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

Schedule 8 medicines prescribing code

Medicines and Poisons Regulations 2016

September 2018

health.wa.gov.au

Citation

This document should be cited as:

Department of Health, (2018), *Schedule 8 Medicines Prescribing Code,* Medicines and Poisons Regulation Branch, Department of Health, Perth, Western Australia

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Foreword

Legislative authority

This Code is issued under provisions of the *Medicines and Poisons Act 2014* and the Medicines and Poisons Regulations 2016.

Approval

This document is approved for publication by the Director General of the Department of Health.

Version

This document is MP00001.3, approved on 25 September 2018.

Definitions and Terms Used

Definitions and terms used in this document are drawn from the *Medicines and Poisons Act 2014* and Medicines and Poisons Regulations 2016.

Contacts

All queries relating to this Code should be directed to:

- Medicines and Poisons Regulation Branch, Public and Aboriginal Health Division, Department of Health
- PO Box 8172, Perth Business Centre, WA 6849
- 08 9222 6883
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Queries relating to prescribing Schedule 8 medicines for individual patients should be directed to the **Schedule 8 Prescriber Information Service** on 08 9222 4424.

Document control

Version	Date	Reason for modification
MP00001	23.01.2017	Original approved for publication
MP00001.1	16.03.2017	Inclusion of prescribing for end of life care and terminal illness
MP00001.2	10.08.2017	Parts 2 and 4 updates
MP00001.3	25.09.2018	Part 3, 4 and 5 updates

Introduction

i. Overview

This Code outlines the requirements for prescribing of Schedule 8 (S8) medicines in Western Australia. S8 medicines are also known as Controlled Drugs. S8 medicines are defined in the *Poisons Standard*[1] as, *"substances which should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence."*

The Code is published under the authority of the Medicines and Poisons Regulations 2016. The prescribing of all S8 medicines must comply with the criteria and conditions outlined in the Regulations and this document, unless otherwise approved in writing by the Chief Executive Officer (CEO) of the Department of Health.

ii. Scope

This Code applies to:

- all **prescriptions** for S8 medicines, written or dispensed in Western Australia; and
- all prescribers authorised under the Medicines and Poisons Regulations 2016 to **prescribe** an S8 medicine, irrespective of health practitioner type.

The prescribing of S8 medicines is limited to lawful practice of the health practitioner, any inherent professional scope or limitations imposed by the respective National Board, and the specific limitations of this Code.

This Code does not apply to:

- **administration** of an S8 medicine by an authorised health practitioner, for the medical treatment of a person, under the care of that practitioner; and
- **administration** of S8 medicines to an animal, or supply to the owner of an animal, when for veterinary treatment and authorised by an approved veterinary surgeon.

This Code replaces all previous S8 prescribing Codes issued by the Department of Health.

[1] *Poisons Standard (the SUSMP)*
http:/www.tga.gov.au/publication/poisons-standard-susmp

Figure 1: Schedule 8 Medicines Prescribing Code - Regulatory Overview

Medicine Type	Treatment category	Regulatory Scheme	Part of Code
General S8	ALL	Medicines and Poisons Regulations 116, 118 Part 11, Division 3, 4, 5	**PART 1: General prescribing conditions**
Opioids **Benzodiazepines** **Miscellaneous**	AUTHORISATION NOT REQUIRED	Medicines and Poisons Regulation 116	**PART 2: Opioids, benzodiazepines and miscellaneous Schedule 8 medicines**
	AUTHORISATION REQUIRED	Medicines and Poisons Regulation 118	
Opioid pharmacotherapy methadone Subutex® Suboxone®	COMMUNITY PROGRAM FOR OPIOID PHARMACOTHERAPY AUTHORISATION REOUIRED	Medicines and Poisons Regulation Part 11 Division 5	**PART 3: Opioid pharmacotherapy**
	DETOXIFICATION NOTIFICATION REQUIRED		
Stimulant dexamfetamine lisdexamfetamine methylphenidate	NOTIFICATION REQUIRED	Medicines and Poisons Regulation Part 11 Division 4	**PART 4: Stimulant medicines**
	AUTHORISATION REQUIRED		
Cannabis-Based dronabinol nabiximols tetrahydrocannabinols or other	NOTIFICATION REQUIRED	Medicines and Poisons Regulation Part 11 Division 3	**Part 5: Cannabis-Based Products**
	AUTHORISATION REQUIRED		

PART 1: General prescribing recommendations

1.1 Regulation of prescribing

The Code takes a risk-based approach to the regulation of S8 medicine prescribing. In certain circumstances prescribing may:

- not require interaction with the Department of Health (the Department);
- require authorised prescribers to notify to the Department that they are treating a particular patient; or
- require written authorisation from the CEO before prescribing can commence.

The restrictions on the prescribing of S8 medicines are intended to ensure both patients and the public are protected from risks associated with use of S8 medicines.

The parameters of the Code have been developed with consideration of available evidence in support of best practice prescribing; however the Code does not provide clinical endorsement of treatment in individual patients. Regardless of whether authorisation is required and irrespective of the type or duration of therapy, prescribers should carefully consider the benefits and risks of any S8 prescribing in each case.

1.2 Prescribing practice

It is recommended that, prior to prescribing an S8 medicine, the prescriber should:

- take an accurate medication history;
- have a clear diagnosis and indication for treatment;
- consider appropriate medicine selection; and
- enter into a treatment contract with the patient where the prescribing may continue beyond 30 days.

Prescribers should maintain and exercise clear practices towards:

- monitoring medicine usage and adherence;
- frequency of treatment review;
- identifying and responding to warning flags;
- urine and other drug screening tests; and
- prescribing for first time patients.

Where possible, prescribing should be limited to a single prescriber. Where care is shared between prescribers, a management plan should be agreed between prescribers regarding responsibility for prescribing S8 medicines and other prescription medicines.

1.3 Prescribing for new or unknown patients

Prior to prescribing an S8 medicine to a new or unknown person, the patient's identity should be recorded and, where possible, verified against an official source of photo identification (e.g. driver's licence).

Prescribers should not prescribe or supply an S8 medicine to any new or unknown patient without first contacting the S8 Prescriber Information Service for a prescription history. This information is provided under the authority of the Medicines and Poisons Act 2014. Information will only be provided to an authorised health professional and only relating to a patient under the care of that practitioner. Any information provided may not be used for any other purpose than for assisting with the management of the patient.

Where it is not possible to validate a person's identity or prior history, only limited supplies should be prescribed until the required information can be obtained. It is recommended that a maximum 2 days (or the next working business day during holiday periods) should be prescribed, where clinically appropriate and safe to do so.

1.4 Warning flags

The warning flags below should be considered before prescribing. Where present, further caution should be exercised and consideration given to not prescribing S8 medicines.

- Patient appears intoxicated or exhibits withdrawal symptoms;
- Patient has an indeterminate diagnosis; is reluctant or refuses to obtain previous notes or undergo diagnostic assessment;
- Patient refuses to sign a treatment contract;
- Patient persistently requests a specific medicine, medicine combination or formulation; is resistant to changes in treatments; requests increased doses or escalates dose without prescriber endorsement;
- Patient refuses to comply with requests to provide urine drug screens;
- Patient's function at work or home deteriorates;
- Patient displays threatening behaviour to prescriber or staff;
- Evidence of prescription forgery or multiple episodes of lost or stolen scripts;
- Patient seeks additional prescriptions from other prescribers without informing the primary prescriber.

Where a patient displays any of the warning flags above, prescribers should contact the S8 Prescriber Information Service to obtain an S8 prescribing history for a patient. This information is provided under the authority of the Medicines and Poisons Act 2014. Information will only be provided to an authorised health professional and only relating to a patient under the care of that practitioner. Any information provided may not be used for any other purpose than for assisting with the management of the patient.

1.5 Prescribing Schedule 8 medicines for self and family members

Prescribers may not prescribe an S8 medicine for themselves. Prescribing an S8 medicine for a family member or relative is strongly discouraged, except in an emergency. Prescribers are referred to the Medical Board of Australia's *Code of Practice*, or relevant National Board standards for guidance on the appropriateness of prescribing medicines for relatives.

1.6 Prescriptions

An S8 prescription must include the following information:

- name, address and telephone number of the prescriber;
- patient full name, address and date of birth;
- date of prescription;
- medicine, strength and form;
- quantity for supply;
- precise dosing directions;
- number of times the prescription may be supplied; and
- a repeat interval, if the prescription is to be supplied more than once.

Prescription documents without the above details are not valid and may not be dispensed. Such documents may be returned to the prescriber for correction or reissue.

S8 prescriptions must only contain one drug type of S8 medicine on one prescription (or same S8 drug type in more than one form). A prescription with both S8 and Schedule 4 items is not valid and cannot be dispensed.

A pharmacist may need to contact the prescriber to verify an S8 prescription prior to dispensing. Where it is not possible to verify the prescriber, the pharmacist may only dispense up to two days' supply.

1.7 Monitoring by the Department

Records of dispensing of S8 medicines within Western Australia are provided to the Department by community pharmacies, hospital pharmacies and dispensing doctors. The records are maintained in a secure database and continuously reviewed.

The Department monitors overall patterns as well as individual patient activities for:

- oversupply;
- excessive doses;
- patients visiting large numbers of prescribers;
- prescribing without authority;
- prescribing that does not match an authority issued (wrong medicine, dose, form);
- other high risk usage (e.g. inappropriate form, inadequate repeat intervals, excessive medicines in combination).

Where there is any concern about specific patients, the prescriber(s) may be contacted and a review of therapy requested. Prescribers will be advised to adhere to the prescribing criteria and/or any authorisation issued under the Code.

In cases of persistent non-compliance or unauthorised prescribing the Department may consider action as provided under the Medicines and Poisons Act 2014, which may include the revocation of S8 prescribing privileges and prosecution. If the CEO decides to revoke a practitioner's professional authority relating to Schedule 8 medicines, the Australian Health Practitioner Agency will be notified and a record of notification may be published.

1.8 Reports of oversupply or drug dependence and notifications of stimulant induced psychosis

An authorised health professional must make a report to the CEO, within 48 hours, when they have reason to believe that a patient is:

- oversupplied: 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; or
- drug dependent: 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.

The CEO may decide to include the name of the person on the drugs of addiction record as an Oversupplied or Drug Dependent person.

A psychiatrist who makes a diagnosis of stimulant induced psychosis in respect of a patient must notify the CEO. The notification must be in writing, in the approved form. Notification must be forwarded to the Department within 72 hours of making the diagnosis.

Where a report of drug dependence, oversupply or a notification of stimulant induced psychosis is received for a patient who is already under treatment with S8 medicines, the CEO may, at their discretion, cancel all existing authorisations and/or issue an instruction not to prescribe or supply to the patient.

Prior written authorisation from the CEO is required when prescribing S8 medicines for a person who has a record of Drug Dependence or Oversupply, or to prescribe stimulant medicines or Cannabis-Based Products for persons with co-morbid psychosis. The treatment must be medically indicated and not for the treatment of addiction.

1.9 Research

Prescribing Schedule 8 medicines in clinical research settings is not exempt from the provisions of this Code. If required under the provisions of this Code, an application for authorisation should be submitted prior to prescribing. A copy of the research proposal and approval by an ethics committee specific to the nature of the research should accompany the application.

PART 2: Opioids, benzodiazepines and miscellaneous Schedule 8 medicines

2.1 Overview

Part 2 outlines when S8 opioids, S8 benzodiazepines and other S8 medicines may be prescribed without authorisation and when prescribers require authorisation by the CEO to prescribe. The method of application and requirements to be met when applying for authorisation are detailed below.

2.2 Scope

This Part applies to all:

- S8 opioid medicines, in all strengths and forms and for all medical indications, except for pharmacotherapy for opioid dependence;
- S8 benzodiazepines (alprazolam and flunitrazepam), in all strengths and forms and for all medical indications; and
- any other S8 medicine, not covered in other Parts of this Code.

This Part does not apply to:

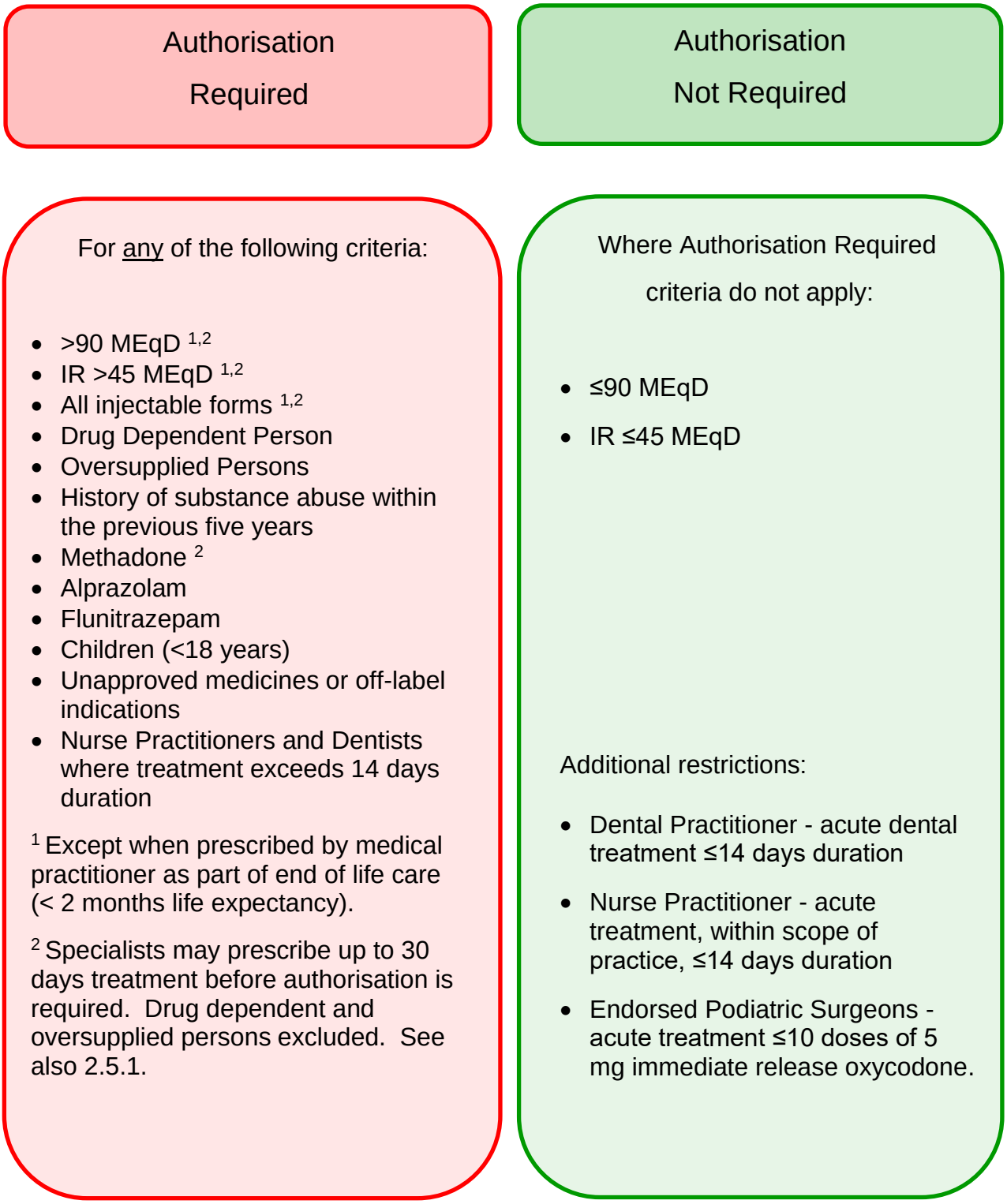
- the administration of the above in hospital for inpatients; or
- prescribing from emergency departments or on discharge from hospital where treatment with Schedule 8 medicines is associated with that episode of care, except for Drug Dependent and Oversupplied persons.

2.3 Authorisation to prescribe

Written authorisation to prescribe is required if any of the prescribing criteria in Section 2.5.1 are met (see Figure 2).

If all of the prescribing criteria in Section 2.4 are met then prescribing is considered as low risk and an authorisation is not required (see Figure 2).

Figure 2: Opioid, Benzodiazepine and other Schedule 8 medicine prescribing - Regulatory Overview



2.4 Authorisation to prescribe not required

Authorisation to prescribe is not required where all of the low risk criteria below are met. If any single criterion is not met, written authorisation from the CEO is required before prescribing.

2.4.1 Prescriber criteria

The following prescribers are eligible to prescribe an S8 medicine without individual authorisation of the CEO:

- medical practitioners, when in accordance with other criteria outlined in this section;
- dental practitioners, when for the acute treatment of a dental condition, where the total duration of treatment is less than or equal to 14 days and when in accordance with other criteria outlined in this section;
- nurse practitioners, when for acute treatment within scope of practice, where the total duration of treatment is less than or equal to 14 days and when in accordance with other criteria outlined in this section;
- endorsed podiatrist surgeons, when for acute treatment and limited to not more than 10 doses of 5mg immediate release oxycodone in accordance with the Medicines List published by the Podiatry Board of Australia.

2.4.2 Patient criteria

The following patients are eligible to receive therapy with an S8 medicine without seeking patient authorisation from the CEO:

- 18 years of age or above;
- no history of substance abuse within the previous five years;
- not recorded as an Oversupplied Person or a Drug Dependent Person; and
- not a current CPOP (opioid pharmacotherapy) patient.

Prior to prescribing, the prescriber must take reasonable steps to satisfy themselves that the patient does not have a condition or restriction that would affect treatment with an S8 medicine, or require authorisation of the CEO. This can be achieved by:

- taking a detailed medical and medicine history;
- undertaking a clinical examination;
- undertaking relevant laboratory or diagnostic tests; and
- contacting the Department of Health S8 Prescriber Information Service (08 9222 4424, 8.30 am to 4.30 pm Monday to Friday) to obtain an S8 prescribing history.

2.4.3 Criteria for medicine, dose and formulation

The following medicine types, daily doses and formulations may be prescribed without authorisation of the CEO:

- opioids in any combination, except methadone, where the total dose is less than or equal to 90 mg morphine equivalents per day; and
- immediate release opioids – where the total dose is less than or equal to 45 mg morphine equivalents per day; or
- opioids prescribed as part of end of life care where the life expectancy of the patient is less than two months.

Morphine equivalent comparisons for each opioid agent are detailed below. These dose limits are intended for regulatory purposes only and indicate the point at which authorisation from the CEO is required.

Authorisation is required when prescribing:

- above 90 mg total morphine equivalents[1];
- above 45 mg morphine equivalents of immediate release opioids[1];
- methadone, alprazolam or flunitrazepam;
- all injectable formulations[1]; and
- other S8 medicines not covered elsewhere in this Code.

[1] except when prescribed by a medical practitioner as part of end of life care.

2.4.4 Daily opioid dose - morphine equivalents

Figure 3 is intended for use to calculate morphine equivalents for the purpose of this Code. It is not suitable to use for calculations when transferring patients between opioid agents.

Figure 3: Morphine Equivalents

	Formulation	Factor to convert doses to morphine milligram equivalents
Buprenorphine	Transdermal (mcg/hr) Oral (mg)	2 37.5
Codeine	Oral (mg)	0.15
Fentanyl	Transdermal (mcg/hr)	3.6
Hydromorphone	Oral (mg)	5
Morphine	Oral (mg)	1
Oxycodone	Oral (mg)	1.5
Tapentadol	Oral (mg)	0.3*

*use conversion with caution in clinical settings as analgesic potency may differ from opioid potency. For the purposes of this Code, when used as a **sole** opioid agent, tapentadol requires authorisation at doses greater than 500 mg per day.

To use this table:

1. Add all daily doses of same formulation of the same opioid agent together, to calculate the daily dose for that agent.
2. Multiply by the correct conversion factor for that opioid, to convert to morphine equivalents.
3. Repeat steps 1 and 2 for any other opioid agents taken concurrently.
4. Add all results from step 3 together.

Prescribers may combine agents and formulations and vary doses within the criteria set out in Section 2.4.3. Written authorisation is required to prescribe outside these criteria.

2.4.5 Treatment contract

A treatment contract must be in place for all S8 prescribing where it is anticipated that treatment may extend beyond 30 days, except when an individual is incapable and unable to sign an agreement. A treatment contract should facilitate agreement and consent between the prescriber and patient.

2.5 Authorisation to prescribe required

Written authorisation from the CEO is required where prescribing meets any of the criteria outlined in Section 2.5.1. Where authorisation to prescribe is required, the application will generally require written specialist support (see Section 2.5.7-2.5.8).

2.5.1 Prescribing that requires prior authorisation

Prior written authorisation from the CEO is required to prescribe where any of the following criteria are met:

- Health practitioner:
  - medical practitioners where any of the other criteria are met; or
  - dentists or nurse practitioners prescribing for more than 14 days; or
  - all other prescribers;
- Patients:
  - under 18 years of age; or
  - persons recorded as Oversupplied or Drug Dependent or with a history of substance abuse within the previous five years.
- Total daily dose:
  - opioids over 90 mg morphine equivalents[1,2] or
  - immediate release opioids over 45 mg morphine equivalents[1,2];
- Drug:
  - methadone[2]; or
  - alprazolam; or
  - flunitrazepam; or
  - other S8 medicines not covered elsewhere in this Code;
- Injectable formulations[1,2];
- Therapeutic Goods Administration (TGA) unapproved products or indications.

[1] except when prescribed by medical practitioners as part of end of life care.

[2] specialists may prescribe up to 30 days treatment before authorisation is required.

2.5.2 Prescribing by specialists

Specialists (see Section 2.5) may prescribe S8 medicines for patients meeting the high risk criteria for up to 30 days without authorisation. Prior written authorisation is required for drug dependent and oversupplied patients and other criteria as detailed in Section 2.5.1.

Continuation of prescribing of high risk treatment beyond 30 days requires authorisation.

At the time of the first prescription, specialists should apply and name a general practitioner or nurse practitioner as a co-prescriber if required. If a co-prescriber is nominated, specialists should provide written advice to the co-prescriber within 30 days, specifying each S8 medicine supported including dose and frequency, and a management plan.

2.5.3 Methadone initiated by specialists only

Treatment with methadone should be commenced and titrated with caution and reserved to specialist practitioners with appropriate expertise and/or experience in its use. Patients should be monitored closely during dose titration. Initiation doses should generally be up to a maximum 20 mg daily in divided doses.

Continuation of prescribing beyond 30 days by specialists requires authorisation, except for end of life care.

2.5.4 Ketamine

Ketamine injections are the only ketamine products listed on the Australian Register of Therapeutic Goods (ARTG).

All other formulations of ketamine such as lozenges, creams or oral liquids are not registered as therapeutic goods in Australia. Prescribing of these products is restricted to pain and palliative care specialists only.

2.5.5 Applying for authorisation

Applications for authorisation must be in an approved form, completed in full and contain the following minimum information:

- prescriber details (name, address, telephone contact);
- patient details (name, address, date of birth);
- diagnosis and treatment plan;
- medicine(s), form(s), strength(s) and dose(s) required; and
- confirmation of specialist support, collaborative care or clinical documentation confirming life expectancy is less than 12 months (see section 2.5.7-2.5.10).

2.5.6 Duration of approval

Authorisations will generally be issued for up to a maximum of 12 months. Longer authorisation periods may be considered at the discretion of the CEO.

2.5.7 General conditions

The CEO may decline an application, at their discretion. The CEO may request any additional information, second opinion, or other review, as necessary to make a decision. Where an application for authorisation is not approved, the applicant may reapply with additional information (such as a second opinion/specialist support, additional clinical reports, the results of previous interventions and/or drug screens) or may make a new application with modified treatment details (medicine, medicine formulation and/or dose).

Authorisations granted are issued to a named prescriber at their practice address. An authorisation allows other prescribers at the same place of practice to prescribe in accordance with the conditions of the authorisation.

Where a new authorisation is granted for a particular drug group, all prior authorisations issued for that drug group (opioid, benzodiazepine) under this Part of the Code will be cancelled. The Department will notify the previously authorised prescriber or practice.

Authorised treatment may not be varied without authority and all prescribing must be consistent with the details of the authorisation. Where it is clinically necessary to vary treatment, a new application for authorisation is required.

The Department will issue renewal reminders prior to the date of expiry of the authorisation.

The CEO may, in writing, instruct a person not to prescribe or supply to an individual patient.

2.5.8 Approved specialists

Applications for authorisation will generally be approved when received from specialist medical practitioners relevant to the diagnosed condition. For the treatment of pain, the following specialists are recognised:

- anaesthetist;
- endocrinologist;
- gastroenterologist;
- neurologist;
- oncologist;
- haematologist
- pain medicine specialist ;
- palliative care specialist;
- general physician;
- rheumatologist;
- surgeon;
- addiction medicine specialist.

For alprazolam and flunitrazepam the following are recognised specialists:

- psychiatrist;
- sleep medicine physician;
- neurologist.

Applications from other specialists relevant to the diagnosis will be considered on a case by case basis.

2.5.9 Specialist support

Where a prescriber is not included in a specialist class above, then specialist support for the proposed regimen from the above recognised specialist groups must be provided with the application to obtain authorisation (see Section 2.5.9 for prescribing by nurse practitioners). Specialist support must be in writing, be current and agree with the proposed S8 regimen requested on the application. Specialist opinion is valid for a maximum period of three years, after which a review and renewed support is required. In certain circumstances the CEO may require endorsement from a specific specialist class (e.g. pain specialist).

Where treatment will require specialist support, prescribers should organise specialist review in advance. This includes patients already established on S8 treatment who may require dose increases or treatment modification that will require authorisation from the CEO.

Where there are conflicting specialist opinions, the CEO may request that a patient is referred for further opinion or multidisciplinary review, as necessary, to inform any decision.

A recent hospital discharge summary (no more than three months old) may qualify as specialist support. This will be valid for a period of three months from the application date, after which time independent specialist review is required. Prescribers are strongly advised to validate patient claims made on outdated or unfamiliar hospital discharge summaries.

Specialist support for a specific opioid regimen may not be required with applications for authorisation from medical practitioners to prescribe for patients with terminal illness where clinical documentation is available to confirm the patient's life expectancy is less than 12 months (see section 2.5.10).

2.5.10 Nurse practitioners

Nurse practitioners require prior written authorisation from the CEO to prescribe for more than 14 days or where any of the other prescribing criteria set out in Section 2.5.1 are met.

Where prescribing meets the criteria set out in Section 2.4, an application for authorisation may be considered without specialist support if accompanied by evidence of collaborative care and confirmation that prescribing falls within the nurse practitioner's scope of practice.

Specialist support is required to accompany the application for authorisation where prescribing meets any prescribing criteria relating to patient, drug, dose, formulation or product as set out in Section 2.5.1. The requirements for specialist support are outlined in section 2.5.8.

2.5.11 Terminal illness

Where treatment of a patient with terminal illness requires authorisation due to dose (>90 mg MEqD) or formulation (immediate release or injectable), medical practitioners may supply clinical documentation confirming life expectancy of less than 12 months, in lieu of specialist support for a specific opioid regimen. Specialist support is still required for other applications for authorisation.

Authorisations may be issued to support dose titration and flexible dosing when required.

Medical practitioners from the same practice or team (e.g. Silver Chain) can apply for group authorisation in the group to allow all palliative care prescribers in the group to prescribe for a patient that is terminally ill.

2.5.12 Treating patients with a history of substance abuse, Oversupplied or Drug Dependent persons

Persons with a history of substance abuse within the previous five years, or recorded as Oversupplied or Drug Dependent, can be authorised to receive S8 medicines. The treatment must be medically indicated and not for the treatment of addiction. For Drug Dependent persons the treatment must have relevant specialist support. Oversupplied Persons will require specialist support to confirm diagnosis and proposed treatment.

Evidence must be provided of measures in place to address misuse and reduce risk of misadventure. Authorisation will ordinarily require standard measures to limit potential misuse, including, but not limited to:

- signed Treatment Contracts;
- supply at one nominated pharmacy only;
- supply limits (daily, twice weekly or weekly dispensing);
- strict repeat intervals; and
- no early or replacement prescriptions.

The CEO may require prescribing of abuse deterrent formulations, where available.

2.5.13 Access to Schedule 8 medicines for emergency administration in residential cares settings.

The administration of high risk S8 medicines for emergency treatment by medical practitioners and nurse practitioners is outside the scope of this Code. Injectable medicines, including from Prescriber Bag supplies or imprest stock, may be used for this purpose and do not require authorisation.

Residential care facilities can be authorised to carry S8 medicines as imprest supplies for this purpose. A current Medicines and Poisons Permit is required.

2.5.14 Termination or variation of authorisation

An Authorised Prescriber may at any time, by writing to the CEO, request cancellation of a patient authorisation. The CEO may at any time, in writing, amend, cancel or suspend a patient authorisation. The CEO may apply conditions to any authorisation.

PART 3: Opioid pharmacotherapy

3.1 Overview

Part 3 outlines when S8 medicines, as pharmacotherapy, may be prescribed and administered to a patient for the purposes of treating opioid dependence. It details how to apply for authorisation to prescribe pharmacotherapy for opioid dependence or administer opioid pharmacotherapy for detoxification. General rules and conditions for the prescribing and administration of pharmacotherapy for opioid dependence are outlined below.

3.2 Scope

This Part applies to methadone and buprenorphine, in any formulation approved for the treatment of opioid dependence (addiction). Rules relating to the use of methadone and buprenorphine for the treatment of pain are contained in Part 2.

3.3 Authority

This Part is issued under provisions of the Medicines and Poisons Regulations 2016, Part 11, Division 5.

3.4 Opioid substitution therapy

A health practitioner may not prescribe or administer an S8 medicine to a person for the treatment of dependence, without the prior permission of the CEO. For the prescribing and administration of S8 medicines for medical purposes that are not treatment of dependence, other Parts of this Code apply.

In Western Australia, Opioid Substitution Therapy (OST) for the treatment of drug dependence is managed through the Community Program for Opioid Pharmacotherapy (CPOP) framework, established under the Medicines and Poisons Regulations 2016. S8 medicines may only be prescribed and dispensed to treat opioid dependence within the CPOP. Treatment must be by an authorised prescriber, from an authorised dispenser and to an authorised patient.

Approved treatments in the CPOP include:

- methadone syrup/solution;
- Subutex® tablets; and
- Suboxone® film.

OST supplied under the CPOP is funded via the Commonwealth Section 100 Opiate Dependence Treatment Program. This program is open to those pharmacies approved by the Department of Health, WA. Treatments funded under this program may not be used or supplied for other purposes.

3.4.1 Prescriber authorisation

3.4.1.1 Prescriber requirements

Registered medical practitioners and nurse practitioners (within their nominated scope of practice) are eligible to be authorised as CPOP prescribers. Professional registration must not have conditions or undertakings relevant to the prescribing of S8 medicines.

The applicant must have first successfully completed the approved training and assessment package delivered by the Community Pharmacotherapy Program (CPP). A practitioner may be authorised to prescribe methadone, Subutex® and Suboxone®, or they may be authorised as a Suboxone® only prescriber.

Prescriber authorisation is valid for a 3 year period. After this time, a re-accreditation process must be completed, involving participation in approved online professional development activities delivered by CPP. Upon successful completion, prescribers may be reapproved for a further 3 years.

3.4.1.2 Applying to become authorised

Prescribers must apply for authorisation, in writing, using the approved form.

Prescribers must ordinarily be practising in Western Australia. The CEO may recognise prescribers who are authorised in corresponding programs in other States or Territories. Authorisations to prescribe for individual patients issued to interstate prescribers will be no more than one month in duration and only issued for patients travelling within, or moving permanently to WA.

To maintain authorisation, prescribers must treat a minimum of 2 CPOP clients annually. The CEO may request refresher training or relevant continuing development activities to maintain authorisation.

The CEO may at any time, in writing, amend, cancel or suspend an authorisation. The CEO may apply conditions to any authorisation.

A prescriber may at any time, by writing to the CEO, request cancellation of their authorisation. In this case, active clients will need to be safely transferred to other prescribers and a transition period is often necessary.

3.4.1.3 Treatment limited to a maximum number of clients

Prescribers authorised for methadone and buprenorphine are limited to treatment of a standard maximum number of clients at any one time. This includes:

- sole metropolitan prescriber: 50 CPOP clients;
- sole regional prescriber: 25 CPOP clients; or
- Suboxone® only prescribers: 5 CPOP clients.

These client numbers may not be exceeded without written authorisation of the CEO. Applications to exceed the standard maximum client number must be in writing and in the approved form.

3.4.1.4 Specialist prescribers

A medical practitioner employed at the Next Step Drug and Alcohol Service may be authorised as a Specialist Prescriber. Specialist Prescribers may write interim prescriptions to continue therapy, without individual patient authorisation, provided:

- the patient is currently participating in CPOP;
- there is a current and valid authorisation;
- OST is prescribed consistent with the details of the authorisation;
- the specialist is satisfied that it is not practical to obtain a prescription from the authorised prescriber; and
- the prescription is for no more than one month.

3.4.1.5 Co-prescribers

Upon application from a Specialist Prescriber, the CEO may authorise a Co-prescriber, who is not an authorised CPOP prescriber, to prescribe OST provided:

- the Specialist Prescriber has a valid authorisation for the patient;
- the Co-prescriber has completed relevant training;
- OST is prescribed consistent with the details of the authorisation; and
- prescriptions are for no more than 3 months.

3.4.1.6 Custodial settings and hospitals

A medical practitioner who is not an authorised CPOP prescriber may prescribe OST for a person in custody or while an inpatient in hospital, provided:

- the patient is currently participating in CPOP;
- there is a current patient authorisation;
- OST is prescribed consistent with the details of the authorisation;
- the practitioner is satisfied it is safe to prescribe OST; and
- treatment is for no more than one month.

Outside these conditions authorisation is required.

OST may be supplied by a private or public hospital for administration to an inpatient currently participating in CPOP. Nursing staff may not administer an OST in hospital unless there is a written order on a medication chart. Hospitals may not supply OST at discharge.

Authorised health professionals are to refer to relevant hospital protocols for the management of CPOP patients in the hospital setting.

At the end of any period of hospitalisation, the authorised prescriber, the authorised pharmacy and the CPP must be contacted to confirm treatment details to ensure safe transfer of care to the community.

3.4.2 Pharmacy requirements

Authorised CPOP prescribers must nominate a pharmacy dosing site on all applications for authorisation.

Pharmacies must be authorised by the CEO to dispense OST under the CPOP. Authorisation is generally limited to 50 clients.

If a dosing site is open less than 7 days per week, and the patient is not eligible for unsupervised dosing, the prescriber must make alternative arrangements to cover the days the pharmacy is not open.

3.4.3 Patient authorisation

OST may not be prescribed or dispensed for a person unless authorised by the CEO.

An S8 and CPOP prescribing history can be obtained by contacting the Department of Health S8 Prescriber Information Service. This information is provided under the authority of the Medicines and Poisons Act 2014. Information will only be provided to an authorised health professional and only relating to a patient under the care of that practitioner. Any information provided may not be used for any other purpose than for assisting with the management of the patient.

3.4.3.1 Record of drug dependence

A patient may only be authorised to receive OST for treatment of opioid dependence. It is a condition of authorisation that patients are recorded as Drug Dependent Persons. A Report of Drug Dependence (as set out in Part 1 of this Code) must accompany all applications for authorisation to prescribe OST.

3.4.3.2 Applying for patient authorisation

Patient applications must be in the approved form, completed in full, and include any clinical information required for a decision. Applications submitted by community CPOP prescribers are reviewed by the CPP prior to authorisation being considered by the CEO.

Patient authorisation is generally issued for a maximum of two years duration. Longer authorisation periods may be considered at the discretion of the CEO. The CEO may place specific conditions on an authorisation, or amend, cancel or suspend any authorisation. Applications for Subutex® are ordinarily for 6 to 12 months, consistent with the reason for use.

Patient authorisation is specific to the authorised prescriber, the patient and the type of OST. A new application is required whenever the following is altered:

- OST type – transfer to or from methadone, Suboxone® or Subutex®;
- treating medical practice (including address); or
- patient details (e.g. name).

Where a time limited authorisation is approaching expiry, but treatment is to continue unchanged, a renewal form may be submitted, rather than a full application. The Department will issue renewal reminders prior to the date of expiry.

A new application is required for any expired authorisation.

3.4.3.3 Authorised dose

The CEO will ordinarily authorise a person to receive up to a maximum daily dose of:

- 120 mg of methadone syrup/solution; or
- 24 mg of buprenorphine as Subutex® or Suboxone®.

Buprenorphine may be dosed at longer daily intervals, where the standard maximum authorised dose is 32 mg every second or third day. Higher doses require written permission. Prescribers must apply in writing using the approved excess dose form. Applications must be reviewed by the CPOP Clinical Review Committee prior to authorisation being considered by the CEO. Specific conditions may be applied, such as ECG monitoring for high dose methadone.

Commencement doses of OST must not exceed those recommended in the *Clinical Policies and Procedures for the Use of Methadone and Buprenorphine in the Treatment of Opioid Dependence* (3rd edition; 2014), published by the Drug and Alcohol Office, Community Pharmacotherapy Program. The CEO may, on the grounds of patient safety, or the recommendation of the CPOP Clinical Review Committee, instruct that higher doses not be used, or specific conditions are met, prior to approval.

3.4.3.4 Subutex®

Subutex® is ordinarily only authorised in conditions where Suboxone® is not clinically appropriate including:

- pregnancy or breastfeeding;
- low dose (6 mg or less) for a duration of less than 6 months; or
- significant allergy to Suboxone®.

A copy of the submitted Adverse Drug Reactions Advisory Committee (ADRAC) form must be supplied in the case of allergy.

3.4.3.5 Transferring between opioid substitution therapy agents

Patient authorisation is specific to the OST type specified in the authorisation. A new application is required if the OST agent is to be changed, such as from methadone to buprenorphine.

Transfer from high doses of methadone, of greater than 40 mg per day, to buprenorphine is not recommended.

3.4.3.6 Termination or variation of authorisation

The CEO may at any time, terminate an authorisation, request a new application, vary an authorisation, or modify conditions of an existing authorisation.

The issue of a patient CPOP authorisation cancels any existing opioid pharmacotherapy authorisations in place for that patient. The Department will notify previous prescribers.

On issuing a CPOP authorisation for a patient who is already under treatment with S8 medicines, the CEO, at their discretion, may cancel existing authorisations and/or issue an instruction not to prescribe or supply to the patient.

A prescriber may terminate an authorisation by notifying the CEO in writing. This may be done when a person exits the CPOP, is lost to follow up, or for any other reason.

3.4.4 Prescribing

All prescribing must conform to best treatment practices as outlined in the *Clinical Policies and Procedures for the Use of Methadone and Buprenorphine in the Treatment of Opioid Dependence* (3rd edition; 2014), published by the Drug and Alcohol Office, Community Pharmacotherapy Program.

In addition to the elements referenced in Part 1 to this Code, CPOP prescriptions must include:

- name of nominated pharmacy dosing site;
- start and end date of the prescription;
- daily dosing schedule;
- precise details of dose increases/decreases and minimum intervals; and
- precise details of takeaway doses, if any.

CPOP prescriptions are intended to authorise and instruct the CPOP pharmacy as to the specific daily dosing requirements of the patient. They must contain enough information so that the precise intentions of the prescriber are clear. This includes prescriptions generated using computer software.

Prescriptions are valid for the period specified and may not contain repeats. After this period a new prescription must be provided. A CPOP prescription should match the schedule of clinical review. Duration of prescriptions should be significantly reduced to safe lengths of time during client induction, dose changes or dosing instability.

3.4.4.1 Take away and modified daily dosing

Prescribing of takeaway doses must comply with the schedules outlined in the *Clinical Policies and Procedures for the Use of Methadone and Buprenorphine in the Treatment of Opioid Dependence* (3rd edition; 2014), published by the Drug and Alcohol Office, Community Pharmacotherapy Program. Dosing outside the schedule requires written approval from the CPOP Clinical Review Committee. This may include patients that do not meet stability criteria, patients that do not meet the exclusion period criteria, or takeaway frequency in excess of the schedules. Prescribers should apply in writing, in the approved form.

Prescribing modified daily dosing, such as for periods of interstate or overseas travel, requires written approval from the CPOP Clinical Review Committee. Prescribers should apply in writing, using the approved form.

3.5 Detoxification therapy

Outside the CPOP a medical practitioner may use an opioid pharmacotherapy for treating opioid dependence, for the short-term therapy of withdrawal from opioids and where authorised by the CEO.

Opioid detoxification treatment is defined for the purposes of this Code as the use of S8 pharmacotherapy during medically supervised withdrawal from opioids. The detoxification period must be short-term and limited to no more than 7 days for any single period.

An authority to use an S8 medicine for detoxification is limited to methadone and buprenorphine formulations approved for the treatment of opioid dependence, as outlined in section 3.2. Other S8 treatments for detoxification are not permitted under this Code.

3.5.1 Prescriber authorisation

3.5.1.1 Prescriber requirements

Registered medical practitioners who are Fellows of the Royal Australasian College of Physicians, Chapter of Addiction Medicine are eligible to be authorised as detoxification prescribers. Professional registration must not have conditions or undertakings relevant to the prescribing of S8 medicines.

In public hospitals, all specialist medical practitioners listed in section 2.5.8 of this Code are eligible to be authorised as detoxification prescribers for the purpose of treating public hospital inpatients.

Prescriber authorisation is valid until revoked or amended. The CEO may at any time, in writing, amend, cancel or suspend an authorisation. The CEO may apply conditions to any authorisation, including those that relate to the use of specific treatment protocols.

3.5.1.2 Applying to become authorised

Prescribers, who are not specialists treating public hospital patients, must apply for authorisation, in writing, using the approved form.

Prescribers must submit copies of patient treatment protocols relating to use of S8 pharmacotherapy for opioid dependence. The CEO may request relevant expert opinion on the safety of any submitted protocol.

In public hospitals, notification of each patient to be treated with the approved buprenorphine protocol is also an application for authorisation.

3.5.1.3 Authorised site

The authorised specialist must nominate the site where detoxification therapy will be provided. Authorisation is restricted to the approved site(s).

Approved sites must be medical treatment facilities - a currently licensed private hospital, public hospital or equivalent. The facility must maintain premises, staffing and equipment suitable for the treatment of opioid dependent persons.

The approved site may obtain and possess OST for detoxification under authority of a health service permit issued in accordance with the Medicines and Poisons Act 2014. Regulations for the storage and recording of S8 medicines apply in full, including keeping of an S8 Register of transactions.

3.5.1.4 Standard conditions

Use of pharmacotherapy is to be consistent with submitted and approved protocols. In the event that protocols are altered, these must be resubmitted to the CEO.

A patient may only be treated by one authorised detoxification prescriber at a time. OST must be administered at the approved site, under the personal direction of the authorised detoxification prescriber. All Regulations applying to record keeping and administration of S8 medicines apply in full, including making a record in the clinical notes of administration on each occasion OST is administered.

OST must be directly administered or observed by qualified health practitioners. Patients may not be supplied OST to self-administer at a later time, or at a different facility, or outside the observation of a health practitioner.

During detoxification, a patient may not be prescribed, supplied or administered any other S8 medicine, without the permission of the CEO. All reasonable steps must be taken to prevent patient access to other S8 medicines during this period. The authorised specialist must inform other S8 prescribers, where known, when detoxification commences.

3.5.1.5 Approved protocol for public hospitals

Specialist medical practitioners providing detoxification treatment for public hospital inpatients are required to prescribe in accordance with the standard Next Step Drug and Alcohol Services buprenorphine (Suboxone®) protocol. Any public hospital based prescriber who is not a Fellow of the Royal Australasian College of Physicians, Chapter of Addiction Medicine must seek advice from an addiction medicine specialist before detoxification of each patient is commenced.

If a specialist medical practitioner wishes to use a different detoxification protocol, an addiction medicine specialist at Next Step Drug and Alcohol Services must be consulted for advice and endorsement. The endorsed protocol must be forwarded to the Department for consideration of approval. Detoxification therapy under the endorsed protocol must not commence until approved by the Department.

3.5.2 Patient notification

3.5.2.1 Notification of detoxification treatment

The Detoxification Prescriber must notify the CEO when a person is treated with opioid pharmacotherapy for detoxification. Notification must occur prior to or at the commencement of treatment.

The Notification must be in an approved manner, and include information on:

- Detoxification Prescriber;

- patient details;
- drug/s of dependence;
- commencement date; and
- details of detoxification protocol used.

3.5.2.2 Report of drug dependence

A patient may only receive detoxification pharmacotherapy for the treatment of opioid dependence. Where the patient is not being treated in a public hospital, a Report of Drug Dependence (as set out in Part 1 of this Code) must accompany detoxification notifications.

For public hospital patients, submission of the approved notification form completes the requirement for making a report of drug dependence.

3.5.2.3 Termination of authorisation or notification

On receipt of a notification of detoxification the CEO may, at their discretion, cancel any existing authorisations and/or issue an instruction not to prescribe or supply to the patient.

A prescriber may terminate an existing detoxification notification by notifying the CEO in writing.

Part 4: Stimulant medicines

4.1 Overview

This Part outlines when S8 stimulant medicines may be prescribed. It outlines the method for notifying a patient to be treated with stimulants and when authorisation is required for a patient to receive stimulants.

4.2 Scope

This Part applies to dexamfetamine, lisdexamfetamine and methylphenidate, in all formulations.

4.3 Authority

This Part is issued under the provisions of Medicines and Poisons Regulations, Part 11, Division 4.

4.4 Prescribing stimulant medicines

S8 stimulant medicines may not be prescribed by a medical practitioner unless authorised by the CEO. Stimulants include all formulations of:

- dexamfetamine;
- lisdexamfetamine (Vyvanse®); and
- methylphenidate (Ritalin®, Ritalin LA®, Concerta®).

4.5 Prescriber authorisation

To prescribe stimulants a medical practitioner must be authorised as a Stimulant Prescriber by the CEO.

4.5.1 Prescriber requirements

Registered specialist medical practitioners in the categories below are eligible to be authorised as a Stimulant Prescriber. Prescribers must ordinarily be practising in Western Australia. Professional registration must not have conditions or undertakings relevant to the prescribing of S8 medicines.

Authorisation may be valid for a time limited or indefinite period, unless suspended or cancelled. A Stimulant Prescriber may at any time, by writing to the CEO, request cancellation of their authorisation. The CEO may at any time, in writing, amend, cancel or suspend an authorisation. The CEO may apply conditions to any authorisation.

4.5.2 Applying to become authorised as a Stimulant Prescriber

Prescribers must apply for authorisation, in writing, using the approved form.

4.5.3 Approved specialists

Specialists that may be authorised as stimulant prescribers include:

- paediatrician;
- paediatric neurologist;
- neurologist;
- respiratory and sleep physician;
- thoracic medicine physician;
- rehabilitation physician;

- paediatric rehabilitation physician;
- psychiatrist;
- child and adolescent psychiatrist; or
- other specialist as determined by the CEO.

4.5.4 General conditions

All prescribing must conform to the criteria and conditions outlined within Part 4 of this Code.

The CEO may, in writing, instruct a person not to prescribe or supply to an individual patient.

4.5.5 Co-prescribers

An authorised Stimulant Prescriber may nominate a Co-prescriber to assist in prescribing stimulants for a patient. Nomination must be through notification to the CEO, in writing, using the approved form.

Co-prescribers must ordinarily be practising in Western Australia. Professional registration must not have conditions or undertakings relevant to the prescribing of S8 medicines.

The nominated Co-prescriber is permitted to prescribe for the patient, in accordance with the Stimulant Prescriber's directions. A Co-prescriber is not permitted to change a patient's treatment and may not alter stimulant type or formulation or dose without authority of the Stimulant Prescriber. Co-prescribers are not permitted to submit notifications of patient treatment.

The Stimulant Prescriber may choose to cease or alter the nominated Co-prescriber for a patient. This can be done by notifying the CEO, in writing. In these cases, the Stimulant Prescriber must inform any existing Co-prescriber of the changes. Where the nomination of a Co-prescriber is ceased, that practitioner, and all other medical practitioners at that particular practice, may no longer prescribe stimulants for that patient.

4.5.6 Registrars

Specialist registrars are not eligible to become authorised Stimulant Prescribers but may be nominated as Co-prescribers and prescribe stimulants in accordance with the Stimulant Prescriber's directions.

4.5.7 Authorised Public Sector Clinics

A Public Sector Clinic (the Clinic), located in Western Australia, may apply to the CEO to be authorised as a stimulant prescribing clinic. This must be done in writing on the approved form. The application must specify the names of the authorised Stimulant Prescribers, who will be prescribing stimulants at the Clinic.

The Clinic must nominate a person to be responsible for corresponding with the Department. This person may be an authorised Stimulant Prescriber practising at the Clinic, or another senior member of staff, such as the Clinic manager. This person is responsible for notifying the Department when an authorised Stimulant Prescriber commences or ceases to practice at the Clinic.

If there is any change in the person nominated to be responsible, the Clinic must nominate a new person and inform the CEO within 14 days.

4.5.8 Prescriber on leave

A Stimulant Prescriber should advise the Department in writing if they wish for alternative stimulant prescribing arrangements to be in place during periods of leave. This should include the time period of leave and name of any medical practitioner required to write interim prescriptions. An authorised Stimulant Prescriber or the nominated Co-prescriber may prescribe in accordance with the current Notification of Treatment. Any other medical practitioner must obtain an interim authorisation from the CEO prior to prescribing. An interim authorisation will be based on the treatment rationale previously notified or prescribed by the Stimulant Prescriber, provided on a case by case basis, at the discretion of the CEO and will be limited to short term arrangements only.

4.5.9 Custodial settings and hospitals

A medical practitioner who is not a Stimulant Prescriber may prescribe stimulants for a person in custody or while an inpatient in hospital, provided:

- the patient is already notified or authorised;
- the prescribing is consistent with the notification or authorisation;
- the practitioner is satisfied it is safe to prescribe stimulants; and
- treatment is for no more than three months.

In all cases, the authorised Stimulant Prescriber must be contacted to confirm treatment details and the medical practitioner should contact the Department of Health S8 Prescriber Information Service to obtain a stimulant notification history and S8 prescribing history.

Outside these conditions, authorisation is required.

4.6 Notification of patient treatment

Where the criteria set out in Section 4.7 of this Code are met, stimulants may be prescribed to a patient so long as notification is provided to the CEO. In cases outside the conditions approved for notification, as detailed below, the written authorisation of the CEO is required to prescribe a stimulant.

4.6.1 When to notify

Notification is required at the commencement of treatment with stimulants for a patient. This includes when a patient transfers to a new Stimulant Prescriber, even if they are already in treatment with stimulants.

A new notification is required if any of the following stimulant treatment details change:

- authorised Stimulant Prescriber;
- nominated Co-prescriber (including change of Co-prescriber place of practice);
- patient name.

4.6.2 How to notify

Notification must be made by an authorised Stimulant Prescriber. For each patient a notification must be made on the approved form and include the following information:

- prescriber details (name, address, telephone contact, Stimulant Prescriber Number);
- patient details (name, address, date of birth);
- diagnosis;
- relevant comorbidities;
- stimulant medicine(s), strength, formulation and daily dose;
- nominated Co-prescriber and place of practice (if any).

The Stimulant Prescriber must provide a copy of the approved form to the nominated Co-prescriber on commencement of treatment and when there are any changes to treatment regimen.

4.6.3 Current prescriber status

Upon notification of treatment to the Department, the notifying prescriber becomes the current Stimulant Prescriber for that patient.

A patient may only have one current Stimulant Prescriber at any one time. Only the current Stimulant Prescriber, or the Co-prescriber and other medical practitioners at a particular practice, nominated in a notification, may prescribe stimulants to that patient.

When a patient transfers to a new prescriber and a new notification is received, the new prescriber becomes the current Stimulant Prescriber. In these cases, the Department will advise the previous Stimulant Prescriber.

4.6.4 Current clinic status

Where a patient notification is received from a Stimulant Prescriber at a current Public Sector Clinic, the clinic becomes the current clinic. Any Stimulant Prescriber at the current clinic may prescribe for that patient.

A patient may only have one current prescriber or one current clinic at any one time. Where there is a current clinic, another Stimulant Prescriber or another Public Sector Clinic is not permitted to prescribe for that patient.

When a patient transfers to a new prescriber or new clinic and a new notification is received, the new prescriber (or clinic) becomes the current Stimulant Prescriber (or current clinic). In these cases, the Department will advise the previous Stimulant Prescriber (or clinic).

4.6.5 Terminating notification

A Stimulant Prescriber may choose to cease prescribing and terminate current prescriber status for a patient. This must be done by notifying the CEO in writing using the approved notification form. Upon receipt of a termination, the notifying prescriber ceases to be the current prescriber for that patient.

4.7 General conditions for notification

Patients prescribed stimulants must meet the criteria outlined in this Section. Where patients are outside these criteria, prior written permission of the CEO is required in order to prescribe.

4.7.1 Comorbidity

Patients must not:

- have a history of stimulant induced psychosis (see Part 1 of this Code);
- have a history of psychosis or bipolar disorder;
- have a history of substance abuse, diversion or misuse of drugs of addiction or Schedule 9 poisons within the previous five years; or
- have a record of drug dependence or oversupply (see Part 1 of this Code);
- be a current CPOP participant.

Where a Stimulant Prescriber or Co-prescriber subsequently becomes aware of a relevant history for a patient, stimulant treatment is to be reviewed. If continuation of stimulant treatment is desired, then authorisation to prescribe is required from the CEO.

Prior to prescribing, the prescriber must take reasonable steps to satisfy themselves that the patient does not have a relevant condition or restriction that would affect treatment with a stimulant, or require authorisation to prescribe. This can be achieved through contacting the Department of Health S8 Prescriber Information Service to obtain an S8 and stimulant prescribing history.

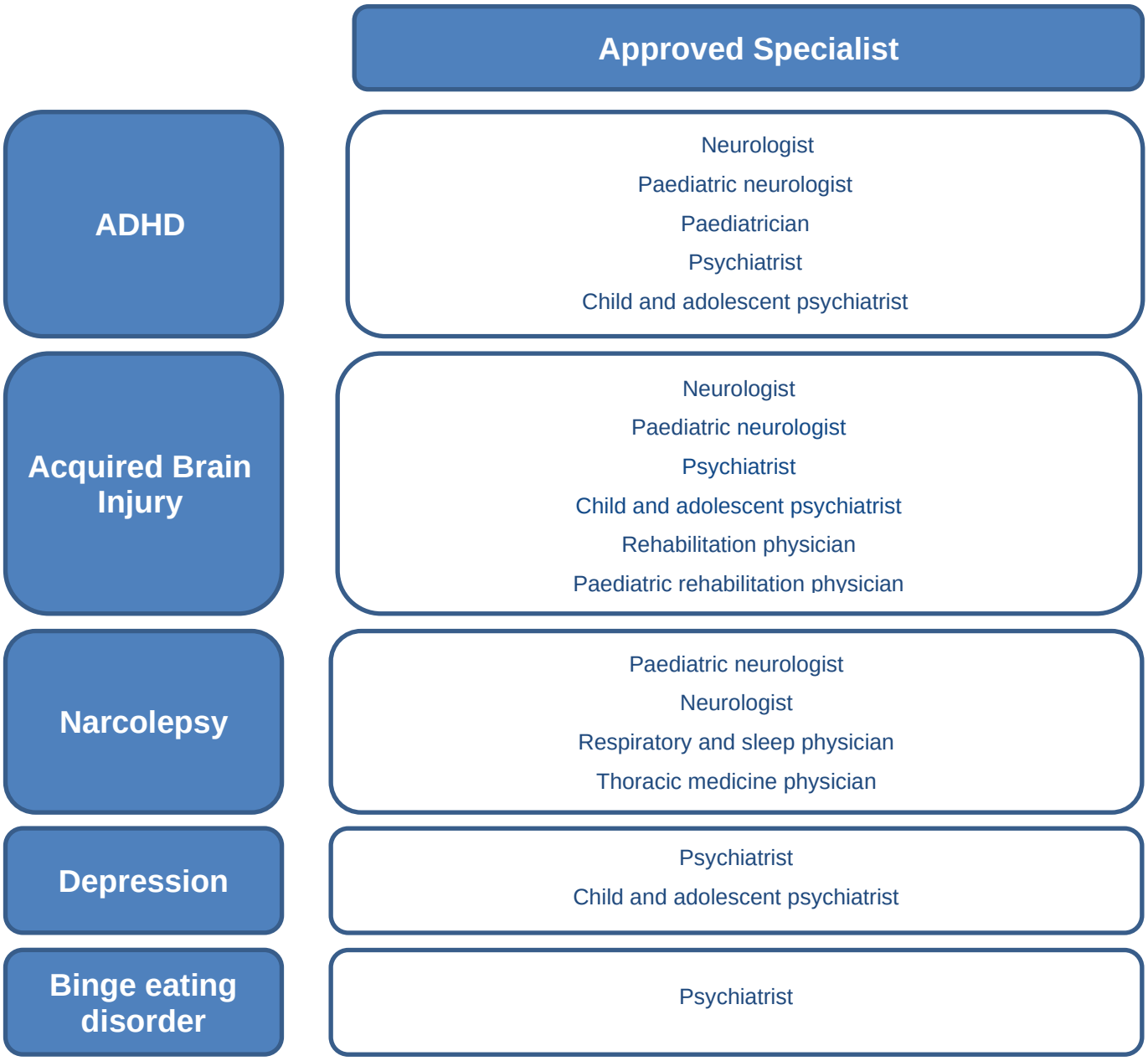
4.7.2 Diagnosis

Patients must have a diagnosis of:

- attention deficit hyperactivity disorder (meeting ICD-10 or DSM-5 diagnostic criteria);
- acquired brain injury;
- narcolepsy;
- depression; or
- binge eating disorder

Approved specialists may prescribe stimulants for approved diagnoses as set in Figure 4.

Figure 4: Stimulant Prescribers: approved specialities and diagnoses



4.7.3 Age

An authorised Stimulant Prescriber specialising in the treatment of adults may treat any patient greater than or equal to 17 years of age. Treatment of patients greater than or equal to 15 years and less than 17 years of age, by an authorised Stimulant Prescriber specialising in adult treatment, requires prior written authorisation of the CEO.

An authorised Stimulant Prescriber specialising in the treatment of children may treat children/patients:

- between four years and 19 years; or
- between 19 and 25 years, if that patient was treated by the Stimulant Prescriber prior to reaching 19 years of age.

Treatment of any child less than 6 years of age with lisdexamfetamine is not permitted.

Treatment of any child between two and four years requires prior written authorisation of the CEO.

Treatment of children below two years of age is not permitted.

4.7.4 Dose

Doses are not to exceed the maximum daily doses outlined below. For sole therapy the maximum doses set out in Figure 5 are approved.

Figure 5: Approved maximum stimulant doses

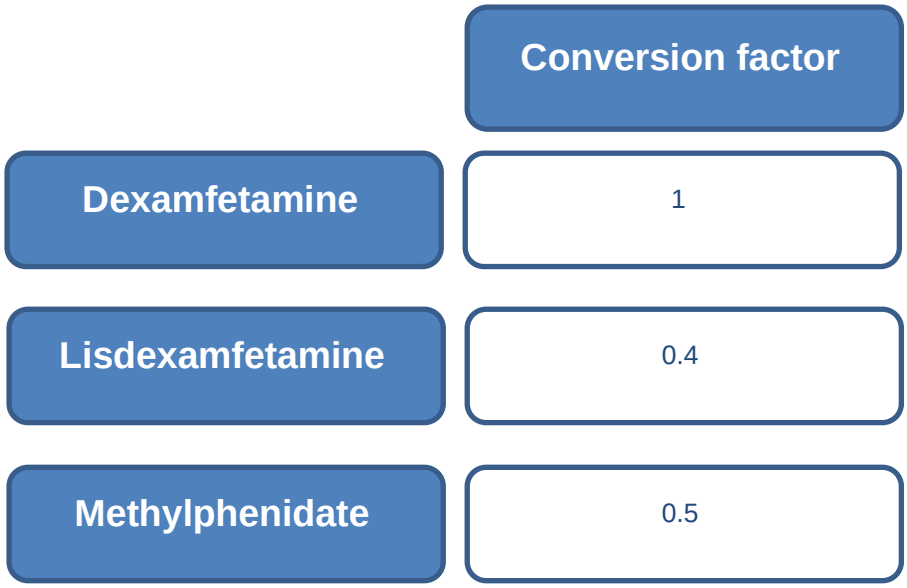
	Dexamfetamine	Methylphenidate	Lisdexamfetamine
Under 18 years	1 mg/kg/day up to max 60 mg/day	2 mg/kg/day up to max 120 mg/day	Bodyweight dosing not recommended. Over 6 years of age commence at 30 mg. Max 70mg/day
Over 18 years	Max. 60 mg/day	Max. 120 mg/day	Max. 70 mg/day

Dose limits apply to the total daily dose prescribed for that stimulant agent. Dose limits apply to the combined total daily dose of both short and long acting formulations when used together.

These dose limits are intended for regulatory purposes only and indicate the point at which authorisation of the CEO is required.

Where any combination of dexamfetamine, methylphenidate and lisdexamfetamine are prescribed together, the dose of all agents must be converted to an equivalent daily dose of dexamfetamine and added together. For combination therapy the total combined dose of all stimulants must not exceed an equivalent dexamfetamine dose of 1 mg/kg/day for those under 18 years up to a maximum of 60 mg/day and a maximum of 60 mg/day for any patient.

Figure 6: Dexamfetamine equivalents



To use this table:

1. Add all daily doses of the same stimulant agent together, to calculate the daily dose for that agent.
2. Multiply by the conversion factor for that stimulant, to convert to dexamfetamine equivalents.
3. Repeat steps 1 and 2 for any other stimulant agents taken concurrently.
4. Add all results from step 3 together.

These conversion factors are for the purposes of this Code and are not intended for use as a guideline in the clinical transfer of patients between different stimulant agents.

A mg/kg dosing regimen is not recommended for lisdexamfetamine.

4.7.5 Frequency of review

An authorised Stimulant Prescriber should ensure that all patients are reviewed on at least an annual basis for the continuation of appropriate stimulant treatment.

4.7.6 Drug screening

A urine drug screen (in accordance with *Australian/New Zealand Standard 4308*) should be undertaken by all patients 13 years and older before treatment with a stimulant is commenced. Further testing is recommended annually and as indicated.

4.8 Patient authorisation

In cases outside the conditions approved for notification, as detailed above, the written authorisation of the CEO is required prior to prescribing a stimulant.

4.8.1 Authorisation

The written authorisation of the CEO is required for any:

- prescriber who is not an approved specialist;
- patient with relevant comorbidities;
- patient who is outside the approved diagnoses;
- person recorded as Oversupplied or Drug Dependent;
- treatment of a child outside the approved age ranges for specialists;
- doses above the approved maximum;
- treatment of binge eating disorder.

4.8.2 Applying for authorisation

For any treatment meeting the authorisation criteria, an authorised Stimulant Prescriber must apply to the CEO to prescribe stimulants. The application must be in writing, in the approved form and include:

- prescriber details;
- patient details, including age and weight;
- diagnosis;
- treatment rationale, including medical evidence to support use in any unapproved indication;
- intended stimulant regimen, including medicine(s), formulation(s) and dose(s);
- supporting clinical information on diagnosis and intended regimen; and
- reason why prescribing by an authorised Stimulant Prescriber is not possible, where applicable.

4.8.3 Duration of approval

Authorisations will generally be issued for up to 12 months. Longer periods of authorisation will be considered at the discretion of the CEO. For active stimulant patients, the Department will issue renewal reminders prior to the date of expiry of the authorisation.

4.8.4 General conditions

The CEO may decline an application, at their discretion. The CEO may request any additional information, second opinion, or other review, as necessary to make a decision. Applications may be referred to the Stimulant Assessment Panel for clinical advice. Where an application for authorisation is not approved, the applicant may reapply with additional information (such as a second opinion/specialist support, additional clinical reports, the results of previous interventions and/or drug screens) or may make a new application with modified treatment details (drug, drug formulation and/or dose).

Authorisations are specific for the medicine(s), form(s) and dose(s) requested. Treatment may not be varied without authority and all prescribing must match the approved therapy. Where it is clinically necessary to vary treatment, a new application for authorisation is necessary.

Authorisation will only be granted to one Stimulant Prescriber at a time. Where a new stimulant authorisation is requested and granted, all prior stimulant notifications or authorisations are cancelled. The Department will notify any previously authorised prescriber.

Where an authorisation is in place, other prescribers may not prescribe stimulant medicines, irrespective of the type of practitioner, patient, or stimulant medicine.

Ordinarily, only Stimulant Prescribers will be granted authorisation to prescribe for these cases. Co-prescribers will not be granted authorisation, other than in exceptional circumstances.

Prescribing for binge eating disorder should only be initiated by psychiatrists. Stimulant treatment of binge eating disorder is only recommended for patients between 18 and 55 years of age. Initial treatment should be for 12 weeks. Patients should then be reviewed to assess whether further treatment is required.

4.8.5 Treating patients with a history of substance abuse, Oversupplied or Drug Dependent Persons

Persons with a history of substance abuse within the previous five years, or recorded as Oversupplied or Drug Dependent can be authorised to receive stimulant medicines. The treatment must be medically indicated and not connected to the treatment of addiction.

Evidence must be provided of treatments in place to address misuse and measures to reduce risk of abuse. Authorisation will ordinarily require standard measures to limit potential misuse, including, but not limited to:

- signed Treatment Contracts;
- adequate trial of non-stimulant agents;
- use of long acting stimulants only;
- dosing restrictions, or adequate trials of lowest effective dose;
- supply limits (daily or weekly dispensing);
- supply at one nominated pharmacy only;
- strict repeat intervals;
- no early or replacement prescriptions;
- urine drug screens;
- other relevant conditions.

4.8.6 Termination or variation of authorisation

A Stimulant Prescriber may at any time, by writing to the CEO, request cancellation of a patient authorisation. The CEO may at any time, in writing, amend, cancel or suspend a patient authorisation. The CEO may apply conditions to any authorisation.

4.9 Patients travelling interstate

Prescriptions written by Western Australian Stimulant Prescribers and dispensed outside this State must meet the regulatory requirements of whichever State or Territory they are dispensed in.

Where interstate travellers require emergency treatment with stimulants, a medical practitioner with a practice address in Western Australia may apply to the CEO for temporary authorisation to prescribe. Authority is provided on a case by case basis, at the discretion of the CEO, and will be limited to short term arrangements only.

Part 5: Cannabis-Based Products

5.1 Overview

This Part outlines when S8 Cannabis-Based Products may be prescribed. It details the method of application for a prescriber to receive authorisation to prescribe Cannabis-Based Products. It outlines when authorisation is required for a patient to receive a Cannabis-Based Product and the method for notifying a patient to be treated with a Cannabis-Based Product.

5.2 Scope

This Part applies to cannabis, nabilone, dronabinol, nabiximols, tetrahydrocannabinol, and any other synthetically or botanically derived cannabinoid included in S8, regardless of presentation or formulation.

It does not extend to cannabidiol or any other cannabinoid specified in Schedule 4.

5.3 Authority

This Part is issued under the provisions of Medicines and Poisons Regulations 2016, Part 11, Division 3.

5.4 Prescribing Cannabis-Based Products

S8 Cannabis-Based Products may not be prescribed by a medical practitioner unless authorised by the CEO. Cannabis-Based Products include all formulations of:

- dronabinol;
- nabilone;
- nabiximols;
- tetrahydrocannabinols;
- cannabis;
- other cannabinoids included in S8.

Cannabis–based products must meet all criteria for inclusion in S8 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), specifically:

- products manufactured in accordance with the *Narcotic Drugs Act 1967*; or
- therapeutic goods imported and supplied in accordance with the *Therapeutic Goods Act 1989.*

A prescription for a Cannabis-Based Product only authorises the supply of that product as an S8 product by a pharmacist in accordance with the Medicines and Poisons Regulations 2016 and does not authorise any other activity.

This Code cannot be applied to any product that is not lawfully sourced, or is included in Schedule 9 of the SUSMP. This Code does not apply to research conducted using cannabis or any cannabis related substance in Schedule 9 of the Poisons Standard.

5.5 Patient authorisation

To prescribe a Cannabis-Based Product, a medical practitioner must be authorised for an individual patient. Individual patient authorisation is required for any case that is outside the conditions and circumstances acceptable for notification, as detailed in Sections 5.6, 5.7 and 5.8. The written authorisation of the CEO is required prior to prescribing a Cannabis-Based Product.

5.5.1 Authorisation

The written authorisation of the CEO is required for any:

- medical practitioner who is not an approved Cannabis-Based Product Prescriber (see Section 5.6);
- patient outside the approved age range;
- patient, product or indication that does not meet the general conditions for notification (see Section 5.8);
- patient with a substance abuse condition, or recorded as Oversupplied or Drug Dependent;
- product in Schedule 8 of the Poisons Standard, outside a clinical trial setting, that does not comply with TGO 93 (such as a pharmacy compounded product).

5.5.2 Applying for authorisation

For any treatment meeting the authorisation criteria, a medical practitioner must apply to the CEO to prescribe Cannabis-Based Products.

Where a Category B SAS approval to prescribe is required from the TGA, an application to the CEO, for authorisation under this Code, will be made through the TGA (in writing or electronically), using the approved process. SAS approval is necessary for any Cannabis-Based Product that is not listed on the Australian Register of Therapeutic Goods (ARTG).

The patient or carer must provide their consent to the applicant to allow the provision of information contained in the application to the TGA and/or the CEO, for the purposes of administering their respective legislative obligations, and for the CEO to share information with the TGA relating to the prescribing of a Cannabis-Based Product to that patient, for the purposes communicating a decision to the applicant.

The application must be in the approved written or electronic format and include:

- prescriber details;
- patient details;
- diagnosis;
- intended Cannabis-Based Product regimen, including medicine(s), formulation(s), dose(s), and treatment plan; and
- any clinical information relevant to the safe use of a Schedule 8 (Drug of Addiction), such as a management or monitoring plan.

Where a Category B SAS approval to prescribe is not required from the TGA, the application to the CEO will be made, in writing, using the approved forms on the Department of Health website, with all required information, as above.

5.5.3 Duration of approval

An authorisation will generally be issued for up to 6 months in the first instance. For repeat applications, in the same patient, an authorisation for up to 12 months will be issued.

The duration of approval may be varied at the discretion of the CEO, at the request of the applicant, or to align with any TGA approvals issued under the SAS program.

5.5.4 General conditions

The CEO will only consider applications that are complete and contain all information required by the approved forms.

Ordinarily, where all required information is provided, and no additional information is necessary for a decision, applications will be considered within 2 working days.

The CEO may request the applicant provide additional information, relevant to the treatment with a Schedule 8 substance, as needed, where necessary to make a decision. Where the information requested by the CEO is not provided within a reasonable time frame, the CEO may consider an application as withdrawn.

The CEO may approve or decline an application, at their discretion.

Applicants will be notified in writing, or electronically, of approval or declining of an application. Applicants will be notified in writing, or electronically, if additional information is required.

The CEO may add any conditions to an approval, in relation to the prescribing or dispensing of a Cannabis-Based Product, believed to be necessary to protect the safety of the patient, in respect of a Schedule 8 substance.

The CEO may request a second opinion, expert review, or other advice on an application, as necessary, to make a decision, relevant to the treatment with a Schedule 8 substance.

It is a general condition of any authorisation granted, that the patient will provide the prescriber with informed consent to treatment with a Schedule 8 substance, and, where relevant, the use of an unregistered therapeutic good. This consent must address issues related to legality and safety of driving a vehicle while taking a Cannabis-Based Product. As with any treatment that involves Schedule 8 medicines, a Treatment Contract is recommended (see Part 1, Section 1.2).

Authorisations are specific for the medicine(s), form(s) and dose(s) requested. Treatment may not be varied without authority and all prescribing must match the approved therapy. Where it is necessary to vary the product or nature of treatment, or a new SAS Category B approval is required, a new application for authorisation, is required.

Authorisation will only be granted to one prescriber at a time. Where a new authorisation is requested and granted, all prior authorisations or notifications are cancelled. The Department will notify any previously authorised prescriber.

An authorisation granted for an individual patient will ordinarily extend to other practitioners, at that same place of practice, unless otherwise indicated. Other practitioners at the same place of practice may prescribe, in cases of emergency or absence of the authorised practitioner, in accordance with the conditions of the authorisation.

Where an authorisation is in place, except as outlined above, other prescribers may not prescribe Cannabis-Based Products, irrespective of the type of practitioner, patient or Cannabis-Based Product.

5.5.5 Treating patients with a history of substance abuse, Oversupplied or Drug Dependent Persons

Persons with a history of substance abuse (cannabis or other drugs) within the previous five years, or recorded as Oversupplied or Drug Dependent can be authorised to receive Cannabis-Based Products. Treatment with a Cannabis-Based Product must not be connected to the treatment of addiction. Treatment must be supported by a relevant specialist. Specialist support must be in writing, be current and consistent with the proposed treatment regimen requested on the application.

Evidence must be provided of treatments in place to address misuse and measures to reduce risk of abuse. Authorisation will ordinarily require standard measures to limit potential misuse, including, but not limited to:

- signed Treatment Contracts;
- dosing restrictions, or adequate trials of lowest effective dose;

- supply limits (daily or weekly dispensing);
- supply at one nominated pharmacy only;
- strict repeat intervals;
- no early or replacement prescriptions;
- regular urine drug screens; or
- other relevant conditions.

5.5.6 Termination or variation of authorisation

A prescriber may at any time, by writing to the CEO, request cancellation of a patient authorisation. The CEO may at any time, in writing, amend, cancel or suspend a patient authorisation. The CEO may apply conditions to any authorisation.

5.6 Approved Cannabis-Based Products Prescriber, for eligible practitioners

If a prescriber is approved as a Cannabis-Based Products Prescriber, prescribing may occur in accordance with that approval, as per section 5.8. Notification to the Department is required at the commencement of treatment of an individual patient.

If a prescriber is not approved as a Cannabis-Based Products Prescriber, or the prescribing is not in accordance with that approval or section 5.8, then individual patient authorisation is required as per section 5.5.

5.6.1 Eligible practitioners

Medical practitioners practicing in Western Australia, who do not have conditions or undertakings relevant to the prescribing of S8 medicines, that may be approved as Cannabis-Based Product Prescribers include:

- a medical practitioner with a current authority as an 'Authorised Prescriber', under Commonwealth legislation, granted by the Therapeutic Goods Administration (TGA), for a Cannabis-Based Product, in relation to the specific patients (or classes of recipients) with a particular medical condition, as specified in that authority;
- a medical practitioner prescribing a Cannabis-Based Product, for a patient enrolled to participate in a clinical trial that is approved by a recognised Human Research Ethics Committee, and in the case that the product is an unapproved therapeutic good, where the clinical trial is notified or registered with the TGA under the respective CTN or CTX schemes; or
- a relevant specialist, or other medical practitioner, as determined by the CEO, for the prescribing of a Cannabis-Based Product, which is on the Australian Register of Therapeutic Goods (ARTG), for the purposes of treating the registered indication.

5.6.2 Applying to become approved as a Cannabis-Based Products Prescriber

Prescribers must apply for approval, in writing, using the approved form. Approval is for an indefinite period, unless suspended or cancelled.

A Cannabis-Based Products Prescriber may at any time, by writing to the CEO, request cancellation of their approval. The CEO may at any time, in writing, amend, cancel or suspend an approval. The CEO may apply conditions to any approval.

5.6.3 General conditions

All prescribing must conform to the criteria and conditions outlined within Part 5 of this Code.

The CEO may, in writing, instruct a person not to prescribe or supply to an individual patient.

5.6.4 Co-prescribers

An approved Cannabis-Based Product Prescriber may nominate a Co-prescriber, at a particular practice, to assist in prescribing Cannabis-Based Products, for an individual patient. Nomination must be through notification to the CEO, in writing, using the approved form.

Co-prescribers must ordinarily be practising in Western Australia. Professional registration must not have conditions or undertakings relevant to the prescribing of S8 medicines.

The nominated Co-prescriber is permitted to prescribe for the patient, in accordance with the Cannabis-Based Product Prescriber's directions. A Co-prescriber is not permitted to change a patient's treatment and may not alter type, formulation or dose without authority of the Cannabis-Based Product Prescriber.

The approved Cannabis-Based Product Prescriber may choose to cease or alter the nominated Co-prescriber for a patient. This can be done by notifying the CEO, in writing. In these cases, the approved Cannabis-Based Product Prescriber must inform any existing Co-prescriber of the changes. Where the nomination of a Co-prescriber is ceased, that practitioner may no longer prescribe Cannabis-Based Products for that patient.

Co-prescribers are not permitted to submit notification of patient treatment.

5.6.5 Registrars, hospital clinics and clinical trials

Specialist registrars, or medical practitioners participating in clinical trials who are not the primary researcher, may be nominated as Co-prescribers and prescribe Cannabis-Based Products in accordance with the approved Cannabis-Based Product Prescriber's directions.

5.6.6 Prescriber on leave

An approved Cannabis-Based Product Prescriber should advise the Department in writing if they wish to use alternative Cannabis-Based Product prescribing arrangements during periods of leave. This should include the time period of leave and name of any medical practitioner required to write interim prescriptions. An approved Cannabis-Based Product Prescriber or the nominated Co-prescriber may prescribe in accordance with the current Notification of Treatment. Any other practitioner must obtain an interim authorisation from the CEO prior to prescribing. An interim authorisation will be based on the treatment rationale previously notified or prescribed by the Cannabis-Based Product Prescriber, provided on a case by case basis, at the discretion of the CEO and will be limited to short term arrangements only.

5.7 Notification of patient treatment by approved Cannabis-Based Product Prescribers

Where the criteria set out in Section 5.8 of this Code are met, an approved Cannabis-Based Product Prescriber, or a nominated Co-prescriber, may prescribe a Cannabis-Based Product to a patient, so long as notification of treatment is provided to the CEO. In cases outside the conditions approved for notification, as detailed below, the written authorisation of the CEO is required to prescribe a Cannabis-Based Product.

5.7.1 When to notify

Notification is required at the commencement of treatment with Cannabis-Based Products for any patient. This includes when a patient transfers to a new approved Cannabis-Based Product Prescriber, even if they are already in treatment with Cannabis-Based Products.

5.7.2 How to notify

Notification must be made by an approved Cannabis-Based Product Prescriber at commencement of treatment of each patient. Notification must be made on the approved form and include the following information:

- prescriber details;
- patient details;
- diagnosis;
- relevant comorbidities;
- Cannabis-Based Product formulation, strength and dose; and
- nominated Co-prescriber and place of practice (if any).

A new notification is required if, in respect of an individual patient, any of the following Cannabis-Based Product treatment details change:

- Cannabis-Based Product Prescriber;
- patient name;
- Co-prescriber (including change of Co-prescriber place of practice);
- change to product prescribed; or
- change to treatment conditions of a clinical trial (see Section 5.10).

5.7.3 Current prescriber status

Upon notification of treatment to the Department, the notifying prescriber becomes the Current Prescriber for that patient.

A patient may only have one Current Prescriber at any one time. Only the Current Prescriber, or the Co-prescriber nominated in a notification, may prescribe Cannabis-Based Products to that patient.

When a patient transfers to a new prescriber and a new notification is received, the new prescriber becomes the Current Prescriber. In these cases, the Department will advise the previous Cannabis-Based Product Prescriber.

5.7.4 Termination

An approved Cannabis-Based Product Prescriber may choose to cease prescribing and terminate Current Prescriber status for a patient. This must be done by notifying the CEO in writing using the approved notification form. Upon receipt of a termination, the notifying prescriber ceases to be the Current Prescriber for that patient.

5.8 General conditions of notification

Patients prescribed Cannabis-Based Products must meet the all the criteria outlined in this Section. Where patients are outside these criteria, prior written authorisation of the CEO is required to prescribe.

5.8.1 Products

Any Cannabis-Based Product prescribed by an approved Cannabis-Based Product Prescriber must be registered on the Australian Register of Therapeutic Goods (ARTG), or otherwise compliant with the Therapeutic Goods Order 93.

It is a condition of approval as a Cannabis-Based Product Prescriber that the prescription and notification of treatment with a Cannabis-Based Product notification is at all times consistent with Therapeutic Goods legislation, including that the product prescribed is:

- registered on the ARTG; or
- exempt – such as within an acceptable clinical trial; or

- authorised – through authorised prescriber status with the TGA.

The CEO may, at their discretion, direct that a specific product, type or formulation of product not be prescribed.

5.8.2 Comorbidity

Patients suitable for notification must not have a history of:

- psychosis or bipolar disorder;
- substance abuse, diversion or misuse of drugs of addiction or Schedule 9 poisons within the previous five years; or
- record of Oversupply or Drug Dependence.

Where a prescriber subsequently becomes aware of a relevant history for a patient, Cannabis-Based Product treatment is to be reviewed. If continuation of Cannabis-Based Product treatment is desired then authorisation to prescribe is required from the CEO.

Prior to prescribing, the prescriber must take reasonable steps to satisfy themselves that the patient does not have a relevant condition or restriction that would affect treatment with a Cannabis-Based Product, or require authorisation to prescribe. This can be achieved through contacting the Department S8 Prescriber Information Service to obtain an S8 and Cannabis-Based Product prescribing history.

5.8.3 Diagnosis

Patients must have a diagnosis consistent with the ARTG approved indication of a product (e.g. Multiple Sclerosis), or the clinical trial protocol inclusion criteria, or the "Authorised Prescriber" treatment indications. Other diagnosis for notification may be approved by the CEO.

Other approved medicines are expected to have been first adequately trialled for the relevant condition and found to be either not suitable or not adequately effective. Severe allergy or contraindications are acceptable reasons not to trial a medicine.

5.8.4 Age

An approved Cannabis-Based Product Prescriber may treat patients aged 18 years or older. The treatment of any patient less than 18 years of age requires the prior written authorisation of the CEO.

Patients under 18 years of age may be treated if consistent with a clinical trial protocol approved by a Human Research Ethics Committee, meeting guidelines for paediatric research.

5.8.5 Frequency of review

An approved Cannabis-Based Product Prescriber should ensure that all patients are reviewed on at least an annual basis for the continuation of appropriate Cannabis-Based Product treatment.

5.8.6 Drug screening

A urine drug screen (in accordance with *Australian/New Zealand Standard 4308*) should be undertaken by all patients 18 years and older before treatment with a Cannabis-Based Product is commenced. Further testing is recommended annually, and as indicated.

5.9 Hospitals

For a patient in a hospital, this Part does not apply to:

- the administration of a Cannabis-Based Product for an inpatient in a hospital; or

- prescribing of a Cannabis-Based Product from emergency departments or on discharge from hospital where treatment with Schedule 8 medicines is associated with that episode of care.

The exception for hospitals does not apply to Drug Dependent and Oversupplied persons, or for the treatment of outpatients (including clinical trials). In these cases, Part 5 of this Code applies in full.

5.10 Clinical trials

Clinical Trials that are approved for the purposes of prescribing Cannabis-Based Products, by an approved Cannabis–Based Products Prescriber, are those that have been approved by a recognised Human Research Ethics Committee, and in the case that the product is an unapproved therapeutic good, where the clinical trial is also notified or registered with the TGA under the respective CTN or CTX scheme.

Treatment with a Cannabis-Based Product is only permitted where it is consistent with the approved trial protocol, for the approved duration. The protocol number of the clinical trial the patient is being treated under is to be provided to the CEO at the time of patient notification. At conclusion of any trial treatment period, ongoing treatment of an individual patient with a Cannabis-Based Product outside the trial setting, must be individually authorised, or otherwise consistent with Section 5.8 of this Code.

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