

Drugs, Poisons and Controlled Substances Regulations 2017 Sunset Review

Discussion Paper

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Drugs, Poisons and Controlled Substances Regulations 2017 Sunset Review

Discussion Paper

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1. Introduction

1.1 Purpose

1. This paper is designed to generate discussion and feedback on the current regulatory framework governing drugs, poisons and controlled substances in Victoria. It does this by setting out the current regulatory requirements, identified issues or opportunities, and potential options for reform. Your responses to consultation questions will shape policy and Regulations and an associated Regulatory Impact Statement (RIS) that will be subject to public consultation via the Victorian Government's online consultation platform, [Engage.Victoria](#) early in the 2026-27 financial year.
2. The paper has been developed following internal consultation within the Department of Health (the department) and Safer Care Victoria. The department invites input from targeted stakeholders including professional associations, peak bodies and organisations on all aspects of the Regulations and potential changes.
3. The issues in this paper are not an exhaustive list of changes being considered for reform and do not reflect endorsed government policy. Minor and technical proposals that are aimed at improving readability of the Regulations or those that are not expected to have a substantive impact are not included in this paper. Such matters are listed at **Appendix A** and further detail can be provided upon request.

1.2 Background

4. The *Drugs, Poisons and Controlled Substances Act 1981* (the Act) and the *Drugs, Poisons and Controlled Substances Regulations 2017* (the Regulations) regulate the manufacture, supply, labelling, packaging, storage, advertising, prescribing, possession and use of scheduled medicines and poisons and controlled substances (henceforth referred to as 'scheduled poisons') in Victoria.
5. Regulations under the Act were most recently reviewed and re-made in full in 2017. In accordance with the *Subordinate Legislation Act 1994*, the Regulations will expire (or 'sunset') on 16 May 2027.
6. The objectives of the Regulations are to:
 - facilitate and enhance the safe and secure storage, sale, supply, prescribing, administration and use of drugs, poisons and controlled substances by registered practitioners, authorised persons, licensed or permitted persons and the public,
 - prescribe fees and other matters relating to the provision of licences and permits issued under the Act, and
 - prescribe forms and other matters necessary to be prescribed for the purposes of the Act.

1.3 Scope of this review

7. This Review is intended to ensure the Regulations are:
 - effective in addressing the underlying causes of harm
 - cost effective
 - proportionate to the harm and risk to the community, and

- appropriately administered and implemented.
8. This will ensure the new Regulations meet the requirements under the *Subordinate Legislation Act 1994* and are informed by the Victorian Guide to Regulation.
 9. The Review will also consider the Drugs, Poisons and Controlled Substances (Precursor Chemicals) Regulations 2017 (the Precursor Chemicals Regulations) which prescribes quantities and purposes for the possession of precursor chemicals, as the department is considering combining these regulations to streamline and improve regulatory transparency.
 10. This discussion paper outlines key opportunities for reform identified within the department. Feedback is sought in relation to discrete issues comprising recent reforms, permissions for certain professionals, storage and destruction. Stakeholders are also welcome to provide broader feedback on matters within the scope of the regulation making powers under the Act.
 11. There are a range of reforms that are out of scope of this discussion paper, which may be included in the new Regulations. Reforms are underway to consider permissions for paramedic practitioners and designated nurse prescribers to possess and administer (as relevant) scheduled poisons, and reforms were recently introduced for Aboriginal and Torres Strait Islander Health Practitioners (ASIHPs), and Aboriginal and Torres Strait Islander health workers. Reforms are also in progress relating to administration of scheduled poisons in aged care. Furthermore, National Health Ministers are continuing to explore harmonisation of national drugs and poisons legislation. Policy development and consultation relating to these reforms is occurring through separate processes and are out of scope for this discussion paper.
 12. The safe implementation of potential reforms will be examined in detail when considering changes. As such, broader reforms such as expansions to scope of practice that require change management activities (e.g. new/updates to clinical guidelines and capability building including training) and the allocation of resources for effective implementation, are outside the scope of this review. Such proposals may be given further consideration in future reforms. Reforms that require amendments to the Act are not within scope of this review; feedback received on Act reforms will be recorded for consideration for future legislative review.

1.4 How to make a submission

13. The Health Regulator within the department is seeking your input on the issues explored in this paper, as well as general feedback on the Regulations. To support your submission, evidence such as deidentified quantitative and qualitative data including case studies and examples are appreciated where practicable.
14. You may also wish to address the following general questions in your response:
 - What works well in the Regulations?
 - What does not work well in the Regulations?
 - If the Regulations reflected best practice, how would we know?
 - What is the ONE thing that would make the biggest improvement to the current Regulations?
15. Submissions can be sent by email to Legislation and Regulation Reform legandregreform@health.vic.gov.au
16. Should you wish to arrange a meeting with the team to discuss anything in more detail, please contact the team via the email address above.
17. Submissions are due by **Wednesday 8 April 2026**.

18. The team may contact you for further discussion following the receipt of your submission.

2. Refining real time prescription monitoring reforms

19. The department is considering opportunities to optimise the public health benefits through potential refinements to the system for real time prescription monitoring and the Real Time Monitored Poisons Database, known as and henceforth referred to as SafeScript. Introduced in 2018, SafeScript enables prescribers and pharmacists to have immediate access to a patient's prescription history for high-risk medicines such as opioids, benzodiazepines, and other Schedule 8 drugs¹. This helps to:

- Prevent harm and save lives by supporting safer use of monitored poisons,
- Improve consumer safety and quality of care,
- Reduce the risk of misuse, diversion, and accidental overdose, and
- Support clinical decision-making and regulatory compliance.

20. Mandatory requirements to check SafeScript apply in most circumstances and were introduced to minimise the risk of harm of uncoordinated prescribing and/or supply of Schedule 8 and Schedule 4 medications that are also drugs of dependence or medications subject to abuse, by multiple practitioners. The database is linked to a prescription exchange service, thereby only medicines that are prescribed are recorded on SafeScript. SafeScript enables critical oversight of the quantity and strength of scheduled poisons previously supplied to a patient, a critical tool to facilitate continuity of care, particularly when the prescriber is not the patient's usual practitioner and enables monitoring for adverse reactions. Pharmacists who dispense the products provide a secondary check for safe prescribing often identify potential risks or interactions.

2.1 Requiring a prescription for medicinal cannabis

The department is considering opportunities promote safer use of medicinal cannabis by strengthening SafeScript oversight, including tighter controls on supply without a prescription. Stakeholder views are sought in relation to the benefits and disadvantages of this proposal.

We also invite stakeholder feedback on broader proposals to mandate prescription-based supply for all monitored poisons. Exemptions would continue to align with existing regulatory provisions where SafeScript checks are not required, including hospital care. Additional exemptions would be developed for in person clinical treatment, emergency situations, or other circumstances where issuing a prescription is not reasonably practicable. Exemptions would continue to align with existing regulatory provisions where SafeScript checks are not required, including hospital care. Additional exemptions would be developed for in-person clinical treatment, emergency situations, or other circumstances where issuing a prescription is not reasonably practicable.

¹ Monitored poisons are listed at Schedule 5, Drugs, Poisons and Controlled Substances Regulations 2017.

21. Access to medicinal cannabis products is governed through complex arrangements at both the state and federal level. Legal access to medicinal cannabis products is facilitated by the Therapeutic Goods Administration (TGA), while the practitioners who prescribe and dispense unapproved medicinal cannabis are regulated by the Australian Health Practitioner Regulation Agency (Ahpra), the Medical, Pharmacy, Nursing and Midwifery Boards of Australia.
22. The DPCS regulatory framework currently permits authorised health practitioners to supply patients under their care with scheduled poisons, including medicinal cannabis, without a prescription. The model enables rapid therapeutic intervention where delays could compromise patient outcomes and plays a particularly important role in hospital and emergency settings. In such environments, authorised health practitioners operate under defined protocols to ensure that supply is safe, clinically justified, and appropriately documented.
23. There are also significant disadvantages to the supply without prescription model, particularly for high risk scheduled poisons such as those prescribed as monitored poisons. Supply without a prescription is not captured in SafeScript, therefore reducing visibility of patient history and limiting opportunities to address concerns around the patient's usage, therapeutic care, and coordination of care with other prescribers. At a systems level, the lack of available data makes it challenging to build a picture of supply and safety for these scheduled poisons across Victoria. At a clinical level, health practitioners may be unable to take into account interactions when diagnosing and developing therapeutic interventions.
24. Such activity has particularly been noted in relation to medicinal cannabis where there are less financial incentives for prescribing and an emergence of single product clinics. Growing patient demand and the widespread use of unapproved medicinal cannabis products has prompted the need to consider current regulatory settings. The TGA has received hundreds of adverse event reports in recent years, and a medical college has warned of a significant increase of admissions to hospital with psychosis after being prescribed medicinal cannabis products. In response, the TGA has initiated public consultation to review access pathways and oversight mechanisms. These developments underscore the importance of balancing patient access with clinical safety and ensuring that regulatory frameworks remain responsive to emerging risks.
25. The department is considering options to build a more comprehensive picture of supply and safety of medicinal cannabis across Victoria and is considering the benefits of requiring health practitioners to use prescription exchange services to supply medicinal cannabis, so information can be recorded in SafeScript. The exceptions for use of SafeScript would still apply. This will improve the quality of data held in SafeScript so future health practitioners can properly consider the therapeutic needs of their patients.
26. Consideration may also be given to limiting the circumstances in which broader monitored poisons can be supplied without a prescription to particular circumstances, in person clinical treatment, emergency situations, circumstances where issuing a prescription is not reasonably practicable, or where a person is not required to check SafeScript under regulation 132G, 132H or 132I. -person clinical treatment, emergency situations, circumstances where issuing a prescription is not reasonably practicable
27. It is noted that issues regarding supply of medicines outside of the monitored poisons database (or its equivalent) vary across jurisdictions and is being considered by various regulatory bodies and jurisdictions across Australia. The department will consider this reform within the broader national context.

2.2 Appropriate actions to be taken after checking SafeScript

The department is considering regulatory amendments to require action from prescribers and suppliers, when a SafeScript check for a patient shows recent prescribing of the same or similar monitored poisons by previous practitioners. In these circumstances, consideration is being given to requiring prescribers and suppliers to take all reasonable steps to communicate with any relevant prescribers, to co-ordinate treatment when a person (the patient) has been prescribed in the last 8 weeks with the same or similar monitored poison. If the prescriber or supplier is unable to communicate with a previous prescriber, the prescriber or supplier must record the steps taken. This requirement is intended to apply only if the practitioner chooses to prescribe or supply a monitored poison. No communication or co-ordination would be necessary if the practitioner chooses to refuse the request and ask the patient to consult with one of the previous prescribers shown on SafeScript.

28. The Act provides that unless the Regulations provide otherwise, pharmacists, registered medical practitioners, nurse practitioners and authorised suppliers must take all reasonable steps to check SafeScript in relation to a person before prescribing or supplying the person with monitored poisons. The Regulations provide circumstances where mandatory checking is not required, including where the patient is an inpatient or outpatient in a hospital or emergency department, a person being treated in a prison or a police goal, or a resident in an aged care service.
29. Mandatory requirements to check SafeScript apply in most circumstances and were introduced to minimise the risk of harm of uncoordinated prescribing and/or supply of Schedule 8 and Schedule 4 medications that are also drugs of dependence or medications subject to abuse by enabling prescribing by multiple practitioners.
30. In addition to the requirement to check SafeScript, the Regulations place additional obligations on pharmacists to notify different prescribers when the patient has been supplied with the same or similar drug of dependence. While prescribers must check SafeScript, there is no requirement for them to act on the information provided, which can lead to a lack of coordination and oversight of patient care. Guidance from the Royal Australian College of General Practitioners (RACGP) '*Prescribing drugs of dependence in general practice*' supports the prescribers liaising with previous prescribers. This reduces the risk of harm from oversupply and provides continuity of care to the patient.
31. There does not appear to be comparable regulatory requirements in other states or territories. Change will require careful consideration of expectations regarding coordinating patient care to support regulatory compliance, and ensure the administrative burden is appropriate. The department welcomes any feedback regarding alternative proposals to support more coordinated care.

Consultation questions: Monitored Poisons Database reforms

- Would you support the changes being considered? Why or why not?

3. Drug-related harm reforms

32. Regulatory reforms in 2024 established a comprehensive framework that enables both mobile and fixed-site drug testing services to operate within Victoria. The drug testing service is staffed

by scientists who provide rapid substance analysis of drug samples, along with harm reduction workers, who provide tailored information and support to help people make more informed and safer choices by giving them information about their drugs and harm reduction advice. Reforms also enable the use of automatic machines in the supply of naloxone for the treatment of opioid overdose. The following reforms are being considered to enable efficient and effective operation of these reforms.

3.1 Transportation of substances obtained by drug-checking service

The department is seeking feedback broadening permissions for possession of a drug-checking substance for the purpose of transportation, including via consignment.

33. Regulation 7 item 2 enables a person who is engaged or employed to transport a Schedule 4, 8 or 9 poison at the request of a person holding a licence or permit issued under the Act or Regulations, for the purposes of delivery to the person to whom the consignment is addressed. There is confusion as to whether this provision extends to authorise such a person to transport a 'drug-checking substance'.
34. The Act specifies that drug-checking permit authorises the holder of the permit, and each special drug-checking worker, engaged by the holder of the permit to do various activities including transporting the drug-checking substance. Given the legal uncertainty around the operation of Regulation 7, this provision is relied upon in practice and has led to inefficiencies and operational challenges.
35. Transportation of a drug-checking substance is required when there is uncertainty as to makeup of substances within a specific drug sample and a secondary analysis of the sample must take place in a laboratory. Samples that are obtained during mobile drug-checking at festivals are first transferred to the fixed site, and then to a secondary laboratory if required, which currently takes place 1 – 2 times per fortnight. On each occasion, 10 or less samples are transported, with each sample weighing approx. 0.001g or less and diluted in methanol.
36. Restricting the lawful transfer of the substance to these few individuals is challenging in practice, given these are operational staff that undertake the drug checking services. The current provisions result in delays in secondary analysis which may impact on public health given the unknown nature of the substance. A potential amendment would enable more frequent transportation of samples, via agent, or courier if required for urgent reasons.

3.2 Alternative recordkeeping for small quantities of Schedule 4, 8 and 9 poisons and drug checking samples

The department is seeking feedback on the benefits and disadvantages of enabling an alternative recordkeeping requirement for small quantities and dilutions of scheduled poisons, and any considerations which may need to be managed.

37. Drug-checking services must comply with the recordkeeping requirements in the Regulations and record the quantity of the transacted. This requirement has proved challenging for permit holders to date, as some drug-checking substances are of such a small quantity that they may not always register on scales outside of specialised scientific instruments used within highly controlled settings. This situation has resulted in uncertainty as to whether current practices are compliant with the Regulations. Despite these minute quantities however, some substances are of such toxicity that they can still be lethal.

38. The department is considering an amendment to enable conditions to be included on a permit, including a drug checking permit, to set alternative record keeping requirements for small samples of Scheduled poisons that are appropriate to the permit. For example, a drug checking service might have an agreed alternative recordkeeping requirement that would allow a drug checking sample to be recorded as 'less than 0.001g'. Potential alternative record keeping conditions may also be used for permits for research, particularly when recording diluted solutions. This flexibility aims to reduce the burden of recording individual changes to diluted substances, where the risk of diversion is low.

3.3 Qualifications of drug-checking director

The department is seeking feedback on broadening the scope of suitable workers that are eligible for employment as a drug-checking director.

39. Drug-checking directors are either general or special drug checking workers that are engaged by a drug-checking permit holder to oversee the drug-checking services. The Regulations prescribe requirements for drug-checking directors, requiring at least 2 years of experience in operational management in the provision of alcohol and other drug treatment services or harm reduction services.
40. Appropriate oversight of drug-checking activities by a qualified individual is vital given the nature of the activity, however current requirements have resulted in challenges in securing individuals with the prescribed experience.
41. The department is seeking feedback on a proposal to alter the requirement for the 2 years management experience being required in an alcohol and other drug or harm reduction setting, to be expanded to include management experience in a broader health setting. This proposal seeks to broaden the scope of suitable workers while recognising transferable skills including managing staff in high stress environments.

3.4 Clarifying administration of Schedule 3 poisons

The department is seeking feedback regarding the benefits and disadvantages of a proposal to stipulate that unless advised otherwise, the administration of Schedule 3 poisons is not regulated.

42. The Regulations govern 'dealings' with Schedule 3 poisons, including restrictions on storage, display, and supply. When first introduced in 2017, these provisions only regulated administration of Schedule 3 substances in so far as it required health practitioners to administer when there was a therapeutic need, and prohibiting administration where it would support drug dependency. Since then, the Regulations have been amended multiple times to recognise the expanded health workforce and the inclusion of naloxone providers to enable organisations to purchase lifesaving schedule 3 poisons, and supply them appropriately. While the overarching intent has remained consistent, these incremental changes have introduced complexity in interpreting requirements the administration Schedule 3 poisons, raising questions about clarity and compliance.
43. This has caused some stakeholders to take a view that administration of schedule 3 poisons, such as naloxone are only permitted in particular circumstances. The issue has also come up in relation to confusion around permitted administration of adrenaline autoinjectors.
44. The department is proposing the addition of a clarifying regulation to confirm the Regulations do not restrict the administration of Schedule 3 poisons except where provided for specifically in

the Regulations (e.g. requiring prescribed health practitioners to take all reasonable steps to ensure a therapeutic need exists for that poison, not supporting a drug dependency).

Consultation questions: Drug related harm reforms

- Would you support the changes being considered? Why or why not?

4. Permissions for specified persons

45. The Regulations outline permissions for specified persons to possess, supply, prescribe, and administer scheduled poisons. The following practitioners are authorised to possess Schedule 4 and Schedule 8 poisons within the lawful practice of their profession:

- Medical practitioners
- Nurse practitioners
- Authorised nurses and midwives
- Dentists
- Pharmacists
- Veterinary practitioners
- Optometrists and podiatrists (for specific Schedule 4 poisons within their scope)
- Dental Hygienists, dental therapists, oral health therapists and dental assistants (for specific Scheduled poisons in circumstances)
- Orthoptists (for specific Schedule 4 poisons in certain circumstances)

46. The Regulations also provide a list of persons authorised to possess Schedule 4, 8 and 9 poisons in more limited capacities and circumstances.

47. Since the making of the Regulations, registered paramedics have been recognised as a profession, and clinical perfusionists have sought clarification and expansion of their roles in the drugs and poisons regulatory framework. To prevent uncertainty, inconsistent implementation across health services, and potential limitations in workforce flexibility, there is a need to assess whether the current permissions reflect contemporary clinical roles and whether additional professions should be recognised under the Regulations. The following reforms are being considered.

4.1 Registered paramedics to possess and administer in broader health services

The department is seeking feedback on enabling registered paramedics to work in a broader range of settings, under suitable governance structures to ensure safe practice.

48. The Regulations were made before registered paramedics were recognised as an Ahpra profession. They enable paramedics to work as operational staff of Ambulance Victoria. Other registered paramedics may work for organisations such as National Emergency Patient Transport (NEPT) and First Aid Services (FAS) within a more limited scope of practice in accordance with the Clinical Practical Protocols of those organisations.

49. Since the making of the Regulations in 2017, paramedics have become registered health practitioners under the Health Practitioner Regulation National Law and regulated by the Paramedicine Board of Australia. Professional standards have been formalised, including scope

of practice, ethical conduct, and continuing professional development. Work is also underway to support advanced practice paramedics.

50. Most jurisdictions in Australia have provided permissions for registered paramedics to possess, supply and administer scheduled poisons as part of their employment with an ambulance service. Several jurisdictions, however, are considering opportunities to enable registered paramedics to work in emergency departments and other community settings. New South Wales has recently run trials to enable paramedics to work in emergency departments, and South Australia has enabled Extended Care Paramedics (ECPs) to work collaboratively with other health care professionals to manage and treat people in their home.
51. There is interest in enabling registered paramedics to work in a broader range of settings within multi-disciplinary teams through administering under instructions, including community health settings and hospital emergency departments. The department is considering recognising registered paramedics in the Regulations and enabling registered paramedics to administer under broadly the same circumstances as a registered nurse.
52. They would be permitted to administer Schedule 4 or 8 poisons when employed or engaged by a public health service entity or health services establishment within the meaning of the *Health Services Act 1988* (other than *Ambulance Victoria*, or a holder of NEPT or FAS). When employed by one of these services, the registered paramedic may administer:
- on written instructions from an authorised prescriber,
 - on verbal instructions from an authorised prescriber if, in the opinion of the authorised prescriber, an emergency exists,
 - on a written transcription (of emergency verbal instructions),
 - in accordance with directions for use on a container supplied by an authorised prescriber or pharmacist (e.g. when administering a person's own lawfully supplied medicine) or
 - in accordance with a standing order developed by the health service
53. This proposal would be to enable registered paramedics to work in multidisciplinary teams, in accordance with the broader clinical governance framework of the health service.

4.2 Permissions for clinical perfusionists to possess and administer

The department is seeking stakeholder views regarding the capacity of clinical perfusionists to possess and administer a prescribed list of poisons, and any governance structures required to ensure safe administration.

54. Clinical perfusionists are responsible for managing extracorporeal circulation during procedures such as cardiac surgery and are a key part of the multidisciplinary team. Enabling them to possess and administer Schedule 4 poisons under defined protocols would support timely and efficient clinical care and reduce reliance on other authorised staff during high-acuity procedures.
55. Clinical perfusionists are a self-regulated profession, with approximately 120 practitioners working across hospitals in Australia and New Zealand. Most hold a Diploma of Perfusion awarded by the Australasian Board of Cardiovascular Perfusion (ABCP), which oversees certification and recertification. The profession is guided by the Australian and New Zealand College of Perfusionists (ANZCP), which maintains standards of practice, continuing professional development, and ethical conduct.

56. Consideration is being given to enabling clinical perfusionists to possess and administer a prescribed list of poisons. This recognition would require careful examination of:
- the definition and recognition of clinical perfusionists as a profession
 - minimum qualifications and training required for safe practice
 - which scheduled poisons should be considered for possession and administration
 - clinical settings in which administration occurs (e.g. health services), and
 - supervisory arrangements and governance protocols, including oversight by medical practitioners or health services.
57. A potential change would likely be implemented through an amendment to enable clinical perfusionists to possess specified Schedule 4 poisons in accordance with a standing order approved by a Drugs and Therapeutics Committee of the health service, or a similar alternative governance structure. The intention would be to limit administration to appropriate health services with the appropriate governance frameworks to ensure the safe delivery of the Schedule 4 poisons.
58. The department will also consider enabling administration of a Schedule 4 or 8 poison during a perfusion under instruction from a registered medical practitioner in a similar manner to registered nurses. This would mean that the routine administration would be under the standing order, but perfusionists may also administer under instruction to respond to any changes during the perfusion.
59. In considering this potential reform, the model currently in place in Queensland will be closely examined, which enables clinical perfusionists to administer scheduled poisons (that are not otherwise restricted) into extracorporeal circulation equipment under a clinical protocol and with the supervision of an anaesthetist or cardiothoracic surgeon. Clinical protocols must be made by an approved person (medical practitioner), be specific to the individual administering, and reviewed at least every 2 years. Those permissions only apply to clinical perfusionists that are employed in hospital and health services or are accredited to work as a clinical perfusionist by the professional body.

Consultation questions: Permissions

- Would you support these professions being provided with permissions under the Regulations? Why, or why not?
- Are there any other permissions that should be considered?
- What supports would be required to facilitate their inclusion in the Regulations?
- Do you have evidence or insights that are relevant to informing an assessment of the appropriateness of the potential new permissions?
- Are there additional professions that should be permitted to possess, supply or administer Scheduled poisons?

5. Storage and destruction

60. The Regulations set out requirements for the secure storage of Schedule 4, 8, and 9 poisons to prevent unauthorised access. These requirements become more stringent in line with an increased risk of misuse and abuse. Schedule 4 poisons must be stored in a lockable storage facility and for Schedule 8 and 9 poisons, the storage facility must meet additional prescribed

standards. Furthermore, specific provisions apply to the use of electronic storage and record-keeping systems.

61. The Regulations provide for some exemptions from prescribed standards, such as when authorised persons store up to six divided doses of Schedule 8 poisons for emergency use. Likewise, an approved provider of an aged care facility can store Schedule 8 poisons that have been dispensed² for a resident of that facility in a lockable room or in a lockable storage facility that is firmly fixed to a floor or wall.
62. It is understood current requirements are broadly effective, however the department is considering providing additional flexibility in some circumstances to ensure that regulatory burden is proportionate to the public health risk. The department is considering enabling specific exemptions to be agreed through a permit, which would provide alternative storage requirements for small volumes and quantities as well as heavily diluted substances. Similar exceptions are also being considered for destroying such substances, in addition to considering providing further regulatory detail outlining expectations around destruction.

5.1 Storage exceptions for small quantities of Schedule 4, 8 and 9 poisons

The department is seeking feedback on enabling permit holders to be exempt from prescribed storage requirements in certain circumstances.

63. The Regulations provide general security requirements for Schedule 4, 8 and 9 medicines. Schedule 4 medicines must be stored in a lockable storage facility, and Schedule 8 and 9 poisons must be stored in a storage facility that is at least equivalent to prescribed specifications.
64. The department recognises there are circumstances where applying the full suite of security requirements may not be proportionate, particularly for small quantities for use in an emergency, a few small quantities for research purposes or solutions containing Schedule 9 poisons that are heavily diluted.
65. The following instances have been identified as benefitting from increased flexibility.

The use of emergency trolleys

66. Many health services store small amounts Schedule 4 medicines in emergency trolleys. This is facilitated through a commitment by a health service at the time of making a permit application, that they will comply with the department's expectations for storing Schedule 4 medicines in emergency trolleys in certain circumstances. They commit to:
- using tamper-evident seals with an individualised serial number each time the facility is secured,
 - ensuring the seal is routinely sighted,
 - ensuring the date and name of the person carrying out the securing is recorded,
 - ensuring the facility is checked after an emergency to ensure no products have gone missing,
 - ensuring the facility is re-secured after an emergency, and

² Undispensed Schedule 8 poisons that may be kept on impress in an aged care facility are required to be stored per regulation 74.

- ensuring that the facility is large enough so that it would be obvious to staff members if it was being removed from a premises.
67. The department's expectations for using emergency trolleys currently conflicts with the general security requirement at regulation 73.
68. As such, the department proposes amendments to create an exemption to the general storage requirement for scheduled poisons in emergency trolleys, instead enabling compliance with standard conditions on a Secretary Approval. The intent of the proposal is to increase transparency and compliance and provide flexibility where appropriate. Whilst the storage requirements relating to emergency trolleys will be standardised, the department will consider the quantities of scheduled poisons involved, and the need for fast access to the poisons before making the reform.
69. The potential exemption would be consistent with the use of emergency trolleys in other states and territories. While most Australian states and territories require Schedule 4 poisons be stored away from public access, these requirements are flexible enough to enable the general use of emergency trolleys. New South Wales regulations also prescribe a specific exemption for prescribed restricted substances on an emergency trolley, anaesthetic trolley or operating theatre trolley.

Schedule 8 and 9 poisons in small quantities and dilutions

70. Licensees and permit holders must comply with storage requirements for Schedule 8 or 9 poisons regardless of quantity. This means that those who only hold one or two doses are required to install a compliant lockable storage facility, which is a significant financial cost. The Poisons Standard allows for a low concentration of Schedules 1 to 8 poisons to not be subject to the scheduled requirements. This exemption does not currently apply to Schedule 9 poisons, and they are still subject to significant storage requirements under regulation 74.
71. Stakeholders have noted situations where the quantities of Schedule 8 and Schedule 9 poisons held on-site are relatively small compared with the storage requirements set out in the Regulations. Examples provided include situations where small quantities have been transported temporarily to support research purposes, or laboratories undertaking secondary analysis. This matter has also been raised in relation to drug checking services, where samples for testing and comparative analysis can be very small.
72. Research facilities may hold one or two doses of Schedule 8 or 9 poisons, or diluted Schedule 9s that may contain 0.001% or less of the poison. Diluted quantities are frequently used in research and in-vitro diagnostics, often require refrigeration, making it expensive to meet regulatory obligations.
73. Similarly to the exemption for emergency trolleys, the department propose setting an alternative storage requirement, through a Secretary Approval which might be more suitable for some organisations. The department will consider the quantities and volume of scheduled poisons as well as the concentration of diluted substances before any reform is made. Any lowering of requirements, such as requiring the use of a simpler lockable facility, would be limited to small quantities, which are to be determined, and dilutions held by organisations.
74. It appears other Australian states and territories do not exempt Schedule 8 or 9 poisons from the prescribed storage requirements. New South Wales allows an authorised practitioner or person to keep a Schedule 8 poison in a bag that is in a room or vehicle if it can be locked when not occupied by the person and that the drug is for emergency use only. Consideration will be given to which circumstances might merit an exemption, and the relevant quantities.

75. It would be useful to understand the scale of the regulatory burden of this issue, as well as whether it affects multiple sectors or is concentrated in areas such as research institutions.

5.2 Storage of cannabis plant materials

The department is seeking feedback on a proposal to exempt Commonwealth Office of Drug Control (ODC) licence holders from storage requirements for large volumes of cannabis plant materials.

76. Schedule 8 and 9 poisons must adhere to storage requirements prescribed in the Regulations. It has been reported that manufacturers and cultivators find it challenging to comply with this need when storing large volumes of cannabis plant materials for processing.
77. Consideration is being given to refining the storage requirements for medicinal cannabis manufacturers to a more flexible approach and removing the requirement for non-processed bulk cannabis raw materials to be stored in a lockable storage facility, if the licence holder is a manufacturer, or cultivator licensed by the Commonwealth Office of Drug Control (ODC) Licencees.
78. ODC licence holders already have significant security requirements under the Commonwealth licensing scheme, and this proposal is intended to reduce regulatory duplication.
79. Other states and territories have varying approaches to the storage of medicinal cannabis. QLD requires medicinal cannabis to be stored like other Schedule 8 poisons, in accordance with the Queensland Health Department's standard "Secure Storage of S8 medicines". While NSW is currently preparing its medicines and poisons regulations for commencement in 2026, the public consultation draft of the Medicines, Poisons and Therapeutic Goods Regulation 2023 differentiated between the storage requirements for schedule 8 poisons stored in Pharmacies hospitals and other places and requires wholesale suppliers to comply with the Australian Code of Good Wholesaling Practice for Therapeutic Goods for Human Use, published by the Commonwealth Government.

5.3 Destruction requirements for small quantities of Schedule 8 and Schedule 9 poisons

The department is seeking feedback on whether a more streamlined approach to destroying small quantities of Schedule 8 and 9 poisons would be appropriate to reduce the regulatory burden in some settings.

80. The Regulations require that the destruction of Schedule 8 and Schedule 9 poisons be conducted by a prescribed person, being a specified health practitioner and prescribed witness, a health practitioner. Requiring a qualified witness when destroying Schedule 8 and Schedule 9 poisons is generally justified to mitigate potential harm, however in some circumstances, the regulatory burden may not be proportionate to the risk the requirement is seeking to mitigate. Section 5 above considers whether the regulatory storage requirements are proportionate to the harms posed by small or diluted samples of Schedule 8 and 9 poisons. In a similar vein, it would be appropriate to consider whether the requirements for two health practitioners to oversee the destruction of small samples of Schedule 8 and 9 poisons are proportionate to the regulatory burden and the reflective of the risk of diversion.
81. The department is aware of circumstances such as university research, where only a small amount of diluted Schedule 8 or Schedule 9 poison is held. Requiring an authorised health practitioner to destroy these poisons may be impractical given the lack of these practitioners

frequenting such facilities and challenges with taking diluted substances to pharmacies. The department is considering enabling authorised persons to witness the destruction of clearly defined small quantities of Schedule 8 or 9 poisons. Consideration will be given to the volume, quantity and concentration of diluted substances, and the risk of diversion. There is potential to streamline operations for organisations such as universities, that do not have health practitioners reasonably available for destruction.

5.4 Providing a definition of ‘destruction’

The department is seeking feedback on whether it is necessary to define the term ‘destruction’ in the Regulations or whether non legislative guidance is more appropriate to support compliance with this requirement.

82. The Regulations do not currently provide a definition of the term ‘destroyed’ for Schedule 8 and 9 poisons. The department has received mixed feedback on whether a definition would assist in supporting compliance for licence and permit holders who may not be clear on their obligations to destroy, as required under regulations. Several other states and territories provide guidance on destruction of scheduled poisons, and this is the current approach in Victoria. Requirements relating to destruction are imposed to ensure that the Scheduled poison is rendered unidentifiable and unrecoverable. It is understood that some means of destruction may not achieve this purpose e.g. using a sharps bin to discard ampoules or IV bags with some medication remaining. Inappropriate destruction can be avenues for misappropriation.

Consultation questions: Storage and destruction

- What are your views on the current requirements for storage under the Regulations?
- Would you support any of the changes being considered? Why or why not?
- Are there any other changes to the storage requirements that should be considered?
- Would you support a regulatory definition of the term ‘destruction’?

Please provide reasons

6. Recent amendments to the Regulations

The department is interested in stakeholder views on the effectiveness of more recent amendments to the Regulations, and any opportunities for improvement.

83. In addition to the significant SafeScript (Chapter 2) and Drug related harm (Chapter 3) reforms, refinements of which are considered earlier in this paper, there have been various amendments to the Regulations to enable significant reforms since their making in 2017. These include permissions for additional professions to enable:

- dental assistants to possess and administer certain Schedule 4 poisons,
- registered Aboriginal and Torres Strait Islander Health Practitioners to possess and administer certain Schedule 4 poisons,
- Rural and Isolated Practice Registered Nurses to obtain, use and supply scheduled medicines following removal of an endorsement under Health Practitioner Regulation National Law,
- registered optometrists to obtain, possess, use, sell or supply certain Schedule 2, 3 or 4 poisons for ophthalmic use in their profession,

- registered podiatrists to obtain, possess, use, sell or supply certain Schedule 2, 3 or 4 poisons for use in their profession, and
- pharmacist prescribing reforms authorising pharmacists to sell, supply or administer certain Schedule 4 poisons without a prescription or other instruction or authorisation in accordance with an approval by the Secretary.

84. Other regulatory amendments include:

- medically supervised injecting centres to reduce overdose deaths and harm and improve safety for neighbouring areas
- removal of Schedule 8 treatment permits for non-drug dependent persons when prescribing Schedule 8 medicinal cannabis products,
- authorisation for First Aid Service Providers and Non-Emergency Patient Transport licence holders to obtain certain scheduled poisons approved by the Secretary,
- changes to Schedule 8 poison notification requirements to enable authorised psychiatrists to prescribe psychedelic medicines,
- the development of the monitored poisons database and addition of new monitored poisons - pregabalin, gabapentin and tramadol,
- reforms to enable supply of Schedule 8 poisons on an electronic National Residential Medication Chart, and
- enabling use of digital images of prescriptions in an emergency.

Consultation questions: Recent amendments

- How effective do you consider the recent reforms, and what opportunities do you see for improving them?

Appendix A: Other potential amendments

Several technical amendments are being considered to clarify existing requirements, strengthen regulatory alignment, and support effective oversight under the Drugs, Poisons and Controlled Substances framework. These include:

- **Ensuring consistent obligations for class approvals** – Potential amendments so that individuals operating under a class approval will be subject to the same security, storage, and operational requirements as licence and permit holders, reflecting the 2023 legislative changes that introduced class-based exemptions that can be made by order of the Secretary.
- **Clarifying possession authorities for authorised nurses and midwives** – The Regulations would confirm that authorised registered nurses and authorised registered midwives may possess Schedule 4 and Schedule 8 medicines required for administration under a compliant standing order, aligning possession requirements with existing health services permit conditions.
- **Strengthening clarity around therapeutic need for prescribing** – Prescribers would be explicitly required to take reasonable steps to confirm a therapeutic need for the full quantity and dose prescribed, including any repeats. This is intended to support appropriate prescribing practices and reinforce the use of SafeScript information.
- **Streamlining SafeScript recording for doctor's bag and health service supplies** – The amendments would remove the need to enter unnecessary patient-specific fields in SafeScript when supplying medicines for doctor's bags or health services where no patient is involved, improving data quality and reducing administrative burden.
- **Requiring production of Schedule 8 prescriptions on request** – Pharmacists would be required to produce Schedule 8 prescriptions to the regulator on demand, aligning Victorian requirements with existing Commonwealth law and strengthening accountability for high-risk medicines.
- **Clarifying written follow-up requirements after emergency verbal orders** – Where pharmacists supply medicines under emergency prescribing provisions based on a verbal instruction, the Regulations would clarify that an original written prescription must be provided within 72 hours, regardless of whether a digital image has also been supplied. This is intended to support PBS claiming processes and reduce the risk of unintentional duplicate dispensing.
- **Allowing delegation of Schedule 9 administration between medical practitioners** – Medical practitioners would be permitted to delegate the administration of Schedule 9 substances to another medical practitioner, extending existing delegation provisions and supporting clinical workflow in specialised settings.
- **Clarifying record-keeping requirements for dispensing registers** – Where pharmacies maintain a separate hard-copy register for Schedule 8 and Schedule 9 poisons, the amendments would confirm that directions for use do not need to be duplicated if they are already captured in dispensing software, reducing duplication while maintaining auditability.

Appendix B: Scheduled poisons

Within this discussion paper, references to Scheduled poisons refer to the classification in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). The SUSMP is a Federal Legislative Instrument that classifies medicines and chemicals into Schedules based on their safety, potential for misuse, and need for regulation and is incorporated into the *Drugs, Poisons and Controlled Substances Act 1981* (the Act)

Schedule	Description
Schedule 1	Not currently in use
Schedule 2	Pharmacy Medicine
Schedule 3	Pharmacist Only Medicine
Schedule 4	Prescription Only Medicine OR Prescription Animal Remedy
Schedule 5	Caution
Schedule 6	Poison
Schedule 7	Dangerous Poison
Schedule 8	Controlled Drug
Schedule 9	Prohibited Substance
Schedule 10	Of such danger to health as to warrant prohibition of sale, supply & use

Appendix C: Collated consultation questions

General questions:

- What works well in the Regulations?
- What does not work well in the Regulations?
- If the Regulations reflected best practice, how would we know?
- What is the ONE thing that would make the biggest improvement to the current Regulations?

Refining real time prescription monitoring reforms

2.1 Requiring a prescription for medicinal cannabis

The department is considering opportunities promote safer use of medicinal cannabis by strengthening SafeScript oversight, including tighter controls on supply without a prescription. Stakeholder views are sought in relation to the benefits and disadvantages of this proposal.

We also invite stakeholder feedback on broader proposals to mandate prescription-based supply for all monitored poisons. Exemptions would continue to align with existing regulatory provisions where SafeScript checks are not required, including hospital care. Additional exemptions would be developed for in-person clinical treatment, emergency situations, or other circumstances where issuing a prescription is not reasonably practicable.

2.2 Appropriate actions to be taken after checking SafeScript

The department is considering regulatory amendments to require action from prescribers and suppliers, when a SafeScript check for a patient shows recent prescribing of the same or similar monitored poisons by previous practitioners. In these circumstances, consideration is being given to requiring prescribers and suppliers to take all reasonable steps to communicate with any relevant prescribers, to co-ordinate treatment when a person (the patient) has been prescribed in the last 8 weeks with the same or similar monitored poison. If the prescriber or supplier is unable to communicate with a previous prescriber, the prescriber or supplier must record the steps taken. This requirement is intended to apply only if the practitioner chooses to prescribe or supply a monitored poison. No communication or co-ordination would be necessary if the practitioner chooses to refuse the request and ask the patient to consult with one of the previous prescribers shown on SafeScript.

- Would you support the changes being considered? Why or why not?

Drug-related harm reforms

3.1 Transportation of substances obtained by drug-checking service

The department is seeking feedback broadening permissions for possession of a drug-checking substance for the purpose of transportation, including via consignment.

3.2 Alternative recordkeeping for small quantities of Schedule 4, 8 and 9 poisons and drug checking samples

The department is seeking feedback on the benefits and disadvantages of enabling an alternative recordkeeping requirement for small quantities and dilutions of scheduled poisons, and any considerations which may need to be managed.

3.3 Qualifications of drug-checking director

The department is seeking feedback on broadening the scope of suitable workers that are eligible for employment as a drug-checking director.

3.4 Clarifying administration of Schedule 3 poisons

The department is seeking feedback regarding the benefits and disadvantages of a proposal to stipulate that unless advised otherwise, the administration of Schedule 3 poisons is not regulated.

- Would you support the changes being considered? Why or why not?

Permissions for specified persons

4.1 Registered paramedics to possess and administer in broader health services

The department is seeking feedback on enabling registered paramedics to work in a broader range of settings, under suitable governance structures to ensure safe practice.

4.2 Permissions for clinical perfusionists to possess and administer

The department is seeking stakeholder views regarding the capacity of clinical perfusionists to possess and administer a prescribed list of poisons, and any governance structures required to ensure safe administration.

- Would you support these professions being provided with permissions under the Regulations? Why, or why not?
- Are there any other permissions that should be considered?
- What supports would be required to facilitate their inclusion in the Regulations?
- Do you have evidence or insights that are relevant to informing an assessment of the appropriateness of the potential new permissions?
- Are there additional professions that should be permitted to possess, supply or administer Scheduled poisons?

Storage and destruction

5.1 Storage exceptions for small quantities of Schedule 4, 8 and 9 poisons

The department is seeking feedback on enabling permit holders to be exempt from prescribed storage requirements in certain circumstances.

5.2 Storage of cannabis plant materials

The department is seeking feedback on a proposal to exempt Commonwealth Office of Drug Control (ODC) licence holders from storage requirements for large volumes of cannabis plant materials.

5.3 Destruction requirements for small quantities of Schedule 8 and Schedule 9 poisons

The department is seeking feedback on whether a more streamlined approach to destroying small quantities of Schedule 8 and 9 poisons would be appropriate to reduce the regulatory burden in some settings.

5.4 Providing a definition of 'destruction'

The department is seeking feedback on whether it is necessary to define the term 'destruction' in the Regulations or whether non legislative guidance is more appropriate to support compliance with this requirement.

- What are your views on the current requirements for storage and destruction under the Regulations?
- Would you support any of the changes being considered? Why or why not?
- Are there any other changes to the storage or destruction requirements that should be considered?
- Would you support a regulatory definition of the term 'destruction'?

End of paper.