(3) An authorised optometrist or an authorised podiatrist who orders the administration of a Schedule 4 poison to a person—

(a) must provide that instruction in writing in a legible and durable form;

(xx) must include the dose and frequency of administration; and

(b) must date and confirm that order with his or her signature.

100 penalty units.

(4) A person must not administer a Schedule 4 poison, Schedule 8 poison or Schedule 9 poison to another person on the instruction of a registered medical practitioner or dentist if—

(a) in the case of a Schedule 4 poison, it is more than 12 months after the date on which the instruction was given; or

(b) in the case of a Schedule 8 poison or Schedule 9 poison, it is more than 6 months after the date on which the instruction was given.

100 penalty units.

(5) A person must not administer a Schedule 4 poison or Schedule 8 poison to another person on the instruction of a nurse practitioner or an authorised registered midwife if—

(a) in the case of a Schedule 4 poison, it is more than 12 months after the date on which the instruction was given; or

(b) in the case of Schedule 8 poison, it is more than 6 months after the date on which the instruction was given.

100 penalty units.

(6) A person must not administer a Schedule 4 poison to another person on the instruction of an authorised optometrist or an authorised podiatrist if it is more than 12 months after the date on which the instruction was given.

100 penalty units.

(7) A person referred to in Column 1 of Part 2 of the table in regulation 5 must not administer a Schedule 4 poison or Schedule 8 poison other than to the extent authorised by Column 2 of Part 2 of the Table.

100 penalty units.

47 Administration of drugs and poisons by a nurse or registered midwife –

(1) A nurse or registered midwife must not administer a Schedule 9 poison to a person other than—

(a) in accordance with the directions for use on the container of the Schedule 9 poison supplied by a registered medical practitioner, pharmacist or dentist; or

(b) on the written instruction of a registered medical practitioner or dentist; or

(c) on the oral instructions of a registered medical practitioner or dentist to the nurse or registered midwife if, in the opinion of the registered medical practitioner or dentist, an emergency exists; or

(d) on the written transcription of the oral instructions referred to in paragraph (c) by another nurse or registered midwife who received those instructions; or

(e) in accordance with regulation 5(2) or an approval of the Secretary under regulation 5(3).

(2) A nurse or registered midwife must not administer a Schedule 8 poison other than—

(a) in accordance with the directions for use on the container of the Schedule 8 poison supplied by a registered medical practitioner, pharmacist, dentist, nurse practitioner or an authorised registered midwife; or

(b) on the written instruction of a registered medical practitioner, dentist, nurse practitioner or an authorised registered midwife; or

(c) on the oral instructions of a registered medical practitioner, dentist, nurse practitioner or an authorised registered midwife to the nurse or registered midwife if, in the opinion of the registered medical practitioner, dentist, nurse practitioner or authorised registered midwife, an emergency exists; or

(d) on the written transcription of the oral instructions referred to in paragraph (c) by another nurse or registered midwife who received those instructions; or

(da) in the case of a nurse who is a nurse practitioner, in accordance with regulation 9(1); or

(db) in the case of a nurse who is an authorised registered nurse, in accordance with regulation 9A(1); or

(dc) in the case of a registered midwife who is an authorised registered midwife, in accordance with regulation 9B(1); or

(e) in accordance with regulation 5(2) or an approval of the Secretary under regulation 5(3).

(3) A nurse or registered midwife must not administer a Schedule 4 poison other than—

(a) in accordance with the directions for use on the container of the Schedule 4 poison supplied by a registered medical practitioner, pharmacist, dentist, nurse practitioner, an authorised registered midwife, an authorised optometrist or an authorised podiatrist; or

(b) on the written instruction of a registered medical practitioner, dentist, nurse practitioner, an authorised registered midwife, an authorised optometrist or an authorised podiatrist; or

(c) on the oral instruction of a registered medical practitioner, dentist, nurse practitioner, an authorised registered midwife, an authorised optometrist or an authorised podiatrist to the nurse or registered midwife, if in the opinion of the registered medical practitioner, dentist, nurse practitioner, authorised registered midwife, authorised optometrist or authorised podiatrist, an emergency exists; or

(d) on the written transcription of the oral instructions referred to in paragraph (c) by another nurse or registered midwife who received those instructions; or

(da) in the case of a nurse who is a nurse practitioner, in accordance with regulation 9(2); or

(db) in the case of a nurse who is an authorised registered nurse, in accordance with regulation 9A(2); or

(dc) in the case of a registered midwife who is an authorised registered midwife, in accordance with regulation 9B(3); or

(e) in accordance with regulation 5(2) or an approval of the Secretary under regulation 5(3).

100 penalty units.

(4) A registered medical practitioner, dentist, nurse practitioner, an authorised registered midwife, an authorised optometrist or an authorised podiatrist who issues oral instructions in accordance with subregulation (1)(c), (2)(c) or (3)(c) (as the case requires) must as soon as practicable—

(a) confirm those oral instructions in writing; and

(b) include them or provide them for inclusion in the treatment records of the person concerned.

100 penalty units.

48 Self-administration of drugs and poisons restricted

A person must not use, prescribe, sell or supply a Schedule 4 poison, a Schedule 8 poison or a Schedule 9 poison (as the case requires) for the purpose of self-administration unless the person—

(a) in the case of a Schedule 9 poison—

(i) is a patient for whom a registered medical practitioner or dentist has prescribed that poison; and

(ii) is not the registered medical practitioner or dentist who prescribed that poison; and

(b) in the case of a Schedule 8 poison—

(i) is a patient for whom a registered medical practitioner, dentist, nurse practitioner or an authorised registered midwife has prescribed that poison; and

(ii) is not the registered medical practitioner, dentist, nurse practitioner or authorised registered midwife who prescribed that poison; and

(c) in the case of a Schedule 4 poison—

(i) is a patient for whom—

(A) a registered medical practitioner, dentist, nurse practitioner or an authorised registered midwife; or

(B) an authorised optometrist or an authorised podiatrist (in accordance with the endorsement of his or her registration)—

has prescribed that poison; and

(ii) is not the registered medical practitioner, dentist, nurse practitioner, authorised registered midwife, authorised optometrist or authorised podiatrist who prescribed that poison; and

(d) in any case, uses that poison to the extent and for the purpose for which it was prescribed, sold or supplied.

100 penalty units.

49 Administration or supply of drugs and poisons prohibited if to support drug dependency

A person must not administer, prescribe, sell or supply a drug of dependence or a Schedule 4 poison, Schedule 8 poison or Schedule 9 poison to any person merely for the purpose of supporting the drug dependence of that person.

100 penalty units.

Division 7—Destruction of Schedule 8 poisons and Schedule 9 poisons

Commentary

Regulation 51 – is amended to enable a nurse, amongst other registered health practitioners, to destroy an unused half tablet or a used transdermal patch of a Schedule 8 or Schedule 9 poison during the process of administration. This is to enable destruction when only one health practitioner is present in circumstances that occur during administration of the medicine and where collection for later use (in the case of half tablets) or destruction may result in greater risks of misuse or medication error or hygiene risks.

50 Wilful destruction prohibited

Subject to this Division, a person must not wilfully destroy a Schedule 8 poison or Schedule 9 poison.

100 penalty units.

51 Exceptions

(1) Regulation 50 does not apply to—

(a) a Schedule 8 poison or Schedule 9 poison destroyed by or under the supervision of an authorised officer; or

(b) a Schedule 8 poison or Schedule 9 poison for which a court order has been granted for its destruction; or

(c) a Schedule 8 poison or Schedule 9 poison which has been taken into possession by a member of the police force and for which an order for destruction has been issued by an officer of rank not below that of Inspector of the Victoria Police; or

(d) a narcotic plant or seed of any narcotic plant as defined in section 70 of the Act.

(2) Subject to subregulation (6), regulation 50 does not apply to a Schedule 8 poison if—

(a) it is destroyed by a nurse practitioner or an authorised registered midwife in the presence of another person who is a registered medical practitioner, pharmacist, veterinary practitioner, dentist, nurse or registered midwife; and

(b) the details of the destruction are recorded in the records required to be kept under regulation 40, including—

(i) the name, strength and quantity of the poisons or controlled substances destroyed; and

(ii) the method and place of destruction; and

(iii) the names of the persons carrying out the destruction; and

(iv) the names of the witnesses.

(3) Subject to subregulation (6), regulation 50 does not apply to a Schedule 8 poison or Schedule 9 poison if—

(a) it is destroyed by a registered medical practitioner, pharmacist, veterinary practitioner or dentist in the presence of another person who is a registered medical practitioner, pharmacist, veterinary practitioner, dentist, nurse or registered midwife; and

(b) the details of the destruction are recorded in the records required to be kept under regulation 40, including—

(i) the name, strength and quantity of the poisons or controlled substances destroyed; and

(ii) the method and place of destruction; and

(iii) the names of the persons carrying out the destruction; and

(iv) the names of the witnesses.

(4) Subject to subregulation (6), regulation 50 does not apply to the unused contents of a previously sterile container containing a Schedule 8 poison or a Schedule 9 poison that are not required for administration to a patient if—

(a) those contents are destroyed by a registered medical practitioner, pharmacist, veterinary practitioner, dentist, nurse or registered midwife; and

(b) the details of the destruction are recorded in the records required to be kept under regulation 40, including—

(i) the name, strength and quantity of the poisons or controlled substances destroyed; and

(ii) the method and place of destruction; and

(iii) the name of the person carrying out the destruction.

(4A) Subject to subregulation (6), regulation 50 does not apply to the unused contents of a previously sterile container containing a Schedule 8 poison listed in the health services permit held by an ambulance service within the meaning of the *Ambulance Services Act 1986* that are not required for administration to a patient if—

(a) those contents are destroyed by an operational staff member (within the meaning of that Act) of that ambulance service; and

(b) the details of the destruction are recorded in the records required to be kept under regulation 40, including—

(i) the name, strength and quantity of the poison or controlled substances destroyed; and

(ii) the method and place of destruction; and

(iii) the name of the person carrying out the destruction.

(5) Subject to subregulation (6), regulation 50 does not apply to the unused half tablet or a used transdermal patch containing a Schedule 8 poison or a Schedule 9 poison that is not required for administration to a patient if—

(a) the unused half tablet or used transdermal patch is destroyed by a registered medical practitioner, pharmacist, veterinary practitioner, dentist, nurse or registered midwife; and

(b) the details of the destruction are recorded in the records required to be kept under regulation 40, including—

(i) the name, strength and quantity of the tablets or patches destroyed; and

(ii) the method and place of destruction; and

(iii) the name of the person carrying out the destruction.

(6) The Secretary may direct a person referred to in subregulation (2), (3), (4), (4A) *or (5)* to comply with any requirements relating to the destruction of a Schedule 8 poison or Schedule 9 poison (as the case requires) specified in writing by the Secretary.

Division 8—Cultivation of narcotic plants

52 Authority to cultivate narcotic plants for non-therapeutic uses

(1) For the purposes of section 72 of the Act, the Secretary may, in his or her discretion, authorise in writing a fit and proper person to cultivate a narcotic plant as defined in section 70 of the Act for a use other than a therapeutic use.

(2) The holder of an authority under subregulation (1) is, for the purpose of that authority, authorized to possess the narcotic plant to which that authority relates for the purposes of sections 72, 72A, 72B and 73 of the Act.

52A Authority to possess narcotic plant

(1) A person listed in column 1 of the following Table who is an employee of, or engaged by, the holder of an authority under regulation 52 to cultivate the narcotic plant Papaver somniferum L., is authorised to possess that narcotic plant in the circumstances and to the extent specified in column 2 of the Table in respect of that person.

(1A) A person listed in column 1 of the following Table who is an employee of, or engaged by, the holder of an authority under regulation 52 to cultivate the narcotic plant Cannabis L., is authorised to possess that narcotic plant in the circumstances and to the extent specified in column 2 of the Table in respect of that person.

Item No.	Column 1 Authorised person	Column 2 Circumstances and extent
1.	A person who transports a narcotic plant cultivated under an authority under regulation 52 after it has been harvested	For the purposes of transport and delivery to the person to whom the consignment of the narcotic plant is addressed
2.	A person who stores a narcotic plant cultivated under an authority under regulation 52 after it has been harvested	For the purposes of storing the narcotic plant after it has been harvested
3.	A person who processes a narcotic plant cultivated under an authority under regulation 52 after it has been harvested	For the purposes of processing the narcotic plant after it has been harvested

(2) In this regulation—

process means treat by mechanical, chemical or other artificial means.

Division 9—Warrants for ovulatory stimulants, prostaglandins, retinoids and thalidomide

53 Requirement for warrants

(1) A registered medical practitioner must not purchase, obtain, use, supply or prescribe an ovulatory stimulant, a prostaglandin, a retinoid or thalidomide unless he or she holds a warrant under the Act to do so.

100 penalty units.

(2) Despite subregulation (1), a registered medical practitioner acting in accordance with the instruction of a registered medical practitioner who holds a warrant may use, supply or prescribe an ovulatory stimulant, a prostaglandin, a retinoid or thalidomide with respect to a specific patient in accordance with the authorisation given by the warrant.

(3) A nurse practitioner acting in accordance with the instruction of a registered medical practitioner who holds a warrant may use, supply or prescribe an ovulatory stimulant, a prostaglandin, a retinoid or thalidomide with respect to a specific patient in accordance with the authorisation given by the warrant.

54 Warrant number to be included in any prescription

(1) A registered medical practitioner who prescribes an ovulatory stimulant, a prostaglandin, a retinoid or thalidomide must include the warrant number on the prescription.

10 penalty units.

(2) A registered medical practitioner or nurse practitioner who prescribes an ovulatory stimulant, a prostaglandin, a retinoid or thalidomide on the direction of the warrant holder must include on the prescription—

(a) the name of the registered medical practitioner who holds the warrant; and

(b) the warrant number.

10 penalty units.

55 Prohibition on dentists

A dentist must not purchase, obtain, use, supply or prescribe an ovulatory stimulant, a prostaglandin, a retinoid or thalidomide.

100 penalty units.

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PART 4—SCHEDULE 3 POISONS

Commentary

Regulation 62 – comment suggests that the prohibition on display of Schedule 3 poisons conflicts with the ability to use in-store advertising Schedule 3 poisons listed in Appendix H of the Poisons Standard. A Note is added to clarify that the regulation does not preclude the advertising of Schedule 3 poisons for sale or supply in accordance with the Poisons Standard.

There have been calls for the mandatory recording of sales of Schedule 3 poisons that are subject to misuse by pharmacists. The regulations do not require mandatory recording of sales of Schedule 3 poisons and given that initiatives are underway through poisons scheduling and real-time prescription monitoring it is not proposed to introduce a regulation at this time. Lack of mandatory recording does not preclude a pharmacist making a record.

57 Therapeutic need to be determined—registered medical practitioners

A registered medical practitioner must not administer, prescribe, sell or supply a Schedule 3 poison unless—

(a) that poison is for the medical treatment of a person under his or her care; and

(b) he or she has taken all reasonable steps to ensure a therapeutic need exists for that poison.

50 penalty units.

58 Therapeutic need to be determined—nurse practitioners

A nurse practitioner must not administer, prescribe, sell or supply a Schedule 3 poison unless—

(a) that poison is for the treatment of a person under his or her care; and

(b) he or she has taken all reasonable steps to ensure a therapeutic need exists for that poison.

50 penalty units.

58A Therapeutic need to be determined—authorised registered nurses

An authorised registered nurse must not administer or supply a Schedule 3 poison unless—

(a) that poison is for the treatment of a person under his or her care; and

(b) he or she has taken all reasonable steps to ensure a therapeutic need exists for that poison.

50 penalty units.

58B Therapeutic need to be determined—authorised registered midwives

An authorised registered midwife must not administer, prescribe, sell or supply a Schedule 3 poison unless—

(a) that poison is for the midwifery treatment of a person under his or her care; and

(b) he or she has taken all reasonable steps to ensure a therapeutic need exists for that poison.

Penalty: 50 penalty units.

59 Therapeutic need to be determined—veterinary practitioners

A veterinary practitioner must not administer, prescribe, sell or supply a Schedule 3 poison unless—

(a) that poison is for the treatment of an animal under his or her care; and

(b) he or she has taken all reasonable steps to ensure a therapeutic need exists for that poison.

50 penalty units.

60 Therapeutic need to be determined—dentists

A dentist must not administer, prescribe, sell or supply a Schedule 3 poison unless—

(a) that poison is for the dental treatment of a person under his or her care; and

(b) he or she has taken all reasonable steps to ensure a therapeutic need exists for that poison.

50 penalty units.

60A Therapeutic need to be determined—authorised optometrists

An authorised optometrist must not administer, prescribe, sell or supply a Schedule 3 poison unless—

(a) that poison is for the ocular treatment of a person under his or her care; and

(b) he or she has taken all reasonable steps to ensure a therapeutic need exists for that poison.

50 penalty units.

60B Therapeutic need to be determined—authorised podiatrists

An authorised podiatrist must not administer, prescribe, sell or supply a Schedule 3 poison unless—

(a) that poison is for the podiatric treatment of a person under his or her care; and

(b) he or she has taken all reasonable steps to ensure a therapeutic need exists for that poison.

50 penalty units.

61 Therapeutic need to be determined—pharmacists

A pharmacist who supplies a Schedule 3 poison other than—

(a) by wholesale; or

(ab) on the residential medication chart of a registered medical practitioner; or

(b) on the prescription of a registered medical practitioner, nurse practitioner, dentist, an authorised registered midwife, an authorised optometrist, an authorised podiatrist or veterinary practitioner—

must do so only for the therapeutic use of a person or animal, after having taken all reasonable steps to ensure a therapeutic need exists for that poison.

50 penalty units.

62 Restrictions on storage and display

A person who is authorised or licensed under the Act to sell or supply Schedule 3 poisons must not keep, store or display any Schedule 3 poison—

(a) in a manner which readily allows self-selection by the public; or

(b) in a manner which will promote the sale of that Schedule 3 poison or draw undue attention to it.

Note Regulation 62 does not preclude the advertising of a Schedule 3 poison for sale or supply in accordance with the Poisons Standard (section 27A(3A) of the Drugs, Poisons and Controlled Substances Act 1981), which in turn considers the Schedule 3 poisons listed in Appendix H.

50 penalty units.

63 Requirements to supply

(1) A registered medical practitioner, pharmacist, veterinary practitioner, dentist, nurse practitioner, an authorised registered nurse, an authorised registered midwife, an authorised optometrist or an authorised podiatrist who sells or supplies a Schedule 3 poison to a person must—

(a) personally deliver or personally supervise its delivery to the person; and

(b) provide directions for the use of the Schedule 3 poison; and

(c) place a label on the container which uniquely identifies the supplier.

50 penalty units.

(2) Subregulation (1) does not apply to a pharmacist who sells or supplies a Schedule 3 poison by wholesale.

(3) Subregulation (1)(a) and (b) do not apply to a pharmacist who sells or supplies a Schedule 3 poison—

(a) on the prescription or residential medication chart of a registered medical practitioner; or

(b) on the prescription of a veterinary practitioner, dentist, nurse practitioner, an authorised registered midwife, an authorised optometrist or an authorised podiatrist.

64 Administration or supply prohibited if to support drug dependency

A person must not administer, prescribe, sell or supply a Schedule 3 poison to a person merely for the purpose of supporting the drug dependence of that person.

50 penalty units.

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PART 5—SCHEDULE 7 POISONS

Commentary

Regulation 66 is deleted because Schedule 7 poison retail storage requirements are now included in the Poisons Standard and adopted by reference under section 27A of the Act.

65 Controls concerning listed regulated poisons

A person must not manufacture, sell, supply, purchase or otherwise obtain, possess or use a listed regulated poison unless the person is authorised, licensed or permitted under the Act or these Regulations to do so.

100 penalty units.

67 Licences, permits or warrants required for special Schedule 7 substances

A person must not possess or use a special Schedule 7 substance unless he or she holds a licence, permit or warrant issued under the Act.

100 penalty units.

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PART 6—GENERAL REQUIREMENTS

Commentary

Regulation 70 has been amended to place an additional requirement on registered medical practitioners, pharmacists, veterinary practitioners, dentists, nurse practitioners, authorised registered midwives, authorised optometrists and authorised podiatrists and licence, permit and warrant holders who become aware of loss or theft of poisons or controlled substances to report the matter to both the Secretary and Victoria Police. It is likely to facilitate investigations if the Department of Health and Human Services is aware of loss or theft where poisons held by registered health practitioners are involved.

Regulation 70 is amended to remove the reference to high level residential care as this term is no longer referenced by Commonwealth *Aged Care Act 1997*. The regulation is to apply to all approved providers on the basis that most approved providers would already need to comply.

68 Poisons to be sold by wholesale and retail in original unopened packs

(1) A person who sells or supplies a poison or controlled substance by wholesale or retail must sell or supply that poison or controlled substance only in the original unopened pack as received from the person who supplied that wholesaler or retailer.

50 penalty units.

(2) Subregulation (1) does not apply to the sale or supply of a poison or controlled substance in the course of his or her professional practice by a person authorised under section 13(1) of the Act with respect to that poison or controlled substance.

69 Transfer of poisons to inappropriate containers prohibited

Except in the course of actual use of a poison or controlled substance, a person must not remove that poison or controlled substance from the container in which it was dispensed, sold or supplied to put that poison or controlled substance—

(a) into an unlabelled receptacle or container; or

(b) into a receptacle or container which does not accurately identify that poison or controlled substance.

50 penalty units.

70 Lost or stolen poisons to be notified

(1) A person to whom this regulation applies who loses a poison or controlled substance or from whom a poison or controlled substance is stolen must immediately upon becoming aware of that loss or theft notify the Secretary or a member of the Victoria Police of the loss or theft.

20 penalty units.

(2) *Subregulation (1)* applies to—

(c) a person who is referred to in Column 1 of Part 2 of the table in regulation 5; or

(d) a person who sells or supplies any Schedule 7 poison by retail; or

(e) a person who is an approved provider of an aged care service *where there is a resident who has been supplied—*

(A) on a prescription or on a residential medication chart with a Schedule 4 poison; or

(B) on a prescription with a Schedule 8 poison or a Schedule 9 poison.

(3) A person to whom this regulation applies who loses a poison or controlled substance or from whom a poison or controlled substance is stolen must immediately upon becoming aware of that loss or theft notify the Secretary and a member of the Victoria Police of the loss or theft.

20 penalty units.

(4) Subregulation (3) applies to—

(a) a registered medical practitioner, pharmacist, veterinary practitioner, dentist, nurse practitioner, an authorised registered midwife, an authorised optometrist and an authorised podiatrist; or

(b) a person who holds a licence, permit or warrant issued under the Act or these Regulations.

71 Access to certain poisons restricted to a needs basis

A person who is authorised by, or licensed or permitted under, the Act or the regulations, to be in possession of a Schedule 4 poison, listed regulated poison, Schedule 8 poison or Schedule 9 poison must take all reasonable steps to restrict access to that poison or controlled substance to—

(a) persons who are authorised by, or licensed or permitted under the Act or the regulations, to be in possession of that poison or controlled substance; and

(b) persons to whom access is required for carrying out essential operations in relation to that poison or controlled substance.

100 penalty units.

72 Form of seizure notice under section 43(1) of the Act

For the purposes of section 43(1) of the Act, the prescribed form is the form of DP4 in Schedule 2.

73 Form of complaint notice under section 43(2) of the Act

For the purposes of section 43(2) of the Act, the prescribed form is the form of DP5 in Schedule 2.

These forms are not included in the Consultation Draft.

PART 7—LICENCES AND PERMITS ISSUED UNDER THE ACT

74 Licences to sell or supply Schedule 2 poisons by retail

The Secretary must not grant to a person a licence under the Act to sell or supply by retail a Schedule 2 poison unless the business premises of that person are situated at least 25 kilometres distance away by the shortest practicable road from the nearest pharmacy business.

75 Fees

Fees are under review and are not included in the Consultation Draft.

PART 7—LICENCES AND PERMITS ISSUED UNDER THE ACT

74 Licences to sell or supply Schedule 2 poisons by retail

The Secretary must not grant to a person a licence under the Act to sell or supply by retail a Schedule 2 poison unless the business premises of that person are situated at least 25 kilometres distance away by the shortest practicable road from the nearest pharmacy business.

SCHEDULE 2

FORMS

FORM DP2A

FORM DP2A PART B: FOR TREATMENT OF AN OPIOID DEPENDENT PERSON WITH METHADONE OR BUPRENORPHINE

Commentary

Form DP2A PART B is to be amended to include a field for the prescriber to add the Aboriginal and Torres Strait Islander status of the person to be treated with pharmacotherapy. Aboriginal and Torres Strait Islander status of Victorian pharmacotherapy clients is to be used in compiling national statistics and in local demographic data for use in developing future programs. Comments are requested on this option or other options for collecting Aboriginal and Torres Strait Islander status of clients receiving pharmacotherapy for the pharmacotherapy program.