Government of **Western Australia**
Department of **Health**

Discussion paper

Amendments to the Medicines and Poisons Regulations 2016 and the Schedule 8 Medicines Prescribing Code

August 2022

Contents

1 Introduction

The Western Australian (WA) Medicines and Poisons Regulations 2016 (the Regulations), which are subsidiary legislation under the *Medicines and Poisons Act 2014* (the Act), commenced on 30 January 2017. The aim of the Medicines and Poisons legislation is to protect public health through regulation of the supply of medicines and poisons. This is primarily achieved by regulating the level of control over consumer access to medicines and poisons.

Section 4 of the Act defines a number of 'schedules', which are lists of chemical substances, where the chemicals within each schedule pose a similar level of risk to public health. In common with other states and territories, WA has agreed to adopt the 'schedules' of the national Poisons Standard by reference and this is achieved via the Regulations.

The Poisons Standard, also known as the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), is included as a legislative instrument on the Federal Register of Legislation and is made under the Commonwealth *Therapeutic Goods Act 1989*.

Once a chemical substance is included in a Poisons Schedule it is subject to a set of regulatory requirements applied to all chemicals in that schedule. The level and nature of the regulatory requirements varies according to the schedule.

Schedule 8 substances (also known as 'controlled drugs') are substances known to cause dependence and addiction but which have established therapeutic uses (use as medicines). These substances are also subject to major international drug control treaties[1], to which Australia is a signatory.

Schedule 4 substances are also known as 'prescription only medicines' and the safe use of these substances requires oversight by an authorised prescriber, such as a medical practitioner, nurse practitioner or dentist.

Minimising harms associated with the non-medical use of pharmaceuticals is a key priority of Australia's National Drug Strategy 2017-2026[2]. It is well recognised that some Schedule 4 medicines, such as benzodiazepines, are used for non-medical reasons. In addition, the combined use of opioids and other sedating drugs such as benzodiazepines and related drugs such as zolpidem and zopiclone is well known to increase a person's risk of excessive sedation, respiratory depression, coma and death.

The introduction of real-time prescription monitoring (RTPM) means prescribers and dispensers have greater and more timely access to information about their patient's exposure to medicines in Schedule 8 (S8) and prior or current use of illicit drugs. RTPM can also be used to monitor the prescribing and dispensing of higher risk Schedule 4 (S4) medicines. This provides an opportunity to consider reducing the regulatory burden for prescribers without diminishing the public health protections afforded by the Medicines and Poisons legislation.

This discussion paper provides options aimed at continuing to protect public health whilst:

- reducing regulatory burden for health professionals
- improving efficiency for the Department of Health, as the agency administering the Medicines and Poisons legislation and
- updating some regulations to reference current standards and legislation.

[1] Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol and Convention on Psychotropic Substances of 1971. See https://www.odc.gov.au/international-conventions.
[2] Available at: https://www.health.gov.au/sites/default/files/national-drug-strategy-2017-2026.pdf.

Section 132 of the Act provides for the Regulations to adopt 'Codes' where a 'Code' is defined as a code, standard, rule, specification or other document. Details of both general expectations when prescribing Schedule 8 medicines and specific criteria where authorisation by the CEO of Health is required are contained within the Schedule 8 Medicines Prescribing Code (the Prescribing Code). The Prescribing Code is defined in Regulation 114 and other regulations make reference to the Prescribing Code.

As there is an integral connection between the Regulations and the Prescribing Code, it is considered appropriate to consult on both simultaneously. The proposed changes to the Prescribing Code included in this discussion paper are essentially consequential to the proposed changes to the Regulations.

2 Why regulate prescribing of Schedule 8 and other monitored medicines?

Australia has a high level of opioid utilisation compared to many other countries in the world.[3] Whilst opioids are effective analgesics for acute pain and cancer-related pain, their use in non-cancer related chronic pain can result in harm outweighing benefit. Prolonged use of opioids and use of higher doses of opioids increases a person's risk of adverse outcomes, including overdose and death. Combining opioids with other sedating medicines, such as benzodiazepines, may further increase the risk of overdose. Tolerance and even hyperalgesia (increased pain) are also known consequences of long-term medical use of opioids for chronic non-cancer pain.

In addition to the risks associated with the medical use of pharmaceutical drugs, the non-medical use of these same products is a world-wide phenomenon. In 2019, 4.2 percent of Australians (14 years and over) reported the non-medical use of pharmaceuticals in the previous 12 months.[4] Opioids and benzodiazepines are the pharmaceuticals most commonly used for non-medical purposes in Australia. There are multiple reasons that people may misuse pharmaceutical drugs including: to induce euphoria, to enhance the effects of alcohol and other drugs, to self-medicate illness or injury and to treat symptoms of alcohol or drug withdrawal.

A recent review found that users of pharmaceutical drugs most commonly source these drugs from friends and family, followed by sourcing from dealers (particularly if the person also uses illicit drugs), with doctor shopping for their own use being used as a source around seven percent of the time.[5]

Various strategies have been suggested to reduce the risks associated with opioids and other pharmaceutical drugs including improved access to pain and addiction services, workforce development, education and development of resources for both health professionals and consumers, improved access to opioid substitution therapy, improved availability of naloxone (for overdose reversal) and coordinated medication management systems, such as RTPM.[6]

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[3] Berterame S, Erthal J, Thomas J et al. Use of and barrier to access to opioid analgesics: a worldwide, regional and national study. Lancet 2016;387:1644-1656.

[4] Australian Institute of Health and Welfare. Alcohol, tobacco and other drugs in Australia: Non-medical use of pharmaceutical drugs. Web report, last updated 20 April 2022. Available at: https://www.aihw.gov.au/reports/alcohol/alcohol-tobacco-other-drugs-australia/contents/drug-types/non-medical-use-of-pharmaceutical-drugs

[5] Hulme S, Bright D, Nielsen S. The source and diversion of pharmaceutical drugs for non-medical use: A systematic review and meta-analysis. Drug Alcohol Depend 2018;186:242-256.

[6] Campbell G, Lintzeris N, Gisev N et al. Regulatory and other responses to the pharmaceutical opioid problem. Med J Aust 2019;210:6-8.e1 Also available at: https://ndarc.med.unsw.edu.au/blog/how-australia-responding-pharmaceutical-opioid-problem

RTPM achieves better access, for both clinicians and regulators, to information about what is being prescribed for a patient and underlying patient related risks, such as a history of drug dependency. RTPM can support clinicians in making informed decisions in relation to prescribing S8 and other monitored medicines. Due to the improved information availability for clinicians, RTPM also presents an opportunity to consider reducing the level of regulatory control over the prescribing of these medicines.

The overall aim of regulatory controls over the prescribing of S8 and other monitored medicines is to:

1. Ensure prescribing is safe for the individual patient, in particular to mitigate the risk of overdose and drug dependence and
2. Ensure the safety of the broader population, through controls to reduce the risk of diversion.

Regulatory controls over the prescribing of S8 and other monitored medicines should support best practice care including:

- An evidence-based approach to prescribing, particularly with respect to indications, doses and dosage forms.
- Prescribing by one general practice prescriber per patient or by multiple prescribers within a single clinic, provided all prescribers have access to a combined medical record.
- Shared care arrangements between specialist medical practitioners and other prescribers.
- Referral to relevant specialist medical practitioners, where high risk factors are present such as:
    - where the patient has a history of drug dependency or ‘doctor shopping’
    - where treatment with higher risk drugs, doses, dosage forms or drug combinations is considered clinically necessary or
    - where specialist input is required for a definitive diagnosis.

3 Schedule 4 reportable medicines

3.1 Background

Section 77 of the Act defines a ‘Schedule 4 reportable medicine’ as a drug of addiction for the purposes of Part 6 of the Act. Part 6 is about reporting and recording people as a ‘drug dependent person’ or an ‘oversupplied person’.

This means a person can be reported to the Department by their treating medical practitioner as a ‘drug dependent person’ if the medical practitioner believes a S4 reportable medicine is the cause of that drug dependence. Similarly, a person could be reported as an ‘oversupplied person’ if they were being prescribed and dispensed quantities of a S4 reportable medicine in excess of therapeutic need. In other words, a person can be recorded as an ‘oversupplied person’ if they ‘doctor shop’ for one or more S4 reportable medicines.

The provisions of Part 6 of the Act also mean prescriptions for S4 reportable medicines will form part of the data within the RTPM system. The Act also includes protections over the information relating to S4 reportable medicines such that the Department can only disclose identifiable information to health practitioners who are treating the patient or dispensing prescriptions for the patient.

Monitoring certain S4 medicines through RTPM can help prescribers make informed clinical decisions by:

1. Ensuring a prescriber is aware if another prescriber is already treating their patient with a S4 medicine with a higher risk of misuse, diversion and associated health harms and
2. Ensuring prescribers have information about S4 medicines being prescribed and dispensed for their patient that may increase the risk of harm from concurrent use of S8 medicines.

Consideration also needs to be given to whether information provision alone is sufficient or whether the prescribing of monitored S4 medicines should be restricted, such as through an authorisation process.

3.2 Determining which Schedule 4 medicines are reportable

All RTPM systems in Australia monitor all S8 medicines. There is some variation between the states and territories as to which S4 medicines are monitored by these systems (see Table 1 for details).

Table 1 Monitored S4 medicines by jurisdiction (as at August 2022)

State or Territory	**Monitored medicine**								
	All S8	Benzo-diazepines	Codeine	Gabapentin	Pregabalin	Quetiapine	Tramadol	Zolpidem	Zopiclone
Australian Capital Territory	✓	✓	✓	✓	✓	✓	✓	✓	✓
New South Wales	✓	✓	✓	×	✓	✓	✓	✓	✓
Northern Territory	✓	✓	✓	✓	✓	✓	✓	✓	✓
Queenslan d	✓	✓	✓	✓	✓	✓	✓	✓	✓
South Australia	✓	✓	✓	✓	✓	✓	✓	✓	✓
Tasmania	✓	✓	✓	✓	✓	✓	✓	✓	✓
Victoria	✓	✓	✓	×	×	✓	×	✓	✓

Other states and territories use the term ‘monitored medicines’, ‘monitored drugs’ or ‘monitored substances’ to describe medicines that are subject to RTPM. Whilst the term used within the Act is ‘Schedule 4 reportable’, it is proposed that within the Regulations, the term ‘monitored medicines’ is defined such that this term can be used to refer to ‘Schedule 4 reportable’ medicines that are named in the Regulations as well as Schedule 8 medicines that are subject to RTPM. This would be consistent with other jurisdictions. This term would also better differentiate ‘Schedule 4 reportable’ medicines from other S4 medicines referred to as ‘S4R’ (Schedule 4 *restricted*) which are restricted through state-wide policy within public hospitals.

As the designation of a S4 medicine as ‘reportable’ has significant regulatory impact, it is important the only those S4 medicines posing the greatest risk of harm are included. Harms may result from misuse, abuse, diversion, substance use disorder and/or overdose. Whilst S4 reportable medicines do not meet the factors associated with inclusion in S8, this is a group of medicines that can still lead to significant harm.

Inclusion of these S4 medicines in RTPM systems may be able to detect and prevent emerging misuse, including therapeutic misadventure, in individual patients. Through RTPM, information about all prescribing and dispensing of these monitored medicines to individual patients will be visible to clinicians. In addition, alerts to clinicians can be activated where the risk of patient harm is increased, such as when a patient is receiving the same monitored medicine from multiple prescribers or where a patient is being prescribed particular S4 monitored medicines (such as benzodiazepines, zolpidem or zopiclone) concurrently with S8 medicines.

Monitoring through RTPM systems may also highlight broader trends suggestive of changes in use or risk of diversion. This information could then be used to inform educational, policy and regulatory responses.

Prior to rollout of SafeScript®, the Victorian RTPM system, a literature review of evidence to inform decisions about inclusion of S4 medicines in RTPM was conducted for the Victorian Department of Health by Austin Health.[7] An update to the review was published in May 2019.[8] Victoria has developed a framework for the inclusion of additional S4 medicines on their RTPM system, based on the main determinants of the literature review.[9]

In conjunction with the launch of their RTPM system, ScriptCheckSA®, the South Australian Department of Health and Wellbeing also published a fact sheet entitled: Monitored drugs: Criteria for the inclusion of a S4 medicine.[10] The criteria are very similar to those used in Victoria.

The New South Wales Government also used a similar set of criteria to determine which S4 medicines will be monitored by their RTPM system, SafeScriptNSW®.[11]

The published criteria are as follows:

- *Evidence of harms* (misuse, abuse, addiction, fatal/non-fatal overdoses): consideration of the severity of harm, total burden of harm relative to the amount of prescribing, whether the harm is associated with the medicine alone or in combination with other high-risk medicines.
- *Trends in prescribing, misuse and abuse*: increasing trend of misuse and abuse in the jurisdiction, consideration of interstate and international evidence to predict locally emerging trends.
- *Potential for the 'substitution effect'*: where monitoring a particular medicine may result in misuse or harm being displaced to other medicines or illicit drugs.
- *Potential for the 'chilling effect'*: where monitoring a particular medicine could result in prescribers being reluctant to prescribe the medicine, resulting in patients receiving sub-therapeutic treatment and poorer health outcomes.

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[7] Department of Clinical Pharmacology and Therapeutics and Pharmacy Department, Austin Health. Evidence to inform the inclusion of Schedule 4 prescription medications on a real-time prescription monitoring system. March 2017. Available at: https://www2.health.vic.gov.au/about/publications/factsheets/real-time-prescription-monitoring-report-literature-review

[8] Medicines Optimisation Service, Austin Health. Evidence to inform the inclusion of additional Schedule 4 prescription medications on the Victorian real-time prescription monitoring system: an updated report. May 2019. Available at: https://www2.health.vic.gov.au/about/publications/factsheets/rt-prescription-monitor-lr-updated

[9] Victorian Department of Health. Criteria for inclusion of additional medicines in SafeScript: Framework for Schedule 4 medicines. 4 September 2019. Available at: https://www2.health.vic.gov.au/about/publications/factsheets/criteria-monitored-medicines

[10] Department of Health and Wellbeing, Drugs of Dependence Unit. Monitored Drugs: Criteria for the inclusion of a Schedule 4 medicine. Available at: https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/resources/monitored+drugs+-+criteria+for+the+inclusion+of+a+schedule+4+medicine.

[11] See https://www.safescript.health.nsw.gov.au/health-practitioners/about-safescript-nsw/what-is-safescript-nsw

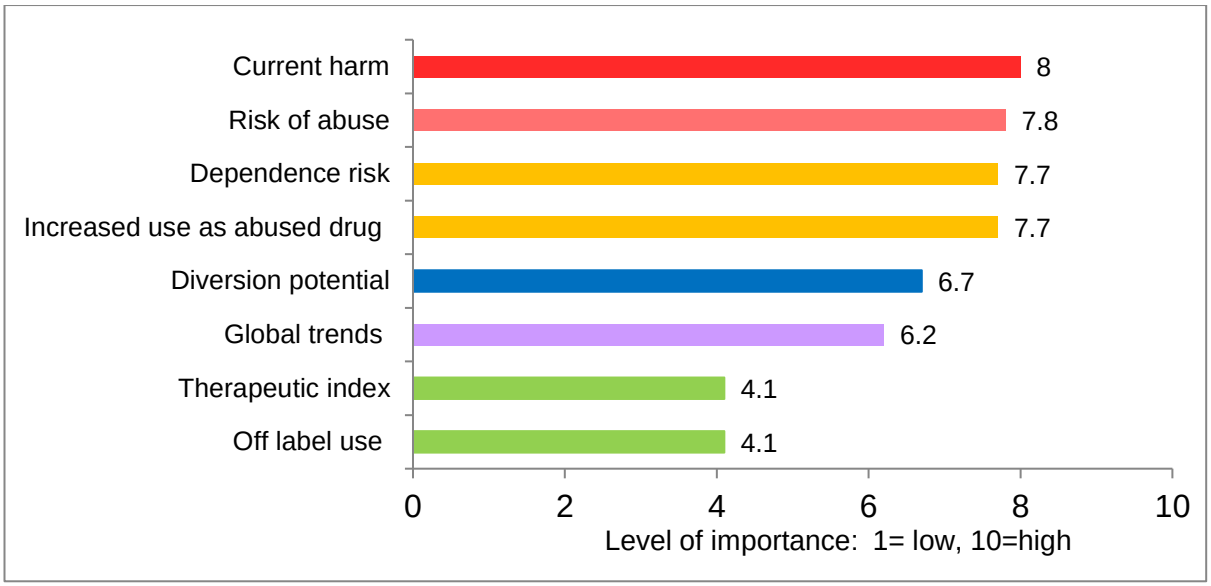
- *Regulatory burden, including cost-benefit*: the regulatory burden for prescribers, dispensers and the regulator must be balanced with the benefits of more informed clinical decision making and safer patient care. This is particularly important where the use of the RTPM system is mandated.
- *Inter-jurisdictional approaches*: consideration of which medicines are monitored in other Australian jurisdictions and in comparable overseas countries.

National alignment is preferable, given that practitioners are nationally registered and medicines are nationally scheduled. Future implementation of a truly national RTPM scheme, with information sharing between jurisdictions, is likely to operate most effectively if the medicines being monitored are consistent across Australia.

During 2019, a series of stakeholder workshops were held in WA. The first workshop on 17 April 2019 focussed on Schedule 4 reportable medicines.

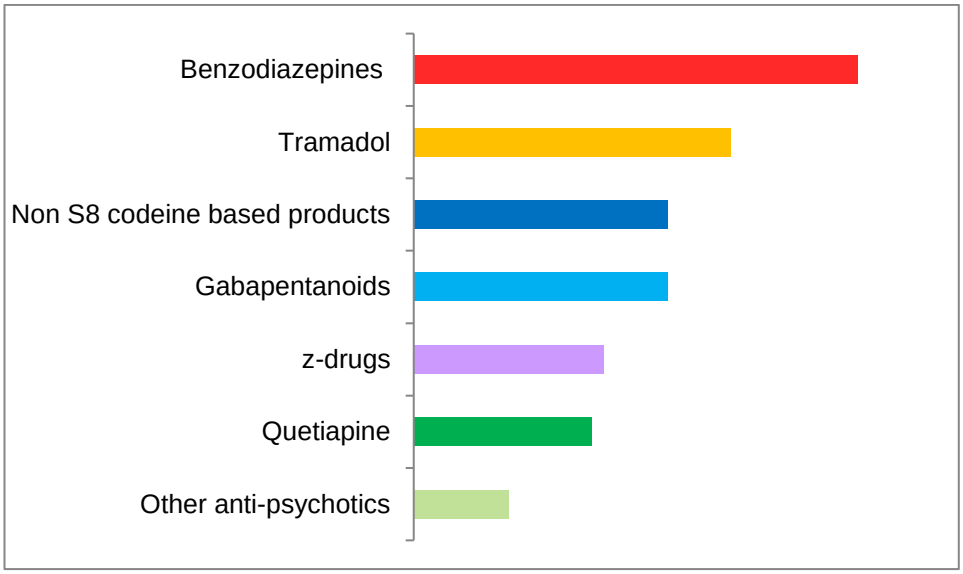
Stakeholders at the workshop were asked to rank eight identified factors that might influence the designation of a S4 medicine as a reportable item. The results are shown in the following diagram.

Figure 1: Ranking of factors influencing designation of S4 medicines as reportable



Workshop participants were also asked to rank types of S4 medicines in order of priority for inclusion in RTPM reporting and monitoring. The following figure shows the results.

Figure 2: Priority ranking of S4 medicines for monitoring



S8 = Schedule 8 medicine, z-drugs = zolpidem and zopiclone

Proposed regulatory options in relation to S4 medicines to be monitored via RTPM are:

Option 1: Do not designate any S4 medicines as reportable (status quo).

Option 2: Designate a list of S4 medicines as reportable and make these S4 medicines visible within the Western Australian RTPM system immediately.

Option 3: Designate a list of S4 medicines as reportable but delay implementation via RTPM for a defined period after rollout of RTPM.

The preferred option is Option 3.

This option allows clinicians time to become familiar with the use of RTPM before adding additional monitored medicines. It also provides opportunity for the Department to fine tune any requirements for authorisation of prescribing S4 reportable medicines and to advise stakeholders of any new requirements.

Taking into account:

- the two reviews conducted by Austin Health,
- the S4 medicines being monitored in other states and territories and
- the views of stakeholder workshop participants,

the following S4 medicines are proposed as 'Schedule 4 reportable medicines' in WA:

- All benzodiazepines in Schedule 4
- Tramadol
- Opioid based preparations in Schedule 4 (currently codeine based only)
- Pregabalin and gabapentin
- Quetiapine
- Zolpidem and zopiclone.

Consultation questions:

1. Which of the three regulatory options is preferred? Please provide reasons for your response.
2. Is the proposed list of Schedule 4 reportable medicines appropriate? If not, why not and what changes would you recommend?
3. Are there any criteria, other than those detailed above, that should be considered when determining which Schedule 4 medicines are designated as reportable? If yes, please describe the criteria.

3.3 Restrictions on prescribing and supply of Schedule 4 reportable medicines

3.3.1 Restrictions through the Regulations

Currently, the Regulations themselves only require a prescriber to be authorised to prescribe S8 medicines for people who are recorded as drug dependent or oversupplied[12]. There are no equivalent provisions in place in relation to the prescribing of any S4 medicines designated as 'reportable' for people recorded as drug dependent or oversupplied.

Regulatory options for controls over the prescribing of S4 reportable medicines are:

Option 1: No restrictions other than those applicable to all prescription only medicines (essentially limited only to which health practitioners have prescribing rights) (status quo).

Option 2: Implementation of prescribing restrictions via detailed requirements in the Regulations.

Option 3: Implementation of prescribing restrictions via a 'prescribing code' with Regulations that refer to this code.

The preferred option is Option 3.

This option is consistent with the approach already used in relation to the prescribing of S8 medicines. Inclusion of prescriptive requirements for the prescribing of S4 reportable medicines in a 'prescribing code' is consistent with the lower risks associated with these medicines compared to S8 medicines.

Consultation question:

4. Which of the three regulatory options is preferred? Please provide reasons for your response.

3.3.2 Restrictions through a 'prescribing code'

To best manage the risks associated with S4 reportable medicines, inclusion of any restrictions on the prescribing of these medicines in a 'prescribing code' rather than including detailed, prescriptive provisions within the Regulations would provide a balance between flexibility and regulatory transparency.

[12] Administration by a health professional does not require authorisation.

It is proposed that prescribing restrictions for S4 reportable medicines be included in the same 'prescribing code' as the prescribing restrictions for S8 medicines and the current 'prescribing code' defined in Regulation 114 be suitably renamed.

As S4 medicines create less risk than S8 medicines, it is considered appropriate for any requirements for authorisation of prescribing to be limited to situations where patient and community harm is significant. For example, prescribing authorisation could be required for monitored S4 medicines in the following circumstances:

- treatment of patients already recorded as drug dependent or oversupplied with doses higher than standard recommended doses of these medicines (cutoff doses would be specified within the 'prescribing code' and would reflect the recommended doses included in approved product information).
- concurrent prescribing of monitored medicines with sedative effects and opioid substitution therapy (current clients of the Community Program for Opioid Pharmacotherapy, CPOP), unless the prescribing is by the person's CPOP prescriber.

It is also proposed that the revised 'prescribing code' include a list of exemptions to requiring prescribing authorisation for S4 reportable medicines. Note that exemptions from requiring prescribing authorisation are not the same as exemptions from needing to check the RTPM system prior to prescribing (see Section 4.2).

The current Prescribing Code does not apply to situations where an authorised health professional is administering the medicine to the patient. In other words, in a hospital or clinic, where a prescriber gives a health professional a direction to administer rather than writing a prescription for the patient to have dispensed at a pharmacy, there are no authorisation requirements through the Prescribing Code. In addition, Regulation 117 allows a health professional to administer S8 medicines to a person recorded as a drug dependent or oversupplied person, without requiring patient specific authorisation from the CEO of Health.

It would be appropriate to also allow administration of S4 reportable medicines without any authorisation requirements.

There are other circumstances where the risk of concurrent prescribing by multiple prescribers and prescription shopping is significantly reduced, such as in prisons and in residential aged care facilities. In these situations where patients are not personally managing their medicines, it could be appropriate to allow prescribing of monitored S4 medicines without any authorisation requirements.

The current Prescribing Code also allows prescribing for 'end of life' care (where the patient's life expectancy is less than two months) without authorisation. It is proposed that any authorisation requirements for S4 reportable medicines be waived for patients recorded as drug dependent or oversupplied, when these patients are being prescribed the S4 reportable medicines as part of 'end of life' care.

It should be noted that prescribing authorisations are separate to any warnings that may be provided to clinicians through the RTPM system. For example, a warning may be used to alert a prescriber that they are about to prescribe a monitored S4 medicine for a person recorded as a drug dependent person, so they can consider the implications of this decision well prior to any potential dose escalation and requirement for prescribing authorisation. Similarly, alerts may be triggered when a prescriber is considering prescribing a benzodiazepine for any patient currently being prescribed a Schedule 8 or monitored S4 medicine by another prescriber.

Other states and territories that have commenced RTPM or are close to commencing RTPM have not implemented any prescribing authorisations for monitored S4 medicines. In

Queensland, there are mandatory documentation and communication requirements for prescribers. For example, before prescribing any monitored medicine (S4 or S8) for a person currently registered on Queensland's opioid substitution treatment (OST) program, the prescriber must document a 'joint prescribing plan' with the OST prescriber. Similarly, documentation of risk mitigation strategies is mandatory for all monitored medicines where particular high-risk clinical scenarios apply, such as patient receiving monitored medicines from multiple prescribers or increased overdose risk due to combined opioid and benzodiazepine combination.

Proposed regulatory options are:

Option 1: No prescribing authorisation requirements for monitored S4 medicines (status quo, acceptance that visibility of information via RTPM is sufficient to support safe prescribing).

Option 2: Mandate prescriber documentation of risk mitigation strategies in defined high-risk clinical scenarios, such as prescribing monitored S4 medicines for people who are currently taking OST or prescribing high doses of monitored S4 medicines to patients recorded as 'drug dependent' or 'oversupplied'.

Option 3: Limited authorisation requirements in high risk clinical scenarios, delayed until at least 6 months after prescribing and dispensing data about monitored S4 medicines becomes available in the RTPM system.

The preferred option is Option 3.

This option is considered most consistent with the principles for prescribing monitored medicines such as one general practitioner prescribing for the patient and shared care arrangements between specialist medical practitioners and other prescribers.

The proposed delayed implementation of this option would allow the Department to use data from real world RTPM use in WA to inform any prescribing restrictions imposed through the 'prescribing code', including whether any such prescribing restrictions are required.

Consultation questions:

5. Which of the three regulatory options is preferred? Please provide reasons for your response.
6. If prescribing authorisation was mandated for monitored S4 medicines, in what circumstances should a prescribing authorisation be required and what should be the criteria for exemption from requiring a prescribing authorisation?

3.4 Requirements for prescriptions for Schedule 4 reportable medicines

3.4.1 Inclusion of patient's date of birth

Once a S4 medicine is designated as 'reportable', data about prescribing and dispensing events associated with these medicines will be sent to the RTPM system. This data must be matched with identified patients to be available to clinicians to support decision making when prescribing and dispensing.

Standard primary parameters used for matching data are the patient's name and date of birth. This means prescriptions for monitored S4 medicines will need to include the patient's date of birth. Otherwise, there is significant risk of unmatched, and therefore unusable, data being captured by the RTPM system. Unmatched data has the potential to significantly reduce the utility of RTPM systems as a clinical decision tool and as a regulatory tool.

With the almost universal use of computer-generated paper-based prescriptions and electronic prescriptions, practice management software can be developed in a manner that reduces the risk of prescribers not including their patient's date of birth on relevant prescriptions. This is already in place for S8 medicines.

The widespread use of computer systems to generate prescriptions, whether fully electronic or paper-based, will limit the regulatory burden for prescribers. These computer systems can be set up to automatically populate the date of birth on a prescription for S4 reportable medicines, in the same way this already occurs for prescriptions for S8 medicines.

It is also standard practice for medical practices to collect a patient's date of birth when the patient first attends the practice and save this information for future visits, meaning it is then available to be entered onto a prescription.

Similarly, date of birth is a standard field in pharmacy dispensing software and is saved between visits, thereby limiting the regulatory burden on pharmacists.

Consultation question:

7. Are there any circumstances where it would not be reasonable to include the patient's date of birth on a prescription for a Schedule 4 reportable medicine? If yes, please describe.

3.4.2 Repeat intervals

For S8 prescriptions with repeats, the prescriber must include the interval at which the repeats can be dispensed. This is a mechanism to reduce the risk of oversupply to the patient and the risk of diversion. Endorsing S8 prescriptions with repeat intervals has been a requirement for prescriptions for S8 medicines across Australia for at least the last forty years.

The Act has provisions for the recording of a patient as an 'oversupplied person' for both S8 and S4 reportable medicines, if the patient is obtaining quantities of the medicine in excess of therapeutic need.

For S4 reportable medicines, regulatory options include:

Option 1: No repeat interval required on prescriptions for S4 reportable medicines (status quo)

Option 2: No repeat interval required but penalties for direct prescriber supply or pharmacist dispensing of a S4 reportable medicine, where the patient should have at least one week's supply remaining, based on the date of previous supply and the dose.

Option 3: Require repeat intervals on prescriptions for S4 reportable medicines.

The preferred option is Option 1.

Given their lower risk profile, a mandatory requirement for repeat intervals on prescriptions for Schedule 4 reportable medicines is not considered necessary, provided both prescribers and dispensers can view evidence of recent prescribing and supply in real-time, via a RTPM system.

Penalties for supply when a patient has sufficient medication available for at least another week would be difficult to administer where the S4 reportable medicine is used on a 'when required' basis. Such penalties may also undermine patient-centred care for medicines that have been nationally assessed as meeting the criteria for 'prescription only' rather than 'controlled drug'.

Even without any mandated repeat intervals, the RTPM system can still include alerts for both prescribers and dispensers to highlight that the patient may still have sufficient quantities of prescribed and dispensed S4 reportable medicines.

Other states and territories that have implemented RTPM systems have not amended their regulations to include a requirement for prescriptions for S4 medicines that are designated as monitored medicines in S4 to be endorsed with a repeat interval.

However, in some states and territories, at least some S4 medicines classified as 'monitored medicines' may be already included on other lists of S4 medicines with additional restrictions on prescribing. For example, in Tasmania, benzodiazepines in S4, codeine in S4, tramadol, zolpidem and zopiclone are all classified as 'declared restricted substances' (S4D) and prescriptions for S4D substances must include a repeat interval if repeats are prescribed.

Consultation question:

8. Which option is preferred? Please provide reasons for your response.

4 Mandates associated with real-time prescription monitoring

Requirements written into law can relate to whether a prescriber or dispenser must register to use the RTPM system or must query the system in particular circumstances. When prescription monitoring systems were first developed in North America, the systems were not particularly 'user-friendly' and user mandates were considered necessary for clinicians to engage with the system.[13]

The effectiveness of current RTPM systems in reducing overdose and death associated with monitored medicines is modest and variable.[14] However, mandates requiring either health practitioner registration for access or health practitioner use of the system when prescribing generally result in improvements in indicators of risky prescribing of S8 and other monitored medicines, such as total number of opioid prescriptions, reductions in the 'oral morphine equivalent daily dose' and reductions in hospital admissions and emergency presentations for adverse medication-related outcomes.[15, 16]

4.1 Requirement for practitioners to have access to real-time prescription monitoring

Reduction in requirements for notification and authorisation when prescribing S8 medicines are predicated on prescribers being able to view details of their patients in the RTPM system and similarly for dispensers to be able to view this information. Prescribers and dispensers will need to complete a registration process to be able to access the Western Australian RTPM system.

Regulatory options with respect to health practitioner access to the Western Australian RTPM system are:

Option 1: Registration for access to the system remains voluntary (status quo).

Option 2: Prescribers and dispensers must complete registration for access to the system.

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[13] Gontaszewski, S (2018). Churchill Fellowship Report: Investigating the implementation of online prescription monitoring programs in the United States and Canada. Winston Churchill Memorial Trust. Available at: https://www.churchilltrust.com.au/project/to-investigate-the-implementation-of-online-prescription-monitoring-programs/

[14] Fink D, Schleimer J, Sarvet A et al. Association between prescription drug monitoring programs and nonfatal and fatal drug overdoses: a systematic review. Ann Int Med 2018;168:783-790.

[15] Wen H, Hockenberry JM, Jeng PJ, Bao Y. Prescription drug monitoring program mandates: impact on opioid prescribing and related hospital use. Health Affairs 2019:38:1550-1556.

[16] Castillo-Carniglia A, Gonzalez-Santa Crus A, Cerda M et al. Changes in opioid prescribing after implementation of mandatory registration and proactive reports within California's prescription monitoring program. Drug Alcohol Depend 2021;218:108405, 2021 01 01.

Option 3: Prescribers and dispensers must complete registration for access to the system and ensure they maintain continued access to the system over time, such as via an annual access check.

The preferred option is Option 2.

In overseas countries, regulators have had concerns that initial registration does not ensure a practitioner has continued access and at least one state in the US has mandated practitioners undertake an annual check of account details.[17] However, it is now common for computerised systems that require the user to register and log in to also have mechanisms for users to retrieve their log in details and reset passwords, so it would seem unnecessary to mandate an annual account check for all users. This would add regulatory burden for practitioners, with little gain. It would also add regulatory burden for the Department due to the need for compliance checks on the annual account checks by practitioners.

Data from California indicates that requirements for mandatory registration for a prescription drug monitoring program increases the number of practitioners with access to the program and also increases the number of active users of the program.[18] Registration mandates have been associated with a nine to ten percent reduction in doctor shopping.[17]

It is proposed that there be at least a six month period from official launch of the RTPM system before access becomes mandatory for health practitioners with prescribing or dispensing rights under the Regulations, where prescribing or dispensing a prescription for a S8 medicine or other monitored medicine is part of the practitioner's usual practice.

There will be some health practitioners who have prescribing or dispensing rights under the Regulations but who do not practice in a setting where they will be writing prescriptions or supplying medicines and the intent is that the Regulations will provide some form of defence for these health practitioners, unless their status changes. Backend compliance checking should be possible through the RTPM system by checking for practitioners who prescribed or dispensed after the date of the access mandate but who have not completed the registration process.

Mandatory registration does not guarantee that a prescriber or dispenser will review the information about their patient every time they prescribe or dispense a S8 medicine or a S4 reportable medicine. However, it does make it difficult for a prescriber to claim they did not know their patient was being treated with S8 or S4 reportable medicines by other prescribers or was on the record as drug dependent or oversupplied. A similar argument would apply to pharmacists who should have no reason to claim they did not know the patient had the same S8 or monitored medicine recently dispensed at another pharmacy.

[17] Gontaszewski, S (2018). Churchill Fellowship Report: Investigating the implementation of online prescription monitoring programs in the United States and Canada. Winston Churchill Memorial Trust. Available at: https://www.churchilltrust.com.au/project/to-investigate-the-implementation-of-online-prescription-monitoring-programs/

[18] Shev AB, Wintemute GJ, Cerda M et al. Prescription drug monitoring program: registration and use by prescribers and pharmacists before and after legal mandatory registration, California, 2010 – 2017. Am J Pub Health 2018;108:1669-1674.

The desired outcome is that prescribers check the RTPM system prior to initiating treatment with a S8 or S4 reportable medicine, as this means the prescriber will have the most up to date information available when making their prescribing decision. It is acknowledged that there will be some circumstances where checking the RTPM system may not be necessary. These are discussed further in Section 4.2.

Consultation questions:

9. What is your preferred option with respect to mandating access to the Western Australian RTPM system? Please provide reasons for your chosen response.
10. Is a six month delay appropriate before mandating prescribers and dispensers registration for RTPM access? If no, please provide reasons for your chosen response.

4.2 Requirements for practitioners to use real-time prescription monitoring

Use mandates by prescribers and dispensers are commonly implemented when prescription monitoring systems are available and have been shown to increase use of these systems by practitioners.[19] Mandates can range from requiring practitioners to check the prescription monitoring system only where deceptive or illegal behaviour is suspected through to requiring a check every time the practitioner is prescribing or dispensing a medicine monitored by the system. A list of exceptions to mandated use is common.

In North American jurisdictions, regulators do not necessarily undertake proactive monitoring against use mandates. Rather, where prescribing is under review, information about a prescriber's use history of the prescription monitoring system would form part of the investigation.[19]

Some other Australian states and territories, where RTPM is already implemented, have use mandates, sometimes preceded by a voluntary use period. Details of whether prescribers are required to check the local RTPM system in other states and territories are shown in the following table (as at April 2022).

Table 2. Use mandates for RTPM in Australia

State or territory	Mandate to check?	Details and exceptions
Australian Capital Territory	No	ACT Government will conduct an evaluation of Canberra Script performance after 12 months, including review of whether to mandate practitioner use of Canberra Script.[20]

[19] Gontaszewski, S (2018). Churchill Fellowship Report: Investigating the implementation of online prescription monitoring programs in the United States and Canada. Winston Churchill Memorial Trust. Available at: https://www.churchilltrust.com.au/project/to-investigate-the-implementation-of-online-prescription-monitoring-programs/

[20] See https://health.act.gov.au/canberrascript/health-practitioner-information/about

State or territory	Mandate to check?	Details and exceptions
New South Wales	No	SafeScript NSW has been available to all prescribers and pharmacists since May 2022. NSW Ministry of Health website indicates use is not mandatory.[21]
Northern Territory	Unknown	Health practitioner access to NTScript commenced on 1 March 2022.[22]
Queensland	Yes	Each time a relevant practitioner (specified in regulation) proposes to prescribe, give a treatment dose (i.e. supply directly to a patient a quantity to take away for later use) or dispense a medicine monitored by QScript, including for residential aged care facilities, on discharge and for administration of doses (e.g. within a hospital).
South Australia	Yes	Clinicians must take 'all reasonable steps' to check relevant information in ScriptCheckSA before prescribing or dispensing a monitored drug. Some exemptions apply.[23]
Tasmania	Not currently, proposed for future.	Legislative amendments to the Poisons Act 1971 on 17 December 2021 include provisions for prescribers and dispensers to take 'all reasonable steps' to check the monitored medicines database[24]. TasScript will replace DORA later in 2022.
Victoria	Yes	Must take 'all reasonable steps' to check SafeScript when prescribing or dispensing a medicine monitored by the system, with exceptions for prescribing and supply within hospitals.[25, 26]

When use mandates are implemented, it is considered appropriate to exempt prescribers and dispensers from checking the RTPM system in circumstances where:

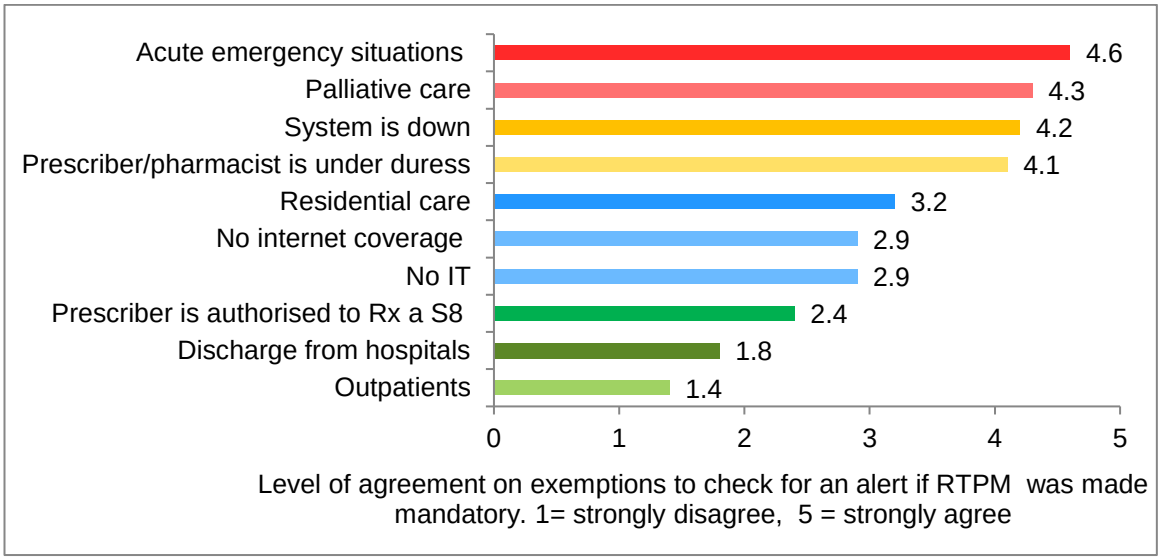
- The risk of the patient attending multiple prescribers and/or multiple pharmacies is reduced, such as where the patient is a resident of an aged care facility or is in prison.

[21] See https://www.safescript.health.nsw.gov.au/health-practitioners/about-safescript-nsw/how-and-when-to-use-safescript-nsw
[22] See https://health.nt.gov.au/professionals/medicines-and-poisons-control2/ntscript-information-for-health-professionals
[23] See https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/clinical+resources/clinical+programs+and+practice+guidelines/medicines+and+drugs/drugs+of+dependence/scriptchecksa+real+time+prescription+monitoring+in+south+australia/scriptchecksa+for+prescribers+and+pharmacists
[24] See https://www.health.tas.gov.au/health-topics/medicines-and-poisons-regulation/medicines-and-poisons-regulation-information-health-professionals/real-time-prescription-monitoring
[25] See https://www2.health.vic.gov.au/public-health/drugs-and-poisons/safescript/health-professionals
[26] See https://www2.health.vic.gov.au/public-health/drugs-and-poisons/safescript/hospital-health-professionals

- The patient does not have personal control of their medications, such as in residential care, in prisons and when the person is in hospital.
- The patient is more likely to be closely monitored over the time when the medicine has its effects, such as when a medicine is administered to the patient in a hospital or clinic.

The second stakeholder workshop in 2019, held on 16 May 2019, included the topic of exemptions if checking the RTPM system was mandated. Workshop participants were asked to rank ten potential situations where a prescriber might be exempted from any mandatory rules in place that require the checking for a patient history or alert supplied by the RTPM system. The results are shown in the following graph:

Figure 3: Level of stakeholder support for exemption from checking RTPM system



Rx = prescription

The workshop participants indicated that the prescriber might be exempted from checking a patient history or alert in the following situations:

- acute emergency service;
- patient is in palliative care;
- the system is unavailable;
- prescriber or pharmacist is under duress; and
- the patient is in a residential care facility.

Workshop participants also indicated that where a RTPM alert had been reviewed by the prescriber and a considered decision made to prescribe, that it should be incumbent on the prescriber to advise the pharmacist (such as on the prescription), that a specific decision had been made.

Regulatory options with respect to health practitioner use of the Western Australian RTPM system are:

Option 1: Use of the system remains voluntary (status quo).

Option 2: Prescribers and dispensers must always view the patient's record on the RTPM system when prescribing and dispensing for that patient.

Option 3: As for option 2 but with a number of exemptions, such as when directing administration or administering doses and when the patient lives at a residential aged care facility.

The preferred option is Option 1.

Mandating use may be considered at a later date, depending on the effects of mandating registration on prescriber compliance with the Regulations and the Prescribing Code and dispenser compliance with the Regulations.

Consultation question:

11. Which option is preferred? Please provide reasons for your response.

5 Regulation of stimulant medicines

5.1 Background

The Stimulants Regulatory Scheme (the Scheme) commenced in August 2003, following concerns about the high level of stimulant prescribing in the WA community. The Scheme was part of the Department's response to a policy, released by the Minister for Health in 2002, entitled: *Attentional Problems in Children: Diagnosis and Management of Attention Deficit Hyperactivity Disorder (ADHD) and Associated Disorders*. In addition to regulating prescribing, the Scheme was intended to allow collection of comprehensive data to enable a better understanding of stimulant use in this state.

Regular reports of stimulant prescribing patterns and use have been published by the Department since the inception of the Scheme. The most recent annual report on the stimulants regulatory scheme shows 31,714 people (children and adults) were being treated with these medicines for ADHD during 2020. The report also shows a steady increase in prescribing of these medicines, as a proportion of the population of WA, since 2008.

The vast majority of prescriptions are issued to treat ADHD. Only 0.3 percent of children and 5.1 percent of adults[27] are treated with stimulant medicines for other medical conditions, such as narcolepsy, depression and brain injury.

WA has a different prescribing pattern for stimulant medicines to other states and territories, with significantly higher levels of prescribing for adults.[28] Based on Pharmaceutical Benefits Scheme (PBS) data from 2017[1], prescribing rates for children (6 to 12 year olds) were higher than WA in Queensland, New South Wales, Tasmania and the Australian Capital Territory (in decreasing order). Similarly, prescribing rates for adolescents (13 to 17 year olds) were higher in New South Wales, the Australian Capital Territory, Queensland and Tasmania (in decreasing order).

The reason for different rates of stimulant prescribing between the jurisdictions is unclear. Geographic variation in rates of stimulant prescribing have also been observed in other countries such as the US[29] and the United Kingdom[30]. Various causes have been postulated including lack of psychology services in some areas (particularly rural and lower socio-economic

[27] Department of Health (WA). Western Australian Stimulant Regulatory Scheme 2015 Annual Report. Available at: http://ww2.health.wa.gov.au/~/media/Files/Corporate/general%20documents/medicines%20and%20poisons/PDF/Stimulant%20Annual%20Report%202015.ashx

[28] Drug Utilisation Sub-Committee (DUSC) Attention Deficit Hyperactivity Disorder: Utilisation Analysis May 2018. Available at: https://www.pbs.gov.au/info/industry/listing/participants/public-release-docs/2018-05/attention-deficit-hyperactivity-disorder

[29] McDonald DC, Jalbert SK. Geographic variation and disparity in stimulant treatment of adults and children in the United States in 2008. Psychiatr Serv 2013;64:1079-1086.

[30] Price A, Ford T, Janssens A et al. Regional analysis of UK primary care prescribing and adult service referrals for young people with attention-deficit hyperactivity disorder. BJPsych Open 2020;6,e7:1-6.

status areas), cost of non-pharmacological treatment modalities for families, waiting times for other treatments and prevailing customs and beliefs of both clinicians and patients.

After eighteen years of the Scheme, it is timely to consider whether it is necessary to continue to regulate the prescribing of stimulant medicines in the same manner. The current scheme is workload intensive for both clinicians and regulators. Some of the outcomes achieved by the current reporting and authorising requirements of the Scheme may be able to be achieved by other mechanisms. In particular, the rollout of RTPM in WA, paves the way for 'red-tape reduction' without compromising the public health benefits of regulating stimulant prescribing.

5.2 Initiation of stimulants by specialist medical practitioners

Currently, only certain specialist medical practitioners can initiate treatment with stimulant medicines. This restriction recognises that the conditions stimulant medicines are used to treat require specialist diagnosis and monitoring, at least until the patient is taking a stable and effective dose of stimulant medicines.

Other states and territories also limit initiation of stimulant prescribing to appropriate medical specialists, although the specific regulatory mechanisms by which this is achieved varies.

Whilst the Royal Australian and New Zealand College of Psychiatrists (RANZCP) position statement on ADHD in childhood and adolescence is under review, the RANZCP refers clinicians to a number of international resources on ADHD: Canadian ADHD Resource Alliance (CADDRA)Practice Guidelines, the UK National Institute of Clinical Excellence (NICE) Diagnosis and management of ADHD in children, young people and adults and the British Association for Psychopharmacology (BAP) Evidence-based guidelines for the pharmacological management of ADHD. The RANZCP also considers the CADDRA and NICE guidelines appropriate for the treatment of adult ADHD by Australian psychiatrists. The Royal Australian College of Physicians published the Australian Guidelines on ADHD in 2009 and indicate that these guidelines remain relevant.

In all cases these guidelines recommend that diagnosis of ADHD, as well as initiation and stabilisation of treatment, is undertaken by psychiatrists (including child psychiatrists if relevant) and paediatricians rather than general practitioners. However, the various guidelines also recommend that a shared care arrangement is considered appropriate for stable patients.

Whilst definitive diagnosis by an appropriate specialist is considered 'best practice', it is acknowledged that general practitioners have a vital role in identifying people who may have undiagnosed ADHD. In addition, it is recognised that access to specialist assessment is not currently keeping up with demand and affordability is also an issue for patients due to limited ADHD care via the public mental health clinics. The RACGP recently launched a new Specific Interest Group in ADHD, Autism Spectrum Disorder and Neurodiversity[31]. Experts have called for upskilling of general practitioners in the diagnosis and management of ADHD and, ultimately, a situation where only more complex cases are referred for shared care.

5.2.1 Designation of individual specialists as 'stimulant prescribers'

Regulation 128 requires the Department designate each individual specialist medical practitioner who wishes to prescribe stimulant medicines for their patients as a 'stimulant prescriber' and issue them with a Stimulant Prescriber Number (SPN).

[31] See https://www1.racgp.org.au/newsgp/racgp/racgp-introduces-new-specific-interests-group

Although the Prescribing Code describes the classes of specialist medical practitioner who can be considered for designation, the current Regulations require each such specialist to apply and be individually designated as a 'stimulant prescriber'.

The designation process for medical specialists was reasonable at the time the Scheme was set up, as details of a medical practitioner's specialist registration were not publicly available. Since the introduction of the national registration scheme for health practitioners, details of whether a medical practitioner is registered in a relevant specialty are publicly available from the Australian Health Practitioner Regulation Agency (AHPRA) Register of Practitioners. This makes the requirement to designate each specialist practitioner as a 'stimulant prescriber' redundant.

5.2.2 Regulatory options in relation to initiation of stimulant prescribing

Through a combination of the Regulations and the Prescribing Code, proposed options to be an initiating prescriber for stimulant medicines are:

Option 1: Designate each prescriber individually (Regulations) and limit to specialists only (Prescribing Code) (status quo).

Option 2: Limit initiation of stimulant prescribing to members of certain medical specialties named in the Prescribing Code.

Option 3: As for Option 2, but also allow designation of an individual prescriber as an initiating 'stimulant prescriber' for any of their patients. This option could potentially be used in the future to authorise a general practitioner with appropriate training to initiate stimulant medicines.

The option for authorisation to prescribe for a specific patient on a case by case basis would also be retained in conjunction with all three options.

Table 3. Risks and benefits for options in relation to initiation of stimulant prescribing

Regulatory option	Benefits	Risks
1. Prescribing initiated by individually authorised specialists only.	Ensures diagnosis and initiation of treatment is by a specialist with both appropriate training and a particular interest in the diagnostic area (as specialists have to actively pursue authorisation by applying to the Department of Health). Consistent with current guidelines on ADHD treatment, noting that ADHD is the most common condition treated with stimulant medicines.	Regulatory burden for both prescribers (time to complete paperwork and cannot prescribe until authorised) and the regulator. Limits patient access to treatment with stimulant medicines. May disadvantage particular patient groups, such as those living in regional, rural and remote areas and those with lower socioeconomic status.
2. Prescribing initiated by named classes of specialists only.	Ensures diagnosis and initiation of treatment is by a specialist with appropriate training.	Some limits on patient access as initiation of prescribing limited to specialists.

Regulatory option	Benefits	Risks
	Consistent with current guidelines on ADHD treatment. Reduced regulatory burden for clinicians and the regulator.	May disadvantage particular patient groups, such as those living in regional, rural and remote areas and those with lower socioeconomic status.
3. Prescribing initiated by named classes of specialists or individually authorised medical practitioners.	Provides greatest flexibility. Would accommodate prescribing by individually authorised medical practitioners, such as senior registrars (such as those in psychiatry or paediatrics training). Could allow future authorisation of individual general practitioners with appropriate training. May improve patient access to treatment with stimulant medicines.	Some regulatory burden for individual prescribers who are not part of a named class of specialist as must apply for authorisation. Some additional burden for the regulator to assess and authorise these prescribers. Potentially inconsistent with current ADHD treatment guidelines.

The preferred option is Option 3.

Publication of a list of approved specialties in the Prescribing Code is considered more efficient than designating each stimulant prescriber individually. However, retaining the option of approving an individual medical practitioner as a prescriber who can initiate stimulant treatment for any of their patients would provide some flexibility and 'future proofing' of the Regulations.

There are already clauses in the *Medicines and Poisons Act 2014*, should it be considered necessary to remove an individual medical practitioner's right to prescribe stimulant medicines.

A caveat on automatic authority to prescribe for a specialist in an approved category should be any relevant restrictions on their practice through their registration, such as limitations on their prescribing of S8 medicines applied by the Medical Board of Australia.

The proposal to remove the requirement for designation of individual stimulant prescribers would reduce workload for both specialist medical practitioners and the Department, without compromising a fundamental aspect of the Scheme, namely that treatment with stimulant medicines is initiated by a medical practitioner who has the specific training, skills and knowledge to diagnose the conditions for which stimulant medicines have an established therapeutic role. The proposal to provide for authorisation of individual medical practitioners provides a future pathway in the event that proposals for upskilling of general practitioners are realised.

Consultation questions:

12. Should designation as a ‘stimulant prescriber’ continue to be required for each individual medical practitioner? If yes, what benefit does this provide that is not already achieved by allowing all medical practitioners within designated specialist categories, to prescribe stimulant medicines?
13. What type of specialist medical practitioner should be able to initiate treatment with stimulant medicines?
14. Should the option of approving a medical practitioner as a ‘stimulant prescriber’ be retained for use on a ‘case by case’ basis? If yes, why? If no, why not?

5.3 Notification of stimulant prescribing by designated stimulant prescribers

Currently, specialist prescribers must notify the Department at the time they first prescribe stimulant medicines for each of their patients and whenever they alter the stimulant used to treat their patient. A copy of the current notification form is available at: https://ww2.health.wa.gov.au/Articles/S_T/Stimulant-medicines

The primary intent of the notification process is to limit a patient to one active stimulant prescriber at any time. This limitation aims to reduce the risk of patients accessing quantities of stimulant medicines in excess of therapeutic need (oversupply). Review of dispensing data shows that a significant number of patients treated with stimulant medicines regularly move between specialists.

At the time the current Scheme was being developed, use of a notification process rather than an authorisation process was considered less onerous for prescribers. A notification process was also considered suitable where prescribing is being initiated by an appropriate medical specialist and is within parameters detailed in the Prescribing Code.

An authorisation process is also available for the prescribing of stimulant medicines. Authorisation is required where the prescriber is not a designated ‘stimulant prescriber’ or when prescribing is outside the parameters detailed in the Prescribing Code, such as for patients with a history of drug dependency or where a ‘stimulant prescriber’ wishes to treat their patient with higher doses of stimulant medicines.

The notification process has allowed the Department to determine which medical practitioner is the current stimulant prescriber for each patient but processing notifications is workload intensive. Very similar information is able to be obtained by reviewing dispensing data submitted by pharmacies and with the introduction of RTPM, this data will be available in a more timely manner than previously. With rollout of RTPM to practitioners, both prescribing and dispensing data will visible to other prescribers and dispensers, when they are considering prescribing and dispensing for the patient.

Completing and submitting the notification form creates work for prescribers and their staff. Many submitted forms are incomplete, which increases workload for Departmental staff. Reviewing notification forms and checking dispensing records to determine whether stimulant prescribing has been notified for each patient also consume considerable work time.

With the introduction of RTPM, dispensing data from community pharmacies will be immediately available to both the regulator and treating practitioners. Review of this information will allow medical practitioners to determine whether their patient has current prescriptions for stimulant medicines from another prescriber and then use this information in their clinical decision making

in relation to prescribing for the patient. The Department will also be able to determine whether the patient has moved from one prescriber to another or obtained excess stimulant medicines.

This means the advent of RTPM makes the notification process redundant with respect to determining which prescriber is the patient's current 'stimulant prescriber'. It is therefore proposed that the Regulations be amended to remove the requirement for notification of stimulant prescribing to the Department.

Even if requirements for notification are removed, prescribers would still need to comply with the requirements of the Prescribing Code. This is consistent with the approach used for opioids and benzodiazepines in S8, where Regulation 116 simply requires the prescriber to comply with the Prescribing Code. The Prescribing Code includes a number of criteria, relating to both the medicine and the patient, that determine whether prior authorisation to prescribe is required or not. Essentially the Prescribing Code divides S8 prescribing into higher and lower risk categories with only higher risk prescribing requiring prior authorisation.

There is a small group of patients where their specialist prescriber will make a conscious decision to cease prescribing for the patient and, in some cases, will cease caring for the patient altogether. Some of the reasons a medical practitioner ceases prescribing stimulant medicines will result in further prescribing of stimulant medicines meeting the high-risk criteria under the Prescribing Code. For example, a patient may be misusing their stimulant medicines or other drugs, may be refusing to provide a urine sample for testing or may be experiencing significant stimulant-related adverse effects.

Currently, part of the notification process is for stimulant prescribers to notify the Department when they cease prescribing for a patient and the reasons. This ensures the Department is aware that the prescriber is no longer the patient's current stimulant prescriber and whether high risk circumstances are now applicable.

A risk of the removal of the formal notification requirement is that specialists will cease to provide advice to the Department about ceasing prescribing. This could create risk for the patient and the community more generally, if the patient is treated by another medical practitioner, who is unaware of the reasons the patient left their previous prescriber and is also unaware of circumstances that could mean prescribing stimulants for the patient would require specific authorisation.

However, any mandatory requirements for notification of ceasing to prescribe for a patient need to be considered in the context of the information available to subsequent medical practitioners via RTPM. Subsequent prescribers will be able to see that another specialist previously initiated stimulant treatment, when the patient last had stimulant medicines dispensed and whether there are any repeats remaining.

In addition to information about prescriptions, RTPM will also provide prescribers with information about a person's status as being recorded as either a drug dependent person (DDP) or oversupplied person (OSP).

5.3.1 Other information collected via current notification form

In addition to information about the S8 medicine used to treat the patient, the current notification form includes information elements related to other matters such as the patient's diagnosis, existence of certain co-morbidities and whether the patient is being treated with other psychotropic medicines. This additional information is not directly mandated by the Medicines and Poisons Regulations 2016, which only requires information about the medicine prescribed, including dosage form and dose.

Some of the additional information, such as the diagnosis and some comorbidities, can be used for review of compliance with the Prescribing Code.

The Prescribing Code currently limits the indications for which stimulant medicines can be prescribed and also limits which category of medical specialist can prescribe for each indication. For example, only psychiatrists are allowed to prescribe stimulant medicines to treat binge eating disorder.

Analysis of annual reports on the Scheme from 2010 to 2015 shows that almost all patients are treated for ADHD rather than other diagnoses (range 94.9 percent to 95.9 percent). This means the benefit of notification of diagnosis is limited as review for compliance with the Prescribing Code is likely to find very few instances of non-compliance.

The Prescribing Code also requires prescribers to seek authorisation where they are prescribing for patients with a history of drug dependency or doctor shopping, illicit drug use (including misuse of pharmaceutical products in S8) or psychosis induced by stimulants (whether illicit or prescribed).

Stimulant notifications are not the primary sources of information about whether a person is recorded as a 'drug dependent person', is recorded as an 'oversupplied person' or has been reported as experiencing stimulant-induced psychosis. This other information will be available to both regulators and prescribers, via the RTPM system.

Prescribing and dispensing data available via the RTPM system will also allow the Department to assess for compliance with both age and dose restrictions for stimulants, as detailed in the Prescribing Code.

The existence of other data sources for information to allow management of public health risk associated with stimulant prescribing means the information collected via the current notification process will have limited additional utility once RTPM is fully implemented.

5.3.2 Proposed regulatory options for notification of stimulant prescribing

Regulatory options in relation to notification of commencing and ceasing prescribing stimulant medicines for a patient are:

Option 1: Require notification of prescribing and cessation of prescribing for every patient, unless high-risk criteria are met when an application for authorisation to prescribe is required (status quo).

Option 2: Require notification of cessation of prescribing only, where the reason for cessation would mean subsequent prescribing of stimulant medicines for the patient would be considered high-risk according to the criteria in the Prescribing Code.

Option 3: No notification requirements for either commencement or cessation of prescribing stimulants for any patient.

Table 4: Risks and benefits for options in relation to notification of stimulant prescribing

Regulatory option	Benefits	Risks
1. Notification of both commencement and cessation of stimulant prescribing required for all patients.	Makes it clear that the patient has or no longer has a current stimulant prescriber, particularly for general practitioners who may be considering prescribing.	Significant regulatory burden for prescribers. Significant workload for the regulator i.e. financial cost to Government.

Regulatory option	Benefits	Risks
	Complements other information available in RTPM system.	Duplicates information already available via RTPM.
2. Notification of cessation of stimulant prescribing required where reason for cessation will mean high-risk criteria are met.	Makes it clear that authorisation would be required to prescribe stimulant medicines for the patient. Complements other information available in RTPM system. Information available to manage both individual patient and broader public health risk.	Some regulatory burden for prescribers but less than Option 1. Some workload for the regulator but less than Option 1.
3. No requirement for notification of commencement or cessation of stimulant prescribing.	Significant reduction in regulatory burden for prescribers. Reduced workload for regulator as no notifications to process.	Reliance on interpretation of information on prescribing, dispensing and DDP/OSP status via RTPM system. May result in unauthorised prescribing for patients meeting high-risk criteria (non-compliant prescribing and potential increased individual patient and public health risk). May result in continuation of prescribing by a general practitioner after the patient's specialist has discharged the patient from their care. May result in requirements for more compliance related activity by the regulator.

The preferred option is Option 2.

This option is considered to provide a balance between regulatory burden and risk mitigation in relation to further prescribing of stimulant medicines.

Consultation questions:

15. Which option is preferred? Please provide reasons for your response.

5.4 Appointment and notification of co-prescribers

Medical specialists must currently initiate treatment with stimulant medicines. However, ongoing treatment with the same drug, where the upper dose is directed by the initiating prescriber, can be prescribed by another prescriber, known as a 'co-prescriber'. Usually this will be the patient's general practitioner. In the public clinic setting, the 'co-prescriber' may be a registrar.

A specialist stimulant prescriber does not have to appoint a co-prescriber but when they do, they must notify the Department of the details. This information is currently collected via the treatment notification form.

The Prescribing Code currently indicates that the specialist prescriber should review their patient annually. This annual review requirement is known to act as a disincentive to appointing a co-prescriber.

Other states and territories also use general practitioner co-prescriber models but the required specialist review periods vary: periods of 12 months, 24 months, 3 years or even up to 5 years are used.

These specialist review periods are set from a regulatory perspective and are based on the maximum time period between specialist reviews considered necessary to protect public health. As a result, these specialist review periods do not take individual patient circumstances into account. Medical specialists may obviously still choose to review their patients more frequently where they consider this clinically appropriate for their patient and this would be expected for patients with significant co-morbidities and where the patient's stimulant treatment (including both the drug being prescribed and the dose being prescribed) is not yet stable. In particular, a long period between specialist reviews may not be suitable for children being treated for ADHD.

The co-prescriber model retains public health safety by limiting initiation and changes to which stimulant medicine is being prescribed to specialists whilst improving patient access to ongoing prescriptions until their next appointment with their specialist, particularly where their condition and treatment is assessed as stable. As S8 prescriptions are only valid for 6 months and maximum PBS quantities are usually limited to an original supply with 5 repeats, it is likely that patients will need at least two prescriptions per year for chronic therapy.

As well as facilitating access to treatment, ongoing prescribing by the patient's general practitioner may reduce cost for the patient.

RTPM will provide potential general practitioner prescribers, specialist prescribers, dispensers and the regulator with information about what stimulant medicines have been prescribed for their patient, when those stimulant medicines were prescribed and how many prescribers have been involved. RTPM will also include alerts when a patient has been prescribed S8 medicines (and in the future monitored S4 medicines) by multiple prescribers over a defined period.

Information within RTPM will not show whether the patient's specialist prescriber and other prescribing general practitioners have a formal shared-care arrangement, which would be considered best practice for the treatment of patients diagnosed with ADHD and other conditions for which stimulant treatment is indicated. The current notification process, where the specialist provides advice about which general practitioner they have agreed to continue prescribing stimulant medicines for the patient, assumes that this means a formal shared-care arrangement exists.

In this era of corporatised medical practices, it is common for all medical practitioners at a general practice to have access to a patient's clinical record. This also means a patient may see a different doctor at the practice, rather than their usual general practitioner. To maintain patient access to stimulant medicines, if a specialist co-prescriber model is retained, it is proposed that

all medical practitioners at the same practice could also act as co-prescribers, provided the prescribing doctor has access to the patient's full clinical record. This model is already in use a public sector clinics where it is not uncommon for a patient to see a different medical practitioner at different times.

Regulatory options in relation to continuation of established, stable treatment with stimulant medicines treatment are:

Option 1: Continue to require notification of co-prescriber appointment with annual specialist prescriber review (status quo).

Option 2: Continue to require notification of co-prescriber appointment but increase mandatory specialist review period to three years.

Option 3: Rescind requirement for notification of co-prescriber appointment and retain annual mandatory specialist review.

Option 4: Rescind requirement for notification of co-prescriber appointment and increase mandatory specialist review period to three years.

Table 5: Risks and benefits for options in relation to stimulant co-prescribing.

Regulatory option	**Benefits**	**Risks**
1. Specialist notification of co-prescriber appointment, annual specialist review.	Information on who should be prescribing for the patient clearly available to prescribers, dispensers and the regulator.	Barrier to shared care arrangements, which creates a barrier for patients to obtain ongoing prescriptions (obtaining appointments, costs). Regulatory burden for specialists and the regulator.
2. Specialist notification of co-prescriber appointment, specialist review at least every 3 years.	Information on who should be prescribing for the patient clearly available to prescribers, dispensers and the regulator. Reduces barrier to shared care arrangements.	Regulatory burden for specialists and the regulator.
3. No notification of co-prescriber appointment, but allow continuation of treatment by general practitioners, annual specialist review.	Less regulatory burden for specialists and the regulator. Limits number of prescriptions likely to be written by a general practitioner (expected one per year). As every second prescription likely to be written by specialist, other prescribers	Barrier to shared care arrangements, which creates a barrier for patients to obtain ongoing prescriptions (obtaining appointments, costs).

Regulatory option	Benefits	Risks
	should be able to readily see who the patient's specialist is via RTPM.	
4. No notification of co-prescriber appointment, but allow continuation of treatment by general practitioners, specialist review at least every 3 years.	Least regulatory burden for prescribers and the regulator. Reduces barrier to shared care arrangements. Information on who is the patient's current stimulant prescriber (specialist and GP) will be available via prescribing and dispensing information on RTPM.	Some patients may try to obtain additional prescriptions from multiple general practitioners (GPs) – however, information in RTPM will show the patient's current specialist and GP prescriber although a new prescriber may need to look back up to 3 years to find the patient's specialist prescriber.

The preferred option is Option 4.

This option utilises the enhanced information available via RTPM to reduce regulatory burden and improve patient access to prescriptions for chronic therapy. Regular specialist review is still required and the rules relating to changes to the particular medicine being prescribed and dose limits (see Section 5.5) will further enhance overall safety for patients being treated with stimulant medicines.

Consultation question:

16. Which option is preferred? Please provide reasons for your response.

5.5 Prescribing Code criteria for stimulant medicines

In conjunction with the preferred options for specialist initiation of treatment with stimulant medicines, the rescinding of notification requirements, the allowance for general practitioner continuation of care with extended periods for mandatory specialist review, the following changes are proposed to the criteria with which prescribers must comply in the Prescribing Code:

Table 6: Proposed criteria for prescribing stimulant medicines without requiring patient-specific prescribing authorisation

Criterion	Current requirement	New requirement	Rationale and other information
Initiating prescriber	List of specialist classes who can apply to become an authorised 'stimulant prescriber'.	List classes of specialist who can initiate treatment with stimulant medicines without further authorisation[(a)].	See section 5.2.2
Diagnosis	Diagnoses for which stimulant medicines can be initiated by a specialist without authorisation[(a)]. Option for specialist to request authorisation to treat other conditions.	No change.	No changes to TGA[#] approved indications for products containing dexamfetamine, lisdexamfetamine or methylphenidate. No changes to practice guidelines issued or endorsed by specialist colleges or other therapeutic guidelines widely in use in Australia.
Diagnosis	Diagnoses and approved class of specialist matrix (page 28 of Prescribing Code)	No change.	Classes of specialists remain appropriate to diagnose and initiate treatment of specified conditions.
Age limits	• Adult specialist can treat patients 17 years and over without authorisation[(a)]. • Paediatric specialists can treat patients aged between 4 and 19 years without authorisation[(a)].	No change.	No changes to Royal Australian College of Physicians Paediatric and Child Health Division applicable age ranges for treatment by adult vs. child specialists.

Criterion	Current requirement	New requirement	Rationale and other information
	• Paediatric specialists can treat patients up to 25 years, provided condition was diagnosed prior to 19 years of age.		Diagnosis cutoff also consistent with PBS restrictions.
Maximum doses	*Under 18 years:* Dexamfetamine: 1 mg/kg/day up to 60 mg/day. Lisdexamfetamine: Dosing is not weight based, over 6 years of age, commence at 30 mg. Maximum 70 mg/day. Methylphenidate: 2 mg/kg/day up to 120 mg/day. *18 years and over:* Dexamfetamine: Maximum 60 mg/day. Lisdexamfetamine: Maximum 70 mg/day. Methylphenidate: Maximum 120 mg/day.	Maximum doses a general practitioner can prescribe for ADHD, once a specialist has initiated treatment with the particular stimulant medicine (unless specialist prescriber has directed a higher dose in writing, including through writing a prescription for the higher dose): *Under 18 years:* Dexamfetamine: 1 mg/kg/day up to 40 mg daily. Lisdexamfetamine: Dosing is not weight based, over 6 years of age, commence at 30 mg. Maximum 70 mg/day. Methylphenidate: 2 mg/kg/day up to 60 mg/day. *18 years and over:* Dexamfetamine: Maximum 40 mg/day Lisdexamfetamine: Maximum 70 mg/day Methylphenidate: Maximum 80 mg/day. Other conditions: Specialist must direct maximum dose general practitioner can prescribe in writing. Maximum doses a specialist prescriber can prescribe without authorisation – no change.	Two-tiered dosing approach would allow co-prescribers treating patients with ADHD to increase doses within the TGA approved therapeutic range, without needing to seek approval from the initiating specialist prescriber.

Criterion	Current requirement	New requirement	Rationale and other information
Frequency of specialist review	Annual	Every three years	Consistent with specialist review periods for other S8 medicines where authorisation to prescribe is required. Improves patient access to ongoing medication, where clinically appropriate, by allowing their general practitioner to continue prescribing for a longer period. Does not stop specialist from choosing to review more frequently or general practitioner from requesting specialist review.
Urine drug screen (UDS) requirements	Prior to commencement for patients starting treatment when aged 13 years or older, then annual recommended.	Encourage rather than making this a mandatory requirement.	UDS is not mandated by other states and territories.

(a) Provided other low risk criteria are met. (b) TGA = Therapeutic Goods Administration.

Consultation questions:

17. Please provide advice about whether you support, do not support, or do not have an opinion for each proposed requirement in the Prescribing Code for the prescribing of stimulant medicines. If you do not support a proposed requirement, please provide your reasons and, if appropriate, an alternative requirement.
18. Are there other requirements you think should be included in the Prescribing Code for stimulant medicines? Please describe and provide reasons.

6 Regulation of cannabis-based products in Schedule 8

6.1 Background and current regulatory scheme

When the Regulations were being developed, the change to move cannabis, for therapeutic use, to Schedule 8 (controlled drugs) was agreed and awaiting implementation. Prior to this change cannabis was classified only as a prohibited substance (Schedule 9), with the exception of nabiximols (Schedule 8) and two individual cannabinoid substances, dronabinol (Schedule 8) and cannabidiol (Schedule 4).

At the time, there was limited information about the type of products that may become available and the projected uptake by prescribers. It was anticipated that, because medicinal cannabis is not considered a first-line treatment for any indication, specialist medical practitioners would be involved in the care of patients commencing treatment with this therapeutic option.

These factors resulted in the development of a regulatory scheme similar to that used for stimulant medicines, where suitable specialists could be designated as a 'cannabis-based product prescriber' and they could appoint a general practitioner or other medical practitioner as a co-prescriber for their patient. Similar to the stimulant regulatory scheme, the patient's situation must meet specific criteria and the specialist prescriber must notify the Department of their prescribing for each patient.

Through the Prescribing Code, the 'cannabis-based product prescriber' notification scheme is applicable to TGA registered products and limited other circumstances: treatment within a clinical trial and prescribing by a TGA Authorised Prescriber (TGA AP).

Almost five years after cannabis became legally available for therapeutic use, the vast majority of cannabis-based products remain unapproved therapeutic goods. Only one product in Schedule 8 (Sativex®, nabiximols) and one cannabidiol only product in Schedule 4 (Epidyolex®) have been approved for marketing across Australia by the TGA.

Unless prescribing of medicinal cannabis products that are unapproved therapeutic goods is within a clinical trial or by a TGA AP, prior authorisation by the Department is currently required to prescribe each product for each patient.

This is consistent with the Prescribing Code rules for other S8 medicines that are unapproved therapeutic goods. This requirement recognises that the risks associated with unapproved therapeutic goods, including compounded preparations, may be higher as there is:

- Less Australian regulatory control over product quality
- Limited documentation of the appropriate dose, indications and side-effects
- A professional responsibility for prescribers to advise patients that they are being treated with a product that has not been assessed by the national medicines regulator as being suitable for supply in the Australian market.

However, the situation for cannabis-based products is slightly different to other unapproved therapeutic goods in S8 in that products must comply with a quality standard issued by the TGA, *Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017*.

It has been argued that as the TGA is already approving prescribing of unapproved therapeutic goods, authorisation at a state level is redundant. However, these two approvals are for separate purposes.

The TGA is focussed on the risk of patients being exposed to an unapproved product rather than an approved product whilst the focus of the states and territories is on managing public health risks associated with use of drugs that can cause dependency and addiction.

There is variation between states and territories around how prescribing access is delivered for medicinal cannabis in S8. However, the majority of jurisdictions have some authorisation requirements when medicinal cannabis is being prescribed in the community. Details are summarised in the table below:

Table 7: Summary of authorisation requirements for prescribing Schedule 8 medicinal cannabis

Jurisdiction	**Authorisation requirements**
Australian Capital Territory	Prior authorisation required for more than 2 months treatment and for patients who are drug dependent. Supporting clinical documentation when required under the Medicines, Poisons and Therapeutic Goods Controlled Medicines Prescribing Standards 2021 (No 1). Exceptions if treatment will be for less than 2 months (provided not drug dependent).
New South Wales	Prior authorisation required to prescribe for patients who are drug dependent, prescribing of an unregistered product within a clinical trial and prescribing for children under 16 years.
Northern Territory	Notification required if treatment will be longer than 2 months.
Queensland	Must comply with Queensland Health Departmental Standard – Monitored medicines, including checking QScript (RTPM system).
South Australia	Prior authorisation required for more than 2 months treatment and for patients who are dependent on drugs. Exceptions for patients aged 70 or older, palliative care patients and where regular use will be for less than 2 months (provided not drug dependent).
Tasmania	Prior authorisation required to treat with medicinal cannabis.
Victoria	Prior authorisation required to treat with medicinal cannabis if the patient is drug dependent (from 28 February 2022). However, SafeScript must be checked before prescribing. Exceptions for palliative care patients and patients in residential aged care facilities.

The TGA will not necessarily have information about a patient's prior history with respect to drug dependency or their concurrent treatment with other S8 medicines. This information will be available to the Department of Health, for use in application assessment. Once RTPM is available to prescribers, they will also have access to information about drug dependency, oversupply and treatment with other S8 medicines at the time of prescribing medicinal cannabis.

6.2 Proposed changes to regulation of prescribing of medicinal cannabis

The number of TGA AP practising in WA has increased considerably over the last 12 months, which means an increasing proportion of prescribing is notified rather requiring authorisation.

Over the last twelve months, over 8000 applications for authorisations and notifications of treatment with medicinal cannabis have been received. Of these, only 7.5 percent have been declined. However, a significant number of applications that have not been approved are because the product is in Schedule 4 (cannabidiol only), which means no application for authorisation was required.

Currently, unless notification is applicable, the Regulations require authorisation to be issued before medicinal cannabis in S8 can be prescribed. This is regardless of whether prescribing would be considered lower risk or high risk.

The majority of both notifications and applications for prescribing authorisation for medicinal cannabis fit within what could be considered lower risk parameters, including:

- Starting dose is low with titration to a maximum of 30 mg tetrahydrocannabinol (THC) per day
- Patients are adults (18 years or older)
- Patients are not recorded as a drug dependent or oversupplied person and there is no other evidence of illicit drug use during the preceding five years
- The medicinal cannabis prescriber is aware of other S8 medicines being prescribed for the patient.

It is therefore proposed that, similar to opioids and benzodiazepines in S8, controls over the prescribing of medicinal cannabis are exercised via the Prescribing Code with criteria for determining whether prescribing is lower risk (no prior authorisation or notification required) or high risk (prior authorisation always required). Similar to other S8 medicines, it is proposed that the Prescribing Code would require specialist support where any of the high risk criteria are met and where a general practitioner still wishes to prescribe medicinal cannabis for their patient.

With the introduction of RTPM, prescribers will have access to information about whether their patient is recorded as drug dependent or oversupplied and will also be able to see which other S8 medicines have been prescribed/dispensed for their patient. The Department will also have access to this information and be able to take compliance action if a prescriber chooses to prescribe without authorisation for a patient flagged as having prior drug dependency or oversupply.

Regulatory options in relation to prescribing cannabis-based products in Schedule 8 are:

Option 1: Continue to require notification or authorisation in all circumstances (status quo).

Option 2: Remove notification requirements and only require authorisation where high risk criteria, as detailed in the Prescribing Code are met.

Option 3: Not require any notification or authorisation when prescribing cannabis-based products in Schedule 8.

The preferred option is Option 2.

This option is similar to the method used to regulate public health risks associated with opioids and benzodiazepines in S8. This option is considered to reduce the regulatory burden for prescribers whilst continuing to limit the risk for vulnerable patients and the community more generally.

Consultation question:

19. Which option is preferred? Please provide reasons for your response.

6.3 Proposed Prescribing Code criteria for lower risk cannabis prescribing

The proposed criteria for medicinal cannabis prescribing to be considered lower risk and the rationale for these criteria are shown in the following table. Lower risk prescribing would not require authorisation. Outside these criteria, authorisation to prescribe for the patient would be required and the support of a relevant specialist medical practitioner would usually be expected as part of this process. A relevant specialist would be a specialist who would normally treat the medical condition for which cannabis treatment is being proposed, unless the reason consultant support is required is due to the patient being recorded as experiencing drug dependency, oversupply or there is other evidence of illicit drug use, where support from a consultant in addiction medicine would be applicable.

Table 8: Proposed criteria for prescribing medicinal cannabis without requiring patient-specific prescribing authorisation

Prescribing Code criterion	**Rationale**
Total daily dose of tetrahydrocannabinol (THC) is less than or equal to 30 mg.	Risk of adverse effects increases above this dose level.[32]
Dose form is not a product for vaporisation.	Vaporisation is subject to more variables which can influence estimated dose.[32] Higher risk of diversion. Vaporisation of medicinal cannabis may be associated with a higher risk of concurrent recreational cannabis use.[33]
No more than two different cannabis-based products in Schedule 8 are being prescribed.	Concerns about the adverse outcomes associated with concurrent use of multiple medicines (polypharmacy).
Patient is an adult (18 year or older).	Exposure to THC is known to carry risks for the developing brain. Note 1: This criterion means treatment of minor (under 18 years of age) with a cannabis medicine containing THC would

[32] MacCallum CA, Russo EB. Practical considerations in medical cannabis administration and dosing. Eur J Int Med 2018;49:12-19.
[33] Morean ME, Lederman IR. Prevalence and correlates of medical cannabis patients' use of cannabis for recreational purposes. Addictive Behaviors 2019;93:233-239.

Prescribing Code criterion	Rationale
	routinely require a recommendation from a specialist medical practitioner. Note 2: Treatment of children with severe epilepsy is with cannabidiol only (Schedule 4) products, rather than products that contain THC.
Patient is not recorded as a drug dependent person or an oversupplied person.	As Schedule 8 substances, medicinal cannabis products have been assessed as having potential for development of dependency and addiction. The issue of cannabis dependence in those using medicinal cannabis has not been adequately studied and therefore the risk of someone with a prior history of drug dependence becoming dependent when taking medicinal cannabis is unknown. Recreational use of cannabis leads to cannabis use disorder (addiction or dependence) in around 1 in 5 users (lifetime risk)[34].
Patient does not have other evidence of illicit drug use within the preceding five years.	See previous criterion.
Patient is not being prescribed other Schedule 8 medicines that would themselves require a prescribing authorisation[35]	Interaction between opioids and medicinal cannabis may increase sedation and therefore increase risk of adverse outcomes. Evidence for 'opioid sparing' effects of medicinal cannabis when used to treat chronic pain (cancer and non-cancer related) is limited[36]. Criterion allows concurrent lower risk S8 prescribing without prescribing authorisation being required.
Patient does not have (or have a previous history of) psychosis or other significant psychiatric diagnoses.	TGA guidance advises that medicinal cannabis products containing THC are generally not appropriate for patients with a previous psychotic or concurrent active mood

[34] Leung J, Chan GCK, Hides L, Hall WD. What is the prevalence and risk of cannabis use disorders among people who use cannabis? A systematic review and meta-analysis. Addict Behav 2020;109:106479.
[35] Authorisation would be required to prescribe cannabis if the patient is concurrently being prescribed higher-risk S8 medicines such as opioid doses over 90 mg oral morphine equivalents per day, opioid injections, S8 benzodiazepines, methadone for pain management and S8 products that are unregistered therapeutic goods.
[36] Noori A, Miroshnychenko A, Shergill Y et al. Opioid-sparing effects of medical cannabis or cannabinoids for chronic pain: a systematic review and meta-analysis of randomised and observational studies. BMJ Open 2021;11:e047717.

Prescribing Code criterion	Rationale
	or anxiety disorder[37]. The TGA advice is endorsed by the Royal Australian and New Zealand College of Psychiatrists (RANZCP)[38]. In their January 2021 Clinical Memorandum, the RANZCP also cautions that there is little evidence that medicinal cannabis improves psychiatric disorders. This criterion means a patient with this medical history or current diagnosis would need the use of medicinal cannabis to be supported by their psychiatrist.

Consultation questions:

20. Please provide advice about whether you support, do not support, or do not have an opinion for each proposed criterion in the Prescribing Code for the prescribing of cannabis-based medicines in Schedule 8. If you do not support a proposed criterion, please provide your reasons and, if relevant, an alternative criterion.
21. Are there other requirements you think should be included in the Prescribing Code for cannabis-based products in Schedule 8? Please describe and provide reasons.

7 Retention of Schedule 8 repeat prescriptions by original pharmacy

Regulations 23(1)(e) and 24(2) require repeats on S8 prescriptions to be retained at the pharmacy at which the original supply was dispensed. This requirement was originally introduced into the previous Poisons Regulations 1965 at the beginning of 2006, as a mechanism to reduce the risk of prescription forgery.

At the time, it was considered necessary for the Department to approve transfer of repeats to another pharmacy because otherwise, there was no ability for the regulator to know that those repeats had been appropriately transferred.

The availability of RTPM data means that the Department will be immediately aware that a repeat has been dispensed and will also know whether this is at the pharmacy at which the original prescription was dispensed or not.

Because fully electronic prescriptions are not stored at a particular pharmacy, repeat retention is not a relevant concept for prescriptions issued in this manner. The forgery processes that the repeat retention clause was intended to reduce would not be possible when an electronic prescription is issued. The security features of electronic prescriptions and the systems used to generate these prescriptions mean the risk of fraudulent activity is greatly reduced.

[37] Therapeutic Goods Administration 2017: Guidance for the use of medicinal cannabis in Australia – Overview, Version 1, December 2017. Available at: https://www.tga.gov.au/publication/guidance-use-medicinal-cannabis-australia-overview

[38] RANZCP Clinical Memorandum – Therapeutic use of medicinal cannabis products. January 2021. Available at: https://www.ranzcp.org/files/resources/college_statements/clinical_memoranda/cm-therapeutic-use-cannabis-products.aspx

In other words, where applicable, pharmacists should provide patients with their token for the next repeat on electronic prescriptions for S8 medicines. It is noted that the Active Script List token management solution is already based on a patient using one pharmacy at a time for all their prescriptions.

Proposed regulatory options are:

Option 1: Retain the requirement for repeats of paper-based prescriptions to be kept by the pharmacy that dispensed the original and continue to require pharmacists to apply to transfer remaining repeats of paper-based prescriptions to another pharmacy (status quo).

Option 2: Retain the requirement for repeats of paper-based S8 prescriptions to be kept by the pharmacy that dispensed the original and continue to only allow transfer of remaining repeats to another pharmacy business. Remove the requirement for authorisation of repeat transfer by the CEO of Health. Clarify that fully electronic prescriptions are not subject to these rules.

Option 3: Remove all requirements for retention of repeats of paper-based S8 prescriptions by the pharmacy that dispensed the original.

The preferred option is Option 2.

The introduction of RTPM and the availability of electronic prescribing means the regulatory burden associated with pharmacists applying to transfer S8 repeat prescriptions is no longer justifiable. However, the risk of forgery using repeats for paper-based prescriptions remains.

Consultation questions:

22. Which option is preferred? Please provide reasons for your response.

8 Use of veterinary medicines to treat humans

Regulation 39 makes it an offence for a health professional to administer or supply a veterinary medicine for human use. For multiple reasons, many veterinary medicines are not suitable for use by humans. In particular, veterinary anabolic steroid products pose significant risks to human health and have a history of misuse as performance and image enhancing drugs (PIEDs).

However, there are some very limited circumstances where a veterinary medicine may be the only available option for treatment of a serious human health condition. For example, the Therapeutic Guidelines mention use of subcutaneous ivermectin treatment for patients who have not responded to other therapy for the treatment of strongyloidiasis[39]. The only available parenteral forms of ivermectin in Australia are veterinary products. It is therefore proposed that the option of approval, by the CEO of Health, of use of a specific veterinary preparation to treat a named patient be included in Regulation 39.

Consultation question:

23. Are there any other mechanisms that could be used to allow use of veterinary medicines to treat humans in specified circumstances? If yes, please provide detail of the mechanisms and the circumstances where their use should be applicable.

[39] Strongyloidiasis [published April 2019]. In: Therapeutic Guidelines [digital]. Melbourne: Therapeutic Guidelines Limited; October 2021 <https://www.tg.org.au>

9 Schedule 3 medicines in Appendix M of the Poisons Standard

In January 2018, following national endorsement by the Australian Health Ministers Advisory Council (now the Health Chief Executives Forum), Appendix M was included in the national Poisons Standard. Appendix M provides for imposition of additional conditions on Schedule 3 (pharmacist only) substances to support their down-scheduling from Schedule 4 (prescription only). The concept of Appendix M is that there may be prescription only medicines where a case can be made for the substance meeting the Schedule 3 factors but where there are some specific additional public health risks that are above those normally considered acceptable for Schedule 3 substances. The Scheduling handbook: Guidance for amending the Poisons Standard[40] lists a number of criteria which would be assessed as part of the inclusion of a substance in Appendix M. The inclusion of these criteria followed public consultation by the TGA, from February to April 2019[41].

Examples of possible requirements that could be included in Appendix M are:

- A requirement for specific pharmacist training on provision of the medicine
- The patient must be supplied with specific information (patient education) when the medicine is supplied
- Limitations on the duration/quantity and/or frequency of supply
- Need for evidence of a prior diagnosis by a medical practitioner
- Requirement for periodic review by a medical practitioner
- Record keeping of supply by the supplying pharmacist, including clinical decision points used when determining the patient's therapeutic need.

There are currently no regulations in WA that adopt or otherwise reference Appendix M. This would mean any restrictions detailed in Appendix M would not be mandatory but the substance would still be able to be legally supplied as a Schedule 3 medicine, as a consequence of the adoption of Schedule 3 of the Poisons Standard by reference into the Medicines and Poisons legislation. Essentially, this would mean supply of these particular Schedule 3 medicines could be seen as inconsistent with the nationally agreed scheduling classification and could create potential for patient harm.

It is recommended that the requirements of Appendix M be adopted by reference such that when a pharmacist makes a supply of any Schedule 3 medicine that is also included in Appendix M, the requirements of the Appendix M entry for that substance must be met.

To effectively monitor for compliance with the requirements of Appendix M, the regulator would require evidence of supply. With the exception of pseudoephedrine in Schedule 3, there are no requirements for a patient related record to be made when a Schedule 3 medicine is supplied by a pharmacy business. It is therefore proposed that, on each occasion of supply, the supplying pharmacist be required to record supply in the patient's clinical record for any Schedule 3 substance that is also included in Appendix M. In the pharmacy setting, the patient's clinical record will be the dispensing system i.e. the same software system as is used to record dispensing of prescriptions.

Recording the supply of a Schedule 3 Appendix M medicine would also mean that a patient specific label could be generated for the product. Labelling could be seen as a further way of differentiating these Schedule 3 medicines, which have been assessed as having additional public health risks, from other Schedule 3 medicines. The additional of a patient specific label

[40] Therapeutic Goods Administration. Scheduling handbook: Guidance for amending the Poisons Standard, July 2019. Available at: https://www.tga.gov.au/publication/scheduling-handbook-guidance-amending-poisons-standard
[41] See https://www.tga.gov.au/consultation/consultation-proposed-criteria-appendix-m-poisons-standard-support-rescheduling-substances-schedule-4-prescription-only-schedule-3-pharmacist-only

makes it clearer to consumers that the medicine is intended for a specific person and would be a disincentive to sharing the medicine with family or friends. It is therefore proposed that when a pharmacist supplied a Schedule 3 medicine which is also in Appendix M, that a patient specific label be applied.

The label should include:

- The name, strength and dosage form of the medicine
- The quantity supplied
- The name of the patient
- The directions for use given by the pharmacist
- The name of the supplying pharmacist
- The name and address of the pharmacy
- The date supplied
- The number generated by the recording system[42].

Consultation questions:

24. Are there any reasons Appendix M should not be adopted by reference? If yes, please provide an explanation for each reason.

25. Are there any reasons a pharmacist should not be required record supply of a Schedule 3 medicine that is also listed in Appendix M? If yes, please provide an explanation for each reason.

10 Regulations that require clarification

10.1 Use of electronic signatures

During the COVID-19 pandemic, allowances have been made for pharmacists to supply prescription medicines to patients, once they have received a 'digital image' of a paper-based prescription from the prescriber. This process was intended to support provision of care via telehealth and was introduced prior to the rollout of fully electronic prescriptions.

An unintended outcome associated with these changes has been prescribers choosing to add an 'electronic signature' to their computer-generated prescriptions and then send an image of that prescription to a pharmacy. In many cases, the mechanisms used to transmit the prescription to the pharmacist negate the validity of the electronic signature. For example, if a photo of the prescription, taken after it has been printed, is used, the pharmacist would be unable to verify the electronic signature. Similarly, if an image file format, such as a .jpg or .png file is used and the electronic signature was generated in some other file format, the pharmacist may be unable to verify the validity of the electronic signature.

Whilst the use of 'digital images' alone for dispensing ceased at the end of March 2022, there are long-standing provisions for pharmacists to supply a quantity of a prescription medicine in an emergency if directed to do so by a prescriber, such as via a telephone call, via a fax or via email. Where fax or email is used, it is common for a 'digital image' of the prescription to be used to direct supply by the pharmacist. In this circumstance, although transmission of the direction to the pharmacist remains electronic, it would not necessarily be in a manner that allowed the pharmacist to validate an 'electronic signature'.

[42] This number may be described as a 'prescription' number on the dispensing system but is a unique indentifying number generated when a supply transaction is entered onto the dispensing software system. The number can be used to find the transaction.

The Regulations current require prescriptions of a type intended to be paper-based at the point of provision to the patient, such as computer generated or handwritten prescriptions, to simply be 'signed' by the prescriber. This has led to interpretation by prescribers that, if they are sending an image of the prescription to a pharmacy, they can legally use an 'electronic signature'.

The purpose of a prescriber adding their signature to a prescription is to provide the pharmacist with evidence that the prescription was created by a health professional authorised to prescribe scheduled medicines. If an 'electronic signature' is applied to the prescription but cannot be verified by the dispensing pharmacist, this assurance of prescription validity is unavailable.

It is therefore proposed that the Regulations be amended to more clearly specify when an 'electronic signature' is a valid mechanism to use to sign a prescription and to ensure the required outcome of the dispensing pharmacist being able to validate the 'electronic signature'.

10.2 Residential care medication chart

In the Regulations, the current definition of a residential care chart is as follows:

residential care chart means a chart recording medicines used, or to be used, for the treatment of a care recipient in a residential care facility that is —

(a) in a form developed by the Australian Council for Safety and Quality in Health Care; or

(b) a medication chart prescription as defined in the *National Health (Pharmaceutical Benefits) Regulations 1960* (Commonwealth) regulation 19AA(1).

The Commonwealth regulations referenced in the definition have been superseded. In addition, electronic national residential medication charts (eNRMC) are currently under development with the support of the Commonwealth Government.[43] In part, the development and funding of eNRMC has been driven by recommendations 64 and 68 of the Royal Commission into Aged Care Quality and Safety Final Report.[44]

Electronic NRMC have a number of benefits for residents, residential aged care providers and staff in facilities, prescribers and pharmacists, including:

- Decreasing medication safety risks, such as inconsistencies between prescriber records and paper-based medication charts
- Increasing visibility of residents' medication records for prescribers, pharmacists and aged care staff
- Supports more timely provision of medications
- Allows tailored alerts and reminders and
- Reduced administration burden for aged care providers, prescribers and pharmacists.

To be considered suitable for use as a mechanism to prescribe PBS medicines, an eNRMC must meet the Commonwealth's technical and legislative requirements, including the Australian Digital Health Agency's current Electronic Prescribing Conformance Profile.[45]

Regulation 14 allows a residential care chart to be used as a prescription but only when the chart is handwritten rather than electronic. However, if an eNRMC was generated by an

[43] See https://www.health.gov.au/health-topics/aged-care/providing-aged-care-services/delivering-quality-aged-care-services/electronic-national-residential-medication-charts
[44] Available at: https://agedcare.royalcommission.gov.au/publications/final-report
[45] Available at: https://developer.digitalhealth.gov.au/specifications/ehealth-foundations/ep-3444-2021/dh-3442-2021

approved electronic prescribing system (Regulation 19), this type of chart would be considered a prescription.

It is recommended that the Regulations be amended to more clearly support the use of eNRMC, provided the system used to create the chart for each resident is an approved electronic prescribing system.

11 Appendix 1 Summary of the Poisons Schedules

Name	Heading on containers	Summary of regulatory controls
Schedule 2 (S2)	Pharmacy medicine	Consumers can purchase from a pharmacy or a licensed country store or be supplied directly by certain health practitioners, as part of a consultation with that practitioner. Licence required to supply by wholesale or retail, unless supply is from a pharmacy registered under the *Pharmacy Act 2010*.
Schedule 3 (S3)	Pharmacist only medicine	Consumers can purchase from a pharmacy, where a pharmacist must determine the suitability of the medicine for the consumer. Can also be supplied directly to consumer by certain health practitioners, as part of a consultation with that practitioner. Licence required to supply by wholesale. Permit required to purchase and use, unless supply has been by a pharmacist or other health practitioner.
Schedule 4 (S4)	Prescription only medicine	Consumers must be prescribed S4 medicines by an authorised prescriber, such as a medical practitioner, nurse practitioner or dentist. There are also animal medicines in S4, which must be prescribed by a veterinary surgeon. Licence required to supply by wholesale. Permit generally required to purchase and use, such as for research use or for administration to patients at a healthcare facility.
Schedule 5 (S5)	Caution	Risk management primarily via packaging and labelling controls. No licence or permit requirements. Cannot be supplied to someone under 16 years of age.

Name	Heading on containers	Summary of regulatory controls
Schedule 6 (S6)	Poison	Risk management primarily via packaging and labelling controls. No licence or permit requirements. Cannot be supplied to someone under 16 years of age.
Schedule 7 (S7)	Dangerous poisons	Cannot be supplied for domestic use. Licence required to supply by wholesale or retail. Suppliers must keep specific records of sales. Permit required to purchase, with some exceptions for primary producers and licensed pest management technicians.
Schedule 8 (S8)	Controlled drugs	Substances with therapeutic uses but which can also result in dependence or addiction. Consumers can only access if prescribed by an authorised prescriber, such as a medical practitioner, nurse practitioner or dentist. Licence required to supply by wholesale. Permit generally required to purchase and use, such as for research use or for administration to patients at a healthcare facility. Specific record keeping and storage requirements.
Schedule 9	Prohibited substances	Substances which can result in dependence and addiction, but which do not have established therapeutic uses. Licence to supply and permit to purchase and use required. Similar storage and record keeping requirements to S8 substances. Licences and permits can only be issued for uses specified in the Act and Regulations.
Schedule 10	Strictly controlled substances	Substances that pose a high risk to public health, but which do not result in dependence or addiction. Provisions for limited access for *bona fide* research purposes.

12 Appendix 2 Glossary of terms

Term	Definition
Benzodiazepines	A class of prescription medicine prescribed to treat anxiety disorders, to relieve insomnia, to control epilepsy and to sedate people before certain medical procedures. All benzodiazepines are central nervous system depressants. Flunitrazepam and alprazolam are classified as Schedule 8 medicines. Other benzodiazepines used as medicines in Australia are classified as Schedule 4 medicines.
Cannabis-based products	Term used to describe medicines that contain substances that naturally occur in cannabis, such as cannabidiol and tetrahydrocannabinol (THC). Also commonly referred to as 'medicinal cannabis'. Most cannabis-based products are in Schedule 8. Medicines that contain cannabidiol with negligible amounts of THC are classified as Schedule 4 medicines.
CEO of Health	Chief Executive Officer of the Department of Health, who is the Director General of the Department. Under Section 9 of the *Health Legislation Administration Act 1984*, CEO powers and duties under the Medicines and Poisons legislation may be delegated to other persons, usually officers employed within the Department of Health.
Drug dependent person	Defined in Section 77 of the *Medicines and Poisons Act 2014* as meaning "a person who has acquired, as a result of repeated administration of drugs of addiction or Schedule 9 poisons, an overpowering desire for the continued administration of a drug of addiction or a Schedule 9 poison". A person can only be reported to the CEO of Health as a 'drug dependent person' (DDP) by a health practitioner who is able to make a medical diagnosis of drug dependency. There are legislated requirements in relation to how the CEO of Health decides to add the person's detail to the Record, what the Department of Health has to do when a DDP report is received and what the Department must tell the person who is the subject of a DDP report. Further information is available at: https://www.healthywa.wa.gov.au/Articles/A_E/Drugs-of-dependence.
Opioids	These are morphine-like drugs. The term encompasses naturally occurring opiates (such as morphine and codeine) which are derived from the opium poppy, semi-synthetic opioids (such as oxycodone) and synthetic opioids (such as fentanyl). Opioids are primarily used as medicines for their analgesic effects but may also be used for their anti-diarrhoeal and cough-suppressant effects.
Oversupplied person	Defined in Section 77 of the Medicines and Poisons Act 2014 as meaning **"**a person who has over a period of time obtained, or obtained prescriptions for, quantities of drugs of addiction that are greater than is reasonably necessary for therapeutic

	use". Sometimes the term 'doctor shopper' is used to describe an oversupplied person (OSP). A person can only be reported to the Department as oversupplied if they are a registered health practitioner with authority to prescribe, supply or dispense scheduled medicines. There are legislated requirements in relation to how the CEO of Health decides to add the person's detail to the Record, what the Department of Health has to do when a OSP report is received and what the Department must tell the person who is the subject of an OSP report.
Poisons Standard	Also known as the Standard for the Uniform Scheduling of Medicines and Poisons, SUSMP. Issued by Commonwealth Government and available on the Federal Register of Legislation website. Available via the Therapeutic Goods Administration website at: https://www.tga.gov.au/publication/poisons-standard-susmp. Contains decisions regarding the classification of medicines and poisons into Schedules for inclusion in relevant state and territory legislation. Also includes model provisions about containers and labels and recommendations about other controls on medicines and chemicals. The Western Australian (WA) Medicines and Poisons legislation adopts the Schedules of the Poisons Standard, by reference. A number of other sections and appendices of the Poisons Standard are also adopted by reference in WA.
Prescribing Code	Referenced by the Medicines and Poisons Regulations 2016. Sets out the criteria with which prescribers must comply when prescribing Schedule 8 and, potentially in the future, Schedule 4 reportable medicines. Criteria relate to the prescriber (type of health practitioner), the medicine (for example, dose and dosage form) and the patient (for example, whether they are recorded as a drug dependent person).
Regulator	For the purpose of the *Medicines and Poisons Act 2014* and the Medicines and Poisons Regulations 2016, the Western Australian (WA) Department of Health is the 'regulator'. This WA Government Department assists the Minister for Health in administering this legislation.
Stimulant medicines or stimulants	Dexamfetamine, lisdexamfetamine and methylphenidate, which are all Schedule 8 medicines. Used to treat attention deficit hyperactivity disorder (ADHD) and some other neurological and psychiatric conditions. Also known as 'psychostimulants'.

13 Appendix 3 Summary current prescribing criteria for S8 opioids and benzodiazepines

Authorisation Required	Authorisation Not Required
For <u>any</u> of the following criteria: • >90 MEqD [1,2] • IR >45 MEqD [1,2] • All injectable forms [1,2] • Drug Dependent Person • Oversupplied Persons • History of substance abuse within the previous five years • Methadone [2] • Alprazolam • Flunitrazepam • Children (<18 years) • Unapproved medicines or off-label indications • Nurse Practitioners and Dentists where treatment exceeds 14 days duration [1] Except when prescribed by medical practitioner as part of end of life care (< 2 months life expectancy). [2] Specialists may prescribe up to 30 days treatment before authorisation is required. Drug dependent and oversupplied persons excluded.	Where Authorisation Required criteria do not apply: • ≤90 MEqD • IR ≤45 MEqD Additional restrictions: • Dental Practitioner - acute dental treatment ≤14 days duration • Nurse Practitioner - acute treatment, within scope of practice, ≤14 days duration • Endorsed Podiatric Surgeons - acute treatment ≤10 doses of 5 mg immediate release oxycodone.

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