Proposed Drugs, Poisons and Controlled Substances Regulations 2017

Regulatory impact statement

VICTORIA State Government | Health and Human Services

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Executive summary

The proposed Drugs, Poisons and Controlled Substances Regulations 2017 will replace the current Drugs, Poisons and Controlled Substances Regulations 2006, which are due to sunset according to the operation of the *Subordinate Legislation Act 1994*. The proposed regulations have partially restructured the existing regulations but introduce only limited amendments.

The *Drugs, Poisons and Controlled Substances Act 1981* (the Act) is the central piece of Victorian legislation that, among other things, seeks to control the manufacture, supply, labelling, packaging, storage, advertising, prescription, possession and use of drugs, poisons and controlled substances (may be referred to collectively in this document as 'drugs and poisons'). By so doing, it seeks to minimise harms to the community due to the misuse of pharmaceutical drugs and commonly used poisons that pose a risk to public health and safety.[1]

The Drugs, Poisons and Controlled Substances Regulations 2006 constitute the principal regulations made under the Act. For drugs and poisons, they establish controls that are commensurate with the relative risks to the public of the various regulated substances on:

- possession
- treatment
- supply
- administration (or use in treatment)
- storage
- record keeping
- destruction.

The regulations provide for secure arrangements when a doctor or other registered practitioner administers, prescribes or supplies a drug. These drugs can only be provided if the patient has a therapeutic need and in containers specifically labelled for individual patients or animals. The regulations establish the rules for issuing a prescription or other instruction and, for pharmacists, the rules for supplying drugs to a patient on a prescription. The regulations require that drugs and poisons are securely stored for access only by practitioners or other authorised persons to prevent theft, diversion or misuse. The records kept under the regulations allow for missing drugs to be identified quickly and steps taken to prevent further loss or diversion. These controls are in place because of the serious consequences of the ineffective use of drugs, the misuse of drugs and exposure to poisons by the public.

The harm associated with the misuse of drugs (including pharmaceutical drugs) and poisons can be substantial and severe. Research indicates that in 2013, 4.7 per cent of the Australian population 14 years of age or older misused pharmaceutical drugs in the preceding 12 months, indicating a significant increase from previous years.[2] In Victoria in 2014, pharmaceuticals were implicated in 82 per cent of the 384 deaths due to drug overdose (involving pharmaceutical drugs, illicit substances or alcohol), while pharmaceuticals were the only drug involved in 42 per cent of overdose deaths.[3]

[1] Poisons may be deliberately used as such in the agricultural context – that is, to control noxious plants or animals – whereas in various industrial contexts, a chemical is used as a result of other, specific properties that it possesses, while its toxicity is a by-product giving rise to the need for control of its use.
[2] Australian Institute of Health and Welfare 2013, *National Drug Strategy Household Survey: detailed report,* AIHW, Canberra. See Chapter 6.
[3] Jamieson, A 2015, *Pharmaceutical drugs in fatal overdose: a coroner's perspective*, International Medicine in Addiction Conference, Melbourne, 21 March 2015.

Fatal and non-fatal drug overdose imposes costs on individuals and society. Non-fatal overdose is a significant cause of hospital admissions, with around 7,000 such admissions occurring across Australia in in 2009–10.[4] The extent of misuse and associated costs may increase in future, given international and national trends towards the more widespread prescription of opioids.

Given the extent of these harms, there is a substantial body of legislation in place that seeks to minimise them, including several international treaties to which Australia is a signatory, as well as federal, state and territory legislation. The proposed regulations discussed in this regulatory impact statement (RIS) necessarily operate within this broader context and are substantially constrained by it. In Australia and Victoria, drugs and poisons have been regulated for many decades under an approach that has remained broadly similar over time. Consequently, the future regulatory regime in Victoria is likely to continue to involve incremental change to the existing regulations to address particular concerns as they are identified and to progressively improve the effectiveness of the regulations.

As the current (and proposed) regulations discussed in this RIS constitute only one part of the broader system of regulation just outlined, it is not possible to directly observe the benefits of the regulations by reference to an unregulated base case. However, the current annual cost of hospitalisations associated with the toxic effects of drugs in Victoria has been estimated at around $8.6 million. In the absence of these regulatory controls on access to pharmaceutical drugs by those who would seek to misuse them, these costs would necessarily increase, most likely by a substantial amount.

The costs of compliance with the proposed regulations were estimated for this RIS from 58 responses to a questionnaire sent to a sample of 300 holders of licences and permits issued under s. 19 of the Act. The key costs identified relate to secure storage, record keeping, drug destruction and regulatory administration.

Table S1 summarises these costs, reporting estimates of both the 'business as usual' (BAU) costs incurred by licence and permit holders (those costs that would be incurred even in the absence of the regulations) and the incremental costs attributed to the regulatory requirements. It shows that if the incremental costs of the regulations are extrapolated across all the licence and permit holders (approximately 1,450) they are estimated to total $6.44 million per annum and to represent an increase on BAU costs of approximately 10.3 per cent.

Table S1: Summary of regulatory costs

Cost category	BAU* costs p.a. (million)	Incremental cost (million)	Incremental %
Storage	$8.6	$0.24	2.8%
Record keeping	$27.5	$2.9	10.5%
Drug destruction	$26.3	$2.8	10.6%
Administration	$0	$0.5	NA
Total	**$62.4**	**$6.44**	**10.3%**

* *These figures estimate the costs that businesses would incur in the absence of the regulations, due to the need to safeguard their commercial interests and reputation, and other factors. The estimated costs are derived from the questionnaire responses received from licence and permit holders.*

[4] Tovell A, McKenna K, Bradley C, Pointer S 2012, *Hospital separations due to injury and poisoning, Australia 2009–10*, Australian Institute of Health and Welfare Injury Research and Statistics Series no. 69, p. 44.

By comparison, it can be noted that the recommended standard Value of a Statistical Life used in the RIS context in Victoria is approximately $4.3 million.[5] This implies that, if the regulations are effective in reducing the number of overdose deaths due to the misuse of pharmaceutical drugs by 1.5 per annum on average, or around one per cent of the current average annual death rate due to pharmaceutical drug overdoses,[6] the regulations would yield net benefits to society. The Department of Health and Human Services ('the department') is satisfied that the impact of the regulations is larger than this and that the proposed regulations will yield substantial net benefits for the Victorian population.

The department considers that the range of alternative approaches to achieving the identified regulatory objectives is constrained as the Victorian regulations constitute an integral part of a larger legislative system. The RIS considers feasible alternatives. It discusses two options for different regulatory approaches and a third option for specific changes to the current regulations that were identified through the consultation and questionnaire processes used to support the development of the RIS.

Licence and permit fees

Licences and permits for business are issued under s. 19 of the Act and patient-specific treatment warrants and permits are issued under s. 19 and s. 34A of the Act and regulation 22B. The regulations may establish fees to be paid by licence, permit and warrant holders.

A review of regulatory costs incurred by the department in administering these regulations and their distribution across the various groups of licence, permit and warrant holders has been conducted as part of the process of developing the proposed regulations. The review has concluded that the regulatory fee for licences and permits issued under s.19 should continue to be cost recovered. It has further concluded that the issuing of patient-specific treatment warrants and permits, currently costing the department approximately $1 million per annum should continue not to incur a regulatory fee in the public interest (see section 4.3).

A new fee structure is proposed for licences and permits issued under s. 19 to be adopted that will achieve a better match between the costs incurred by the department and the fees paid by licence and permit holders. This will result in some significant changes in individual fees, with some increasing and others decreasing. However, there will be no change in the total revenue the department collects from the fees.

Table S2 summarises the existing and proposed fees for new licence and permit applications, renewals and amendments. It shows that most new licence application fees will increase significantly. For five licence categories the increases will be more than 50 per cent, while for a further five categories the increase will be 40–50 per cent. Conversely, two licence categories will see virtually no change in application fee, while three will experience fee reductions in the vicinity of 13 per cent.

In contrast to the position with new licence and permit applications, the majority of licence and permit categories will see significant reductions in licence and permit renewal fees. Seven of 17 licence and permit categories will see renewal fee reductions of approximately 30 per cent or more, while six more categories will see smaller reductions. Four renewal categories will increase, with the maximum increase being 18.8 per cent.

The amendment fee where inspections are required will increase in line with the new application fee. Amendments where inspections are not required will also increase. An amendment fee for wholly administrative changes will not be separately charged.

[5] See the OCBR website at www.ocbr.vic.gov.au for an explanation of the sources of this estimate.
[6] As shown in section 2, there have been an average of 369 overdose deaths in Victoria in the six years to 2014, while 42 per cent – or around 155 per annum – have been solely attributable to pharmaceutical drugs.

Table S2: Comparison between the existing and proposed regulatory fees for applications, renewals and amendments for licences and permits issued under s. 19 of the Act

Licence/ Permit	Code	Licence or permit	Application: Proposed fees (existing fees) and difference (%)	Renewal: Proposed fees (existing fees) and difference (%)	Amendment:[*, †, ‡] Proposed fees (existing fees) and difference (%)
Licences	MA	Manufacture and sell or supply by wholesale any Schedule 8 or Schedule 9 poison other than heroin	$1,316.99 ($1,499.90) –12.2%	$282.53 ($1,028.80) –72.5%	$189.00 ($73.90) 155.8%
	MP 4	Manufacture and sell or supply by wholesale any Schedule 4 poison alone or with any Schedule 2, 3 or 7 poison	$1,165.70 ($1,098.50) 6.1%	256.79 ($538.10) –52.3%	$189.00 ($73.90) 155.8%
	MP 2, 3, 7	Manufacture and sell or supply by wholesale any Schedule 2, Schedule 3 or Schedule 7 poison	$1,165.70 ($793.20) 47.0%	256.79 ($280.20) –8.4%	$189.00 ($73.90) 155.8%
	MPR 7	Manufacture and sell or supply by retail any Schedule 7 poison	$1,165.70 ($687.20) 69.6%	256.79 ($259.30) –1.0%	$189.00 ($73.90) 155.8%
	WA	Sell or supply by wholesale any Schedule 8 or Schedule 9 poison other than heroin	$1,316.99 ($1,499.90) –12.2%	$282.53 ($1,028.80) –72.5%	$189.00 ($73.90) 155.8%
	WP 4	Sell or supply by wholesale any Schedule 4 poison alone or together with any Schedule 2, 3 or 7 poison	$1,165.70 ($1,098.50 6.1%	256.79 ($538.10) –52.2%	$189.00 ($73.90) 155.8%
	WP 2, 3, 7	Sell or supply by wholesale any Schedule 2, 3 or 7 poison	$1,165.70 ($793.20) 47.0%	256.79 ($280.20) –8.4%	$189.00 ($73.90) 155.8%
	WA Indent	Sell or supply by wholesale any Schedule 8 or Schedule 9 poison other than heroin by indent	$1,014.41 ($687.20) 47.6%	231.05 ($465.60) –50.4%	$189.00 ($73.90) 155.8%
	WP 4 Indent	Sell or supply by wholesale any Schedule 4 poison (alone or in combination with any Schedule 2, 3 or 7 poison) by indent	$1,014.41 ($687.20) 47.6%	231.05 ($316.40) –27.0%	$189.00 ($73.90) 155.8%
	WP 2, 3, 7 Indent	Sell or supply by wholesale any Schedule 2, 3 or 7 poison alone or any combination of those poisons by indent	$1,014.41 ($687.20) 47.6%	231.05 ($259.30) –10.9%	$189.00 $73.90 155.8%

Licence/ Permit	Code	Licence or permit	Application: Proposed fees (existing fees) and difference (%)	Renewal: Proposed fees (existing fees) and difference (%)	Amendment:[*, †, ‡] Proposed fees (existing fees) and difference (%)
	GDL	Sell or supply by retail any Schedule 2 poison	$1,014.41 ($469.80) 115.9%	231.05 ($196.60) 17.5%	$189.00 ($73.90) 155.8%
Permits	Permit 8, 9	Permit to purchase or otherwise obtain and use for industrial, educational, advisory or research purposes any Schedule 8 or Schedule 9 poison (alone or together with any Schedule 2, 3, 4 or 7 poison)	$1,316.99 ($666.30) 97.7%	$282.53 ($255.10) 10.8%	$189.00 ($73.90) 155.8%
	Permit 2, 3, 4, 7	Permit to purchase or otherwise obtain and use for industrial, educational, advisory or research purposes any Schedule 2, Schedule 3, Schedule 4 or Schedule 7 poison	$1,165.70 ($610.60) 90.9%	256.79 ($216.10) 18.8%	$189.00 ($73.90) 155.8%
	HSP Type A	Health service: Single site with no beds	$1,014.41 ($504.60) 101.0%	231.05 ($200.70) 15.1%	$189.00 ($73.90) 155.8%
	HSP Type B	Health service: Residential aged care with single storage facility (no bed limit) *or* single site with 1–30 beds	$1,014.41 ($773.70) 31.1%	231.05 ($285.80) –19.2%	$189.00 ($73.90) 155.8%
	HSP Type C	Health service: Multiple sites with no beds *or* single site with 31–100 beds	$1,316.99 ($1,063.60) 23.8%	$282.53 ($476.70) –40.7%	$189.00 ($73.90) 155.8%
	HSP Type D	Health service: Multiple sites *or* single site with more than 100 beds	$1,316.99 ($1,508.30) –12.7%	$282.53 ($673.30) –58.0%	$189.00 ($73.90) 155.8%

[*] *Amendments of licences or permits that require inspection of the premises incur the application fee.*

[†] *Amendments that do not require an inspection of the premises incur this amendment fee.*

[‡] *The fee for wholly administrative amendments is included in the renewal fee.*

In summary, the proposed regulations discussed in this RIS have been arrived at via an iterative process of refinement and improvement of the existing regulations. Section 5 considers alternatives in the remaking of the current regulations. Section 9 explains why the department considers that the most feasible option at this time is to modify provisions of the existing regulations. The process of refining the regulations is an ongoing one, and there is potential for some identified policy options to be considered in the future. The most likely next amendments to the remade regulations will concern the introduction of real-time prescription monitoring.

Public Comments

Public comments are invited on the RIS and the proposed Regulations. All comments must be in writing and should be marked 'DPCS Regulation Review'.

Comments must be received no later than 5pm on **Thursday 20 April 2017** via email to: dpcs@dhhs.vic.gov.au

or by mail to: Project Manager, DPCS Regulation Review, Drugs and Poisons Regulation, Department of Health, 50 Lonsdale Street, Melbourne, Victoria 3000.

All comments and submissions will be treated as public documents, unless the person making the comment or submission requests that it not be publicly available.

1 Background

1.1 Introduction

The Drugs, Poisons and Controlled Substances Regulations 2006 are the current principal regulations made under the *Drugs, Poisons and Controlled Substances Act 1981* ('the Act'). The proposed Drugs, Poisons and Controlled Substances Regulations 2017 ('the proposed regulations') will replace the current regulations, which will sunset in May 2017 due to the operation of the *Subordinate Legislation Act 1994*.

The Act is the central piece of Victorian legislation that, among other things, seeks to control the manufacture, supply, labelling, packaging, storage, advertising, prescription, possession and use of drugs, poisons and controlled substances (may be referred to collectively as 'drugs and poisons'). In so doing, it seeks to promote safe use and minimise harms to the community due to the misuse of pharmaceutical drugs and commonly used poisons that pose a risk to public health and safety.

The scope of the Act and current regulations includes pharmaceutical drugs and poisons that:

- are subject to significant risk of misuse
- have a potential to cause harm if administered inappropriately and thus must be taken subject to expert advice, or
- require legislative control due to their inherent dangers (includes agricultural, consumer and industrial chemicals that pose a risk to public health).

The current regulations establish treatment, supply, administration, storage, reporting and destruction requirements, which vary in stringency according to the public risk of the drugs or poisons in question.

The proposed regulations do not alter the intent of the current regulations and make only limited amendments.

1.2 International and national regulatory context

The approach taken by federal, state and territory governments to the regulation of pharmaceutical drugs and poisons is guided by the operation of a number of intergovernmental treaties and agreements. These include international treaties, to which the federal government is a signatory, and Commonwealth–state agreements. Many quite extensive and specific obligations exist as a result of these international and national obligations.

At the international level, three significant conventions can be identified:

- the United Nations *Single Convention on Narcotic Drugs* (1961) – this convention applies to cannabis, cocaine and opium, as well as drugs with like effects (for example, synthetic variants)
- the United Nations *Convention on Psychotropic Substances* (1971) – this convention covers a range of additional drug types, most of which had only become widely available in the 1960s, including amphetamine-type stimulants, benzodiazepines, barbiturates and psychedelics
- the United Nations *Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances* (1988) – this convention includes provisions designed to prevent trafficking in the drugs covered by the above conventions and includes controls on precursor chemicals.

The conventions have been adopted pursuant to a generally accepted view that the non-therapeutic use of the drugs within their scope causes substantial harm to public health. The prohibitionist approach adopted by the conventions, as translated into federal, state and territory legislation, gives rise to the need to implement controls to limit access to these drugs. Drugs and poisons legislation in each state and territory assist Australia in meeting its monitoring and reporting obligations under the

conventions. A substantial proportion of the pharmaceutical drugs that are within the scope of the Act and current regulations are addressed by one or more of the above conventions.

Australia has an extensive set of Commonwealth, state and territory legislation governing access to, and supply of, pharmaceutical drugs and restricted poisons. Commonwealth legislation largely controls importation and the assessment of end-use safety, quality and efficacy of medicines and agricultural chemicals registered for use in Australia. State and territory legislation imposes control-of-use restrictions that cover who may supply these substances, to whom they may be supplied and under what circumstances.

In line with this delineation of responsibilities between the two levels of government, the Commonwealth government administers a national system for applying restrictions on access to drugs and poisons under the *Therapeutic Goods Act 1989*. Substances deemed to be a risk to public health are classified in accordance with the *Scheduling policy framework*, a guideline of the Australian Health Ministers' Advisory Council and published in the Standard for the Uniform Scheduling of Medicines and Poisons (the 'Poisons Standard'), a Commonwealth regulatory instrument.

The *Scheduling policy framework* establishes a classification framework for pharmaceutical drugs and poisons, with each drug or poison that meets specific criteria being included in a schedule (Schedules 2–10) of the Poisons Standard.

All states and territories adopt the Schedules of the Poisons Standard through their respective drugs and poisons legislation. As a result, there is a high degree of uniformity with respect to the legislation and regulatory controls applied across the states and territories. That said, some differences between state or territory controls do exist, such as those surrounding medicinal cannabis.

1.3 Regulatory arrangements in Victoria

In Victoria the Act and the current regulations constitute the key legislative instruments that control access to poisons within Schedules 2–10 of the Poisons Standard and how they may be handled and used. The general approach, which has been in place in Victoria for many decades, involves restricting access to these substances to those who need them, and to those properly equipped to handle them. The key mechanisms under the Act to achieve this are:

- **authorisation** of registered practitioners and others under the Act to obtain, possess, use, sell or supply (including prescribe) drugs and poisons as the case requires
- **licences** that authorise people to manufacture, sell and/or supply drugs and poisons
- **permits** that allow people to purchase or obtain drugs, poisons or controlled substances for industrial, educational, advisory or research purposes, or for providing health services
- **adopting by reference** the schedules and the labelling, packaging, storage and advertising provisions of the Poisons Standard.

A key function of the regulations is to establish secure treatment, supply, administration, storage and reporting and destruction requirements, commensurate with the inherent risk of the substances that have been allocated to Schedules 2–10 of the Poisons Standard. The regulations give effect to the Act in a number of ways:

- They **authorise particular classes of people** who would not otherwise be authorised to be in possession of drugs and poisons. If the regulations did not exist, the only people able to obtain, possess and use a drug or poison would be a registered practitioner. The Act envisages, however, that regulations may authorise others (such as carers, nurses, ambulance officers, emergency workers, ship and yacht crew members and other practitioners outside the professions) to be in lawful possession of drugs or poisons in certain specified circumstances consistent with their specific professional or personal role.

- They **establish consistent standards** for equivalent functions such as the writing of a prescription, making a record of the supply of a medicine and the secure storage needed for medicines, carried out by the range of registered practitioners and others.
- They **set limits on the scope of lawful practice** of practitioners in relation to the use, supply and prescription of drugs and specify that activity outside this scope constitutes an offence. This includes that practitioners can only administer, supply or prescribe medicines to patients who are under their care and have a therapeutic need for those medicines.
- They prescribe **forms and fees**.

It should be noted that various parts of the Act effectively prohibit certain activities except to the extent that they are specifically authorised by the regulations. To this extent, the regulations can be seen as permitting, rather than prohibiting, various matters in connection with drugs and poisons.

The Act and the regulations are administered by the Department of Health and Human Services ('the department') and apply to a wide range of stakeholders including:

- registered practitioners, including medical practitioners, pharmacists, dentists, dental hygienists, dental therapists, oral health therapists, optometrists, orthoptists, veterinary practitioners, podiatrists, nurse practitioners, nurses and midwives
- the pharmaceutical, chemical and other industries
- educational and research bodies
- organisations providing healthcare services such as ambulance services, non-emergency patient transport, medical clinics, day procedure centres, hospitals and approved providers of residential aged care
- miscellaneous organisations with a genuine need to possess drugs or poisons such as ship masters, yacht owners, qualified ski patrollers, the director of State Emergency Services and municipal officers, environmental health officers and immunisation nurses
- the public (members of the public may possess scheduled medicines supplied for therapeutic purposes to themselves or people under their care)
- certain poisons retailers
- animal custodians.

Table 1 details the number of practitioners in each of the categories of registered practitioners affected by these regulations.

Table 1: Registered practitioners, Victoria (November 2016)

Practitioner type	Number (Victoria)
Medical practitioners	25,574
Pharmacists	7,070
Dentists*	4,857
Veterinarians	2,963
Nurses and midwives†	98,678
Nurse practitioners	274
Optometrists‡	1,280
Podiatrists^	1,443

* *Includes dental therapists, dental hygienists and oral health therapists*

† *Includes nurses with a rural and isolated practice endorsement (164)*

‡ *Includes optometrists with a scheduled medicines endorsement (839)*

^ *Includes podiatrists with a Scheduled Medicines endorsement (24)*

As part of its role in administering the regulations, the department administers[7] approximately 1,500 licences and permits that relate to premises (issued under s. 19 of the Act) (see Table 2). Licences allow manufacturing, wholesaling or retailing activities of drugs and poisons (Schedule 2, 3, 4, 7, 8 and 9 poisons) and permits allow educational, research and industrial entities and health services to obtain the drugs and poisons (Schedule 2, 3, 4, 7, 8 and 9 poisons) that they need. Almost half of the permits are issued to health services. The department assesses all new applications, with the assessments including inspection of the applicant's premises, and conducts regular audits of the premises of licence and permit holders. It reviews security and storage arrangements, as well as internal processes such as ordering and supply systems, to assess their capacity to comply with the regulations. The costs incurred by the department in conducting these activities are fully recovered by licence and permit holders through fees (see section 8).

The department issues a variety of licences and permits. Table 2 sets out the number of current licences and permits by broad category, as of November 2016. A total of 123 applications for new licences and permits (as distinct from renewals of existing licences and permits) were received in 2015–16, a figure that is broadly similar to the annual number of new licence and permit applications received in recent years.

Table 2: Licences and permits according to broad category, November 2016*

Licence/permit category	Number
Licence to manufacture and sell by wholesale scheduled poisons†	146
Licence to sell scheduled poisons by wholesale‡	294
Licence to sell scheduled poisons by wholesale by indent^	26
Permit – educational	116
Licence as a general dealer in poisons	18
Permit – industrial	230
Permit – health services	687
Licence to manufacture and sell Schedule 7 poisons (other than listed regulated poisons) by retail	3

* *Data current as of November 2016; some organisations hold more than one category of permit*

† *Includes multiple classes, including scheduled poisons, controlled substances and drugs of addiction (other than heroin)*

‡ *Includes multiple classes, including scheduled poisons, controlled substances and drugs of addiction (other than heroin)*

^ *Includes multiple classes, including scheduled poisons, controlled substances and drugs of addiction (other than heroin); indent refers to licences whereby substances are ordered from but not stored at the premises*

The department is required to inspect the proposed premises of any applicant for a new licence or permit to ensure they are able to meet the required security and storage requirements. In addition, the department conducts a program of audits of existing licence and permit holders to check that they are continuing to comply with the security, storage, record keeping and related requirements of the regulations. Other departmental activities in connection with licence and permit holders include assistance in investigations of misappropriation, including being engaged in prosecutions of individual practitioners. Importantly, the department also works to support proactive responses, for example by:

[7] That is, issues, renews, amends and monitors.

- considering the scope for system review and redesign to enable the objectives of the regulations to be achieved more effectively
- informing and educating registered practitioners where breaches of the legislation are identified. Approximately 2,000 of these interventions are recorded each year.

Investigations are initiated where more serious or extensive breaches are identified. There may be more than 30 active investigations at any time, predominantly concerning practitioners. Approximately six cases are successfully prosecuted each year. The department works cooperatively with the Australian Health Practitioner Regulation Agency (AHPRA), the Veterinary Practitioners Board of Victoria and Victoria Police and refers cases as appropriate.

The department issues warrants under s. 19 of the Act and administers patient-specific Schedule 8 treatment permits issued under s. 34A of the Act. These warrants and permits do not attract a regulatory fee. Approximately 51,500 permits and 114 warrants were issued to medical practitioners or nurse practitioners on behalf of their patients in 2015–16.

The department also provides direct assistance on the requirements of the Act and regulations to practitioners, licence/permit holders and members of the public via telephone and email advice lines.

2 Nature and extent of the problem

2.1. Misuse of controlled substances

In the context of the current regulations, a poison is a substance that may produce harmful effects in people if they are exposed inappropriately – that is, exposed to too much of the substance or in the wrong way. Pharmaceutical drugs are therefore poisons that may have beneficial therapeutic effects but can still cause harm if used incorrectly. Incorrect use can include treatment with the wrong drug, incorrect use of a correctly prescribed drug (for example, due to human error or other reasons such as inadequate labelling) and intentional misuse (whether for hedonic reasons or as a vehicle for suicide).

The regulations broadly address two general areas: the use and misuse of pharmaceutical drugs; and the use and misuse of poisons for agricultural, consumer, industrial or other purposes.[8]

2.2. Misuse of pharmaceutical drugs

Misuse of pharmaceutical drugs can be defined as the use of these drugs for non-therapeutic purposes or use that, while commenced for therapeutic reasons, occurs in inappropriate doses or durations. Misuse may result in harm. Some in the community seek to misuse pharmaceuticals that may have been provided on a prescription written by a doctor or other practitioner (substances in Schedule 4 and Schedule 8 of the Poisons Standard) or available following consultation with a pharmacist (substances in Schedule 3 of the Poisons Standard). Such misuse can have substantial negative health impacts on the affected individuals and impose major societal costs on the health system and the broader economy.

Extent of misuse of pharmaceutical drugs

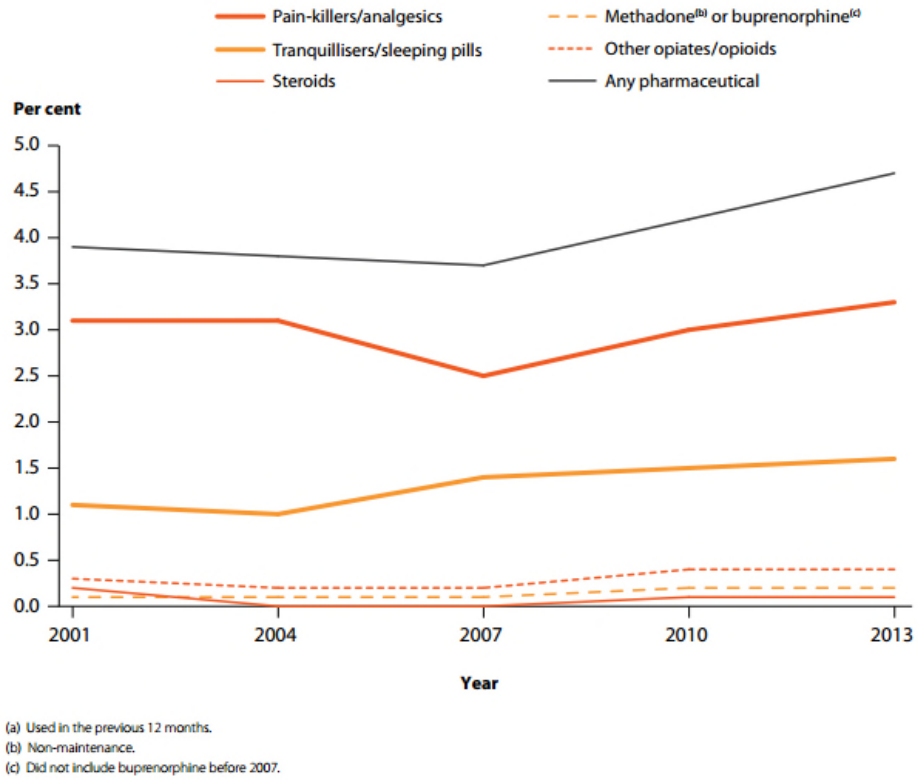
Government data indicates that, even in the presence of existing legislative controls on the supply of prescription pharmaceuticals, a significant and increasing proportion of the population misuses these drugs.

The 2013 National Drug Strategy Household Survey,[9] carried out by the Australian Institute of Health and Welfare, reported that 4.7 per cent of Australians 14 years of age or older, or 900,000 people, had misused pharmaceuticals in the 12 months preceding the survey. This was an increase from 4.2 per cent in 2010. Longer term data demonstrated an increase in lifetime incidence of pharmaceutical misuse, with 11.4 per cent of the population reporting misuse at some point in their lifetime, up from 7.4 per cent in 2010. Painkillers/analgesics were found to be the most commonly misused drug (3.3 per cent of the population), followed by tranquillisers/sleeping pills (1.6 per cent).

Figure 1 reflects an overall increasing trend of pharmaceutical misuse[10] since 2001. Of note, it demonstrates a sharp increase from 2007, reflecting large absolute increases in the misuse of analgesics and tranquillisers.

[8] Poisons may be deliberately used as such in the agricultural context (to control noxious plants or animals), whereas in various industrial contexts, a chemical is used as a result of other, specific properties that it possesses, while its toxicity is a by-product giving rise to the need for control of its use.
[9] Australian Institute of Health and Welfare 2013, *National Drug Strategy Household Survey: detailed report*, AIHW, Canberra.
[10] That is, misuse at any time within the preceding 12 months.

Figure 1: Rate of misuse of pharmaceuticals since 2001



Source: Australian Institute of Health and Welfare 2013, National Drug Strategy Household Survey: detailed report, *AIHW, Canberra, p. 72.*

Of people misusing pharmaceuticals, 31 per cent of females and 28 per cent of males did so at least weekly. Among misusers of analgesics, 78 per cent misused over-the-counter drugs and 51 per cent misused prescription drugs. The rates of misuse of pharmaceuticals differ relatively little between states and territories, and the overall rate of misuse in Victoria is approximately equal to the national average.[11]

The recorded increases in pharmaceutical drug misuse have occurred despite existing, long-term regulations controlling availability. Nonetheless, the department considers that the extent of harm associated with the misuse of pharmaceutical drugs would be greater in the absence of the current legislative and regulatory interventions, including the current regulations, and other recent policy initiatives addressing pharmaceutical misuse such as the adoption of the *National pharmaceutical drug misuse framework for action (2012–2015)* and Project STOP, an online decision-making tool supporting pharmacists in the supply of pseudoephedrine-containing products.

2.3 Harms due to misuse of pharmaceutical drugs

The harms that arise due to the misuse of pharmaceuticals can be broadly divided into 'acute' and 'chronic' harms. In the former category are overdose-related deaths, hospital treatment admissions and emergency department visits, while the latter category includes issues following from drug dependence including reduced productivity, increased chronic health problems and a range of social problems.

[11] Australian Institute of Health and Welfare 2013, op. cit., p. 81.

Deaths due to overdose

In the six years to 2014, 2,214 deaths due to drug overdose were recorded in Victoria, which is equivalent to an average of 369 deaths per year. This total includes deaths due to overdoses from all types of drugs including illicit drugs, pharmaceuticals and alcohol. Evidence from the Coroner's Court (Table 3) shows that a substantially higher proportion of overdose deaths in Victoria involve pharmaceuticals rather than illicit drugs or alcohol.

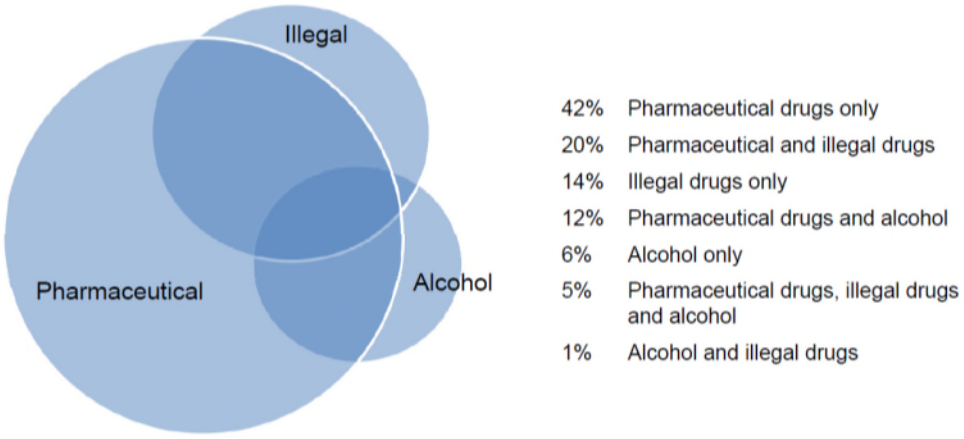
Table 3: Involvement of major drug categories in overdose deaths, Victoria

Year	2009	2010	2011	2012	2013	2014
All overdoses	379	342	362	368	379	384
Pharmaceutical (%)	77.8	77.8	76.0	83.4	82.3	82.0
Illicit (%)	38.8	43.6	42.3	36.1	43.8	42.2
Alcohol (%)	24.8	24.9	24.3	21.7	24.8	24.2

Source: Jamieson A 2015, Pharmaceutical drugs in fatal overdose: a coroner's perspective*, International Medicine in Addiction Conference, Melbourne, 21 March 2015.*

Both the total number of overdose deaths and the proportion involving pharmaceuticals have demonstrated a gradual upward trend over the past six years. More than one type of drug is typically implicated in overdose deaths. Figure 2 demonstrates the interaction between the various drug categories in terms of the extent of their involvement in overdose deaths.

Figure 2: The pharmaceuticals–illegal drugs–alcohol nexus (2014)



Source: Jamieson A 2015, Pharmaceutical drugs in fatal overdose: a coroner's perspective*, International Medicine in Addiction Conference, Melbourne, 21 March 2015.*

Pharmaceutical drugs constitute the sole cause of 42 per cent of all overdose deaths. This is the largest category of drugs implicated in overdose deaths, responsible for more overdose deaths in Victoria than any other drug type or combination of drug types. Although the data does not differentiate between accidental or intentional overdose, the increased availability of pharmaceutical drugs compared with illicit drugs does support the premise that increasing availability of pharmaceutical drugs contributes to increased public harm.

Hospitalisations due to poisoning by pharmaceuticals

Non-fatal poisoning from the misuse of pharmaceuticals also results in significant morbidity. Table 4 reflects hospitalisations due to poisoning by pharmaceuticals in Australia in 2009–10: more than 6,600 people were admitted to hospital, a rate of 29.8 per hundred thousand population. This accounted for around 1.5 per cent of all hospitalisations due to injury and poisoning.

Table 4: Hospitalisations due to poisoning by pharmaceuticals, Australia, 2009–10

Indicator	Males	Females	Persons
Separations from hospital due to poisoning by pharmaceuticals	3,374	3,491	6,865
Percentage of all community injury separations	1.3	1.8	1.5
Estimated cases*	3,242	3,362	6,604
Crude rate/100,000 population†	29.4	30.2	29.8
Total patient days‡	29.4	29.6	29.5
Mean length of stay (days)	7,698	8,299	15,997
Estimated cases with a high threat to life	37	40	77
Percentage of cases with a high threat to life	1.1	1.2	1.2

* *Excludes records with a mode of admission of 'transfer from another acute hospital'*

† *Standardised to the Australian estimated resident population 30 June 2001*

‡ *Includes records with a mode of admission of 'transfer from another acute hospital' as contributing to hospital burden due to injury*

Source: Tovell A, McKenna K, Bradley C, Pointer S 2012, Hospital separations due to injury and poisoning, Australia, 2009–10*, p. 44. Australian Institute of Health and Welfare Injury Research and Statistics Series no. 69.*

Data for 2012–13[12] show that the average hospitalisation cost per admission due to 'injuries, poisoning and the toxic effects of drugs' across Australia was $4,987. Thus, direct hospital costs Australia-wide associated with these admissions is approximately:

$4,987 × 6,865 = $34.2 million.

However, inpatient treatment constitutes only a small proportion of costs to society associated with pharmaceutical drug misuse. As discussed by Birnbaum et al, associated healthcare costs, workplace costs (including lower levels of employment and lost productivity of both patients and carers) and criminal justice costs also contribute to the economic burden.[13] The Value of a Statistical Life provides a valid proxy of the economic benefit of saving one life. It is currently set at $4.3 million per person.

2.4. The misuse of other controlled poisons

The regulations extend controls over some dangerous poisons. These poisons are included in Schedule 7 of the Poisons Standard and include pesticides, industrial chemicals, veterinary medicines and vertebrate pest poisons. These poisons are highly toxic.

[12] See p. 244 of the *National hospital cost data collection Australian public hospitals cost report 2012–2013, Round 17*, which can be downloaded from the IHPA website at <https://www.ihpa.gov.au/publications/national-hospital-cost-data-collection-australian-public-hospitals-cost-report-2012>.

[13] Birnbaum HG, White AG, Schiller M et al 2011, 'Societal costs of prescription opioid abuse, dependence and misuse in the United States', *Pain Medicine*, no. 12, pp. 657–667. Birnbaum's initial work on this issue reports data for 2001 and was published as Birnbaum HG, White AG, Reynolds JL et al. 2006, 'Estimated costs of prescription opioid analgesic abuse in the United States in 2001: a societal perspective', *Clinical Journal of Pain*, vol. 22, no. 8, pp. 667–676.

Many of the chemicals included in Schedule 7 are used in occupational settings and are covered by: occupational health and safety (OHS) legislation; national agricultural and veterinary chemicals registration; and control-of-use legislation. Despite the other regulatory arrangements that apply, in Victoria the Act and regulations require that certain high-risk chemicals included in Schedule 7 must only be available to certain authorised persons to protect the public from accidental exposure. Substances such as arsenic, cyanide, fluoroacetic acid (1080 poison, concentrate) and strychnine are regulated as high-risk Schedule 7 poisons. Their extreme toxicity means that users of those poisons need to implement strict controls to keep the substances out of the public domain.

The Australian Centre for Agricultural Health and Safety collects data on harm due to pesticide exposure, which may include substances listed in Schedule 7. This data indicated 944 hospital separations due to the 'toxic effects of pesticides' in a two-year period between 1999 and 2001, or approximately 470 cases per annum.[14] It is reasonable to suggest that the regulations would be one of the regulatory mechanisms covering many of these substances. Pesticides were reported to be the agent of 81 fatal poisonings in the same period, representing approximately 4.5 per cent of calls to the New South Wales and Victorian poisons information centres over the period 1998–2002.[15]

Although not all of these events are attributable to Schedule 7 poisons, it demonstrates the risks of exposure and the importance of appropriate regulatory controls. OHS legislation and the Agricultural and Veterinary Chemicals Code Regulations reduce some of the risk associated with Schedule 7 poisons; however, these controls may not be applicable to the general public. The proposed regulations cover this regulatory gap.

While it is not possible with available data to provide an accurate assessment of the cost of the harms associated with the poisons controlled under the regulations, the available figures suggest that fatal and non-fatal poisonings would incur a cost. Occupational health incidents and calls to poisons information centres suggest ongoing risk and concerns from the community about exposure to poisons and support the need for continued regulation of dangerous poisons.

[14] Australian Centre for Agricultural Health and Safety 2005, *Pesticides and adverse health outcomes in Australia – the facts*, Rural Industries Research and Development Corporation and Australian Centre for Agricultural Health and Safety, publication no. 05/051.

[15] Strictly speaking, not all of these cases will be to Schedule 7 pesticides, since the same chemicals, when mixed at a lower strength, may be classified as Schedule 5 or 6 poisons, which are available domestically and not directly regulated via the current regulations. It is believed that the great majority of these recorded harms relate to the use of Schedule 7 versions of these chemicals, although specific data on harms from Schedule 7 chemicals alone are unavailable.

3 Objectives

The objective of government action in the context of drugs and poisons is to continue to protect the public from the harmful effects of misuse while ensuring there are effective mechanisms in place to enable these substances to be available to people and organisations who have a legitimate need for them.

A secondary objective is to ensure the relevant costs of controls are recovered from regulated entities.

4 Description of the current regulations and proposed changes

4.1 Drugs and poisons subject to the current regulations

'Scheduling' is a national classification system that controls how drugs (medicines) and poisons are made available to the public in Australia. Drugs and poisons are classified into Schedules according to the level of regulatory control over availability that is considered necessary to protect public health and safety. The level of control increases through the Schedules (from 1 to 10) as the potential health risks of the substances increase, with the strictest controls for use applying to substances listed in Schedules 8 and 9. Schedule 10 is for prohibited substances. Within each Schedule, the controls and requirements contained in the regulations apply consistently to any substance in that Schedule.

The regulations that apply in Victoria and that are the subject of this regulatory impact statement (RIS) aim to ensure the safe supply and use of the drugs and poisons that are contained in Schedules 2–10 of the Poisons Standard and available within a national framework described in section 1.2. These are summarised in Table 5.

Table 5: The drugs and poisons Schedules

Schedule 1	Not currently in use.
Schedule 2	Pharmacy Medicine – these drugs can only be sold in pharmacies but can be sold by any pharmacy employee.
Schedule 3	Pharmacist Only Medicine – use of these drugs entails greater risk if improperly used, so these drugs must only be dispensed by a pharmacist.
Schedule 4	Prescription Only Medicine *or* Prescription Animal Remedy – these drugs must be dispensed by a pharmacist and only on the prescription of a registered medical practitioner or other authorised practitioner.
Schedule 5	Caution – poisons of low potential for causing harm. These are available to the public with appropriate packaging providing simple warnings and safety directions on the label.
Schedule 6	Poison – poisons of moderate potential for causing harm. These are available to the public with distinctive packaging providing stronger warnings and safety directions on the label, as well as storage requirements.
Schedule 7	Dangerous Poison – poisons of high potential for causing harm that require special precautions during manufacture, handling or use. They are available only to specialised or authorised users who have the skills to handle them safely.
Schedule 8	Controlled Drug – these drugs are subject to a range of additional controls because of additional risks, including dependence. Victorian medical practitioners and nurse practitioners need to hold treatment permits for more than short-term use.
Schedule 9	Prohibited Substance – these substances are prohibited and may be made available in certain, limited circumstances for specific purposes such as research.
Schedule 10	Substances of such danger to health as to warrant prohibition of sale, supply and use.

Most of the controls that apply in Victoria via the regulations being reviewed in this RIS are concerned with drugs in Schedules 3, 4, 8 and 9. The current regulations do not impose specific controls on poisons in Schedules 5 and 6 and have limited controls on poisons in Schedule 7. However, the regulations do apply a small number of general controls across all the Schedules. These include

restrictions on access except for essential operations, controls on repackaging of retail products, controls on removing contents to unlabelled containers and a requirement to notify the authorities of loss or theft. The drugs and poisons subject to controls in the current regulations are also subject to controls in the proposed regulations.

4.2 Controls adopted under the current regulations and maintained in the proposed regulations

The controls applied under the current regulations largely address the questions of who can possess various classes of drugs and under what conditions drugs and poisons can be supplied, stored, recorded, destroyed and used. These controls are maintained in the proposed regulations.

Those who need access to drugs that have been lawfully supplied to them for personal use, when caring for or assisting another person, or when delivering a consigned drug, also receive their authorisation via the regulations. Others are authorised to possess, but not to supply, various drugs by virtue of their profession. This includes practitioners such as registered nurses, midwives, podiatrists, optometrists and ambulance officers, as well other occupational groups including ships' masters and emergency services providers, who may need access to a limited number of drugs in specific circumstances. Where tighter restrictions are required to protect the public, practitioners require a specific permit or warrant approved by the Secretary to the department.

The key controls contained in the current regulations for drugs in each Schedule are shown in Table 6.

Table 6: Hierarchy of controls applied through the Schedules of the Poisons Standard for supply of drugs by registered practitioners

Schedule	Supply	Storage	Records	Destruction	Example(s)
2	Available for self-selection from a pharmacy only	Stored in a pharmacy	No records of supply required	Documentation not required	Paracetamol tablets, antifungal cream
3	No prescription required; a pharmacist must be consulted	Stored behind the counter at a pharmacy	No records of supply required	Documentation not required	Salbutamol inhaler, Epipen®
4	Must be prescribed by an authorised practitioner	Stored in a locked cupboard or dedicated room with limited access	Records of prescriber, details of supply and patient required	Documentation not required	Blood pressure medication, cholesterol medication
8	Must be prescribed by an authorised practitioner; a permit may be required	Locked, compliant safe with limited access	Comprehensive records of supply, continuous balance checks*	Destruction must be witnessed and documented	Morphine, oxycodone
9	Must be prescribed by an authorised practitioner; a permit is required	Locked, compliant safe with limited access	Comprehensive records of supply, continuous balance checks	Destruction must be witnessed and documented	Heroin

[*] *That is, reconciliation of current stock levels in relation to supplies brought in and drugs prescribed/supplied.*

A more detailed summary of the key controls imposed by the regulations in each key area is provided below.

Possession

The current regulations allow possession of Schedule 4, Schedule 8 and Schedule 9 drugs by either:

- licence, permit or warrant holders or their agents
- a person who has been lawfully supplied the drugs for their own treatment or that of a person or animal under their care
- a person who may need to possess Schedule 4 or Schedule 8 drugs in the course of their occupation or function, or
- authorising possession to specific drugs or under an approval or permit.

Activities (including manufacturing, selling (including by retail), supplying, possessing and using) relating to certain Schedule 7 poisons are also regulated.

Treatment

Circumstances under which practitioners can treat (administer, prescribe or supply) patients with Schedule 4, Schedule 8 or Schedule 9 drugs include:

- that there is a therapeutic need for the treatment
- that the treatment is for a patient under the care of the practitioner and within the scope of practice of the practitioner
- in the case of treatment with Schedule 8 or Schedule 9 drugs, that the identity of the patient (or owner of an animal patient) has been determined.

In relation to prescriptions for Schedule 4, Schedule 8 or Schedule 9 drugs, the regulations specify:

- who may prescribe
- the details that must be included on the prescription
- how the prescription must be written
- what information must be included on the label (if the drug is supplied by the practitioner or the pharmacist under a prescription)
- the circumstances under which a pharmacist may supply the drug on a prescription or an instruction on a medication chart (a hospital or residential medication chart)
- additional permit requirements for certain psychoactive medications (for example, methadone, amphetamines and cannabis (in Schedule 8 and outside the Victorian medicinal cannabis scheme))
- requirements for medical practitioners to hold warrants to treat patients with certain medicines that can cause serious adverse effects during pregnancy.

Supply

Before a pharmacist can supply Schedule 3, Schedule 4, Schedule 8 or Schedule 9 drugs, the pharmacist must have taken reasonable steps to determine:

- that there is a therapeutic need for treatment (for drugs of dependence and Schedule 3 drugs)
- the identity of the patient (for drugs of dependence)
- that the person supplied has been prescribed the medicine or is otherwise allowed to possess the medicine (for Schedule 4 and Schedule 8 drugs)

- that the prescription was written by the purported prescriber (Schedule 8 or Schedule 9 drugs).

The pharmacist may make a limited supply of a Schedule 4 drug in an emergency or under continued dispensing arrangements.

For drugs of dependence, Schedule 8 and Schedule 9 drugs, the pharmacist is required to retain the prescription once it is completed and to notify prescribers if the patient has multiple prescribers.

In relation to Schedule 3 drugs, the pharmacist (or other people such as doctors authorised to supply Schedule 3 drugs) must personally be involved in the supply. This differentiates Schedule 3 drugs from Schedule 2 drugs that may be obtained from a pharmacy without the direct intervention of a pharmacist.

Containers of Schedule 3, Schedule 4, Schedule 8 and Schedule 9 drugs that are supplied by the practitioner must be labelled with specific details before they are supplied.

Across all Schedules, drugs and poisons must be supplied in their original unopened pack and not transferred into containers that are not adequately labelled, except as authorised.

Administration

The regulations:

- specify who can authorise administration of Schedule 4, Schedule 8 and Schedule 9 drugs, who may be administered the drug and how the administration instruction is given
- allow administration by a pharmacist of a Schedule 4 drug without an instruction from a practitioner under an approval
- prohibit administration or supply of Schedule 3, Schedule 4, Schedule 8 and Schedule 9 drugs if it merely supports drug dependence
- prohibit self-administration of Schedule 4, Schedule 8 and Schedule 9 drugs by practitioners.

Storage

The regulations:

- set out storage requirements for Schedule 4, Schedule 8 and Schedule 9 drugs
- allow for the Secretary to approve variations from these requirements if they are considered necessary or appropriate
- restrict the storage and display of Schedule 3 drugs so that self-selection by the public is not promoted or readily allowed (‘behind the counter’ storage)
- restrict access to stores of Schedule 4, Schedule 8 and Schedule 9 drugs and listed regulated poisons to authorised persons on a needs basis.

Record keeping

Regulations for Schedule 4, Schedule 8 and Schedule 9 drugs specify:

- the transactions to be recorded
- who must keep records
- what records should be kept, (for example, the date and nature of the transaction, details of the drug and the person authorising the transaction)
- how records should be kept and retrieved (for example, for how long, in what form and how they are protected)
- for what purposes records should be kept

- that discrepancies between stocks and storage records must be investigated and reported if not resolved.

Miscellaneous

In addition to the controls above, the regulations also:

- set out the circumstances under which Schedule 8 and Schedule 9 poisons may be destroyed and who is authorised to destroy them
- allow the Secretary to authorise certain people to cultivate and possess narcotic plants for non-therapeutic use
- prescribe forms for notifications and for applying for treatment permits and other purposes as required by the Act
- require notification of loss or theft of poisons or controlled substances to the Secretary and the police
- provide an authority for owners/occupiers of land or premises to allow their land or premises to be used for cultivation or use of drugs of dependence for authorised purposes (the regulation applies also to cultivation or use of medicinal cannabis)
- set fees for issuing, renewing or amending licences and permits issued under s. 19 of the Act.

4.3 Licences and permits with a prescribed fee

S 19 the Act allows for a range of organisations wishing to manufacture, sell, supply purchase or use drugs and poisons to obtain a licence or permit and establishes a prescribed fee. The code refers to the poisons Schedules involved and the activity (such as for licences – manufacturing and/or wholesaling or retailing and for permits – for industrial, educational, research or health services purposes). Licences and permits are issued with conditions. Licence and permit holders must pay fees for applications, renewals and amendments of licences and permits. The fees are discussed in detail in section 8.

The licenced and permitted activities in relation to the respective poisons Schedules are set out in Tables 7 and 8.

Table 7: Licence categories

Code	Licence category
MA	Manufacture and sell or supply by wholesale any Schedule 8 or Schedule 9 poison other than heroin
MP 4	Manufacture and sell or supply by wholesale any Schedule 4 poison (alone or together with any Schedule 2, 3 or 7 poison or combination of those poisons)
MP 2, 3, 7	Manufacture and sell or supply by wholesale any Schedule 2, Schedule 3 or Schedule 7 poison alone or any combination of those poisons
MPR7	Manufacture and sell or supply by retail any Schedule 7 poison
WA	Sell or supply by wholesale any Schedule 8 or Schedule 9 poison other than heroin
WP 4	Sell or supply by wholesale any Schedule 4 poison alone or together with any Schedule 2, 3 or 7 poison or combination of those poisons
WP 2, 3, 7	Sell or supply by wholesale any Schedule 2, 3 or 7 poison alone or

Code	Licence category
	in combination
WA Indent	Sell or supply by wholesale any Schedule 8 or Schedule 9 poison other than heroin by indent
WP 4 Indent	Sell or supply by wholesale any Schedule 4 poison (alone or in combination with any Schedule 2, 3 or 7 poison) by indent
WP 2, 3, 7 Indent	Sell or supply by wholesale any Schedule 2, 3 or 7 poison alone or any combination of those poisons by indent
GDL	Sell or supply by retail any Schedule 2 poison

Table 8: Permit categories

Code	Permit category
Permit 8, 9	Permit to purchase or otherwise obtain and use for industrial, educational, advisory or research purposes any Schedule 8 or Schedule 9 poison (alone or together with any Schedule 2, 3, 4 or 7 poison or combination of those poisons)
Permit 2, 3, 4, 7	Permit to purchase or otherwise obtain and use for industrial, educational, advisory or research purposes any Schedule 2, Schedule 3, Schedule 4 or Schedule 7 poison or any combination of those poisons
HSP	Permit to purchase or otherwise obtain and use any poison or controlled substance for the provision of health services by the following types of health service provider:
HSP Type A	Single site with no beds
HSP Type B	Residential aged care with single storage facility (no bed limit) *or* single site 1–30 beds
HSP Type C	Multiple sites with no beds *or* single site with 31–100 beds
HSP Type D	Multiple sites *or* single site with more than 100 beds

The regulatory fees payable by licence and permit holders are intended to recover the costs incurred by the department in administering the licence and permit system under s. 19 of the Act and for compliance monitoring.

Fees for licences and permits have been in place since 1983 and have been set at full cost recovery levels since 1995. Section 8 of this RIS provides a detailed analysis of the department's licence and permit administration costs and their distribution across licence and permit categories. It sets out a revised fee structure for the proposed regulations.

Regulatory fee revenue does not seek to recover costs associated with applications for warrants under s. 19 of the Act or patient-specific Schedule 8 permits for therapeutic use issued under s. 34A of the Act or regulation 22B. The department processes approximately 51,500 permit applications and 100 warrant applications and receives approximately 25.000 phone calls from practitioners and pharmacists annually in administering this system. For the purpose of this RIS, the current cost to the department of administering the warrant and patient-specific Schedule 8 permit system has been estimated at approximately $1 million in 2015–16, which equates to approximately $19 per application

processed. It has been government policy that these patient treatment-related costs are funded by consolidated revenue in the public interest. The department maintains that it remains in the public interest not to cost recover these patient treatment-related costs. Such costs are likely to be passed on to the patient, potentially causing a reluctance for patients to seek regular care. In addition, patients treated under the Opioid Replacement Treatment program are frequently at-risk clients. It is important that barriers to treatment are minimised.

4.4 Proposed substantive changes to the current regulations

The department consulted with stakeholders within Commonwealth and state/territory health authorities and policy and program areas of the department while reviewing the current regulations and preparing this RIS. The overall outcome of this consultation and the department's assessment of the operation of the current regulations over the past 10 years is that the regulations are, in general, continuing to work effectively to reduce the risk of misuse of drugs and poisons. However, some specific areas have been identified in which improvements can be made to the current regulations that will reduce regulatory burdens on those required to comply and/or improve the effectiveness of the regulations in achieving their objectives. Hence, a number of changes to the current regulations are incorporated in the proposed regulations, as detailed below. **None of the changes is expected to add an appreciable regulatory compliance burden for any particular sector**.

The proposed regulations are similar in content to the existing regulations. However the structure of the regulations has changed to the form and standard required for contemporary legislative drafting. For each activity, there is a separate regulation for each class of practitioner. The restructure has necessarily altered the appearance of the regulations and increased their number and length.

Structure of the proposed regulations

The proposed regulations continue the approach of the current regulations that is to apply consistent controls to all the drugs and poisons within each Schedule of the Poisons Standard. Controls are grouped under:

- Schedule 4, 8 and 9 poisons
- Schedule 2, 3 and 7 poisons
- miscellaneous matters that affect drugs and poisons generally.

In contrast with the current regulations, the proposed regulations apply the controls precisely to the type of practitioner or pharmacist or other person concerned. For example, for practitioners who are not pharmacists, there are controls on administration, authorising administration, providing chart instructions, writing prescriptions and sale or supply. For pharmacists, the regulations differentiate between the circumstances under which they may supply and the duties they must perform in making that supply. For practitioners, pharmacists and others there are controls on administration and administration authorisations where applicable.

Controls on labelling, storage, record keeping, destruction, notification of loss or theft and others are incorporated within the proposed regulations, with some iterative changes to improve effectiveness.

The existing controls on warrants continue in the proposed regulations.

The proposed regulations have clarified and strengthened requirements in relation to:

- practitioners wishing to hold a Schedule 9 permit for various activities
- differentiating the Schedule 8 treatment permits for certain high-risk medicines under the regulations from the Schedule 8 permits relevant to s. 34A of the Act
- the issuing of Secretary approvals. Consistent provisions in the proposed regulations require Secretary approvals to be published in the *Government Gazette* and take effect on the date

published or a subsequent date. The requirement need not apply to Secretary approvals for individuals.

The existing authority to cultivate narcotic plants for non-therapeutic uses and the use of premises in the legitimate trafficking or cultivation of drugs of dependence continue in the proposed regulations.

Regulations concerning prescribed fees and forms, as occur in the existing regulations, are included in the proposed regulations.

Content of the proposed regulations

The content of the proposed regulations is consistent with the content of the current regulations. However, iterative changes are made to improve the operation of the regulations. Details are provided in Appendix 1.

Consistency

The regulations will provide greater consistency of regulatory controls in some specific areas, notably by:

- introducing consistency between the matters to be included on prescriptions written by veterinary practitioners and those to be included on the label for the dispensed medicines
- extending the storage and record-keeping requirements that currently apply to most aged care services to all facilities within the sector.

Extending authorised possession

The range of groups authorised to possess certain scheduled drugs will be expanded slightly to address issues where existing restrictions have been found to impose costs that are disproportionate to the size of the risk or address an identified need. Specifically, the following occupations will be able to possess the medicines they require:

- boat captains requiring life rafts with a medical kit under Victorian law to treat seasickness
- emergency workers employed on-site in mines and power stations to provide pain relief.

Clarity

Additions, definitions and explanatory notes are to be added to the proposed regulations to assist readers to interpret the requirements correctly and remove potential overlap between controls in the Act and the regulations.

Security

Prescribers writing prescriptions for a single supply of Schedule 8 poisons will be required to write explicitly that there are to be no repeat supplies, where this is the case. This will reduce opportunities for others to fraudulently alter prescriptions by adding repeats and reduce the risks of misuse of these drugs. Schedule 8 prescriptions will also include the date of birth of the patient to assist in data matching for real-time prescription monitoring, which is expected to be adopted in Victoria in the near future.

Veterinary practitioners will be required to label all multipack supplies of Schedule 4 poisons, reversing an exemption made in the existing regulations because of emerging problems with the unlawful supply of veterinary antibiotics.

Pharmacists will be able to lawfully supply a medicine contrary to the prescriber's instruction if certain criteria on need and safety are met. This is intended to provide appropriate flexibility to pharmacists and patients, while averting potential harms that may arise in particular circumstances.

Minimum standards are included for storage facilities for Schedule 8 poisons where use of electronic storage and recording equipment is considered within health services. These provisions address the increasing demand for use of electronic equipment in this area, facilitating its adoption while maintaining adequate levels of security.

Reflecting Commonwealth legislation

The proposed regulations reflect changes to the National Health (Pharmaceutical Benefits) Regulations 1960.

Pharmacists supplying Schedule 4 or Schedule 8 poison medicines to patients at discharge in a hospital or day procedure centre will be able to supply those medicines from an instruction on the hospital medication chart rather than requiring a separate prescription. The medication chart is to be completed in accordance with the National Health (Pharmaceutical Benefits) Regulations 1960. The amendment allows the pharmacist to supply discharge medications for a period of up to one month's supply and includes medicines that may not be subject to a Pharmaceutical Benefit.

References to the National Health (Residential Medication Chart) Determination 2012 are replaced with references to the Commonwealth regulations, the National Health (Pharmaceutical Benefits) Regulations 1960.

Schedule 4 prescriptions retained under the Commonwealth regulations are to be produced to Victorian authorised officers upon request for compliance investigations.

Record keeping and destruction

Under the proposed regulations practitioners who administer or supply opioid replacement therapy will be able to update their Schedule 8 register daily instead of maintaining a continual balance. This is expected to reduce compliance burdens without materially affecting security.

Persons required to create a record for a Schedule 8 or Schedule 9 poison are to prevent their personal access codes from being shared with others. This is expected to reduce opportunities for creation of fraudulent electronic records for high-risk medicines.

Nurses, midwives and other practitioners acting alone will be able to destroy unused partial doses of solid-form Schedule 8 poisons or Schedule 9 poisons in their role of administering medication. This will reduce compliance burdens with relation to the current requirement for two authorised practitioners to be present when these drugs are destroyed.

Veterinary medicines

Instructions for a written order from a veterinary practitioner to a stock food manufacturer to manufacture and supply by wholesale stock food containing Schedule 4 poisons (anticipated to be predominately antibiotics) are now specified.

Revised regulatory fees

The regulatory fees for licences and permits have been updated using data on outputs and resources provided by the department – see section 8.

Prescribed forms

The prescribed form for prescribers to apply to the department for a permit to provide pharmacotherapy has been amended so the prescriber can include the Aboriginal and/or Torres Strait Islander status as provided voluntarily by the pharmacotherapy client.

Other

The proposed regulations will also be modified to better address the risk of fraud and consequent misuse of drugs and poisons. All practitioners will be required to establish the identity of patients to whom they intend to supply drugs of dependence.

All practitioners and licence and permit holders will now need to notify the department and Victoria Police of loss or theft of medicines or poisons.

A redundant regulation relating to the storage of Schedule 7 poisons in retail premises is removed, as this matter is now addressed in the Act.

A redundant regulation relating to the authorisation of interstate veterinary practitioners is removed.

5 Feasible alternatives to remaking the current regulations

The department considers that the range of feasible alternatives to remaking the current regulations is substantially constrained by the broader legislative environment within which they operate. First, as discussed in section 1.2, this includes Australia's position as a signatory to several major United Nations conventions that establish a wide range of obligations on signatories. The Act and regulations, together with their equivalents in other states, constitute an important means by which Australia establishes compliance with these conventions.

Second, the introductory sections of this RIS have noted a significant degree of national harmonisation of regulation in drugs and poisons. This derives in part from the fact that there are both federal and state government areas of responsibility that interact in a complex manner and in part from recognition of the reality of a nationally focused industry. This national regulatory harmonisation also limits the extent to which alternative regulatory approaches can be considered practical and feasible.

Finally, account must be taken of the terms of the Act under which the proposed regulations are made. The Act establishes the framework of regulatory arrangements, while the regulations give effect to the Act by specifying particular elements.

Within the framework set out by the Act, as well as the broader political and legislative environment, there are few options to the existing form of regulations. The major identifiable alternatives are considered below.

5.1 Regulation by individual practitioner organisations

While the Act provides the overarching framework of regulatory arrangements, which cannot be deviated from, it is possible to envisage an alternative form of the regulations that is less specific about the obligations of members of registered health professions in relation to the treatment, possession, storage, prescription and supply of drugs and poisons and the range of drugs and poisons to which they would have access in the course of undertaking their professional roles.

The most plausible alternative to the regulations' approach of setting out these matters in a single body of regulation would be to provide a substantial role for the relevant practitioner registration bodies in regulating the drugs required within each profession's scope of practice, specifying the restrictions that should apply in respect of each particular profession's handling and use of those drugs.

This alternative would still require regulations to be made under the Act. For example, the Act states that possession and supply of drugs and poisons can only be done by practitioners in the lawful practice of their professions, and the regulation must therefore define the scope of that lawful practice. While the scope of that lawful practice must be defined by regulations, it is not necessary that these regulations be in the current proposed form. Substantive elements currently covered under the regulations would, instead, be covered under individual practitioner Acts and Regulations.

Moreover, it is possible that requirements in respect of prescription, supply, storage, record keeping and destruction could be set out in quasi-regulatory or self-regulatory instruments such as codes of practice, guidance notes and the like. Such an approach could, however, result in inconsistencies in requirements applied by different professions, with no overall coordination or standards setting. Adoption of a common framework for regulating a wide range of health professions, through the Health Practitioner Regulation National Law and AHPRA, would potentially provide a coordinating mechanism to reduce the size of these inconsistencies; however, it is unlikely that this would be

wholly effective. While safer for the community than self-regulation, it is unlikely to capture all the regulated entities (including those not covered by AHPRA such as the Veterinary Practitioners Registration Board of Victoria, organisations representing non-registered professions, and occupational and industry organisations) or be as efficient or effective overall as the current system. This approach is considered to be feasible but not desirable.

Expected benefits of the alternative

The main benefit of this alternative would be that decisions regarding possession and prescribing of drugs and poisons by a particular profession would be made by the board responsible for regulating that profession. Registration boards have a detailed and specific understanding of the nature and scope of a profession's practice. They also have thorough understanding of training undertaken by members of the profession and the extent to which this equips them to make professional decisions involving drugs.

These factors may support better decision making regarding appropriate access to drugs; the principle of *subsidiarity* suggests that making decisions at a level closer to the regulated parties promotes better regulatory effectiveness and efficiency.

The dynamic nature of regulations lends itself to this approach. Individual practitioner registration boards may be able to respond more quickly to changes in the nature and scope of practice of their profession and the emergence of new drugs into the market. This approach would take advantage of a profession's expertise.

Expected costs of the alternative

A potentially significant cost of the alternative relates to the need to ensure consistent application of standards across health professions. This could include the establishment of an independent entity to monitor and compare the effectiveness of the separate bodies, or an expansion of an existing body such as AHPRA, to enable it to carry out this function. This would necessarily entail responses to regulation becoming a two-tiered process, possibly reducing efficiency and efficacy in applying consistent and uniform standards.

A further issue relates to potential conflicts of interest inherent in self-regulation; practitioner boards are, by their very nature, closely aligned with their regulated professions. Such bodies may be unduly influenced by their profession's ambitions to broaden access to drugs and change regulations surrounding handling and security. The perception that such a regulatory body is not independent could be seen as inconsistent with the underlying presumption of the regulations, which is to ensure that the controls surrounding access to drugs are safe and transparent.

Finally, the regulation of drugs and poisons is complex and requires the coordination of multiple jurisdictions and regulatory bodies. The integration of existing regulations into individual Acts and regulations specific to each profession would require significant upskilling and place significant burden on each practitioner regulatory body. Inexperience in regulation may result in unsatisfactory outcomes and detract from their existing responsibilities.

5.2 Adoption of national model regulations to regulate medicines and poisons listed in the Poisons Standard

Description of the alternative

Another alternative is the development of national regulations. This approach was used in the development of national poisons controls as recommended in a 2008 Productivity Commission research report entitled *Chemicals and plastics regulation, research report.* This report recommended

that state and territory governments adopt uniform regulatory controls for poisons through either a template or model approach, as published in the Poisons Standard.[16]

Following this recommendation, an approach was taken based on the adoption by reference by each jurisdiction of agreed controls to be contained in the Poisons Standard. The key benefit of adopting this approach was to reduce unnecessary regulatory complexity and inconsistency associated with each jurisdiction adopting its own regulatory arrangements, thereby reducing regulatory costs and burdens for businesses operating across jurisdictions. This approach has been adopted for the regulation of Schedule 5, 6, and some Schedule 7 poisons but has not been initiated for the regulation of the medicines Schedules because it would be a very complex national task.

Expected impacts of the alternative

Implementation of national regulation would promote greater clarity around regulatory requirements and reduce inconsistencies between jurisdictions. Moreover, this process would focus on overall regulatory control rather than individual control on the health professions, thereby capturing all affected parties and potentially avoiding gaps in regulatory coverage.

Although a desirable option, it requires significant policy and regulatory work by multiple state (and the federal) governments and is not considered to be a feasible alternative within the current time constraints.

5.3 Modifying provisions of the current regulations

The preceding discussion considers broad alternatives to government regulation (as encompassed by the current regulations) for controlling access to and handling of drugs and poisons by various users. A narrower way to consider alternatives and a matter of practical necessity involves reviewing and revising the specific provisions of the current regulations to consider whether they should be changed or removed.

The development of the proposed regulations has involved identifying and weighing a number of options for changes to particular aspects of the current regulations. These potential changes have been put forward by regulated entities or the department. Section 11 describes the consultation process used to prepare the new regulations and collates and summarises the suggestions that have or have not been proceeded with. Consultation was conducted broadly across stakeholders (Rounds 1 and 2) with follow-up for specific stakeholders (Round 3) and targeted to licence and permit holders via a questionnaire on regulatory impacts (Round 4).

Appendix 1 describes the changes that have been adopted in the proposed regulations.

Appendix 3 describes those changes suggested but not adopted through both the broad consultation and questionnaire.

[16] National Co-ordinating Committee on Therapeutic Goods 2012, *Strategies to implement a national approach to poisonous chemical controls: decision regulatory impact statement.* Download from the Queensland Health website at <www.health.qld.gov.au/ph/documents>.

6 Expected costs of the proposed regulations

6.1 Overview

The broad legislative structure governing the use of pharmaceutical drugs and poisons clearly imposes substantial costs on a wide range of parties in society. These include, for example, the costs of prescription medicines including the requirement to visit a doctor or other relevant practitioner to obtain a prescription in order to be supplied with pharmaceutical drugs. However, while the current and proposed regulations form an integral part of this broader system of control, it is essential for current purposes to focus on the costs imposed by the specific requirements contained within the proposed regulations.

The key requirements of the current and proposed regulations that potentially impose substantive costs are:

- the costs of complying with secure storage requirements
- the costs of complying with the recording requirements
- the costs associated with drug destruction requirements
- the costs associated with obtaining, amending and renewing licences and permits.

These costs are imposed on a wide range of parties including:

- health service providers, pharmacists and individual practitioners
- manufacturers, wholesalers and retailers of drugs and poisons
- industry, educational and research organisations needing to purchase or obtain drugs or poisons
- other occupational groups authorised to be in possession of certain poisons.

In addition, registered medical practitioners and nurse practitioners incur costs in making applications for Schedule 8 treatment permits, pharmacotherapy permits and warrants to prescribe and supply certain restricted poisons, while the department incurs costs in administering the Act and regulations, some of which are recovered through licence and permit fees.

6.2 Cost estimation

As part of the research undertaken in reviewing the current regulations and preparing this RIS, a questionnaire was developed and sent to a sample of 300 of the 1,446 current licence and permit holders (approximately 20 per cent). The department received 58 completed questionnaires, representing a response rate of 19.3 per cent of the questionnaires sent and around 4.0 per cent of all licence and permit holders. Analysis of the responses indicated that at least one response was received from each category of licence and permit holder. Rates by category ranged from 1.2 per cent to 33.3 per cent; in all but four cases the response rate ranged between 2.4 per cent and 8.3 per cent.

The questionnaire sought a range of information including: the actions taken by licence and permit holders to comply with the storage, recording and drug destruction requirements; the costs of those actions; and any other costs incurred by this group in complying with the regulations. General views were also sought as to the appropriateness of the regulations, and suggestions for improvement were solicited explicitly.

Importantly, the questions regarding the costs incurred in relation to the secure storage of drugs, the recording of drug movements and drug destruction arrangements specifically sought to distinguish between ‘business as usual’ (BAU) costs – that is, those that would be incurred for commercial or other reasons, even in the absence of specific regulatory duties – and those incurred specifically as a

result of the need to comply with the regulations. This approach reflected the department's view that, even in the absence of specific regulatory requirements, most of the affected parties would have significant incentives to ensure the secure storage of drugs and to track their movements.

Storage costs

As anticipated, the results of the questionnaire responses, when analysed, revealed a substantial difference between the reported 'gross costs' incurred in relation to drug storage and recording and the incremental costs that licence and permit holders identified as being incurred specifically as a result of the need to comply with the regulations.

Table 9 lists the average costs reported in respect of the supply and installation of storage devices by respondents in each licence or permit category,[17] the total number of licence or permit holders in that category and the notional total installed cost of storage items for all holders in that category. The most commonly used storage items were drug fridges (31 respondents), locked safes (25 respondents) and locked cabinets (26 respondents). Fourteen respondents reported using locked rooms, cages or vaults to store drugs but were generally unable to estimate the costs of these facilities.

Table 9: Costs of storage devices

Licence/permit code	Total no. of licence or permit holders	Average cost	Total cost
GDL	18	$5,800	$104,400
HSP Type A	270	$9,283	$2,506,410
HSP Type B	184	$7,433	$1,367,672
HSP Type C	125	$10,750	$1,343,750
HSP Type D	60	$1,050,000	$63,000,000
MA	16	$255,333	$4,085,328
MP 2, 3, 7	41	NA	NA
MP 4	84	$3,051	$256,284
MPR 7	3	$1,700	$5,100
Permit 2, 3, 4, 7	236	$44,000	$10,384,000
Permit 8,9	104	$1,570	$163,280
WA Indent	19	NA	NA
WP 2, 3, 7	48	NA	NA
WP 4	158	$15,766	$2,491,028
WP 4 Indent	49	NA	NA
Total	**1,446**		**$85,707,252**

NA: not available

[17] For an explanation of the licence and permit categories see Tables 7 and 8.

Table 9 shows that the estimated value (at purchase price) of the storage devices in use is in the vicinity of $85.7 million. The expected lifespan of the storage devices was reported to be between 5 years and 20+ years, with drug fridges having shorter estimated lifespans of five to 10 years and drug safes and cabinets typically having estimated life spans of 15–20 years or more. Taking a rough average of 10 years, the above suggests that at least $8.6 million per annum is expended on average by licence and permit holders as a group to purchase and install secure drug storage facilities. In practice, this figure is likely an underestimate since no average costs were able to be obtained in respect of four licence categories and no estimates were able to be obtained in respect of the costs of secure rooms/cages/vaults.

These figures should be understood as providing only the broad order of magnitude of the costs associated with drug storage, given the relatively small number of observations reported and the wide variation in the reported costs within licence and permit categories. However, they indicate that significant expenditures are undertaken in ensuring that drugs are kept secure.

It is necessary to separate clearly the BAU costs of drug storage from those that result from the specific requirements of the regulations. Respondents to the questionnaire were asked whether they would make any changes to their current drug storage arrangements in the absence of specific regulatory requirements. Of 58 respondents, 50 (86 per cent) said they would make no changes in the absence of the regulations. Of the eight respondents (14 per cent) who indicated that they would make some change, most suggested that any such changes would be modest in extent. In particular, several of this group indicated that they currently have multiple levels of security on site, with (for example) locked drug safes or fridges being located within areas that already feature restricted access. The most common response among this group was that they would reduce the number of levels of security, eliminating what was seen as unnecessary duplication in this regard.

Six respondents provided dollar figures in response to a question asking what savings would be likely to be made were they able to introduce such changes. These ranged in size from $300 to $2,000 per site. However, several indicated that these savings were ‘one off’ rather than being annual cost savings. Thus, it is likely that:

- only a small proportion of licence and permit holders (fewer than one in six) incur additional drug storage costs as a result of the specific requirements of the regulations
- these additional costs constitute only a small proportion of the total costs they incur for commercial and other reasons.

Thus, the size of the incremental costs imposed by the regulations in respect of drug storage requirements is clearly very modest in practice. If it is assumed that the 14 per cent of licence and permit holders identifying incremental costs in this area due to the regulations each incur a 20 per cent increase in their storage costs; this suggests that the incremental costs of the regulations in relation to drug storage are of the order of 20% × 14% × $8.6 million p.a. = $0.24 million.

Record-keeping costs

The responses received in relation to the costs of recording drug movements showed a similar pattern to that described above in relation to drug storage. That is, some significant costs, in terms of staff time devoted to these tasks, were identified, but a large majority of respondents indicated that there would be no change to their practices in the absence of the specific regulatory requirements in this area. Table 10 summarises the average amount of staff time taken to complete recording requirements for respondents in each licence category. It also provides estimated average and total costs for these activities based on the assumed costing of staff inputs at average weekly earnings and the application of a 75 per cent uplift for on-costs and overheads.

Table 10: Estimated drug recording time and costs

Licence/permit code	Average time (hrs/week) (a)	Total no. of licence or permit holders (b)	Total cost* ((a)x(b)x$69.82)
GDL	6	18	$7,540.56
HSP Type A	2	270	$37,702.80
HSP Type B	8	184	$102,775.04
HSP Type C	4.5	125	$39,273.75
HSP Type D	37.3	60	$156,257.16
MA	15.67	16	$17,505.27
MP 2,3,7	NA	41	NA
MP 4	2.5	84	$14,662.20
MPR 7	0.1	3	$20.95
Permit 2, 3, 4, 7	2.33	236	$38,392.62
Permit 8, 9	0.8	104	$5,809.02
WA Indent	40	19	$53,063.20
WP 2, 3, 7	1.5	48	$5,027.04
WP 4	4.5	158	$49,642.02
WP 4 Indent	0.25	49	$855.30
Total cost (weekly)			$528,526.93
Total cost (annual)			**$27,483,400.20**

* *Based on ABS Cat. 6302.0: Average adult full-time ordinary time weekly earnings for May 2016 of $1,516, divided by 38 hours, equals $39.89/hour. Adding 75% for on-costs and overheads gives a total hourly labour cost of $39.89 × 1.75 = $69.82.*

Table 10 shows that the annual cost of all activities related to the recording of drug movements is estimated at $27.5 million. This is more than three times the cost of drug storage facilities, as estimated above. However, in this area as well, questionnaire respondents stated, for the most part, that they would not alter their current practices in the absence of specific regulatory requirements. Nine of the 58 respondents (15.5 per cent) said they would change their record-keeping practices in the absence of the regulations.

Analysis of these responses indicates that most of this group of respondents felt there were some opportunities to streamline the recording of drug movements:[18]

- The most common response, made by three respondents, was that the organisations in question would move to a purely electronic recording system in the absence of the regulatory requirements.
- Two respondents indicated that they would prefer to streamline recording by integrating drug recording with other records. In one case of a health services provider, the medical record was nominated, while in another the requirements of the OHS Act were referenced.

[18] These suggestions, together with the department's responses, are discussed further in Appendix 3.

- Two respondents said they would undertake less checking activity, with one specifically noting that they would not require two people to be present when certain activities were undertaken.

Six of this group of nine respondents were able to provide an estimate of the savings they would incur if not constrained by the current regulatory requirements. These ranged from 0.1 hours per week to 8 hours per week, with an average of 3.6 hours per week. Given the above estimated cost of $69.82 per hour, this suggests a cost saving of:

3.6 × 52 × $69.82 = $13,070 per respondent per annum.

As noted, around 15.5 per cent of respondents expected to realise such savings if not constrained by the current regulations. This suggests that the total incremental cost of the drug recording requirements of the current regulations is approximately:

1,446 licence and permit holders × 15.5% × $13,070 = $2,929,379 per annum.

As with the storage cost estimates discussed above, this should be regarded as an imprecise estimate, providing no more than the likely order of magnitude of the costs in question. However, comparison with the total drug recording figure highlighted in Table 10 suggests that the impact of the current regulations is to increase BAU drug recording costs by only around 12 per cent.[19]

Drug destruction

The third type of cost explored in the questionnaire related to drug destruction. Some 54 of the 58 respondents said they undertook drug destruction activities, while 25 of this group or 46.3 per cent (43.1 per cent of the respondent group as a whole) use the services of external providers for at least some of their drug destruction requirements.

A large majority of respondents (45 of the 54 reporting drug destruction activities) provided estimates of the amount of staff time devoted to this activity, with the average time taken being 250 hours per annum. Given the average hourly rate used above, this implies an annual cost of internal staff resources of:

$69.82 × 250 = $17,455 per respondent.

Given that 54 of the 58 respondents (93.1 per cent) reported undertaking drug destruction activities, this implies a total annual cost among the 1,446 current licence and permit holders of:

$17,455 × (1,446 × 0.931) = $23,498,375.

In addition, 13 of the respondents were able to estimate the annual cost of paying external contractors to undertake drug destruction services for them, with the average annual cost being $4,450. Given that 25 respondents (43.1 per cent of the sample) use external contractors for this purpose, the estimated cost of paying external contractors to undertake drug destruction is:

1,446 licence and permit holders × 43.1% × $4,450 per holder = $2,773,356.

Summing these two figures indicates that the total annual cost of carrying out drug destruction activities is:

$23,498,375 + $2,773,356 = $26,271,731.

This is very similar to the estimated costs of recording drug movements, as calculated above.

The questionnaire did not specifically ask whether respondents would change their practices in relation to drug destruction in the absence of the regulatory requirements. However, given the consistent responses noted above in relation to drug storage and the recording of drug movements, it can be inferred that the extent of the changes in practice that would occur in the absence of

[19] That is, $2.9 m/($27.5 m – $2.9 m) = 12%. The total cost figure in Table 10 implicitly includes the $2.9 m incremental cost, suggesting that the BAU cost is ($27.5 m – $2.9 m).

regulatory requirements would also be limited. If the figure of 12 per cent incremental cost, estimated above in relation to the recording of drug movements, is adopted, this suggests that the incremental cost of the regulations in relation to drug destruction may be of the order of $2,814,828.

Administrative costs

In addition to the above substantive compliance costs, the regulations impose administrative costs. These entail two key elements:

- the costs incurred by the department in administering the regulations, monitoring compliance and enforcement
- the costs incurred by licence and permit holders in applying for and renewing licences and permits.

Costs to the department of administration, monitoring and enforcement

The total cost to the department of administering the Act and the regulations is approximately $2.1 million per year. Of this, the costs of administering the system for licences and permits issued under s. 19 of the Act are cost-recovered through a regulatory fee and have been reviewed for the purposes of this RIS.

Appendix 2 provides a detailed breakdown of the administration, monitoring and enforcement costs the department incurs in connection with the regulations for licences and permits issued under s. 19 of the Act. Table 11 summarises these costs. The activities undertaken are as follows:

- **Inspection.** Inspections of the proposed premises are undertaken for all new licence and permit applicants as well as applicants for a different category of licence or permit. In addition, a program of audits of existing licence and permit holders is undertaken.
- **Advice.** Advice on matters relating to licence and permit applications and regulatory obligations is provided to both applicants and existing licence and permit holders.
- **Approval.** All new licence and permit applications, including applications for a different category of licence or permit, must be approved by the departmental Secretary or delegate. The delegate is at the level of a senior medical advisor.

Table 11 shows that the total annual cost of administering the regulations with respect to the licence and permit system is $525,000. The largest single cost, accounting for well over 50 per cent of the total, is the cost of undertaking inspections of the premises of new licence and permit applicants and audits of the premises of current licence and permit holders to ensure they have the capacity to conform with the requirements of the regulations. The next largest activity, accounting for slightly more than one-quarter of the total, is the advice function.

Table 11: Summary of the department's regulatory administration, monitoring and enforcement costs for licences and permits issued under s. 19 of the Act

Activity	Staffing (EFT)	Salary	Salary cost	On-costs	Overheads	Total
Inspection	1.2 VPS 5.1	$95,194	$114,232	$23,293	$34,236	$171,761
	0.8 VPS 5.2	$104,570	$83,656	$17,058	$23,011	$123,725
Subtotal inspection						**$295,486**
Admin support	0.6 VPS 4	$83,737	$50,242	$10,245	$6,896	$67,383
Subtotal admin support						**$67,383**
Advice	0.6 VPS 4	$83,737	$50,242	$10,245	$6,896	$67,383
	0.6 VPS 5.1	$95,194	$57,116	$11,646	$7,068	$75,831
Subtotal advice						**$143,214**
Approval	0.08 SMA	$185,715	$14,857	$3,029	$1,123	$19,010
Subtotal approval						**$19,010**
Total						**$525,093**

SMA = senior medical advisor; VPS = Victorian public service

Source: Source: Internal data, Department of Health and Human Services

The costs of administering and enforcing the regulations for the licence and permit holders are recovered through the licence and permit fees charged, as outlined in section 8.

Administrative costs to licence and permit holders in applying for and renewing licences and permits

In addition to the need to pay the applicable fee for licences and permits issued under s. 19 of the Act, licence and permit holders incur administrative costs associated with the process of applying for an initial licence or permit and renewing them annually. These costs are discussed below. It should be noted that these costs represent the department's estimates of the average cost incurred based on an analysis of the requirements that current and intending licence and permit holders must meet and have not been verified directly with licence and permit holders.

New licence applications

To make a new licence or permit application, the person needs to complete:

- the application form
- the responsible person form
- the appropriate *Poisons control plan*.

The completed forms must then be forwarded to the department, together with the prescribed fee. In practice, the department frequently sends a fee invoice following receipt of the application forms, and the fee may be paid online.

The required forms are simple, entailing very limited compliance costs.

The *Poisons control plan* is a means by which the licence or permit holder is able to demonstrate compliance with the relevant provisions of the Act. A template is available, and the applicant completes the relevant sections.

It should be noted that the licence and permit application process is established by s. 19 of the Act. Hence, the costs of this process are attributable to the Act rather than to the proposed regulations.

Renewals

The process of renewing an existing licence or permit is straightforward. The department sends a renewal form and a tax invoice for the renewal fee to each current licence and permit holder each year. This form simply requires that the licence or permit holder:

- verifies that the stated licence or permit particulars remain correct
- declares that the holder is operating in accordance with the licence or permit conditions
- declares that the holder is operating in accordance with their approved *Poisons control plan*
- declares that the nominated responsible person remains employed by the holder and remains responsible for the maintenance of the *Poisons control plan*.

The completed form must be returned to the department. The licence renewal fee can be paid online.

The department estimates that the process of completing and sending the renewal form would take no more than 10 minutes on average. This reflects the simple nature of the form and in particular the fact that the declarations required to be made reflect matters that must be monitored as part of ongoing licence or permit compliance and any changes in these areas notified to the department in the course of the year.

Administrative cost summary

The above discussion sets out in broad terms the nature and extent of the administrative costs incurred by licence and permit holders (and applicants). This discussion has been included for the sake of completeness. However, as noted above, the licence and permit application process, including the specific requirements that must be met, are established in s. 19 of the Act. Therefore, these costs must be considered to be attributable to the primary legislation rather than to the proposed regulations. This being the case, they are not included in the following cost summary for licence and permit holders.

Cost summary

Table 12 summarises the preceding cost data and, in particular, distinguishes the BAU costs incurred by licence and permit holders and the incremental costs of the regulations.

Table 12: Summary of regulatory costs

Cost category	BAU costs p.a. (million)	Incremental cost (million)	Incremental %
Storage	$8.6	$0.24	2.8%
Record keeping	$27.5	$2.9	10.5%
Drug destruction	$26.3	$2.8	10.6%
Administration	$0	$0.5	NA
Total	**$62.4**	**$6.44**	**10.3%**

Table 12 shows that the total annual costs likely to be incurred by licence and permit holders in the areas of drug storage, record keeping and drug destruction are of the order of $62.4 million. In addition, the department incurs costs of around $500,000 in regulatory administration, monitoring and enforcement.

The incremental costs imposed on licence and permit holders as a result of the existence of the regulations (including licence and permit fees paid to recover the costs of regulatory administration) are estimated at approximately $6.44 million per annum. This is equivalent to a modest 10.3 per cent of the BAU costs identified. Thus, the regulations can be seen to impose small and proportionate costs on regulated parties.

While the costs incurred by individual licence and permit holders necessarily vary widely given the differences in the nature and extent of the activities undertaken by this group, the identified incremental cost of the regulations are equal to an average annual cost of $4,453 for each of the 1,446 current licence and permit holders.

7 Expected benefits of the proposed regulations

The estimation of the benefits of the proposed regulations is necessarily subject to substantial uncertainty, for several reasons. First, the regulations form a subsidiary part of a larger legislative structure (including national and international requirements) regulating drugs and poisons. It is conceptually very difficult to separate the specific impact of the current regulations under review from the operation of the legislative structure as a whole. In practice, the regulations form a necessary element of the broader legislative structure, particularly by giving practical effect to various provisions established in the Act. The regulations are also 'permissive' in effect in some areas – that is, they expand the range of people able to have access to drugs and poisons in specific circumstances that relate to their occupation or business.

Second, as similar regulations have been in place for some decades in Victoria, in Australia and internationally, it is not possible to observe directly the consequences of an unregulated approach to the use of these substances or the adoption of substantially different regulatory approaches.

Nonetheless an indication of the size of the benefits likely to be associated with the regulations can be obtained by considering the substantial data on the nature and extent of the harms that arise when pharmaceutical drugs are misused that has been set out in section 2. This shows that:

- pharmaceutical drugs are implicated in 82 per cent of the average of 369 overdose deaths occurring in Victoria annually (equivalent to around 303 deaths)
- pharmaceutical drugs have been found to be solely responsible for 42 per cent of overdose deaths in Victoria (equivalent to around 155 deaths annually)
- the costs of hospitalisations associated with the toxic effects of drugs are around $34.2 million per annum nationally (equivalent to around $8.6 million in Victoria[20]).

By implication, if the regulations contribute to these costs being even slightly lower in percentage terms than would be the case in their absence, they will yield net benefits to society. As an example, it can be noted that the recommended standard Value of a Statistical Life used in the RIS context in Victoria is approximately $4.3 million. This implies that, if the regulations are effective in reducing the number of overdose deaths due to the misuse of pharmaceutical drugs by even 1.5 per annum on average – or around one per cent of the current average annual death rate due to pharmaceutical drug overdoses[21] – the regulations would yield net benefits to society.

The department is satisfied that the actual impact of the regulations is significantly larger than this and that, as a result, the proposed regulations will yield substantial net benefits for the Victorian population. This impact is believed to be achieved through the contribution the regulations make to the secure supply, storage and destruction of drugs prone to misuse, as well as the impact of record-keeping requirements in helping to minimise drug diversion.

[20] Based on Victoria's approximate 25 per cent share of the national population.
[21] As shown in section 2, there have been around 369 overdose deaths in Victoria in the six years to 2014, while 42 per cent – or around 155 per annum – have been solely attributable to pharmaceutical drugs.

8 Fees and charges

8.1. Allocation of the cost base

As noted in section 4.3, the department's costs incurred in administering the licence and permit system relevant to s.19 of the Act and monitoring compliance of the licence and permit holders with the regulations have historically been recovered via the fees charged for the issue of new licences and permits and renewals. The department's costs incurred in administering the warrant and patient-specific permit systems relevant to s.19, s.34A and existing regulation 22B are not cost-recovered.

It is proposed to continue this approach of recovering the relevant cost base from licence and permit holders under the proposed regulations. The cost to the department in administering the licence and permit system is estimated at $525,093 (section 6.2, Table 11). As part of the process of reviewing and revising the current regulations, a detailed analysis of the costs associated with administering the licence and permit system has been undertaken, with a view to achieving better matching of fees and system administration costs. This matching of fees and costs has been undertaken in terms of allocating:

- costs and fees between existing licence and permit holders and new applicants
- costs between different licence and permit categories.

The application of this process has led to the proposal to significantly change the licence application and renewal fees that apply in the current regulations. However, there would be little net change in expected fee revenue under the proposed regulations.

The tables in this section of the RIS summarise all fees under the current regulations and the proposed regulations and indicate how fees will change. The cost allocation methodology used to arrive at the proposed fee structure is described in broad terms below. Additional detail on the department costs can be found in Appendix 2.

Inspection and audit costs

As shown in Table 11, annual inspection costs total $295,486. In 2015–16, 157 inspections were undertaken in relation to applications for new and amended licences and permits. In addition, an average of 246 audits of existing licence and permit holders were conducted. The department advises that the average cost of an audit and of an inspection is identical. Thus, the average unit cost of an inspection or audit is:

$295,486 ÷ 403 = $733.22.

However, average time costs for inspections vary for different categories of licence. These differences reflect the different scale and level of complexity of the businesses (or other activities) undertaken by different licence and permit holders. They also reflect differences in the risk profile associated with different licence or permit categories. Given these differences, the department has assigned the different licences and permits as low, medium or high risk in Table 13. For explanation of the licence and permit categories, see Tables 7 and 8.

Table 13: Risk level categorisation

Licence/permit code	Assessed risk level
MA	High
MP 4	Medium
MP 2, 3, 7	Medium
MPR 7	Medium
WA	High
WP 4	Medium
WP 2, 3, 7	Medium
WA Indent	Low
WP 4 Indent	Low
WP 2, 3, 7 indent.	Low
GDL	Low
Permit 8, 9	High
Permit 2, 3, 4, 7	Medium
HSP Type A	Low
HSP Type B	Low
HSP Type C	High
HSP Type D	High

Source: Internal data, Department of Health and Human Services

Assessment of the estimates of the time taken to undertake audits/inspections shows that these vary from 6.09 hours to 9.5 hours, including the associated pre-screening and review functions. In light of this, the cost of inspections has been allocated between licence and permit categories so that those in the medium risk category are allocated 1.25 times the cost of those in the low risk category, while those in the high risk category have a cost 1.5 times that of the low risk category allocated to them. This broadly mirrors the department's different average time inputs in undertaking these inspections, since greater scrutiny is generally applied in circumstances where the risks of harm due to noncompliance are greater.

On this basis, the cost allocations in respect of initial (pre-licence) inspections is $605.15, $756.44 and $907.73 respectively for low, medium and high risk licence categories.

A similar approach is adopted in relation to audits of existing licence and permit holders. However, an average of 246 audits is conducted each year across a population of around 1,446 licence and permit holders. This means that the allocated cost per licence or permit renewal is equal to a fraction of the actual cost of completing an audit, given that only a proportion of existing licence and permit holders is audited each year. This fraction is equal to the proportion of licence and permit holders audited, or 246 ÷ 1,446.

Thus, for example, in the case of renewal of a low risk licence, the allocated audit cost is equal to:

$605.15 × (246 ÷ 1,446) = $102.95

The medium risk and high risk audit cost is $128.69 and $154.43, respectively.

Administration costs

As shown in Table 11, 0.6 EFT at the VPS 4 level is devoted to administrative support, with the total cost of this input being $67,383 per annum. The department provided estimates of the time taken to complete the administrative functions required in relation to individual new applications and renewals, and these were costed using the above rates. This process yielded cost estimates of $71.49 and $9.85 for new licence applications and renewals respectively, with no significant difference being identified in terms of the size of these inputs with respect to different licence or permit categories. However, multiplying these 'bottom-up' estimates by the annual number of transactions processed yielded a total administrative cost of only $25,469 per annum. Thus, the bottom-up estimates underestimate the true administrative costs by a factor of more than 50 per cent. To correct for this systemic underestimation, the top-down estimate of administrative costs was divided by this amount to obtain an 'uplift factor' of 2.646.

This has the effect of allocating the true cost of the administrative functions across the various transaction types in the same proportion as that estimated by the department. This implies that the cost allocated to administrative functions is:

- $71.49 × 2.646 = $189.14 for new licence and permit applications and amendments requiring inspection
- $9.85 × 2.646 = $26.06, plus the $3.00 administrative amendment cost, totalling $29.06 for renewals.

Costs of approval function

As shown in Table 11, the annual cost of the departmental Secretary (or delegate) formally approving new licence applications is $19,010. Given an annual 157 applications requiring inspection and hence, formal approval, this is equal to an average approval cost per new licence or permit application or substantive amendment of $121.08.

Cost of advice function

The 1.2 EFT identified in Table 11 as being allocated to this function was calculated as costing $143,214. This cost is spread across all licence and permit holders and applicants based on an effective presumption that all are broadly equally likely to seek advice from the department. This gives an average annual cost per licence and permit (or application) of $99.04, which is then applied to the cost base for each initial application and renewal.

8.2 Determination of the fees

The proposed fees have been determined using the cost allocations set out above. Thus, in generic terms, fees for new licence and permit applications are derived as the sum of:

- initial inspection cost (varied according to whether the application relates to a low, medium or high risk licence)
- administrative cost
- approval cost
- advice cost.

Similarly, the fees for licence and permit renewals are derived as the sum of:

- allocated audit cost (varied according to whether the licence is a low, medium or high risk category)
- administrative cost
- advice cost.

Fees for new applications

Table 14 sets out the proposed fees for new licence and permit applications, comparing them with the existing fees.

Table 14: Comparison of existing and proposed fees for new licence and permit applications

Licence code	Current fee (from 1/7/16)	Proposed cost-based fee	Difference ($)	Difference (%)
MA	$1,499.90	$1,316.99	–$182.91	–12.2%
MP 4	$1,098.50	$1,165.70	$67.20	6.1%
MP 2, 3, 7	$793.20	$1,165.70	$372.50	47.0%
MPR 7	$687.20	$1,165.70	$478.50	69.6%
WA	$1,499.90	$1,316.99	–$182.91	–12.2%
WP 4	$1,098.50	$1,165.70	$67.20	6.1%
WP 2, 3, 7	$793.20	$1,165.70	$372.50	47.0%
WA Indent	$687.20	$1,014.41	$327.21	47.6%
WP 4 Indent	$687.20	$1,014.41	$327.21	47.6%
WP 2, 3, 7 indent.	$687.20	$1,014.41	$327.21	47.6%
GDL	$469.80	$1,014.41	$544.61	115.9%
Permit 8, 9	$666.30	$1,316.99	$650.69	97.7%
Permit 2, 3, 4, 7	$610.60	$1,165.70	$555.10	90.9%
HSP Type A	$504.60	$1,014.41	$509.81	101.0%
HSP Type B	$773.70	$1,014.41	$240.71	31.1%
HSP Type C	$1,063.60	$1,316.99	$253.39	23.8%
HSP Type D	$1,508.30	$1,316.99	–$191.31	–12.7%

Table 14 shows that most new licence and permit application fees will increase significantly. For the five categories shaded in blue, the increases will be more than 50 per cent, while for a further five categories, the increase will be between 40 per cent and 50 per cent. Conversely, two categories will see virtually no change in application fee, while three will experience fee reductions in the vicinity of 13 per cent.

Fees for renewals

Table 15 sets out the proposed fees for licence and permit renewals compared with the existing fees.

Table 15: Comparison of existing and proposed licence and permit renewal fees

Licence code	Current renewal fee (from 1/7/16)	Proposed cost-based renewal fee	Difference ($)	Difference (%)
MA	$1,028.80	$282.53	–$746.27	–72.5%
MP 4	$538.10	$256.79	–$281.31	–52.3%
MP 2, 3, 7	$280.20	$256.79	–$23.41	–8.4%
MPR 7	$259.30	$256.79	–$2.51	–1.0%
WA	$1,028.80	$282.53	–$746.27	–72.5%
WP 4	$538.10	$256.79	–$281.31	–52.3%
WP 2, 3, 7	$280.20	$256.79	–$23.41	–8.4%
WA Indent	$465 60	$231.05	–$234.55	–50.4%
WP 4 Indent	$316.40	$231.05	–$85.35	–27.0%
WP 2, 3, 7 Indent	$259.30	$231.05	–$28.25	–10.9%
GDL	$196.60	$231.05	$34.45	17.5%
Permit 8, 9	$255.10	$282.53	$27.43	10.8%
Permit 2, 3, 4, 7	$216.10	$256.79	$40.69	18.8%
HSP Type A	$200.70	$231.05	$30.35	15.1%
HSP Type B	$285.80	$231.05	–$54.75	–19.2%
HSP Type C	$476.70	$282.53	–$194.17	–40.7%
HSP Type D	$673.30	$282.53	–$390.77	–58.0%

Table 15 shows that, in contrast to the position with new applications, the majority of licence and permit categories will see significant reductions in renewal fees. The green shaded rows identify licence and permit categories for which renewal fees will fall by more than 30 per cent. Seven of 17 categories will see renewal fee reductions of at least 30 per cent, while six more categories will see smaller reductions. Only four renewal fees shaded in blue will increase, with the maximum increase being 18.8 per cent.

As the above indicates, the proposed fees imply a general rebalancing of the fee structure, with initial application fees generally rising and renewal fees falling. This broad shift largely reflects the fact that, while all premises must be inspected prior to a licence being issued, only around one-sixth (or 17 per cent) of licence and permit holders are audited in any given year. This means that the inspection/audit cost, which accounts for more than half of the total cost to the department of administering the regulations, is largely incurred in relation to new applications. This is appropriately reflected in an initial licence and permit application fee that is significantly larger than the renewal fee. Adding to this effect is the fact that the more detailed administrative process surrounding initial applications means that a larger administrative cost is allocated to initial applications than renewals.

To the extent that some initial applications will fall and some renewal fees will rise is a reflection that the previously employed cost allocation methodology did not provide for a close matching of costs and fees across individual licence and permit categories. The proposed fees address this issue,

particularly through the allocation of licence and permit categories to low, medium and high risk bands.

Medium-term impact of the proposed fees

The medium-term impact of the proposed fees is expected to be modest for almost all licence and permit categories. Table 16 models this impact, comparing the total amount paid in fees by a new applicant over a five-year period under both the existing and proposed fee structures.

Table 16: Medium-term impact of proposed fee changes

Licence code	Current five-year fee cost	Proposed five-year fee cost	Difference ($)	Difference (%)
MA	$5,615.10	$2,447.11	–$3,167.99	–56.4%
MP 4	$3,250.90	$2,192.86	–$1,058.04	–32.6%
MP 2, 3, 7	$1,914.00	$2,192.86	$278.86	14.6%
MPR 7	$1,724.40	$2,192.86	$468.46	27.2%
WA	$5,615.10	$2,447.11	–$3,167.99	–56.4%
WP 4	$3,250.90	$2,192.86	–$1,058.04	–32.6%
WP 2, 3, 7	$1,914.00	$2,192.86	$278.86	14.6%
WA Indent	$2,549.60	$1,938.61	–$610.99	–24.0%
WP 4 Indent	$1,952.80	$1,938.61	–$14.19	–0.7%
WP 2, 3, 7 indent.	$1,724.40	$1,938.61	$214.21	12.4%
GDL	$1,256.20	$1,938.61	$682.41	54.3%
Permit 8, 9	$1,686.70	$2,447.11	$760.41	45.1%
Permit 2, 3, 4, 7	$1,475.00	$2,192.86	$717.86	48.7%
HSP Type A	$1,307.40	$1,938.61	$631.21	48.3%
HSP Type B	$1,916.90	$1,938.61	$21.71	1.1%
HSP Type C	$2,970.40	$2,447.11	–$523.29	–17.6%
HSP Type D	$4,201.50	$2,447.11	–$1,754.39	–41.8%

Table 16 shows that four licence categories would see increases in total fee costs of 40 per cent or more (shaded in blue) over a five-year period, while six categories would see reductions of at least 20 per cent (shaded in green). In the remaining seven licence categories, the net impact of the proposed fee changes would be relatively small, with changes ranging from a decrease in costs of 17.6 per cent to an increase of 27.2 per cent. Two of these licence categories would see virtually zero change in the total fee cost over five years.

The proposed changes in overall licence fee costs are distributed relatively evenly across risk categories, with the largest increases (40 per cent +) in five-year cost being incurred by two categories of low risk licence, one category of medium risk licence and one category of high risk licence. However, the significant cost reductions (> 30 per cent) are more concentrated towards the medium and high risk categories, with two medium risk licence categories and three high risk categories being affected.

Fees for amendments to licences and permits

In addition to new licence and permit applications and renewals, a third transaction undertaken by the department is that of processing requests to amend existing licences and permits. These amendment applications are of three broad types.

One type involves substantial changes in the licence or permit such as a change in the category or the substitution of significantly different conditions. Where this type of application is made, the department typically undertakes an inspection of the applicant's premises to determine whether they will be able to comply with the proposed new licence or permit arrangements. Where an inspection takes place, the cost of the processing is essentially the same as for a new application. It is proposed that the fees set out in Table 14 would apply to this type of amendment application.

The second type of amendment application involves making changes to licence or permit conditions that, while substantive, do not require a premises inspection. The cost of processing such applications is clearly significantly lower than the cost of applications requiring an inspection. A lower fee is proposed. Based on the department's costing analysis, the key element of which was the conduct of a desk-based technical assessment, this fee is proposed to be set at $189.00 to apply to all licence and permit categories.

The third, and most common, type of amendment application involves making minor administrative changes, typically changing the name of the responsible person recorded on the licence or permit. This type of application accounted for 172 of the 225 amendments processed without inspection in 2015–16. The proposed fee for this type of amendment application is $26.00, which represents the cost of the administrative process required to approve and record the relevant change. The administrative costs associated with this type of transaction currently costs the department approximately $4,500 per annum. It is proposed to waive a separate amendment fee for wholly administrative amendments, such as changing the name of the responsible person. The cost will be incorporated into the renewal fee. This change reduces any disincentives to keep records up to date while incurring minimal additional costs on licence and permit holders.

9 Conclusion

9.1. Assessment of benefits and costs

The proposed regulations represent a remaking of the sunsetting regulations with a partial restructure and a limited range of amendments and improvements. Section 2 demonstrates that the problem of misuse of pharmaceutical drugs is a major one, in Victoria, in Australia as a whole and internationally. Various trends suggest that the size of the problem has continued to grow in recent times. In particular, changes in prescribing practices mean that misuse of pharmaceutical drugs is an increasingly important contributor to overall drug overdose deaths. As set out in section 4, the existing and proposed regulations include a range of measures that are specifically designed to limit opportunities for drug diversion and as a result to limit the potential for misuse.

The costs imposed by the regulations have been estimated as being quite limited. These amount to around $6.44 million per annum, equivalent to $52.23 million in present value terms over the expected 10-year life of the proposed regulations (using the Office of the Commissioner for Better Regulation's recommended 4 per cent real discount rate).

These costs are small in relation to the costs of drug misuse. Using the recommended standard Value of a Statistical Life in Victoria of $4.3 million, the regulations will yield net benefits to society if they reduce the number of overdose deaths due to pharmaceutical drug misuse by 1.5 per annum on average – or around one per cent of the current average annual death rate due to pharmaceutical drug overdoses[22].

The department is satisfied that the impact of the regulations is significantly larger than this and that, as a result, the proposed regulations will yield substantial net benefits for the Victorian population.

9.2 Assessment against feasible alternatives

As the regulations form a part of a larger legislative structure involving international treaties and national harmonisation arrangements, the range of options that can realistically be considered as a feasible means of achieving the identified regulatory alternatives is quite limited. Section 5 discusses three alternative approaches to remaking the current regulations.

Given constraints in the regulatory environment, the most feasible approach at this time is to continue an ongoing process of making specific changes identified by stakeholders to the existing regulations. Section 11 discusses a range of specific potential changes to the existing regulations that were proposed in the consultation draft of the proposed regulations, as well as changes suggested by licence and permit holders responding to a recent questionnaire. In each case, the rationale for the potential change has been identified. Where a suggestion has been included in the proposed regulations, this has been noted, while reasons have been provided to explain why other proposals are not included in the proposed regulations.

In summary, the proposed regulations have been arrived at via an iterative process of refinement and improvement of the existing regulations. Section 5 demonstrates at a micro level why the proposed regulations are considered to be superior to the various specific options considered during this process and, by implication, why the department believes the proposed regulations are superior to all feasible alternatives. That said, the process of refining the regulations is an ongoing one, and the department will continue to consider and consult on policy options.

[22] As shown in section 2, there have been an average of around 369 overdose deaths in Victoria in the six years to 2014, while 42 per cent – or around 155 per annum – have been solely attributable to pharmaceutical drugs.

10 Monitoring and evaluating the effectiveness of the proposed regulations

Following the remaking of the Drugs, Poisons and Controlled Substances Regulations 2017, the department will monitor the stakeholder response to the regulations through the activities of the program area.

Stakeholders may also leave comments on the **Drugs and Poisons Regulation** website at https://www2.health.vic.gov.au/public-health/drugs-and-poisons/comments.

The program area maintains a substantial interface with the regulated entities through phone, email and site visits and inspections. It also maintains close contact with supporting authorities such as Victoria Police, AHPRA and the Veterinary Practitioners Registration Board of Victoria (on matters of practitioner compliance) and other Victorian government departments such as the Department of Economic Development, Jobs, Transport and Resources (regarding controls on Schedule 7 poisons used for vermin control) and the Department of Justice and Regulation (in developing legislation that intersects with the department's responsibilities), as well as the Commonwealth (on the scheduling of medicines and poisons). Formal and informal processes are used and will continue when the new regulations are in place.

The department has not yet considered conducting an early formal review to monitor the acceptance of and compliance with the regulations.

The proposed regulations will also be subject to sunset provisions and review following 10 years of operation as required under the Subordinate Legislation Act to determine if there is still a problem that requires government intervention.

Drugs and poisons regulation is in the midst of active change and development. In the 10 past years at least 13 amendment regulations were made. It is anticipated that as more practitioners seek and obtain scheduled medicines under the Act, consequential amendments will be made to the regulations. In addition, the introduction of real-time prescription monitoring will require changes to the Act and the regulations. The anticipated future amendments will provide opportunities to make ad hoc amendments to improve the effectiveness of the regulations.

11 Consultation for the RIS and future consultation

The department conducted four formal rounds of consultation with external stakeholders to prepare the RIS and the proposed regulations. It also conducted internal consultation with relevant groups within the department. The following summarises the consultation undertaken, key issues raised and the response and steps for consultation following release of this RIS.

11.1 External consultation

Round 1 – April 2015

Approximately 120 external stakeholders with an interest in the regulations were contacted via a letter from the Chief Officer of Drugs and Poisons Regulation, seeking written suggestions for improvements to the existing regulations. A notice was also placed on the department's website.

Seventy-six replies either acknowledged receipt of the letter or provided comment.

The stakeholders contacted included:

- organisations representing practitioner groups in the fields of pharmacy, medical, dental, veterinary, nursing/midwifery, optometry, podiatry, Chinese medicine and ambulance services
- practitioner registration bodies
- industry groups representing areas such as aged care, primary industry, yachting, ski patrollers, horse racing and the mining, chemical, pharmaceutical and medicines industries
- hospital and healthcare organisations
- consumer bodies representing consumers and senior Victorians
- Commonwealth, state/territory and local government departments and statutory authorities
- Victoria Police.

Comments received were assessed and used to prepare the *Drugs, Poisons and Controlled Substances 2016 consultation draft* (a non-legal document). The department provided written feedback on the comments received, including explanations where suggestions could not be incorporated in the proposed regulations.

Round 2 – December 2015

Approximately 140 external stakeholders, comprising the groups identified above plus some others, were provided with an electronic copy of the *Drugs, Poisons and Controlled Substances 2016 consultation draft* and invited to comment on the document. A notice was placed on the department's website. Thirty-four written responses were received.

Round 3 – 2016

Telephone or face-to-face meetings were held with stakeholders who provided substantive comment that required further discussion. Sixteen meetings were held with various practitioner groups, government departments, regulatory bodies, industry organisations and commercial enterprises.

Round 4 – June 2016

A questionnaire was developed to estimate the costs of compliance with the proposed regulations and sent to 300 holders of licences and permits issued under the Act. The key costs identified by the 58 respondents relate to secure storage, record keeping, drug destruction and regulatory administration.

11.2 Reasons for excluding matters arising from consultation

Proposals that could not be addressed in the new regulations were those that were not within scope of the regulations, were addressed in or would require amendment to the Act, were addressed in the regulations or would require substantial policy development within the department before they could be considered for adoption.[23]

A number of suggestions sought greater consistency between the Victorian regulations and equivalent regulation in the other states, territories and the Commonwealth. This concept is generally supported in principle but would require extensive multijurisdictional policy development to resolve.

11.3 Matters considered in developing the proposed regulations

The department's response in the proposed regulations to issues raised during consultation is summarised in Table 17 and grouped thematically. Matters that could not be considered in the proposed regulations for the reasons above are not included.

See Appendix 1 for further details on the matters included in the proposed regulations and Appendix 3 for matters not included in the proposed regulations.

Table 17: Summary of matters considered in developing the proposed regulations

Key issues raised	Response in proposed regulations
Definitions	
• To be included for 'authorised prescriber', 'care' and 'form' and 'type' of stock food	Not adopted because the terms are not used in the proposed regulations or are covered by the ordinary meaning.
• To be included for 'prescription'	A definition of 'prescription' is proposed.
• To be included for 'nurse practitioner' and 'registered midwife'	Not adopted because the terms are already defined in the Act and cannot be replicated in the regulations.
• To be removed for 'aged care service'	Adopted because 'aged care service' is defined in the Act and cannot be replicated in the regulations.
Possession	
• That the Secretary approves a broader scope of ophthalmic preparations that may be used by orthoptists	A new regulation is proposed.
• That workers trained in first aid are able to possess and administer pain relief in certain industrial settings where medical assistance is not immediately available	A new regulation allows the possession and administration of Schedule 4 poisons by on-site emergency response workers trained in Advanced First Aid at mine sites and power stations, subject to approval by the departmental Secretary.
Treatment	
• That all practitioners are required to determine the identity of the patient they are treating with	The new regulations adopt this suggestion, ensuring consistent treatment requirements for

[23] In these latter cases, the suggestions received were referred to the relevant departmental policy areas for further consideration in accordance with departmental priorities.

Key issues raised	Response in proposed regulations
drugs of dependence	all practitioners with respect to drugs of dependence.
• That the Secretary has the power to approve Schedule 8 poisons requiring a treatment permit under the regulations, rather than amending the regulations each time a new substance is needed	This suggestion is not adopted but may be considered when future amendments to accommodate real-time prescription monitoring are made.
Supply Proposals concerning supply related mainly to pharmacist supply: • That the recording of supply of Schedule 3 drugs of dependence be mandated where there is a significant risk of misuse	This suggestion is not adopted, consistent with the department's long-held position that the recording of Schedule 3 poisons would introduce an unreasonable regulatory burden.
• That the medicines active substance name has first-line prominence on dispensing labels	The regulations are not amended. Changes to standardised dispensing labels would require significant policy development and community engagement, preferably at the national level, to ensure safe implementation.
• That supply may occur in contravention of the written instructions on a prescription	The regulations are amended to enable a pharmacist to supply in contravention of the instructions of the prescriber if specified conditions are met on need and safety.
• That prescriptions are retained for Schedule 4 poisons for two years	The suggestion is not adopted. Instead, where prescriptions for Schedule 4 poisons are retained, they are to be provided on request to authorised officers.
Administration • That dose administration aids (DAAs) are not allowed in residential aged care facilities	The regulations are not amended. The use of DAAs for medicines prescribed by a doctor and dispensed and checked by a pharmacist in aged care facilities is consistent with the provision of dispensed medicines within the community. In the absence of evidence to the contrary, DAAs provide a safe and practical method of medication delivery.
• That administration of medicines in residential aged care facilities is limited to registered and endorsed enrolled nurses	The existing regulation that allows carers to assist with administration of prescribed medication has not been amended. The management of administration of medication in aged care facilities is covered under the Act. Restrictions on the residential aged care workforce are beyond the scope of the regulations.
• That administration instructions from the practitioner include the dose and frequency of administration	The regulation is not amended because it may be restrictive.
Storage of Schedule 4 and 8 poisons Several proposals regarding the storage of Schedule 8 poisons were received:	

Key issues raised	Response in proposed regulations
• That Schedule 8 poisons are able to be stored in dispensing robots/electronic dispensing systems • That Schedule 8 safe requirements are altered to enable electronic locking and monitoring	A new regulation provides for the storage of Schedule 8 poisons in electronic storage facilities and dispensing robots in some circumstances.
• That items other than Schedule 8 poisons are able to be stored together with Schedule 8 poisons in a safe	The regulations are not amended. Co-location of other items would unnecessarily increase opportunities to access Schedule 8 and Schedule 9 poisons, thus compromising security.
• That drug storage devices are not necessary and controls through swipe cards, closed-circuit television and the like are sufficient	The regulations are not amended and will continue to apply minimum standards for storage in lockable facilities or a drug safe.
• That educational and government institutions are exempted from storage regulations	The regulations are not amended and will continue to apply minimum standards. The risk of diversion is not necessarily lower in these types of institution.
• That storage of drugs is becoming increasingly onerous in aged care facilities	The regulations are not amended. There are minimal regulations for storage of Schedule 4 and Schedule 8 poisons supplied on prescription.
Record keeping • That the regulations should allow drug records to be integrated into other records such as medication records or OHS records	The regulations are not amended. Specific records for Schedule 4 and Schedule 8 poisons facilitate timely and accurate audits and the identification of diversion.
• That educational and government institutions are exempted from record-keeping regulations	The regulations are not amended and will continue to apply minimum standards. The risk of diversion is not necessarily lower in these types of institution.
• That record keeping for drugs is becoming increasingly onerous in aged care facilities	The regulations are not amended as there are minimal regulations for record keeping for Schedule 4 and Schedule 8 poisons supplied on prescription.
Destruction of Schedule 8 and Schedule 9 poisons Three key proposals emerged regarding the destruction of Schedule 8 poisons: • That individual nurses are able to destroy partial doses • That two nurses are able to destroy all Schedule 8 poisons	A new regulation allows an individual nurse, midwife or other practitioner to destroy a part-dose of a Schedule 8 poison or a Schedule 9 poison during the process of administration. The regulation does not need to be amended to enable individual nurses, midwives or other practitioners to destroy partially consumed doses including used transdermal patches.
• That experienced or qualified (but unregistered) staff are allowed to destroy Schedule 8 poisons	The regulations are not amended. Unregistered staff are not authorised to possess Schedule 8 poisons for the purpose of destruction.

Key issues raised	Response in proposed regulations
• That devices could be used in the destruction of Schedule 8 poisons	The regulations are not amended. They do not prohibit the use of devices as long as the end result complies with the regulations.
Veterinary • Improve description of animal identity on prescriptions and labels	The new regulations ensure animal identity is consistent for prescriptions and labels on containers provided by veterinary practitioners.
• Remove the exemption from labelling for bulk (multipack) supplies	The new regulations require veterinary practitioners to label each pack of a multipack supply.
• Broaden the exemption from labelling bulk (tanker) supplies to cover animals that are not solely 'in flocks or herds'	A new regulation retains and broadens the exemption by removing the reference to 'flocks and herds'.
• Include a new regulation on items required in a veterinary order for stock food containing Schedule 4 poisons	A new regulation is provided that itemises requirements for an order for a Schedule 4 poison written by a veterinary practitioner to a stock food manufacturer.

11.4 Consultation following the release of this RIS

This RIS is being published for a 28-day consultation period. The significant pre-RIS consultation undertaken to date did not reveal substantial stakeholder concerns with the content of the proposed regulations.

The RIS, including the settled proposed regulations, has been advertised in a major daily newspaper and the *Government Gazette*, as required by the Subordinate Legislation Act and published on the department's website. It has also been forwarded directly to key stakeholders to ensure they are aware of the RIS and the opportunity for further consultation.

Comments received in response to the RIS will be considered in the making of the final regulations.

11.5 Release of the Drugs, Poisons and Controlled Substances Regulations 2017

In readiness for the release of the Drugs, Poisons and Controlled Substances Regulations 2017, the department will prepare a guide to the new regulations and update information available through the **Drugs and Poisons Regulation** website at https://www2.health.vic.gov.au/public-health/drugs-and-poisons.

12 Statement of compliance with national competition policy

The National Competition Policy Agreements set out specific requirements regarding all new legislation adopted by jurisdictions that are party to the agreements. Clause 5(1) of the Competition Principles Agreement sets out the basic principle that must be applied to both existing legislation, under the legislative review process, and to proposed legislation:

> The guiding principle is that legislation (including Acts, enactments, Ordinances or Regulations) should not restrict competition unless it can be demonstrated that:
>
> (a) The benefits of the restriction to the community as a whole outweigh the costs; and
>
> (b) The objectives of the regulation can only be achieved by restricting competition.

Clause 5(5) provides a specific obligation on parties to the agreement regarding newly proposed legislation:

> Each party will require proposals for new legislation that restricts competition to be accompanied by evidence that the restriction is consistent with the principle set out in sub-clause (1).[24]

Therefore, all RIS must provide evidence that the proposed regulatory instrument is consistent with these *National competition policy* obligations. The OECD *Competition assessment toolkit*[25] provides a checklist for identifying potentially significant negative impact on competition in the RIS context. This is based on the following four questions:

- Does the proposed regulation limit the number or range of suppliers?
- Does the proposed regulation limit the ability of suppliers to compete?
- Does the proposed regulation limit the incentives for suppliers to compete?
- Does the proposed regulation limit the choices and information available to consumers?

According to the OECD, if all four of these questions can be answered in the negative, it is unlikely that the proposed regulations will have any significant negative impact on competition, and further investigation of competition impacts is not likely to be warranted.

The proposed regulations do not explicitly limit the number of suppliers of scheduled drugs and poisons or the ability or incentives for suppliers to complete. It is clear that the existence of a system of licences and permits does have a tendency to limit entry into the market to some extent. However, the system of licences and permits is established in the Act, rather than in the regulations.

As section 4.2 demonstrates, parts of the regulations are permissive in nature. Thus, for example, regulation 5 (existing regulations) establishes who is authorised to possess Schedule 4, 8 and 9 poisons and in what circumstances.

Other key elements of the regulations clearly restrict the supply and use of scheduled drugs in a variety of ways. However, the restrictions adopted are considered to be the minimum necessary to achieve the harm-reduction objectives of the broader legislative structure – that is, to minimise the risk of drug diversion and misuse, as well as avoiding harms due to inappropriate prescribing and use of drugs. It is important to note that the regulations do not establish any limits on the number of practitioners authorised to have access to scheduled drugs.

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[24] *Competition Principles Agreement*, Clause 5. 1995. See the NCC website at <www.ncc.gov.au>.

[25] See: OECD 2011, Competition assessment toolkit. volume 1: Principles, OECD, Paris, pp. 8–9.

A key indicator of this approach of minimising restrictions is the fact that the range of practitioners has been progressively expanded over time as contexts have been identified in which it is appropriate to allow practitioners of particular health professions to have access to some scheduled drugs.

In sum, the proposed regulations minimise the extent of any restrictions on competition that they impose, consistent with the need to ensure the harm-reduction objectives underpinning them are met. The department is satisfied that the benefits to the public of these restrictions clearly outweigh the costs that they impose.

Appendix 1: Details on new matters to be included in the proposed regulations

The following sets out proposed changes to specific regulations under the relevant Chapter, Part and Division (if appropriate) of the proposed Drugs, Poisons and Controlled Substances Regulations 2017, together with the rationale for the change and its expected impact.

Chapter 1 – Preliminary

Definitions

New or amended definitions for the terms below are included as a result of the drafting of the new regulations:

- Australian Sailing Limited
- authorised midwife (previously defined as an authorised registered midwife)
- chart instruction
- Commonwealth Regulations
- general labelling requirements
- general Schedule 9 permit
- hospital medication chart
- prescription
- residential medication chart
- special Schedule 8 permit
- special Schedule 8 poison
- St John Ambulance

The following definition was deleted:

- aged care service

Chapter 2 – Schedule 4, 8 and 9 Poisons

Part 1 – Possession

The proposed regulations introduce a broader range of Schedule 4 poisons that may be used by an orthoptist, introduce one new category of authorisation to possess a poison or controlled substance and make an administrative change to the registered optometrists and registered podiatrists authorised to possess Schedule 4 poisons, as follows:

Orthoptists

Orthoptists are authorised in the current regulations to use Schedule 4 poisons that are local anaesthetics and cycloplegics in topical applications in the eyes of patients. The proposed regulations will enable orthoptists to seek an approval from the Secretary to the department to use ophthalmic preparations that are not confined to being local anaesthetics and cycloplegics.

Expected impact

The proposed regulation will enable orthoptists to expand the Schedule 4 preparations they are competent to use for the benefit of the public. The risks will be managed because the substances will be determined within the Secretary approval process.

Emergency workers in mining and electricity generation industries

A new authorisation is for emergency workers within specified industries,[26] to administer certain Schedule 4 poisons (methoxyflurane for pain relief is a likely candidate) to injured workers in advance of treatment provided by emergency services such as Ambulance Victoria. The amendment was requested on behalf of emergency workers employed at power stations and mine sites. The authorisation would apply where the power station or the mine is located in a position that cannot be quickly reached by Ambulance Victoria. Frequency of use is difficult to estimate and may vary according to the site. Estimated use of once or twice a year (and generally less) has been provided by industry. The linking of this amendment to a Secretary approval will allow the Secretary to establish conditions that address the need for and competency of the emergency workers to provide the emergency treatment. The conditions are expected to include a requirement that the emergency arrangement is included in the organisation's formal occupational health and safety risk management plans and approved by the workplace operator.

Expected impact

This change is expected to make pain relief available to injured workers in regional areas and in high-risk work spaces where timely access by ambulance officers may be difficult. No significant risks in terms of drug misuse are expected to arise as a result because conditions for safe possession and use will be established under an approval by the Secretary.

Registered optometrists and registered podiatrists

An administrative amendment is proposed to make it clear that the registered optometrists and registered podiatrists that are authorised to be in possession of Schedule 4 poisons through the regulations are not in conflict with the authorised optometrists and authorised podiatrists operating in accordance with a scheduled medicines endorsement under s. 13 of the Act.

Expected impact

There is no impact as the proposed regulations will continue to enable the registered optometrists and podiatrists to possess Schedule 4 poisons under the existing Secretary Approval and any future Secretary Approval.

Part 3 – Prescriptions

Establishing patient Identity – issuing prescriptions

The current regulations require medical practitioners and dentists to take all reasonable steps to establish the identity of a person before administering, prescribing, selling or supplying a drug of dependence. Proposed new regulations will extend this obligation to other practitioners who are authorised to administer, authorise administration, issue a prescription, sell or supply a drug of dependence, being certain registered nurses (including nurse practitioners) and midwives and optometrists and podiatrists.

[26] Not including state-based emergency services personnel or government incident responders.

Expected impact

The proposed change will affect practitioners when they are administering, authorising administration, issuing prescriptions, selling or supplying a drug of dependence other than a Schedule 8 poison. In most cases the practitioner will be familiar with the patient and their history, and the reasonable steps required will be minimal. However, the regulation places a stronger obligation on practitioners who are not familiar with the patient to take extra steps to prevent making an unsafe supply. This situation could arise, for example, where a person visits a doctor while travelling interstate. However, it may also arise where patients are 'doctor shopping' and is intended to reduce the risk of unsafe supply of pharmaceuticals in such cases.

This change is expected to reduce the risk of drug misuse by reducing opportunities for a person to obtain a drug of dependence that is a Schedule 4 poison (for example, certain codeine formulations, benzodiazepines or anabolic steroids) without having a legitimate therapeutic need. Additional steps will need to be taken to verify identity in only a relatively small proportion of cases in which the relevant drugs are being supplied, while the time taken to conduct additional verification in these cases is expected to be limited – for example, checking a driver's licence. Thus, the department believes that the overall impact of this change on the additional practitioners will be small.

Registrant data available from the Australian Practitioner Registration Agency indicates that Victoria has 274 nurse practitioners, 164 nurses with a scheduled medicines (rural and isolated practice) endorsement, 47 midwives with a scheduled medicines endorsement (as of June 2016), 896 optometrists with a scheduled medicines endorsement and 24 podiatrists with a scheduled medicines endorsement (as of September 2016). Thus, a total of around 1,405 practitioners are potentially affected by this change.

The extent to which this change will affect the additional practitioners will depend upon the content of the lists of Schedule 4 poisons approved by the Minister for Health under the Act for use by each practitioner group.

Establishing patient Identity by practitioners other than pharmacists for sale or supply of drugs of dependence is also addressed in Part 5 – Sale and supply by practitioners other than pharmacists

Establishing patient Identity for authorising administration of drugs of dependence is also addressed in Part 8 – Authorising administration.

Establishing patient Identity for administration by practitioners other than pharmacists of drugs of dependence is also addressed in Part 9 – Administration by practitioners other than pharmacists.

Matters concerning information required on prescriptions

Identifying information on prescriptions for animals

At the request of veterinary stakeholders, it is proposed to expand the range of identifying information that must be included on prescriptions written for animals. Whereas the current requirement is limited to the 'name and species' of animal, it is proposed that prescriptions will need to include the 'species and identity (age, breed and sex)' of the animal. This proposed change reflects concerns on the part of veterinary practitioners that current requirements are not sufficient to identify the animal for which the drug is prescribed.

Expected impact

This change will result in a very small addition to administrative burdens for veterinary practitioners but will introduce consistency with nomenclature used in other veterinary standards and reduce the potential for inappropriate administration of veterinary medicines due to confusion regarding the animal for which it has been prescribed.

Additional required information for prescriptions

It is proposed to add two new information requirements to be included whenever a prescription for a Schedule 8 poison or a Schedule 9 poison is written.

Inclusion of date of birth on prescriptions

The second proposed change requires that prescriptions for Schedule 8 or 9 poisons include the date of birth of the person named in the prescription. The absence of this information from a prescription will not prevent pharmacists from dispensing the prescribed drug in the short term, although this may change following the implementation of real-time prescription monitoring.

Expected impact

This change is intended to facilitate the matching of patient identities by the practitioner and the pharmacist and help ensure that the prescription is written for the correct person. It will also support the introduction of the real-time prescription monitoring system in Victoria by improving the matching of patient information including dispensing records and Schedule 8 permit records. Real-time prescription monitoring is an initiative intended to identify circumstances in which patients may be obtaining excessive quantities of prescription drugs that may be subject to misuse. Including the date of birth will improve the integrity of the information available to practitioners and reduce the need for follow-up and reconciliation of records.

This requirement will also essentially only affect handwritten prescriptions, as the software used by prescribers has the capacity to include the date of birth.

Explicitly identify when repeats are not authorised

The first new authorisation requires that where a prescription is to be supplied only once, the prescriber specifically writes that there is to be no repeat supply. There is an existing requirement for the practitioner to write in if repeats are needed, but if no repeats are needed, nothing else needs to be written. The regulation will apply to those prescribers who are authorised to provide prescriptions with repeats.

Expected impact

This change is expected to reduce the incidence of fraudulently altered prescriptions, whereby another person seeking to misuse the medication unlawfully adds repeats to the prescription. It will create an additional task for practitioners only if they issue handwritten prescriptions, as the software used to create computer-generated prescriptions already includes a statement to indicate that there are to be no repeats unless repeats are ordered by the prescriber. It is estimated that only a small proportion of prescriptions are now handwritten, while this proportion can be expected to continue to decline over time.

Part 4 – Stock food orders and chart instructions

Division 1 – Stock food orders

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

A proposed regulation will specify the particulars to be included in a written order from a veterinary practitioner to a stock food manufacturer to manufacture and supply a Schedule 4 poison as part of a stock food preparation.

There is currently no regulation that defines the terms of an order for supply written by a practitioner. The new regulation is included at the request of veterinary stakeholders. The regulation will require the veterinary practitioner to provide an instruction to the stock food manufacturer that contains

sufficient information to enable the manufacturer to manufacture the Schedule 4 poison stock food product and supply it to the correct person who owns or has the custody or care of the animals and their location. The new regulation will require the veterinary practitioner who writes the order to keep a record of the order for a period of three years, which is consistent with other record-keeping periods in the regulations. The order may be transmitted electronically.

Specifically the regulation will require the order for a Schedule 4 poison written by a veterinary practitioner to contain:

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

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

(c) the species and type (breed, age and sex) of the animals

(d) the date on which the order was written and the date not more than three months later when the order expires

(e) the signature of the veterinary practitioner issuing the order (it may be an electronic signature)

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

(g) the name of the Schedule 4 poison that is to be used in the manufactured stock food

(h) the final concentration of the Schedule 4 poison that is to be in the manufactured stock food

(i) the quantity of the manufactured stock food required, to a maximum quantity for supply for three months

(j) directions for use

(k) time(s) of supply as instructed by the veterinary practitioner.

Manufacturers and suppliers of stock food that is a Schedule 4 poison in Victoria are required to hold a licence under s. 19 of the Act. It is a condition of that licence that the stock food suppliers only supply on the basis of a written order from a veterinary practitioner.

Expected impact

The new regulation will improve the audit trail for supplies of stock food containing antibiotics to animals raised for food production and thus facilitate investigation of cases where it is suspected that the supply may not have been lawfully made.

The proposed regulation will impose a small additional burden on veterinary practitioners who provide orders to stock food manufacturers, in that it will set out a minimum information set to be included that will, in some cases, be larger or provided more frequently than currently occurs. The requirement to retain the order for three years will impose an additional burden.

However, given the importance for human and animal health of maintaining a clear audit trail for the supply of stock food containing Schedule 4 poisons, in particular antibiotics, this burden is seen as reasonable and proportionate.

Division 2 – Chart instructions

It is proposed to add a new regulation to authorise practitioners to write medication chart instructions, thereby giving an instruction to a pharmacist to supply a medicine in accordance with that instruction. The chart instructions are defined as those set out in the Commonwealth National Health (Pharmaceutical Benefits) Regulations 1960. The Commonwealth regulations allow a pharmacist to claim a benefit under the PBS for supplying drugs in accordance with an instruction entered on the

PBS *Hospital medication chart*. The Commonwealth rules apply to a pharmacist supplying medicines for inpatients in hospital and day procedure centres and in supplying discharge medications.[27]

The intent of the amendment is to clearly establish that supply of drugs in accordance with the Commonwealth National Health (Pharmaceutical Benefits) Regulations 1960 is authorised within Victorian health services. Written instructions signed by a practitioner will enable the pharmacist to supply Schedule 4 or Schedule 8 medicines for inpatients, including at discharge, regardless of whether the medicine is listed on the PBS. A standard PBS *Hospital medication chart* to accompany the introduction of PBS claiming from an instruction on the chart was developed and introduced nationally on 1 July 2016. The new regulation will not preclude the use of an electronic PBS *Hospital medication chart*.

Expected impact

The proposed amendment will streamline the process of providing discharge prescriptions in Victorian hospitals and day procedure centres and is expected to be of benefit to both prescribers and pharmacists. The Commonwealth advised informally that the need for the prescriber to write a separate discharge prescription, as opposed to completing the discharge instruction on a medication chart, was an important driver for this reform at the Commonwealth level.

It is not possible to estimate from available data the number of discharge prescriptions or the expected resource saving that would follow the introduction of the proposed change. However, it will apply within the 84 currently registered private hospitals, 91 currently registered day procedure centres and the 126 metropolitan and rural hospitals and health services in Victoria – a total of 301 facilities.

Stakeholders are generally supportive of this amendment, although one stakeholder expressed concern that it could foster the supply of excessive quantities of discharge medication and deter a patient from revisiting their primary practitioner.

The regulations for the pharmacist who sells or supplies in accordance with a chart instruction given on a hospital medication chart or a residential medication chart are included in Part 6 – Sale and supply by pharmacists.

Part 5 – Sale and supply by practitioners other than pharmacists

Limitations on bulk supply of veterinary medicines

The proposed regulation will place new limitations on an existing exemption that enables veterinary practitioners to supply Schedule 4 poisons in bulk for the treatment of flocks or herds of animals without labelling individual containers. In the proposed regulations, where multiple containers make up a bulk supply, the veterinary practitioner will be required to label each container.

Supply in bulk transport (tankers) where there is no packaged product and consequently no container to label will continue to be allowed under a labelling exemption.[28] A further minor change to the exemption will clarify that it applies to all types of animals by removing the reference to 'flocks or herds', which is not applicable to animals such as horses or to fish.

[27] The Commonwealth rules for Schedule 4 and Schedule 8 poisons do not preclude use of the PBS *Hospital medication chart* for supplying medicines that do not have a PBS benefit and apply to hospitals (public and private) and day procedure centres with or without pharmacy departments. Where there is no pharmacy department the Commonwealth requires that the hospital or day procedure centre has an association with an external pharmacy or pharmacist. Commonwealth rules establish maximum quantities of discharge medicines to be supplied, commonly up to one month's supply.

[28] Note that, in these circumstances, the veterinary practitioner is required to provide written instructions to the owner or person having custody of the animals.

Expected impact

The proposed change responds to identified limitations in investigating potential unlawful supply or possession that have occurred because of the difficulty in tracing the source of supply of unlabelled containers of a Schedule 4 product. Facilitating investigations of potential noncompliance is particularly important in cases where the supply and use of veterinary antibiotics may have implications for human, as well as animal, health.

The requirement to add a label to each container in a multiple supply is not expected to impose an appreciable burden given the existence of automatic labelling technology. The amendment is being made at the request of veterinary stakeholders who want to ensure the veterinary practitioner's instructions are attached to and remain with the product so the product can be correctly used and the supplier traced if necessary.

Part 6 – Sale and supply by pharmacists

Pharmacist administration, sale or supply authorised from outside Victoria

The proposed regulations will also not include an equivalent of existing regulation 17, which specifically authorises a pharmacist to supply a Schedule 4 poison on the prescription of an interstate veterinary practitioner.

The definition of 'veterinary practitioner' contained in the Act means that veterinary practitioners registered interstate are deemed to be registered in Victoria subject to any conditions that might be applied on the interstate registration, a provision that is generally applied in relation to nationally registered practitioners. Given this, there is no need for a specific authorisation of the kind contained in existing regulation 17.

Division 1 – Circumstances of sale or supply

Circumstances in which prescriptions may be filled contrary to the prescriber's instructions

This new regulation lists circumstances under which a pharmacist may supply drugs contrary to the instructions on the prescription. These include where the prescriber has given further verbal or written instructions, where the patient may request supply contrary to the prescriber's instructions or where it may not be practicable for the pharmacist to comply with the prescriber's instruction at that time. The pharmacist is to be satisfied that not to supply would pose an unreasonable difficulty to the patient and to supply would not put the patient at risk. The pharmacist must inform the prescriber that a supply has been made and make a record. Consultation with pharmacy stakeholders revealed that pharmacists do on occasion supply contrary to the instructions on a prescription without the express authorisation of the practitioner. Circumstances may involve brand substitution or supply of multiple repeats. The pharmacist may be convinced that it is safe for the patient to make the supply, and the patient may have exceptional circumstances; for example, they may be unable to travel to a pharmacy, intend to travel overseas or live in a remote location.

Expected impact

This proposed change is expected to yield small but important reductions in the risks associated with the supply of Schedule 4 and Schedule 8 poisons by allowing for the pharmacist to consider further verbal or written instructions from the prescriber or requiring the pharmacist to take all reasonable steps to ensure the supply would not represent a health and safety risk to the patient.

Conversely, complying with some elements of the proposed new regulations enabling supply contrary to the prescriber's instructions will be time-consuming and costly for pharmacists who choose to make the supply. To the extent that supply currently occurs contrary to these instructions, the new arrangements can be expected to lead to a combination of:

- additional time costs for pharmacists who contact prescribers for further instructions
- reducing the ready availability of Schedule 4 or Schedule 8 poisons for people requesting multiple simultaneous supplies where pharmacists do not consent to undertake the above steps, due to time or other constraints.

Division 2 – Duties of pharmacists relating to sale or supply

Retention of original prescriptions or orders once supply completed

Regulation 32 of the Commonwealth National Health (Pharmaceutical Benefits) Regulations 1960 requires a pharmacist who supplies a Schedule 4 poison that is subject to a Pharmaceutical Benefits Scheme (PBS) subsidy to keep the prescription for two years. The proposed new regulation will require a pharmacist to produce these prescriptions on demand to an officer who is authorised under s. 41 of the Act. This new provision has the effect of extending an existing requirement for retained prescriptions for Schedule 8 or Schedule 9 poisons to be produced to authorised officers on demand to also include Schedule 4 poisons.

Expected Impact

The new regulation will not add a record-keeping or storage burden on pharmacists because it will only oblige them to produce Schedule 4 prescriptions they already hold. The new regulation will assist in compliance investigations in relation to Schedule 4 poisons, which will predominantly focus on those subject to misuse.

Part 7 – Labelling and storage

Division 1 – Labelling

Clarifying and streamlining labelling requirements

This proposed regulation lists fewer items that a practitioner, pharmacist or authorised registered nurse must include on a container when they are supplying a Schedule 4, 8 or 9 poison for the treatment of a specific person (or animal in the case of a veterinary practitioner). This is because the items needed on dispensing labels are included in Appendix L (*Requirements for dispensing labels for human and veterinary medicines*)[29] of the Poisons Standard. Requirements for sedation warnings are also included in the Poisons Standard as per the substances listed in Appendix K of that standard.

Section 27A(1) of the Act requires a person who sells or supplies a poison or controlled substance[30] to label the container in accordance with the Poisons Standard.

The proposed regulations include a small number of additional items that exist in the current regulations that are deemed necessary to ensure the label contains sufficient information for consumers.

The additional items are:

- the species and identity (age, breed and sex) of the animal for which the drug is prescribed and the name of the owner or person having custody or care of it
- the date of recording the information
- exceptions to providing the directions for use.

[29] See Appendix L – Requirements for dispensing labels for human and Veterinary medicines.
[30] Except for a substance in Schedule 1.

Expected impact

This change will eliminate overlap between the Act and the regulations on the items needed on dispensing labels. Regulatory gaps are filled so that labels that comply with s. 27A of the Act and the proposed regulations will contain sufficient information to assist the public in the correct handling of the substance. No substantive increase in regulatory burden has been identified.

Identifying information on labels for animals

At the request of veterinary stakeholders, it is proposed to expand the range of identifying information that must be included on the labels of medicines supplied for animals. Whereas the current requirement is limited to the 'name and species' of animal, it is proposed that labels will need to include the 'species and identity (age, breed and sex)' of the animal. This proposed change reflects concerns on the part of veterinary practitioners that current requirements are not sufficient to identify the animal for which the drug is prescribed.

Expected impact

This change will result in a small addition to administrative burdens for veterinary practitioners but will introduce consistency with nomenclature used in other veterinary standards and reduce the potential for inappropriate administration of veterinary medicines due to confusion regarding the animal for which it has been prescribed.

Division 2 – Storage

Minimum standards for electronic storage and recording equipment

Current regulation 35(1) provides that Schedule 8 and Schedule 9 poisons must be kept in a lockable storage facility that provides 'not less security' than a safe with the described characteristics.[31] The wording 'not less security' allows for flexibility in lockable storage facilities; however, no specific performance standards have been set to guide regulated parties as to what can be considered to be 'not less security'.

A new regulation is proposed to specifically allow for the use of electronic storage and recording equipment ('automated medicine cabinets') in hospitals, day procedure centres and their on-site pharmacies as an alternative to a traditional safe for Schedule 8 poisons. The new regulation includes a set of minimum performance standards that must be met if a facility is to be regarded as providing at least an equivalent level of security. This will provide certainty regarding compliance to intending users of this equipment, as well as assurance from the regulatory perspective that adequate standards are being maintained.

The proposed minimum performance standards for the use of electronic storage and recording equipment that might provide no less equivalent security than the prescribed features of a safe are:

(a) Access is restricted to persons to whom the system administrator has given access rights for Schedule 8 poisons.

(b) Access is restricted to the Schedule 8 poisons specified by the person given access rights.

(c) In-built features of the equipment to record and report access, attempted access and discrepancies are turned on.

(d) The equipment gives visual, electronic or audible alerts if it is left open, is damaged or is disconnected from the power supply.

(e) The equipment automatically locks if the power is disconnected.

[31] That is, as set out in the body of the regulation.

(f) The equipment generates reports or notices for the system administrator to track discrepancies and security breaches such as unauthorised movement or forced entry.

The proposed change is to be adopted to clarify that such devices are accepted under the regulations, subject to appropriate standards being met. This is considered necessary given the fact that a number of large Victorian hospitals now use electronic storage and recording equipment[32] within the hospital pharmacy department or a pharmacy co-located with a hospital or other treatment areas of the hospital where the pharmacists and nursing and medical staff need ready access to imprest medicines[33] for treating patients.

It is proposed to limit the use of electronic storage devices to permit holders offering inpatient treatment. These settings are those most likely to reap significant efficiency gains from the use of these devices while also being generally better placed to withstand break-ins, given that many would be staffed at all hours.

Expected impact

This change will validate existing practices and provide greater control over the use of electronic storage facilities. To the extent that it enables a larger number of permit holders to adopt this option, the efficiency gains associated with electronic storage and recording devices will be spread more widely throughout the regulated group.

Pharmacy and medical stakeholders generally support the regulations addressing the matter of electronic storage and recording equipment for the storage of Schedule 8 poisons, in particular for hospitals.

At this time, law enforcement and regulators do not support the use of electronic storage and recording equipment for the storage of Schedule 8 and Schedule 9 poisons in community settings, where the level of physical security surrounding the equipment is not seen as sufficient to equate to not less security than would be afforded by storage in a compliant safe. Accordingly, the proposed regulatory change is to be limited to inpatient settings.

Drug storage requirements in residential aged care to apply with all residents

Current regulation 36 describes the storage facilities required for Schedule 4, Schedule 8 and Schedule 9 poisons. It recognises that aged care services are a low-risk environment for medicine diversion and allows Schedule 8 poisons or Schedule 9 poisons supplied on a prescription to be stored in a lockable storage facility firmly affixed to the wall or floor, rather than requiring that a drug safe be used. This provision applies across the aged care service when there is at least one high-care resident who has been supplied with their own Schedule 4, Schedule 8 or Schedule 9 poison.

Since the current regulation was first made in 2006, the proportion of high-care residents in residential care has increased. In June 2005 there were 818 residential services and 40,708 aged care residents, of which 59 per cent (or 24,018) were classified as high care. The Commonwealth definition of ‘high care’ no longer exists; however, it is possible to determine residents that require an equivalent level of care. In 2014–15 there were 58,514 residents in permanent care, of whom up to 89 per cent (or 52,077) were identified as requiring a high level of care. The effect of the trend is that there are now very few residential care providers who are not already caring for residents with the equivalent of high-care needs. These providers are therefore subject to regulation 36.

The proposed amendment would extend the operation of the existing alternative storage arrangement to all aged care facilities with one or more residents who have been prescribed a Schedule 4, 8 or 9

[32] They are required to have security reports that attest that they comply with the general requirements of current regulation 35(1).
[33] That is, those not supplied subject to a prescription for the use of a specific person.

poison, regardless of whether the residents fall within the former (no longer operative) definition of a resident with high-care needs.

Expected impact

Given the very high proportion of 'high care' residents among the residential aged care population, this change is expected to have limited practical impact because most aged care providers will already have compliant storage facilities in place.

Consultation with members of the residential aged care industry found that most services operate a uniform system for medicine storage across the service. They agreed that the proposed change would affect very few services because almost all would have one or more residents at the previous 'high care' level at any time. The industry consulted with their respective members and no concerns were reported.

Part 13 – Records

Drug record-keeping requirements in residential aged care to apply with all residents

Current regulation 39 defines who needs to keep a record of transactions involving Schedule 4, Schedule 8 and Schedule 9 poisons. It includes the provider of an aged care service where there is at least one high-care resident who has been prescribed a Schedule 4, Schedule 8 or Schedule 9 poison. The proposed amendment would require the approved provider to comply with the regulation when any resident has been supplied with a Schedule 4, Schedule 8 or Schedule 9 poison, regardless of whether the resident has the equivalent of high-care needs. Thus, the proposed change mirrors that relating to drug storage and described above.

The existing exemption in regulation 39 that does not require the approved provider to maintain a Schedule 8 or Schedule 9 poison register for prescribed medicines remains in the proposed regulations. This regulation recognises that it is not practical to retain a register when the medications are provided in individually labelled dose administration containers.

Expected impact

For the reasons identified above, as the scope of the current exemption is expanded, the practical impact of this change is expected to be limited.

Methods by which records are to be retained and retrieved

The proposed amendments to this regulation are intended to reduce the burden of having to amend the Schedule 8 poison register each time a dose of methadone or buprenorphine for opioid replacement therapy is administered to a patient. The amendment validates the provisions of the 2016 Department of Health and Human Services *Policy for maintenance pharmacotherapy for opioid dependence, Records of administration* (page 49), which allows the Schedule 8 poison register to be updated with the remaining balance on at least a daily basis, and which is already being followed by practitioners.

Under the policy the pharmacist or other practitioner must retain an accurate record of each dose administered to each patient and reconcile the actual remaining balance each day. The regulations require that any discrepancy found in the balance for Schedule 8 poisons must be reported as a loss or theft if it is not resolved.

Expected impact

The amendment will reduce the regulatory compliance burden on pharmacists and other practitioners providing supervised pharmacotherapy doses. The Australian Institute of Health and Welfare's *National opioid pharmacotherapy statistics 2014* reports that in 2013–14 Victoria had 478

pharmacotherapy dosing pharmacies, 11 dosing correctional facilities and 15 dosing facilities in other locations including hospitals. Practitioners in these settings will be able to take advantage of the new regulation if they determine it is appropriate for their particular setting. Some of these practitioners may already be operating in accordance with this proposed new provision, which is consistent with the department's pharmacotherapy policy but are consequently technically in breach of the current regulations. To this extent, the substantive impact on practice will be less than suggested above, but current practice will be explicitly authorised in the regulations.

Amending electronic records

The proposed regulation will state that the personal access codes created by individuals to enable them to make electronic records must not be shared with other practitioners. This amendment applies only for electronic transactions for Schedule 8 poisons and Schedule 9 poisons, as those poisons are at high risk of diversion.

Expected impact

This change is being adopted to reduce the potential for false records to be created as cover for the unlawful diversion of drugs that are at high risk of misuse and to facilitate the conduct of compliance investigations.

This change is not expected to create any additional regulatory burden.

Part 14 – Destruction of Schedule 8 poisons and Schedule 9 poisons

Exceptions

The current regulation defines who is authorised to destroy a Schedule 8 or Schedule 9 poison and who is authorised to be a witness, if a witness is needed. The regulations enable a practitioner or pharmacist who is authorised to possess Schedule 8 poisons and/or Schedule 9 poisons to destroy the Schedule 8 poison or the Schedule 9 poison and those same groups of practitioners and pharmacists, plus nurses and registered midwives, to act as witnesses.

The regulations also currently enable a nurse, registered midwife and practitioners (as above) to destroy the remains of a Schedule 8 poison or a Schedule 9 poison supplied in a previously sterile container without a witness.

It is proposed to amend the regulations to also enable a nurse, midwife and practitioner (as above) to destroy the unused portion of a Schedule 8 poison or a Schedule 9 poison that is a tablet or lozenge, without a witness.

Expected impact

The proposed amendment will allow nurses, midwives and the other practitioners to destroy portions of tablets and lozenges that are not able to be reused without waiting for a witness or having to store them for destruction by others at some later date. The person destroying the drug is required to make a record of the destruction, consistent with requirements under the existing regulations. The amended provision will apply during the act of administration of the drug, which is when a nurse or registered midwife is in legal possession of the medicine. It recognises what is reported to be a common practice adopted in health services for practical reasons to enable destruction of small quantities of unusable medicines.

This change will reduce the compliance burden by enabling small quantities of drugs to be destroyed in circumstances where nurses and registered midwives may be working alone and a witness is not available.

However, it is not proposed at this time to extend the amendment to apply to all forms of Schedule 8 poisons and Schedule 9 poisons. It would apply solely to oral dose forms (tablets and lozenges) that may be broken to administer a smaller dose. That is, it applies to drugs that have already been obtained for immediate administration. The amendment does not apply to the destruction of Schedule 8 poisons or Schedule 9 poisons generally – for example, the destruction of unused stocks or collections of unusable or partially used tablets.

Nursing and health service (hospital) stakeholders have requested this amendment. It is anticipated that it will predominantly affect nurses and registered midwives who may choose to destroy the medicine immediately, rather than removing it to storage in the Schedule 8 poison or Schedule 9 poison storage facility for later destruction.

Chapter 3 – Schedule 2, 3 and 7 poisons

Part 1 – Schedule 2 poisons

Captain operating a boat required to have a life raft

A new regulation is for a captain operating a vessel required to have a life raft to possess those Schedule 2 poisons required by State law to complete the medical equipment of that life raft. Life rafts may be required to hold anti-seasickness medicine, which may be in Schedule 2, in the medical equipment. By authorising captains to possess medicines in Schedule 2, it will become legal for those who service life rafts (including their medical equipment) to supply these medicines by wholesale to the boat operators as part of the medical equipment, without the boat operator needing to hold a permit issued under s. 19 of the Act.

Expected impact

This proposed change will reduce an administrative burden by eliminating the current need for captains of vessels carrying life rafts to obtain permits in order to ensure the life rafts can be supplied with required Schedule 2 poisons. This is considered an appropriate change given the low risks associated with Schedule 2 substances (which are otherwise available for self-selection in pharmacies), the fact that the life raft medical equipment is regulated and that the current compliance rate of the regulated sector is believed to be low.[34] To the extent that the latter is the case, the major impact of the change may be to eliminate a situation in which these captains are inadvertently noncompliant with the legislation.

There will be little risk with authorising possession of the Schedule 2 poison in life rafts for seasickness.

Part 3 – Schedule 7 poisons

Current regulation 65 is amended

The regulation prohibits the manufacture, sale, supply, purchase or obtaining, possession or use of a listed regulated poison (a high risk poison that is not available to the general public) except by authorised persons. The proposed regulation removes references to manufacture, sale or supply as these activities are regulated under the Act and cannot be duplicated in the regulations.

Expected impact

There is no expected impact from this administrative change.

[34] It is believed that many captains operating boats with life rafts would not be aware of the current requirement under the Act to hold a permit, and levels of compliance with the current requirement may be relatively low.

Current regulation 66 to be removed

This regulation deals with the storage obligations applied to retail suppliers of Schedule 7 poisons. It is to be removed because storage obligations for retail suppliers of Schedule 7 poisons are now included in the Poisons Standard, paragraph 3.1(2). The obligations on suppliers to comply with storage controls of the Poisons Standard are adopted by reference in the Act under s. 27A(2A).

Expected impact

Given the application of the Poisons Standard requirements, allowing the current regulation to lapse will simply eliminate an area of regulatory duplication and will not compromise security of storage of these poisons.

Chapter 4 – Miscellaneous matters

Part 1 – General requirements

Lost or stolen poisons to be notified

Current regulation 70 establishes reporting obligations applying to authorised persons and licence or permit holders who have lost poisons or controlled substances or from whom poisons or controlled substances have been stolen. The existing regulation allows the person to report the loss or theft to *either* the Secretary (to the department) *or* Victoria Police. The proposed amendment will require the practitioners and licence, permit or warrant holders under the Act or regulations to notify *both* the departmental Secretary and Victoria Police.

Expected impact

The change is being made because the notified information may give rise to investigations conducted by both organisations. Reporting to only one of the organisations does not ensure that both organisations become aware of the theft or loss and may compromise compliance investigations.

The change will place a small additional burden on notifiers, given the need to notify two organisations rather than one. The departmental Secretary currently receives 25–35 notifications of loss or theft per quarter, or 100–140 notifications annually. However, in practice, some notifiers already routinely notify both organisations in these circumstances. Hence, a relatively modest increase in the current number of notifications is expected to be required as a result of this regulatory change. The potential benefits to compliance investigations are considered sufficiently large as to mean that the additional burden is considered reasonable and appropriate.

The existing requirement to notify either the Secretary or Victoria Police will remain in place in respect of potentially lower risk situations, namely the cases of those authorised under the regulations to be in possession of poisons or controlled substances but not to supply them, retailers of Schedule 7 poisons and approved providers of aged care services who have taken responsibility for control of residents' own prescribed medication.

Part 2 – Licences and Permits issued under the Act

Fees – the revised regulatory fee for applications, renewals and amendments to licences and permits issued under s. 19 of the Act are included in section 8 of this RIS. Fees in the regulations are expressed as fee units, at the current value of $13.94. Fees for new applications, amendments with inspection and renewals are included in the table in Schedule 3.

Schedules

Schedule 2 – Forms

Forms – collection of Aboriginal and/or Torres Strait Islander status

The department has oversight of Victoria's pharmacotherapy policy and programs. The Australian Institute of Health and Welfare requests that reports on state and territory pharmacotherapy programs include information on the participation rates of Aboriginal and/or Torres Strait Islander clients, where that data is available. Victoria collected Aboriginal and/or Torres Strait Islander status for pharmacotherapy clients through the annual pharmacotherapy census conducted at pharmacotherapy dosing points for the first time in 2016.

To address gaps in prescriber data, departmental program areas have requested that Aboriginal and/or Torres Strait Islander identification status be included on the prescribed form in the regulations, currently form DP2A. The new question on the form requires an amendment to the prescribed form DP2A and is categorised as health information under the *Health Records Act 2001*.

Form DP2A in the current regulation is Form 3 in the proposed regulations. The amendment occurs in Form 3 *Part B: For treatment of an opioid-dependent person with methadone or buprenorphine*.

The form is used by registered medical practitioners and nurse practitioners when applying to the department for a permit to prescribe a Schedule 8 poison for pharmacotherapy patients. The registered medical practitioners and nurse practitioners are to collect (by consent) information on Aboriginal and/or Torres Strait Islander status directly from individuals when completing the application form. The form will include a 'no' option. The department will assess the application for the Schedule 8 treatment permit irrespective of whether the Aboriginal and/or Torres Strait Islander status question is completed on the form.

The department may use the Aboriginal and/or Torres Strait Islander status on the form in reporting aggregated data to the Commonwealth to help compile national statistics on pharmacotherapy prescribing and participation rates and in planning and assessing the effectiveness of health services in meeting the needs of Victorian Aboriginal and Torres Strait Islander communities.

The burden for providing the data on Form 3 will fall on those registered medical practitioners and nurse practitioners making new applications for pharmacotherapy permits. In the past five years, the department has received an average of 7,726 applications for pharmacotherapy permits per year. Stakeholders support this approach to collecting Aboriginal and/or Torres Strait status for pharmacotherapy clients.

Schedule 3 – Fees

Fees for new applications, amendments with inspection and renewals for licences and permits issued under s. 19 of the Act are included in the table in Schedule 3.

Appendix 2: Breakdown of the department's costs of regulatory administration and enforcement of licences and permits issued under s. 19 of the Act

Activity	EFT	Officer level	Salary*	Total salary cost	On-costs†	(Total salary and on-costs)	Overhead costs‡:	Total cost
Inspection	1.2	VPS5.1	$95,194	$114,232	$23,294	$137,525	$34,236	$171,761
	0.8	VPS5.2	$104,570	$83,656	$17,058	$100,714	$23,011	$123,725
	Subtotal							$295,486
Admin support	0.6	VPS-4	$83,737	$50,242	$10,244	$60,487	$6,896	$67,383
Advice Function	0.6	VPS-4	$83,737	$50,242	$10,244	$60,487	$6,896	$67,383
	0.6	VPS5.1	$95,194	$57,116	$11,646	$68,763	$7,068	$75,831
	Subtotal							$143,214
Approval	0.08	SMA	$185,715	$14,857	$3,029	$17,887	$1,123	$19,010
	Total			$370,346	$75,516	$445,863	$79,231	$525,093

**Salary level indicates mid-range paypoint at June 2016*

†On-costs include Superannuation (9.5 per cent), Payroll tax (5.31 per cent), Workcover expense (0.58 per cent) and Direct operating costs (5.0 per cent).

‡Overhead costs include Long Service Leave (2.5 per cent), Office Accommodation (fixed rate), Vehicle costs (fixed rate), Depreciation costs (fixed rate) and Fitout/ amortisation costs (fixed rate).

Appendix 3: The department's responses to stakeholder suggestions

Consultation Rounds 1, 2 and 3 amendments not proceeded with

Definition and use of 'authorised prescriber'

The regulations considered using the term 'authorised prescriber' throughout the regulations as appropriate to refer to the practitioners authorised to prescribe under s. 13(1) of the Act as a group. While this proposal received a high level of stakeholder support, it could not be used because of the construction of the Act.

Definition of 'care'

The regulations considered defining 'care' at the request of stakeholders to show that care could be provided by people as part of their employment as well as by family or friends. These meanings are determined to be covered by the ordinary meaning of care.

Definitions of 'form' and 'type' of stock food

Definitions of form and type (of stock food) were initially to be included in the regulations but were removed because the terms were ultimately not used in the proposed regulations.

Definitions of 'aged care service', 'nurse practitioner' and 'registered midwife'

Definitions of aged care service, nurse practitioner and registered midwife were initially to be included in the regulations but were removed because the terms were defined in the Act.

Amendment to Schedule 8 poison permit requirements (current regulations 21–22B)

An amendment to the current regulations was initially proposed for substances that require a Schedule 8 poison to be in place before they may be prescribed. Currently, an amendment is made each time a new substance is included. The proposed amendment would provide for the permit to be in place for substances that were instead approved and listed in the *Government Gazette*. This change was expected to have the benefit of enabling new substances to be added to the gazetted list, which is an easier and more timely response than amending regulations each time a new substance needs to be included.

The department continues to believe that this change has merit but has decided to defer any changes until later discussions on the integration of these controls with amendments needed to support the introduction of real-time prescription monitoring. Introduction of real-time prescription monitoring is likely to result in changes to the Schedule 8 treatment permit system that will impact on the Act and regulations.

The proposed amendment is not imperative. The most efficient approach for the department and practitioner stakeholders will be to consider and consult on all potential amendments to the Schedule 8 treatment regulations at the one time.

Amendment to existing regulation 29(1)(d): Containers of drugs to be labelled with certain details

The proposed amendment to current regulation 29(1)(d) would have required the name of the poison or controlled substance to be in the primary position on the label and the trade name in a secondary position. It was proposed as a safety measure to reduce potential confusion for patients who, due to the substitution of a generic medicine for a branded product (or vice versa) might receive an unfamiliar package and be unsure of its contents.

This proposal received some stakeholder support but was not proceeded with because stakeholders identified a number of complexities and concerns with the proposal. The department acknowledges the significance of the issues raised and has agreed with stakeholder views that it is preferable for labelling matters to be addressed nationally. This would involve using national mechanisms established via the Therapeutic Goods Administration for product labels or pursuing amendments to the Poisons Standard for dispensing labels.

Amendment to existing regulation 33: Retention of original prescriptions or orders once supply completed

The proposed amendment would have required a pharmacist to retain a Schedule 4 prescription for a drug of dependence for two years to assist in compliance investigations. The requirement was seen as being consistent with a recent change in regulation 32 of the Commonwealth National Health (Pharmaceutical Benefits) Regulations 1960 that allows pharmacists to make a PBS claim without providing the prescription, as long as they retain it for two years.

Stakeholders had mixed views on whether the regulation should apply to all Schedule 4 medicine prescriptions, including private (non-PBS) prescriptions. They were also concerned about the burden of retaining the prescriptions in a dedicated file and the potential for confusion if the required time for retaining these records were to differ from the standard three-year timeframe under other regulations.

The department acknowledged these concerns and amended the proposal so as not to introduce a new burden under the new regulations. The proposed regulation now requires that where the pharmacist does retain prescriptions for Schedule 4 poisons, those prescriptions should be available to an authorised officer upon request. The new regulation will be of assistance in Victorian compliance investigations but will not require all such prescriptions to be retained.

Amendment to existing regulation 46: Administration of drugs and poisons to be authorised

The proposed amendment would have expressly required an administration instruction from a registered practitioner to specify the dose and frequency of administration. The amendment aimed to address situations where instructions are not clearly expressed and, as a result, there is a potential for harm if an incorrect dose (or dosing frequency) is adopted.

The proposal received some support from stakeholders as an additional safety measure, although other stakeholders noted that an instruction would usually contain these details. The practical impact of the change may therefore be quite small. However, other stakeholders were concerned that the amendment was too prescriptive and might not be able to be complied with in all circumstances.

The department opted not to make the regulation more prescriptive by requiring dose and frequency to be included.

Amendment to existing regulation 51: Exceptions

The proposed amendment enables a nurse or other registered practitioner to destroy the unused portion of a tablet or lozenge or a used transdermal patch containing residual Schedule 8 or Schedule 9 poison.

The amendment had the support of stakeholders, particularly in hospitals and other settings providing nursing services.

The proposed amendment remains, but the reference to used transdermal patch is removed. Advice is that a partially consumed dose including a used transdermal patch may already be disposed of by a nurse or other registered practitioner without restriction.

Consultation Round 4 amendments not proceeded with

A questionnaire was sent to 300 of the 1,446 current licence and permit holders during the development of the proposed regulations and this RIS to ascertain the costs of complying with the regulations (see section 6). Of the 58 respondents, 56 (96 per cent) agreed that the regulations struck an appropriate balance between risk management and compliance costs.

The questionnaire included a separate question on how the regulations could be improved. Eighteen of the 58 respondents (31 per cent) made one or more suggestions in response to this question.

Below are the suggestions from stakeholders who received in the questionnaire developed for this RIS. The department's response is included.

Storage/security requirements

Eight of the 58 respondents (14 per cent) said they would change their drug storage arrangements in the absence of regulatory arrangements and identified only small potential savings from such changes. Despite this, several respondents to the question about how the regulations could be improved indicated that the security requirements for storing drugs of dependence could be made more flexible. In particular, a small number of respondents suggested that the requirements for locked drug safes or cabinets were unnecessary and impeded work flow in circumstances where there were multiple levels of security on site. That is, where access to the site and to specific rooms was controlled by swipe card systems, CCTV and the like, it was argued that an additional level of security for the specific drug storage device was unnecessary.

The department notes that the regulations define minimum security requirements necessary to prevent drug diversion and thus protect the public. While some licence or permit holders may adopt additional security arrangements for commercial or other reasons, and this practice is encouraged, it cannot be assumed that these alternative arrangements offer comparable levels of protection, so the regulations are not amended.

A second suggestion was that the regulations should allow for the storage of scheduled poisons in robotic/electronic dispensing facilities. The current regulations do not exclude the storage of scheduled poisons in robotic/electronic dispensing systems. In relation to the storage of Schedule 8 and Schedule 9 poisons, it is the responsibility of the person storing the substances to ensure the storage meets the minimum security standards of the regulations.

The department notes that the proposed regulations include minimum security and access requirements that will allow for the storage of Schedule 8 poisons in robotic/electronic dispensing facilities, as requested by these stakeholders. The proposed regulation is directed to health services offering inpatient treatment together with any co-located pharmacies, as these larger settings offer increased protection against burglary compared with community settings.

Dispensing

One respondent who was a major health services provider argued that the requirement for a pharmacist to be present at all times limited what would otherwise be their use of 'satellite' pharmacies within their facilities, at significant cost in terms of lost efficiencies. Another respondent also argued that the

guidelines on restrictions of access of pharmacy staff to dispensaries when no pharmacist is present creates 'enormous' problems in terms of opening hours, service provision and operational planning.

The department indicates that enabling greater access to scheduled poisons by unregistered persons would require policy development and legislative change across multiple areas of the health system to be implemented effectively without compromising the achievement of the key objectives of the regulations. These changes would require time for development and further stakeholder consultation. For practical reasons, such changes are beyond the current process of remaking the sunsetting regulations and so the regulations are not amended.

Record keeping

Record-keeping requirements were found to be the largest single-cost item associated with the current regulations, in terms of both business-as-usual costs and the incremental costs of the regulations. However, it must be recognised that record keeping is an important mechanism supporting the safe delivery of healthcare, robust research and efficient industry processes. Although administrative tasks should not pose undue burden on industry, robust systems enable early identification of diversion and allow for comprehensive auditing. The value of record keeping is reflected in the 84.5 per cent (49/58) of respondents who stated they would not change their record-keeping practices in the absence of the regulations.

Electronic record keeping

Nine respondents made proposals for change in the area of record keeping. Of these, four stated that they would move to greater use of electronic record-keeping arrangements if not constrained by the regulations.

The department notes that the existing regulations do not prevent the use of electronic record keeping and that many facilities, particularly pharmacies and pharmaceutical wholesalers, use electronic records. The availability of fit-for-purpose electronic record-keeping tools in the market may pose a perceived barrier to adopting electronic records. There may be merit in the department providing more explicit guidance on the use of electronic records. The department will keep up with developments on the use of electronic records into the future and consider the scope for regulatory improvements in this area as part of its ongoing policy development. The regulations do not need to be amended.

Checking and recording

Four of the 58 respondents stated that they would reduce the amount of checking or recording if not constrained by the regulations.

The department notes that the regulations do not establish a specific required frequency of checking, with decisions on this issue to be determined on the basis of risk assessment.

Two respondents noted that the regulations require them to keep duplicate records of drug movements in various contexts and that such duplication could be eliminated via regulatory change. For example, it was suggested that drug movements only be recorded in a patient's medical chart.

The department notes that current regulations 41 (1)(a) and 41(1)(b) require that records of transaction of Schedule 8 poisons be 'readily sorted by poison or controlled substance' and show the 'true and accurate balance'. The purpose of this provision is to enable the timely and accurate audit of Schedule 8 poisons. It is considered that the use of uncentralised records would reduce the effectiveness of such audit activity, thus increasing the risk of diversion and preventing the prompt identification of incidents. The regulations are not amended.

Exemptions

A suggestion was made that educational and government organisations could be exempted from permit and record-keeping requirements for Schedule 4 poisons. However, the department believes that the risks of diversion associated with Schedule 4 poisons, particularly drugs of dependence, are not necessarily lower where they are being used by these types of institution and so the regulations are not amended.

Drug destruction

One of the 58 respondents suggested they would choose not to have two qualified persons undertaking various operations. The department notes that the current regulations only require two registered practitioners to be present for the destruction of Schedule 8 and Schedule 9 poisons. This requirement is consistent with other state and territory legislation and is designed to protect against drug diversion, which is a particular risk at the point of disposal. A suggestion received that controlled drug waste be recorded in the patient's medical record instead of the controlled substances record would likely pose similar risks, as audit would be very difficult. The regulations are not amended.

The department also notes that, while 45 of 58 respondents estimated the amount of staff time devoted to drug destruction, only six respondents stated that they spent more than 50 hours per quarter on this activity. Given the modest costs involved, it is not considered appropriate to compromise the current requirements and thereby increase drug diversion risks.

Conversely, a specific issue of apparent inconsistency in the requirements in relation to drug destruction was also raised. Nurses are currently able to dispose of half ampoules of morphine but not half tablets or other solid dosage forms. The ability to do so (notably, destruction of half Endone tablets) was considered to be appropriate and likely to decrease risk of diversion and time and cost associated with managing Schedule 8 poison use.

The department believes this is a reasonable proposal and has incorporated it into the proposed regulations.

The use of devices in the destruction of Schedule 8 poisons was also suggested as a means of reducing the regulatory burden associated with drug destruction. The department notes that the current regulations do not prohibit the use of devices and that they may be used if the end result complies with the regulations.

The requirement that two qualified staff be present when Schedule 8 and Schedule 9 poisons are destroyed via an external provider of drug destruction was identified as an example of over-regulation by one respondent. The department notes, however, that the risk of diversion is not mitigated by the use of an external company. It therefore believes it is appropriate to maintain this requirement and so the regulations are not amended.

Schedule 8 poisons

The increasing use of Schedule 8 poisons in the community, and its implications for increased compliance costs including storage and record keeping in aged care facilities, was highlighted by a small number of respondents. In particular, respondents noted that the requirements of the regulations in relation to managing these drugs in aged care settings, which are typically characterised by low staff–patient ratios, were increasingly seen as onerous.

The department notes that increased usage of certain drugs increases the risks of drug diversion, all else being equal. Thus, it is difficult to see how this observation can be used to support the adoption of less strict standards. Moreover, in the setting of aged care facilities, the regulations already allow for reduced record-keeping and storage requirements for Schedule 8 poisons supplied on prescription, commensurate with the lower risk of diversion believed to exist in this setting. Medicine supplied on

prescription accounts for the vast majority of medicines used in residential aged care**.** To reduce record-keeping or storage requirements further would likely increase the risk of diversion and associated harm. Consequently the regulations are not amended to lessen current controls.

Licences and permits

A number of changes were suggested in relation to licences and permits, with the goal of streamlining these requirements. One respondent argued that permits could be issued with longer duration (for example, three years), thus reducing the burden associated with the renewal process. The department notes that a change to the renewal duration cannot be implemented through the regulations but would require amendment to the Act.

Another proposal was made by a licence holder who has up to 200 separate licences[35] covering individual storage places for a single substance (nitrous oxide). It was suggested that a single, statewide licence could be issued, covering all of these storage facilities.

The department notes, however, that each site has separate security arrangements, requiring individual assessment and review to determine that they are adequate. The issue of single licence would be difficult to reconcile with a need to conduct such individualised reviews. Therefore, the retention of separate licences for each site is consistent with the general arrangements for distributors across the state.

It was also suggested that nitrous oxide could be exempted from the coverage of the regulations. However, this change would be dependent upon a change to the current entry for nitrous oxide in the Poisons Standard and would need to be considered through a different process to the remaking of the regulations.

Finally, several, apparently small-scale, operators felt that the cost of the licence or permit was excessive, given their usage patterns. However, the department notes that its review and inspection obligations for each permit holder are independent of individual ordering patterns. The cost-based justification of the current licence and permit fees is contained in section 8 of this RIS.

END OF DOCUMENT

[35] The department notes that not all these licences are held in Victoria.