

Schedule 8 substances

Volume 1: Issuing prescriptions, supplying schedule 8 substances

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Document Control

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V1	G. Lavery	Scheduled Substance Clinical Advisory Committee	S. Skov	21 March 2014

Definitions

Throughout the Code, definitions used are consistent with the [Medicines, Poisons and Therapeutic Goods Act 2012](#) (MPTGA).

The following definitions are used throughout this Code of Practice:

Act refers to the [Medicines, Poisons and Therapeutic Goods Act 2012](#) (MPTGA). The Act is administered by the Medicines & Poisons Control section of the Environmental Health Branch of the DoH, on behalf of the Chief Health Officer. Please note that reference to sections in legislation may be abbreviated to 's' e.g. s3 = section 3.

Administer means to apply or introduce the substance into a person's body.

Amphetamine is defined under section 11 of the MPTGA as:

- a) An amphetamine includes:
 - (a) beta-aminoisopropylbenzene; and
 - (b) a substance structurally derived from amphetamine or beta-aminoisopropylbenzene by substitution in the side chain or by ring closure (or both).
- b) However, a substance mentioned in section 11(1)(a) or (b) is not an amphetamine when contained in a Schedule 2, 3 or 4 substance.

Authorised health practitioner refers to:

- c) a NT doctor or NT nurse practitioner; or
- d) another NT health practitioner prescribed by regulation who holds an authority to supply a restricted Schedule 8 substance under section 139(c)(ii) the Act.

CHO refers to the Chief Health Officer of the Northern Territory, which is a statutory appointment under the [Public and Environmental Health Act 2011](#). The CHO is the ultimate source of authority under the [Medicines, Poisons and Therapeutic Goods Act 2012](#) (MPTGA). In practice the CHO will delegate certain powers to other persons to allow the smooth operation of the Act in day-to-day practice.

Doctor means a medical practitioner.

DoH refers to the Department of Health of the Northern Territory Government (NTG).

Dose means:

- a) for divided preparations (e.g. tablets, capsules, ampoules etc.) one discrete dosage unit;
- b) for undivided preparations (e.g. bulk powders, mixtures etc.) the normal amount administered as a single adult therapeutic dose.

Key means any method for unlocking a drug storage cabinet, safe or strong room and includes a combination, personal identification number (PIN), password, electronic card or electronic proximity device.

NT doctor means a medical practitioner who practises in the Northern Territory.

NT nurse practitioner means a nurse practitioner who practises in the Northern Territory.

Opiate Pharmacotherapy, Opioid Pharmacotherapy, and Opioid Substitution Treatment are synonymous. Refer to Part 3 (page 18) of this document.

Opioid Pharmacotherapy – Refer to ‘Opiate Pharmacotherapy’.

Opioid Substitution Treatment – Refer to ‘Opiate Pharmacotherapy’.

Patient and **Person** are synonymous.

Person – Refer to ‘Patient’.

Prescriber in Part 1 (page 8) applies to ‘Dentists’, ‘Eligible Midwives’, ‘Medical Practitioner’, ‘Nurse Practitioner’, and ‘Podiatrists’. In Part 2 (page 15) and Part 3 (page 18) it applies to ‘Medical Practitioner’ and ‘Nurse Practitioner’.

Restricted Schedule 4 or 8 substance means a Schedule 4 or 8 substance declared as restricted by the CHO under section 246 of the Act and published in the Government Gazette. Amphetamines are restricted S8 under section 10(2)(a) of the MPTGA.

‘Schedule 4’ is often abbreviated as S4.

‘Schedule 8’ is often abbreviated as S8.

Scheduled substance is a Scheduled substance contained in the [Poisons Standard](#) (also known as the ‘Standard for the Uniform Scheduling of Medicines and Poisons’ (SUSMP)) Schedules.

Supply is defined under section 21(1) of the MPTGA as:

(1) Supply, of a regulated substance, includes:

- (a) Sell the substance; and
- (b) Provide the substance on prescription; and
- (c) Provide the substance to a person in accordance with a Schedule substance treatment protocol.
- e) However, supply of a regulated substance does not include issue a prescription for the supply of the substance.

Committee refers to the ‘Scheduled Substances Clinical Advisory Committee’ (CLAC) which is constituted as a statutory committee under section 260 the Act. The secretariat is located at Medicines & Poisons Control.

USD refers to ‘Unsupervised Doses’ of Opioid Substitution Treatment medicines (buprenorphine, buprenorphine/naloxone, and methadone), which are also known as ‘Takeaways’.

f) Please note:

- Pursuant to section 245(1) of the Act, the CHO may exempt a particular authorised health practitioner from a requirement to hold an authorisation under the Act.
- Pursuant to section 245(4)(b) of the Act, the CHO may by Gazette notice exempt a class of authorised health practitioners from a requirement to hold an authorisation under the Act.
- Pursuant to section 245(5) of the Act, an exemption notice may include conditions.

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- It is an offence to contravene a condition of an exemption under section 245(6), attracting a maximum penalty of 200 penalty units or 2 years imprisonment.
- Please contact Medicines & Poisons Control to ascertain current information regarding exemptions that have been granted.

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Supply of Unrestricted Schedule 8 Substances

1.1 Health practitioner prescribers of unrestricted Schedule 8 substances

The MPTGA authorises specific health practitioner groups to issue a prescription for unrestricted S8 substances under s83.

These practitioner groups are:

- Dentists
- Doctors
- Eligible midwives
- Nurse practitioners
- Podiatrists, or
- Another class of health practitioner prescribed by regulation

Eligible midwives and nurse practitioners are required by the National Nursing and Midwifery Board and under the [National Health Act 1953](#) (Cth) to have a collaborative arrangement in place with a medical practitioner.

Podiatrists (including podiatric surgeons) are limited by the list of Scheduled medicines they may prescribe approved by the [Podiatry Board of Australia](#).

1.2 Legislative framework for the supply of unrestricted Schedule 8 substances

Supply of unrestricted S8 substances is governed by sections 83 and 84 of the MPTGA. Section 83 of the MPTGA states that the issuing of a prescription for an unrestricted S8 substance is an offence, unless the person is a dentist, doctor, eligible midwife, nurse practitioner or podiatrist, or another health practitioner prescribed by regulation, or a veterinarian as defined under the *Veterinarians Act*.

The health practitioners listed above may issue a prescription for an unrestricted S8 substance:

- without an authorisation, for the therapeutic use of not more than the prescribed number of persons (refer to 1.3 on page 9); or
- if the prescriber holds an authorisation or is exempted under section 245 of the MPTGA;
 - for more than the prescribed number of persons; or
 - for the use of a particular person for the treatment of addiction.

The framework for the supply of unrestricted S8 substances is derived from:

- The requirement under sections 48, 83, and 84 of MPTGA to apply for and receive an authorisation from the CHO if a prescriber wishes to supply an unrestricted S8 substance for therapeutic use to more than the prescribed number of persons, or to a particular person for the treatment of addiction.

- Section 143 (1) (b) (ii) of the Act provides for a code of practice to set the conditions for the granting of a S8 authority. A condition for a S8 authorisation is to comply with the Code of Practice.
- Section 147 makes it an offence not to comply with the conditions of the authority.

The CHO is the ultimate source of authority under MPTGA. In practice the CHO will delegate certain powers to other persons to allow the smooth operation of the Act in day-to-day practice. All requests for authorisations, notifications of supply and other correspondence are to be directed to Medicines & Poisons Control. Please refer to Enquiries (page 4) for details.

1.3 The prescribed number of persons

The prescribed number of persons for unrestricted S8 substances is **fifteen (15)**.

The prescribed number of persons does not include:

- A person receiving palliative care exclusively or partially from a recognised specialist provider of palliative care (whether an individual or body corporate);
- A person admitted to a hospital for treatment as an in-patient;
- A person receiving emergency medical treatment that requires the administration of an unrestricted S8 substance. Emergency medical treatment in this sense means treatment for an acute illness, exacerbation of an existing illness, or an acute injury that requires the administration of an unrestricted S8 substance for less than 48 hours in total;
- A person excluded by the CHO by notice in writing; or
- A person who belongs to a class of persons excluded by the CHO by notice in the *Gazette*.

If a prescriber wishes to supply an unrestricted S8 substance to **more than fifteen (15) persons** at any one time, he or she must have an authorisation from the CHO or his/her delegate to do so.

Prescribers wishing to obtain such an authorisation must apply in writing to the CHO or his/her delegate, providing details of the prescribers' training and experience in managing persons in need of unrestricted S8 substances, and must include a justification for the request.

The CHO will refer such requests to the Committee, which will review each application on a case by case basis and make a recommendation to the CHO.

1.4 Requirements for Notification of Supply

Prescribers **must** notify the CHO or his/her delegate of the supply of unrestricted S8 substances in accordance with this Code.

Prescribers **must** notify the CHO of supply of an unrestricted S8 substance **the first time** any of the following circumstances apply:

1. The prescriber supplies, intends to supply, or thinks it likely to be necessary to supply an unrestricted S8 substance to a patient for **more than eight (8) weeks**. This eight (8) week period is an aggregate period, and includes all periods of supply over the preceding 12 months, and also includes periods for which the prescriber is aware that another prescriber supplied the S8 substance, or

2. The prescriber supplies an initial daily dose of any one of the following unrestricted S8 substances in excess of:
 - 10mg buprenorphine patch; or
 - 240mg of oral codeine; or
 - 12mcg/hour fentanyl patch; or
 - 8mg of hydromorphone; or
 - 20mg of methadone tablets; or
 - 60mg of oral morphine; or
 - 40mg of oral oxycodone; or
 - any form or amount of pethidine; or
 - any form or amount of alprazolam.
3. The prescriber supplies any daily dose of any one of the following unrestricted S8 substances in excess of:
 - 20mg buprenorphine patch; or
 - 240mg of oral codeine; or
 - 25mcg/hour fentanyl patch; or
 - 16mg of hydromorphone; or
 - 40mg of methadone tablets; or
 - 100mg of oral morphine; or
 - 80mg of oral oxycodone; or
 - any form or amount of pethidine; or
 - any form or amount of alprazolam.
4. The prescriber supplies a combination of the above substances such that the total dose equivalent exceeds the limits described above. The doses described above for the different substances may be considered dose equivalents.
5. The prescriber supplies for a client because the patient claims that their medication was lost or stolen, or that the previously supplied medication was consumed earlier than intended by the client.
6. The prescriber supplies for a patient who is already taking a S8 substance supplied by another prescriber, or who asserts they have been supplied a S8 substance from another prescriber, or indicates a desire to transfer from another prescriber. An exception to this would be where the other prescriber who supplied the S8 substance is a member of the same practice as the first prescriber, or is a specialist who is co-managing the patient with the first prescriber.
7. If a prescriber has previously made a notification of supply of an unrestricted S8 substance for a particular person and, **twelve (12) months after the initial notification**, is

still supplying and intends to continue to supply the substance, the prescriber **needs to renew the notification only if there has been a significant change to the S8 medication or a change to the person's circumstances** (e.g. change of address, change of medical condition etc.). Otherwise there is no need to renew the notification. The prescriber is not obliged to notify each time they write a prescription for the person.

For patients under the direct care of a palliative care specialist or palliative care service, no notification is required by the specialist or the service.

Prescribers **may** notify the CHO of supply of an unrestricted S8 substance if they have any concerns for the safety of the patient, or concerns about circumstances surrounding the patient and the patient's need for or use of the substance. For example:

- younger patients requiring more than a very brief period of opiates;
- patients with unusual diagnoses, or diagnoses that would not ordinarily require the use of opiates;
- patients with non-malignant conditions;
- patients with conditions requiring repeated, regular injections of opiates;
- patients who are not well known to the practitioner who require one-off injections of opiates.

Prescribers **must** notify the CHO of the supply of unrestricted S8 substances under the conditions described in this Code. An exception to this requirement applies to prescribers supplying S8 substances to hospital inpatients whilst they remain inpatients, or to hospital outpatients for a maximum period of **seven (7) days**.

Notification is to be made to the CHO on a Notification of Supply of an Unrestricted S8 Substance form ([Appendix A](#)). This completed form must be forwarded to the CHO **within seven (7) days** of the supply of the unrestricted S8 substance.

Information to be provided concerning notification of supply

The following information must be supplied to Medicines & Poisons Control using a Notification of Supply of an Unrestricted S8 Substance form - ([Appendix A](#)).

Patient:

- Full Name;
- Gender;
- Date of Birth;
- Residential Address;
- Name of parent or guardian if child under 18 years;
- Medicare Number. and (if known) Health Care Card Number;
- Substance;
- Intended Dose;
- Intended start-date for supply;

- Duration of prescription;
- Likely duration of need for S8 treatment;
- Reason for notification;
- Clinical indication;
- Palliative care status of patient;
- Whether the patient has had specialist assessment and, if so, the type of specialist;
- Whether the patient has had previous treatment for opiate dependency;
- Whether the patient has had previous treatment for other drug or alcohol dependency;
- Whether the patient has ever injected drugs;
- Whether the patient has ever been under the care of the Alcohol and Other Drugs program in the NT or a similar program elsewhere in Australia; and
- Dates of most recent specialist(s) assessment(s), together with name and contact details for specialists.

Please note: further details and copies of correspondence must be supplied to the CHO if requested.

Prescriber:

- Name;
- Practice Address;
- Phone Number;
- Fax Number or email; and
- Prescriber Number.

1.5 Contents of prescriptions for unrestricted Schedule 8 substances

Section 87(1)(a) provides for the contents of a prescription be prescribed by regulation. Additionally, section 87(1)(b) provides for the contents of a prescription for S8 and restricted S4 to be prescribed by a code of practice.

Therefore, in addition to the requirements for contents of prescription detailed in regulation 8, every prescription for an unrestricted S8 substance must also satisfy the requirements detailed in regulations 10 and 17.

1.6 Regulation 8: Prescription issued by health practitioner

For section 87(1)(a) of the Act, a prescription issued by an authorised prescriber who is a health practitioner must:

- (a) state the following particulars of the authorised prescriber:
 - (i) name;
 - (ii) business address and telephone number;

- (iii) health profession; and
- (b) state the date of issue; and
- (c) state the name and address of the person for whom it is issued; and
- (d) state the name of the substance, and the dose, form and strength, for which it is issued; and
- (e) if it is for an unusual or dangerous dose – include the authorised prescriber's initials beside an underlined reference to the dose; and
- (f) state the quantity of the substance to be supplied; and
- (g) if it is a repeat prescription – state the number of repeats permitted; and
- (h) state the start date for supply, if different from the date the prescription is issued; and
- (i) include directions for the use of the substance that are adequate to allow the substance to be taken or administered safely; and
- (j) be written in terms and symbols used in ordinary professional practice; and
- (k) if it is issued by:
 - (i) a dentist – state it is issued for dental purposes only; or
 - (ii) an optometrist – state it is issued for the treatment of a condition of the eye only; or
 - (iii) a podiatrist – state it is issued for podiatry treatment only; and
- (l) if it is issued for a S8 substance – meet the requirements specified in regulation 10; and
- (m) be signed by the authorised prescriber.

1.7 Regulation 10: Additional requirements for prescription for Schedule 8 substance

(1) A prescription for a S8 substance must state:

- (a) if it is issued for:
 - (i) a person – the date of birth of the person; or
 - (ii) an animal – sufficient information to identify the animal; and
- (b) the quantity of the substance to be supplied in words and numerals; and
- (c) if it is issued by an authorised health practitioner under a S8 authorisation or S8 exemption – the number or other identifier of the authorisation or exemption; and
- (d) if it is a repeat prescription – the minimum repeat interval.

(2) In addition, a prescription for a S8 substance of a particular form and strength must not authorise the supply of any other substance, including a S8 substance of a different form or strength.

1.8 Additional requirements

Regulation 17 requires that any prescription **must be written in ink** unless it is issued electronically.

If there are changes to any of the details in the prescription, **the initials of the person** who issued the prescription and the **date the change** was made must appear beside each change. It also states that:

- It must not be written in pencil or any other easily erasable material;
- The type of preparation to be dispensed must be specified, for example tablets;

Please note: It is recommended, but not mandatory that the name of the pharmacy from which the substance is to be dispensed be written on the prescription.

1.9 Period of effect of prescription and permissible supply for unrestricted Schedule 8 substances

Pursuant to section 88 of the MPTGA prescriptions are valid for **six (6) months**.

Pursuant to section 91 of the Act:

- prescriptions for unrestricted S8 substances must only allow for a maximum of six (6) months quantity with no more than one month's supply to be dispensed at any one time; except
- prescriptions written as 'private prescriptions' or 'privately funded prescriptions' (i.e. prescriptions which are not to be dispensed under Commonwealth, State or Territory government-funded pharmaceutical schemes, must only be for a maximum of thirty (30) days' supply at a time, and must NOT contain endorsements for repeat prescriptions.

Part 2: Supply of Restricted Schedule 8 substances – Overview

2.1 Health practitioner prescribers of restricted Schedule 8 substances

The MPTGA section 85 authorises an authorised health practitioner (NT medical practitioner or NT nurse practitioner) to issue a prescription for a restricted S8 substance.

Nurse practitioners are required by the National Nursing & Midwifery Board and under the [National Health Act 1953](#) (Cth) to have a collaborative arrangement in place with a medical practitioner.

2.2 Legislative Framework for Issuing Prescriptions for Restricted Schedule 8 Substances

Issuing a prescription for a restricted S8 substance is governed by section 85 of the MPTGA. Under section 85 it is an offence to issue a prescription for a restricted S8 substance to a person, unless the prescriber has a S8 authorisation or exemption.

Pursuant to section 139 of the Act, the CHO may issue a S8 authorisation to an authorised health practitioner. However, section 139(1)(b) requires that the substance is only supplied for an authorised purpose.

An authorised purpose for the use of **amphetamine** is defined under section 5 as:

1. therapeutic use for a medical condition declared under section 247, or
2. analysing or testing specimens for the diagnosis, treatment and prevention of disease of humans or animals; or
3. providing a higher education course; or
4. forensic science

An authorised purpose for the use of a restricted S8 substance **other than an amphetamine** is defined under section 5 as:

- 1.therapeutic use; or
- 2.treating an addiction to a substance; or
- 3.analysing or testing specimens for the diagnosis, treatment and prevention of disease of humans or animals; or
- 4.providing a higher education course; or
- 5.forensic science.

2.3 Declaration of a Restricted Substance

Pursuant to section 246 of the Act, the CHO may declare a Schedule 4 or 8 substance as restricted under section 246 of the Act by notice in the *Government Gazette*.

The following S8 substances have been declared as restricted:

- dexamphetamine in all preparations and forms
- lisdexamfetamine in all preparations and forms
- methylphenidate in all preparations and forms
- methadone
 - 5mg/ml strength liquid for oral administration
- buprenorphine
 - 0.4mg, 2mg or 8mg for sublingual administration
- buprenorphine/naloxone
 - buprenorphine 2mg/naloxone 0.5mg for sublingual administration
 - buprenorphine 8mg/naloxone 2 mg for sublingual administration

2.4 Contents of prescriptions for restricted Schedule 8 substances

Section 87(1)(a) provides for the contents of a prescription be prescribed by regulation. Additionally, section 87(1)(b) provides for the contents of a prescription for a restricted S8 or restricted S4 substance to be prescribed by a code of practice.

Therefore, in addition to the requirements for contents of prescription detailed in regulation 8, every prescription for a restricted S8 substance must also satisfy the requirements detailed in regulations 10 and 17.

2.5 Regulation 8: Prescription issued by Health Practitioner

For section 87(1)(a) of the Act, a prescription issued by an authorised prescriber who is a health practitioner must:

(a) state the following particulars of the authorised prescriber:

- (i) name;
 - (ii) business address and telephone number;
 - (iii) health profession; and
- (b) state the date of issue; and
- (c) state the name and address of the person for whom it is issued; and
- (d) state the name of the substance, and the dose, form and strength, for which it is issued; and
- (e) if it is for an unusual or dangerous dose – include the authorised prescriber's initials beside an underlined reference to the dose; and

- (f) state the quantity of the substance to be supplied; and
- (g) if it is a repeat prescription – state the number of repeats permitted; and
- (h) state the start date for supply, if different from the date the prescription is issued; and
- (i) include directions for the use of the substance that are adequate to allow the substance to be taken or administered safely; and
- (j) be written in terms and symbols used in ordinary professional practice; and
- (k) if it is issued by:
 - (i) a dentist – state it is issued for dental purposes only; or
 - (ii) an optometrist – state it is issued for the treatment of a condition of the eye only; or
 - (iii) a podiatrist – state it is issued for podiatry treatment only; and
- (l) if it is issued for a S8 substance – meet the requirements specified in regulation 10; and
- (m) be signed by the authorised prescriber.

2.6 Regulation 10: Additional requirements for prescription for Schedule 8 substance

(1) A prescription for a S8 substance must state:

- (a) if it is issued for:
 - (i) a person – the date of birth of the person; or
 - (ii) an animal – sufficient information to identify the animal; and
- (b) the quantity of the substance to be supplied in words and numerals; and
- (c) if it is issued by an authorised health practitioner under a S8 authorisation or exemption – the number or other identifier of the authorisation or exemption; and
- (d) if it is a repeat prescription – the minimum repeat interval.
- g) In addition, a prescription for a S8 substance of a particular form and strength must not authorise the supply of any other substance, including a S8 substance of a different form or strength.

2.7 Regulation 17: Additional requirements

Regulation 17 requires that any prescription **must be written in ink** unless it is issued electronically.

If there are changes to any of the details in the prescription, **the initials of the person** who issued the prescription and the **date the change** was made must appear beside each change. It also states that:

- It must not be written in pencil or any other easily erasable material;
- The type of preparation to be dispensed must be specified, for example tablets;

Please note: It is recommended, but not mandatory that the name of the pharmacy from which the substance is to be dispensed be written on the prescription.

Part 3: Supply of Restricted Schedule 8 substances – Amphetamines (Psychostimulants)

Amphetamines are controlled under the Act by being declared as a restricted S8 substance under section 10(2)(a) and may only be used for an authorised purpose as defined under section 5.

Under section 247 of the Act; declared medical condition, the CHO may, by *Gazette* notice, declare a medical condition for which an authorised health practitioner (NT doctor or NT nurse practitioner) may issue a prescription for the supply of an amphetamine for therapeutic use for the condition.

Conditions that have been declared under this section of the Act are:

- Narcolepsy;
- Hyperkinetic brain damage (including attention deficit disorder); and
- Autosomal hypersomnolence

3.1 Authorisation Framework for Supply of Restricted Schedule 8 Substances Dexamphetamine, Lisdexamfetamine and Methylphenidate

The basic framework for the authorisation to supply restricted S8 substances dexamphetamine, lisdexamfetamine and methylphenidate is:

1. A prescriber (NT doctor or NT nurse practitioner) submits an application for an authorisation to the CHO to supply a restricted S8 substance dexamphetamine, lisdexamfetamine or methylphenidate for each individual patient.
2. The CHO decides in relation to each individual application whether the prescriber is competent and whether the circumstances are appropriate in relation to the patient (**Please note:** the Act does not provide for a prescriber to receive a general “accreditation” to supply restricted S8 substances).
3. Details about administration, criteria to judge competence and appropriate circumstances as specified in Part 3.
4. If considered competent, a prescriber may only supply restricted S8 substances dexamphetamine, lisdexamfetamine and methylphenidate for a prescribed number of persons at any one time.
5. A prescriber may apply in writing to the CHO for an authority to supply for more than the prescribed number of persons.

All requests for authorisations and other correspondence are to be directed to Medicines & Poisons Control. Please refer to Enquiries (page 4) for details.

3.2 Authorisation to Supply

- Prescribers wishing to supply dexamphetamine, lisdexamfetamine or methylphenidate for a person must be authorised to do so by the CHO;
- Prescribers must apply for an authority to supply dexamphetamine, lisdexamfetamine or methylphenidate for a person using the Application for Authority to Prescribe a Restricted S8 Psychostimulant Medication form ([Appendix B](#));

- For each application two judgements will be made: whether the prescriber is competent to safely supply restricted S8 substances dexamphetamine, lisdexamfetamine or methylphenidate and whether all requirements in relation to the patient have been fulfilled;
- A prescriber will be considered competent to supply dexamphetamine, lisdexamfetamine or methylphenidate if they are recognised in Australia as a specialist paediatrician, psychiatrist, neurologist or physician, or a registrar in training in one of these disciplines, or if they are a medical practitioner co-managing a patient with a specialist or a registrar in training in one of these disciplines, or if they are a nurse practitioner whose scope of practice is paediatrics; and
- The CHO is able to make routine approvals for authorisations under prescribed conditions. If the CHO has concerns about an application, or it does not conform to the prescribed conditions, the application will be referred to the Committee immediately for advice, which must be considered prior to the granting of any authorisation. The Committee will regularly review all approvals.

3.3 Prescribed conditions for routine authorisations

Pursuant to sections 139(1)(b) and 139(1)(c)(ii) of the Act, the CHO may, without first considering the Committee's advice, issue an authorisation to supply restricted S8 substances if all the prescribed conditions apply.

The prescribed conditions for restricted S8 substances (psychostimulants), dexamphetamine, lisdexamfetamine and methylphenidate are:

- The clinical decision to initiate either dexamphetamine, lisdexamfetamine or methylphenidate must be made by a specialist paediatrician, psychiatrist, neurologist, physician or registrar in training (see below);
- A registrar in training in the disciplines of paediatrics, neurology, psychiatry or medicine, who is resident in the NT, may make the initial clinical decision to commence dexamphetamine, lisdexamfetamine or methylphenidate providing that this occurs within a supervised training environment, which may include clinics outside the major hospital environment;
- A medical practitioner or nurse practitioner who is registered and practising in the NT (other than a specialist paediatrician, psychiatrist, neurologist, physician, or registrar in training in one of these disciplines) may only supply dexamphetamine, lisdexamfetamine or methylphenidate once it has been initiated by, or on the recommendation of, a specialist or registrar in training. Such medical practitioners or nurse practitioners must be co-managing the patient with a specialist paediatrician, psychiatrist, neurologist, physician or registrar in training and this co-management must involve the specialist paediatrician, psychiatrist, neurologist or physician, or their registrar in training reviewing the patient at least every twenty four (24) months;
- Medical practitioners and nurse practitioners, other than specialist paediatricians, psychiatrists, neurologists, physicians or their registrar in training, who intend to supply dexamphetamine, lisdexamfetamine or methylphenidate for a person, must complete a formal declaration that the patient has been recently reviewed by a specialist or their registrar in training, including details of the specialist's name and address. When renewing an authority to supply, the medical practitioner or nurse practitioner must also declare that the patient has been reviewed by a specialist or their registrar in training **in the previous 24 months.**

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- The application must be made on the Application for Authority to Prescribe a Restricted S8 Psychostimulant Medication form ([Appendix B](#)) along with all required information.
- If a specialist paediatrician, neurologist, psychiatrist or physician is based interstate, then the NT doctor or nurse practitioner applying for the authority to supply the substance must personally verify the decision to initiate these substances with the interstate specialist, rather than rely solely on a letter from the specialist which is carried by the patient.
- Letters from interstate registrars will not be accepted.
- For international visitors who are in the NT for less than 3 months, the medical practitioner or nurse practitioner must:
 - Contact the patient's doctor via telephone, fax or email to verify the history of the patient;
 - Complete the Application for Authority to prescribe a Restricted S8 Psychostimulant Medication form ([Appendix B](#)); and
 - Once the authorisation has been approved, supply only one prescription to the patient with a maximum of one repeat if required.
- For international visitors who will be residing in the NT for longer than 3 months, the medical practitioner or nurse practitioner must:
 - Contact the patient's doctor via telephone, fax or email to verify the history of the patient;
 - Complete the Application for Authority to prescribe a Restricted S8 Psychostimulant Medication form ([Appendix B](#)); and
 - Once the authorisation has been approved, supply an appropriate prescription to the patient.
- Specialist paediatricians or their registrars in training may not initiate the supply of restricted S8 substances dexamphetamine, lisdexamfetamine or methylphenidate to patients who have attained the age of eighteen (18) years. It is recommended that paediatricians only supply these substances until a patient's 18th birthday and that after this time the supply of these substances should be taken over by an adult neurologist, psychiatrist, physician or their registrar in training.

3.4 Important notes concerning authorisation and supply of amphetamines

- If the specialist paediatrician, neurologist, psychiatrist or physician is based interstate or overseas, an NT based general medical practitioner or nurse practitioner may supply for a maximum of six (6) months only, in which time the patient must be reviewed by an NT based specialist paediatrician, neurologist, psychiatrist, physician or registrar in training in one of these disciplines.
- When a specialist paediatrician or their registrar in training, as the sole supplier of the substance, is granted an authority to supply the substance, the authority will be valid until the patient **attains the age of eighteen (18) years**.

- The authority to supply for a particular patient must be **renewed every two (2) years** for specialist neurologists, psychiatrists, physicians or their registrars in training, who are the sole suppliers of the substance.
- The authority to supply for a particular patient must be **renewed every two (2) years** by medical practitioners or nurse practitioners who are co-managing the patient with a specialist paediatrician, neurologist, psychiatrist, physician or registrar in training.
- When an authorised prescriber **ceases to supply** these substances for a patient, he or she must notify the CHO or his/her delegate **within fourteen (14) days** using the Application for Authority to Prescribe a Restricted S8 Psychostimulant Medication form ([Appendix B](#)).
- If the patient is less than four years of age, it is recommended that a second opinion be gained from another specialist supporting the diagnosis and recommendation to supply dexamphetamine, lisdexamfetamine or methylphenidate.

3.5 Information to be provided on application

The following information is to be supplied to the CHO using the Application for Authority to Prescribe a Restricted S8 Psychostimulant Medication form ([Appendix B](#)):

- Patient
 - Full name
 - Gender
 - Date of birth
 - Residential address
 - Name of parent or guardian (if child under 18 years)
 - Medicare number and (if known) Health care card number
 - Condition being treated
 - Substance
 - Dose
- Prescriber
 - Full name
 - Practice address
 - Phone number
 - Fax number or email
 - Prescriber number
 - Type of practitioner
 - Date most recently seen by specialist
 - Whether the specialist is based interstate

- If yes, whether the NT medical practitioner has personally verified the prescription with the interstate specialist

Please note: If the specialist paediatrician, neurologist, psychiatrist or physician is based interstate or overseas, an NT-based general medical practitioner or nurse practitioner may supply for a maximum of **six (6) months only**, in which time the patient must be reviewed by an NT-based specialist paediatrician, neurologist, psychiatrist, physician or registrar in training in one of these disciplines.

3.6 Initial application, renewal, change of substance and cessation

The Application for Authority to Prescribe a Restricted S8 Psychostimulant Medication form ([Appendix B](#)) is to be used for:

- New applications for authority to supply;
- Renewal of applications for authority to supply;
- Application for amendment to the authority to supply (i.e. changing from one substance to the other); and
- Notification of cessation of supply.

3.7 Renewal of authority to supply

- The Application for Authority to Prescribe a Restricted S8 Psychostimulant Medication form ([Appendix B](#)) must be completed by the authorised prescriber and forwarded to the CHO **within fourteen (14) days of the expiry** of their authorisation.
- An authorisation to supply dexamphetamine, lisdexamfetamine or methylphenidate, for paediatricians or their registrars in training who have sole management of a patient, is valid until the patient attains the age of eighteen (18) years, unless otherwise specified on the authorisation. Upon the patient attaining the age of eighteen (18) years, the paediatrician or registrar in training must either renew the authority or transfer the client to the care of an adult specialist.
- An authorisation to supply dexamphetamine, lisdexamfetamine or methylphenidate for psychiatrists, neurologists, physicians and registrars-in-training who have the sole management of a patient is **valid for two (2) years** from the date of the authorisation, unless otherwise specified on the authorisation. After the expiration of the two-year period the psychiatrist, neurologist, physician or registrar in training must apply for a renewal of the authority to supply.
- A medical practitioner or nurse practitioner who is co-managing a patient with a specialist or registrar-in-training must renew the authority to supply dexamphetamine, lisdexamfetamine or methylphenidate **every two (2) years**. An application for renewal of an authorisation in these circumstances must be accompanied by a declaration by the medical practitioner or nurse practitioner that the patient has been reviewed by a specialist paediatrician, psychiatrist, neurologist, physician or registrar-in-training **in the past two (2) years**.

3.8 Change of substance

- If the substance is changed from dexamphetamine, lisdexamfetamine to methylphenidate or vice versa, the CHO must be notified, in writing, **within fourteen (14) days**.

- This notification must be made on the Application for Authority to Prescribe a Restricted S8 Psychostimulant Medication form ([Appendix B](#)) with all required, specified information.

3.9 Cessation

- If a medical practitioner or nurse practitioner ceases to supply dexamphetamine, lisdexamfetamine or methylphenidate, the CHO must be notified, in writing, **within fourteen (14) days**.
- This notification must be made on the Application for Authority to Prescribe a Restricted S8 Psychostimulant Medication form ([Appendix B](#)) with all required specified information.

3.10 The prescribed number of persons

The prescribed number of persons a **specialist** paediatrician, psychiatrist, neurologist, physician or registrar may supply dexamphetamine, lisdexamfetamine or methylphenidate to, pursuant to section 85 of the Act, is **two hundred (200)**.

The prescribed number of persons a nurse practitioner or a medical practitioner who is **not a specialist** paediatrician, psychiatrist, neurologist or physician may supply dexamphetamine, lisdexamfetamine or methylphenidate to, pursuant to section 85 of the Act, is **ten (10)**.

Pursuant to section 139, the CHO may grant a medical practitioner or nurse practitioner an authorisation to supply restricted S8 substances to more than the prescribed number of persons, with the following conditions:

- The medical practitioner or nurse practitioner must apply in writing to the CHO for authority to supply restricted S8 substances dexamphetamine, lisdexamfetamine and methylphenidate to more than the prescribed number of persons, providing a justification for the request.
- The CHO will refer this application to the Committee for advice and a recommendation to the CHO concerning its appropriateness and also the number of patients the medical practitioner or nurse practitioner may supply for.
- In considering an application pursuant to section 133 of the Act, the Committee may consider the following matters:
 - The expertise and experience of the medical practitioner or nurse practitioner;
 - The accessibility and availability of the medical practitioner or nurse practitioner to the patients; and
 - The availability of other clinicians and ancillary services.
- The CHO may impose whatever conditions are considered appropriate on any authorisation granted.

3.11 Period of effect of prescription and permissible supply

Pursuant to section 88 of the Act:

- S8 substance prescriptions are valid for six (6) months, **unless a shorter period is prescribed by a code of practice** under section 88(a).

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- Prescriptions for restricted S8 substances dexamphetamine, lisdexamfetamine or methylphenidate may allow a **total supply period of up to six (6) months**.
- In addition, no more than one (1) month's supply of dexamphetamine, lisdexamfetamine or methylphenidate is permitted to be dispensed at any one time, unless the prior written authorisation by the CHO has been obtained.
- For dexamphetamine tablet prescriptions which are endorsed by the prescriber to be for compounding into a sustained released form, unopened bottles of 100 tablets may be ordered and supplied at one time instead of the calculated one month's supply.
- Supply on one prescription in excess of six months' supply requires prior authorisation by the CHO under section 133 of the Act. It is the responsibility of the prescribing medical practitioner or nurse practitioner to request this well in advance (minimum of two (2) weeks turnaround). Approval is not automatic, and the request will be subject to consideration and recommendation by the Committee. Prescriptions of this type must be endorsed with the date and details of the authorisation to be valid and able to be dispensed by the pharmacy. A Guideline to assist medical practitioners and nurse practitioners making a request of this type is available from Medicines & Poisons Control. Please refer to Enquiries (page 4) for details.

Part 4: Supply of Restricted S8 Substances – methadone, buprenorphine and buprenorphine/naloxone (Opioid Substitution Treatment)

Section 85 of the MPTGA states that restricted S8 substances may be supplied by an authorised health practitioner (NT doctor or NT nurse practitioner) for therapeutic use only if the authorised health practitioner holds a S8 authorisation. Section 139(1)(b) specifies that the CHO is able to authorise a prescriber to supply or administer a restricted S8 substance for an authorised purpose. For the purpose of section 85 of the Act, an authorised purpose for a restricted S8 substance other than an amphetamine under section 5 includes use for the treatment of an addiction to a substance.

4.1 Authorisation Framework for Supply of Restricted Schedule 8 Substances methadone, buprenorphine and buprenorphine/naloxone

The basic framework for the authorisation to supply restricted S8 substances methadone, buprenorphine and buprenorphine/naloxone is:

1. A prescriber (NT doctor or NT nurse practitioner) submits an application for an authorisation to the CHO to supply a restricted S8 substance methadone, buprenorphine and buprenorphine/naloxone for each individual patient.
2. The CHO decides in relation to each individual application whether the prescriber is competent and whether the circumstances are appropriate in relation to the patient (**Please note:** the Act does not provide for a prescriber to receive a general 'accreditation' to supply restricted S8 substances).
3. Details about administration, criteria to judge competence and appropriate circumstances as specified in Part 4.
4. If considered competent a prescriber may only supply restricted S8 substances methadone, buprenorphine and buprenorphine/naloxone for a prescribed number of persons at any one time.
5. A prescriber may apply in writing to the CHO for an authority to supply for more than the prescribed number of persons.

The CHO is the ultimate source of authority under the Act. In practice the CHO will delegate certain powers to other persons to allow the smooth operation of the Act on a day to day basis. All requests for authorisations and other correspondence are to be directed to Medicines & Poisons Control. Please refer to Enquiries (page 4) for details.

4.2 Collaborative Models – Nurse Practitioners

Nurse Practitioners are required by the National Nursing and Midwifery Board and under the [National Health Act 1953](#) (Cth) to have a collaborative arrangement in place with a medical practitioner.

4.3 Authorisation to supply

- Before an authorised prescriber can supply a restricted S8 substance buprenorphine, buprenorphine/naloxone or methadone the prescriber must be authorised to do so by the CHO.

- An application for authorisation to supply a restricted S8 substance buprenorphine, buprenorphine/naloxone or methadone for a patient must be made to the CHO using the Application for Authority to Prescribe a Restricted S8 Substance for the Treatment of Addiction form ([Appendix C](#)).
- Pursuant to section 139 of the Act the CHO may grant an authorisation to supply a restricted S8 substance (see below).
- For each application two judgements will be made: whether the authorised prescriber is competent to safely supply restricted S8 substances buprenorphine, buprenorphine/naloxone or methadone, and whether all requirements in relation to the patient have been fulfilled.

If the CHO has concerns about an application, or it does not satisfy the prescribed conditions, the application will be referred to the Committee immediately for advice. In this instance, the CHO must consider the advice of the Committee prior to making a decision on any application.

- In considering an application pursuant to section 139 of the Act, and whether the authorised prescriber is competent to safely supply the substance, the Committee may have regard to whether the authorised prescriber has, within the past twelve months undergone appropriate training; and
- For those authorised prescribers who completed training more than twelve months ago consideration will be taken of whether he/she has:
 - been the subject of any complaint or concern about his/her management of S8 or restricted S4 patients;
 - managed at least two restricted S8 buprenorphine, buprenorphine/naloxone or methadone patients in the past twelve (12) months; or,
 - undertaken any formal update training in this area in the past two (2) years.

Authorised prescribers who are intending to apply for an authorisation to supply restricted S8 substances buprenorphine, buprenorphine/naloxone and/or methadone should advise the Chairperson of the Committee (who is appointed under section 268 of the Act) of their desire to do so, and provide proof of their competence. The Chairperson will forward this to the Committee for consideration.

4.4 Prescribed conditions for routine authorisations

Pursuant to section 139 of the Act, the CHO may issue an authorisation to supply restricted S8 substances if all the prescribed conditions apply.

The prescribed conditions for restricted S8 substances buprenorphine, buprenorphine/naloxone and methadone are:

- The Committee has previously made a judgement that it considers the authorised prescriber is competent to safely supply the substance;
- Where the authorised prescriber was initially considered competent by the Committee over twelve months ago, the CHO has ascertained that the authorised prescriber has maintained a level of patient management as indicated above, and is not aware of any complaints or concerns about the authorised prescriber's practice in this area;

- The application has been made on the Application for Authority to Prescribe a Restricted S8 Substance for the Treatment of Addiction form ([Appendix C](#)) along with all required information and a recent photo of the person for whom the substance is to be supplied;
- The patient for whom the substance is to be supplied is not currently notified by another authorised prescriber for a S8 substance as far as the CHO is able to ascertain;
- If the patient is to undergo a maintenance program (i.e. not a short withdrawal program of up to 30 days; see below) the client must sign a restricted S8 prescribing contract with the authorised prescriber or agency which specifies, as a minimum:
 - the name of the substance;
 - the period of duration of the contract;
 - that the patient agrees not to seek opiate S8 substances from other authorised prescribers;
 - that the patient agrees for a copy of the contract to be forwarded to the CHO or his/her delegate for dissemination to other authorised prescribers and pharmacists in the NT; and
 - that the patient understands the nature of the takeaway dosing framework to be adhered to.
- A copy of this contract is forwarded to the CHO or his/her delegate at the same time as the Application for Authority to Prescribe a Restricted S8 Substance for the Treatment of Addiction form ([Appendix C](#));
- The CHO is not aware of any concerns about the patient for whom the application is being made that might militate against the granting of the authorisation.

If the prescribed conditions do not apply, the CHO will withhold the authorisation, inform the authorised prescriber and refer the matter to the Committee. If possible, the discussion/consultation with the Committee may be completed by email or if necessary a teleconference can be convened. The CHO will consider the advice of the Committee and make a decision as to whether or not to grant the authorisation.

4.5 Information to be provided on application

The following information is to be supplied to the CHO using the Application for Authority to Prescribe a Restricted S8 Substance for the Treatment of Addiction form ([Appendix C](#)).

Patient:

- Full name;
- Gender;
- Date of birth;
- Indigenous status;
- Residential address;

- Medicare number, and (if known) Health Care Card number;
- Photographic identification;
- Name of substance;
- Maintenance or short withdrawal course;
- Initial dose; and
- Intended start date for supply

Supplying medical practitioner or nurse practitioner:

- Name;
- Practice address;
- Phone number;
- Fax number or email; and
- Prescriber number

4.6 Important notes concerning authorisation and supply

- Authorisations are issued subject to the prescribed conditions applying to the supply of the substance to that person.
- Unless otherwise stated, it is a condition of every authorisation that the authorised prescriber shall not supply restricted S8 substances buprenorphine, buprenorphine/naloxone and methadone, except in accordance with the NT 'Code of Practice S8 Substances' as approved by the CHO in the Government Gazette and published on the Department of Health website.
- Authorisations may be requested for maintenance pharmacotherapy. An authorisation for maintenance pharmacotherapy is only valid for a period of two (2) years. After this time an authorised prescriber must apply for a renewal of the authorisation as if it were an application for a new authorisation.
- If an authorised prescriber ceases to supply a restricted S8 substance for a person on maintenance pharmacotherapy, a formal cessation notice using the Application for Authority to Prescribe a Restricted S8 Substance for the Treatment of Addiction ([Appendix C](#)) must be provided to the CHO (see below).
- An authorisation period of a maximum of 30 days may be requested for short withdrawal programs. At the end of this period, no formal cessation notice is required. If, at any time during or at the end of this period, the authorised prescriber wishes to change the client onto a maintenance program, a new application for authorisation must be made including the provision of a restricted S8 prescribing contract.
- Unless otherwise stated it is a condition of every authorisation that there be a maximum of three (3) takeaway unsupervised doses (USD) per week permitted for persons on daily buprenorphine, buprenorphine/naloxone or methadone, and a maximum of one (1) takeaway unsupervised dose (USD) per week for persons on alternate daily buprenorphine or buprenorphine/naloxone.

- Authorised prescribers wishing to prescribe takeaway doses in excess of this limit must apply in writing to the CHO for a variation to the authorisation (see “Takeaway Unsupervised Doses (USD)” below for conditions and process).
- Authorisations to supply maintenance pharmacotherapy for persons under the age of 18 years will only be granted to specialist clinicians working in the Alcohol and Other Drugs program area, or to General Practitioners or Nurse Practitioners who are co-managing the client with a specialist.

Pursuant to section 245 of the Act the CHO may exempt an authorised health practitioner or class of authorised health practitioners from a requirement to hold an authorisation under the Act. Section 245(3) requires the CHO to seek advice from the Committee prior to issuing the notice.

An exemption notice may include conditions.

Please contact Medicines & Poisons Control for information regarding any exemptions that have been granted. Please refer to Enquiries (page 4) for details.

4.7 Initial application, renewal, modification and cessation

The Application for Authority to Prescribe a Restricted S8 Substance for the Treatment of Addiction form ([Appendix C](#)) is to be used for:

- new applications;
- authority renewals;
- request for a variation of the authorisation (i.e. changing from one drug to another or from a withdrawal program to maintenance); and
- notification of cessation of supply.

4.8 Renewal of authority to supply

- The Application for Authority to Prescribe a Restricted S8 Substance for the Treatment of Addiction form ([Appendix C](#)) with all specified information and a new identification photograph of the patient must be completed by the authorised prescriber and forwarded to the CHO prior to the expiry of the existing authorisation.
- The authorisation to supply must be renewed by the CHO prior to the authorised prescriber continuing to supply beyond the initial authorisation period.

4.9 Change of substance/nature of program

- If the substance being supplied is changed from methadone to buprenorphine or to buprenorphine/naloxone, or vice versa, or if there is a change from a withdrawal program to a maintenance program, the CHO must be notified in writing within **fourteen (14) days**.
- This notification must be made on the Application for Authority to Prescribe a Restricted S8 Substance for the Treatment of Addiction form ([Appendix C](#)) with all required specified information.

- A new restricted S8 prescribing contract specifying the new substance or program must be signed by the patient and forwarded to the CHO.

4.10 Direct transfer of patient to another prescriber

- Where a patient is transferred immediately from one authorised prescriber to another, the original prescriber must notify of the cessation within fourteen (14) days, and the new medical practitioner or nurse practitioner must submit a new application for authorisation fulfilling all requirements of the Act and the code prior to the new prescriber supplying any restricted S8 substance.

4.11 Cessation of supply

- If an authorised prescriber ceases to supply a restricted S8 substance, the CHO must be notified in writing within fourteen (14) days; and
- This notice of cessation must be made on the Application for Authority to Prescribe a Restricted S8 Substance for the Treatment of Addiction form ([Appendix C](#)) with all required specified information.

4.12 The prescribed number of persons

Volume 1 The prescribed number of persons pursuant to section 84(2)(a) of the Act for restricted Schedule 8 substances, buprenorphine, buprenorphine/naloxone and methadone is **ten (10)** except for NT Government Alcohol and Other Drugs Clinical Services.

Pursuant to sections 139(1)(b), 139(1)(c)(ii) and 133 of the Act, the CHO may grant a prescriber an authorisation to supply restricted S8 substances to more than the prescribed number of persons.

- A prescriber may apply in writing to the CHO or his/her delegate for authority to supply to more than the prescribed number of persons.
- The CHO or his/her delegate will refer this application to the Committee for advice and for a recommendation to the CHO concerning its appropriateness and the recommended number of patients the prescriber may supply for.
- In considering an application pursuant to section 134 of the Act, the Committee may consider the following matters:
 - the expertise and experience of the prescriber in treating drug dependence;
 - the accessibility and availability of the prescriber to the patients;
 - whether the prescriber is working full time or part time in drug dependence treatment; and
 - the type of patients and type of setting in which the prescriber is providing S8 pharmacotherapy treatment, including for example, the availability of other clinicians and ancillary services.
- The CHO may impose whatever conditions considered appropriate on any authorisation granted.

4.13 Prescriptions

The prescriber must forward to the dispensing pharmacy the prescription for buprenorphine, buprenorphine/naloxone or methadone, a current photograph of the patient endorsed by the prescriber, and a letter specifying the date of administration of the first dose. These must reach the pharmacy or dosing point prior to the patient receiving the first dose.

4.14 Contents of prescriptions

In addition to meeting the requirements for contents of prescriptions for restricted S8 substances in Part 2, the following requirements must be met:

- The name of the pharmacy or dosing point(s) from which the substance is to be dispensed must be written on the prescription;
- The dosage regimen must be clearly and precisely specified; and
- The nature of any takeaway privileges (if any) must be written.

4.15 Period of effect of prescription and permissible supply

Pursuant to section 88(a) of the Act:

- A prescription issued in accordance with the Act for restricted S8 substances, buprenorphine, buprenorphine/naloxone or methadone, remains in effect for **three (3) days from the date of issue** or from the start date if that is different from the date of issue (inclusive of the date of issue or start date);
- Prescriptions not presented to the pharmacy or dosing point within this time are invalid and cannot be dispensed; and
- Prescriptions for restricted S8 substances buprenorphine and buprenorphine/naloxone and methadone may allow only for a **total supply period of three (3) months**.

4.16 Dispensing of the substance

As regards the dispensing of the substance from a pharmacy or dosing point:

- The substance is to be dispensed one day at a time and consumed in front of the dispensing pharmacist, nurse or medical practitioner (subject to takeaway dose privileges; see below). This is a requirement for all circumstances and does not need to be written on the prescription.

4.17 Takeaway Unsupervised Doses (USD)

Consistent with national guidelines and safety, the Opioid Pharmacotherapy Program (OPP) is based on supervised drug administration. Supervised dosing allows assessment of patients before dosing and minimises harm from drug overdose, abuse and diversion.

Takeaway doses are unsupervised doses that are not consumed immediately in front of the dispensing pharmacist, nurse or medical practitioner. Gradual introduction of takeaway USD for patients who respond to treatment can be a valuable incentive and reward for treatment progress, promotes responsibility, and improves quality of life. Their provision remains a sensitive issue and subject to scrutiny.

Diversion and use by an opioid naive person is potentially lethal. Any injection of takeaway doses by the patient carries substantial risks to the health and life of the patient.

To minimise risks and ensure consistent application for the benefit of patients, prescribers and dispensers, prescribers must therefore comply with the requirements set out below.

No take-away doses during the first two months of treatment. A prescriber may consider an application from the patient for exceptional circumstances e.g. travel for family crisis. At times, takeaway doses must be provided if there is no pharmacy that is open on a public holiday, or in situations such as cyclone threat.

Please note the following:

- For patients whose problem opioid use has involved ONLY excess ORAL codeine preparations, who has no other drug/substance use problems, and who meets stability criteria ([Appendix D](#)), a prescriber may consider an application from the patient to begin to provide Suboxone takeaway USD once the Suboxone dose is stable (from two (2) weeks), to facilitate work. The rate of increase approved by the CHO by special authorisation (see below) can be faster.
- The maximum number of takeaway USDs that can be prescribed under the Code without special authorisation from the CHO is three (3) per week for daily methadone, buprenorphine or buprenorphine/naloxone preparations, or one (1) per week for alternate day¹ buprenorphine or buprenorphine/naloxone preparations.
- Many patients on buprenorphine or buprenorphine/naloxone preparations can be effectively treated with alternate-day² regimens dosing on four or three days a week that greatly reduce the need for USD.
- With continuing evidence of active lifestyle improvement and abstinence from unsanctioned drug or medication use, including urine drug screens demonstrating absence of any illegal substance or unsanctioned/undisclosed psychoactive medication (please see '**Clinical assessment for the level of supervised dosing**' ([Appendix D](#))), application may be made to the CHO to approve gradual increases beyond this level. The CHO will obtain advice from the Committee before making a decision on whether to approve the application.
- In the case of continuing illicit cannabis use, after twelve (12) months of continued stability according to all other criteria, increased takeaway USD above the maximum under the Code may be considered to facilitate work. However, extended Suboxone provisions will be limited to one observed dose each week rather than one per fortnight (see **Buprenorphine/naloxone (Suboxone) – extended USD below**).
- All such increases should progress in gradual steps, one at a time, supported by clear evidence of continuing stability and progress (**Table 4 'Maximum Regular Takeaway Unsupervised Doses'**).
- All such applications must be in the approved format, or contain the same information in a letter, by the prescriber, through Medicines and Poisons Control, directed to the Manager of Medicines and Poisons Control. Applications require a minimum of five (5)

¹ Alternate day dosing includes four (4) day per week and three (3) day per week dosing arrangements.

² Alternate day dosing includes four (4) day per week and three (3) day per week dosing arrangements.

working days' notice prior to the first desired day of extra takeaway doses (please see [Appendices E1 and E2](#)).

- For buprenorphine without naloxone (Subutex) and methadone liquid, the regular maximum takeaway USD allowance that will be approved is four (4) per week for methadone or daily buprenorphine, or one (1) per week for *alternate day buprenorphine i.e. 4 days of unsupervised dosing per week.

4.18 Buprenorphine/naloxone (Suboxone) - extended USD

Due to the greater safety of buprenorphine compared with methadone, together with the reduced potential for diversion of buprenorphine/naloxone compared with buprenorphine alone, substantially extended takeaway USD provisions are available for buprenorphine/naloxone ONLY. This extension is limited to a maximum thirteen (13) consecutive days of unsupervised buprenorphine/naloxone medication: there must be one observed dose every 14 days. This extension is NOT available to patients treated with buprenorphine due to proven allergy or adverse reactions with buprenorphine/naloxone (but, see 'pregnancy' below).

4.19 Patients transferring from interstate or between prescribers

In assessing takeaway USD allowances for patients transferring from interstate or between programs or practitioners it is reasonable to consider previous treatment stability.

4.20 Pregnancy - Buprenorphine/naloxone

Buprenorphine, buprenorphine/naloxone and methadone are all classified Category C, but there is insufficient evidence regarding the safety of buprenorphine/naloxone in pregnancy. Women being treated with buprenorphine/naloxone who become pregnant must therefore be changed to buprenorphine alone, or methadone. Prescribers will use clinical judgement for setting the number of USD with reference to previous approved doses.

4.21 Pregnancy - Methadone

Pregnant women on methadone beyond twenty (20) weeks of gestation may require a twice-daily dose with a takeaway for each day's evening dose (i.e. dose splitting due to increased metabolism of methadone). An authorised prescriber may supply methadone takeaways in excess of three (3) doses per week to a woman in late pregnancy for the purpose of dose splitting without special application to the CHO. This applies only to takeaways for the evening dose. The woman must still attend the pharmacy on the same number of days per week as is required under her regular takeaway privileges. Once the woman is no longer pregnant, the authorisation reverts to a single daily dose.

4.22 Cyclone/disaster/extended public holiday periods

An authorised prescriber may supply takeaways for a period up to an extra three days under the practice/agency cyclone/disaster plan, or to cover pharmacy closure or transport problems over Easter and Christmas breaks if dosing alternatives are not practically possible. This can be done without application to the CHO.

4.23 Applications for additional USD

In all circumstances for takeaway USD above the maximum other than these exceptions (methadone dose splitting in pregnancy; cyclone/disaster/extended public holidays) an

authorised prescriber must make a written application to the CHO for a variation to the takeaway dose condition. The CHO will obtain advice from the Committee before making a decision on whether to approve the application. The application must specify:

- Full name, residential address, date of birth, and Medicare number of the client;
- The dose and type of substance;
- Length of time on the program; and
- Explanation of the nature and amount of extra takeaway privileges and rationale for them.

Situations for considering such approval include:

- Stable patients in regular work or study for whom daily dosing might represent a significant impediment to continued work or study. Clients must provide documentary or other proof of their employment or study and its nature ([Appendices E1 and E2](#));
- Stable patients in special situations that the prescriber believes to justify consideration ([Appendices E1 and E2](#));
- A one off allowance to allow safe transfer and travel to a prescriber interstate ([Appendix F](#)); and
- A one off allowance for holiday purposes for a stable client ([Appendix F](#)).

4.24 Conditions for takeaway USD

Non-supervised doses are only available for stable patients responding to treatment with active lifestyle changes, cessation of unsanctioned drug use, and subject to the following:

- There must be no suspicion of diversion of prescribed medication or illicit dealing in drugs;
- All patients must confirm that they are able to provide storage that prevents access by children (their own or visitors);
- Combined buprenorphine/naloxone rather than buprenorphine alone is to be used for all patients receiving takeaway USD in the absence of a medical contraindication e.g. pregnancy; observed sensitivity to available buprenorphine/naloxone preparations that is formally reported to the TGA; observed significant adverse effects that are clinically attributable to available buprenorphine/naloxone preparations and formally reported to the TGA. Apart from these medically indicated exceptions, patients treated with buprenorphine alone do not qualify to be prescribed any regular takeaways;
- Takeaway USD for patients treated with buprenorphine alone due to a medical contraindication are limited to four (4) days of unsupervised dosing per week. The rate of increase to this maximum is the same as for buprenorphine/naloxone;
- Patients must be advised to provide adequate security to prevent theft, loss or damage to takeaway USD;
- Requests for replacements must be refused and access to continuing USD should be reviewed;

- Providing regular takeaway USD requires the authorised prescriber to be satisfied that the patient is reliable and stable; and
- Patients who become less stable and no longer fulfil the stability criteria on which a USD allowance was approved should have takeaway doses reduced to a safe level, with increased prescriber review and support to regain stability (see **Reducing takeaway USD** below).

4.25 Assessment of stability

Stability should be evaluated according to the Clinical assessment for the level of supervised dosing form ([Appendix D](#)): and will incorporate the following conditions:

- no hazardous use of opioids and other drugs (including alcohol);
- improved social functioning;
- compliance with program requirements;
- prior history of responsible use of takeaway doses;
- able to provide adequate storage arrangements for takeaway doses; and
- understanding the potential risks to children of accidental ingestion.

4.26 Absolute contraindications to takeaway USD

- any concern that any child living in the patient's household may be at risk of harm;
- current chaotic or unpredictable behaviour, including any intoxicated presentation for dosing or review;
- assessed as at risk of self-harm;
- current hazardous use of drugs, including benzodiazepines, alcohol, stimulants; or
- diversion of the medication.

4.27 Reducing takeaway USD

Deciding on a safe level of reduced takeaway USD involves assessment of several factors and exercises the judgement of the prescriber, and may be contested by a patient. In making decisions and discussion with a patient, prescribers should apply the following:

- If the reduction in stability falls into any of the categories that are **absolute contraindications to takeaway USD, then all takeaway USD doses should be ceased at once;**
- In the case of other indicators of instability such as unsanctioned/illicit use of benzodiazepines, opioids or stimulants detected by urine drug screen, or behaviour that is of concern, but in **the absence of absolute contraindications to takeaway USD**, then **any extended takeaway USD above the legal maximum allowed without authorisation from the CHO or delegate must be ceased at once.** Any subsequent increases in takeaway USD are then subject to the usual authorisation process – there is no provision for reinstatement without new authorisation;

Schedule 8 substances: Code of Practice
Volume 1: Issuing Prescriptions, supplying schedule 8 substances

- A prescriber who is concerned about a patient and unsure what level of reduction to apply should contact Medicines & Poisons Control for advice;
- A prescriber who is concerned about a patient and unsure of the safest course may contact the Alcohol & Other Service of the NT Department of Health for advice, and can arrange to transfer the patient to that service for management of the situation if the prescriber wishes; and
- Prescribers have full discretion to make greater reductions in takeaway USD than the above as indicated for safety.

4.28 Maximum Regular Takeaway Unsupervised Doses

Table 1 - Maximum Regular Takeaway Unsupervised Doses

Months in Treatment	Buprenorphine /naloxone daily <u>maximum</u>	Buprenorphine /naloxone alternate days ¹ <u>maximum</u>	Methadone <u>maximum</u>
0-2	0	0	0
3-4 Making progress & meeting stability criteria	Progressive increase up to 2/week (5 attendances /week)	1/week (2 attendances/week)	1/week (6 attendances /week)
5-6 Making progress & meeting stability criteria	Progressive increase up to 4/week (3 attendances /week)	1/week (or at least 2 attendances /week)	2/week (5 attendances /week)
7-12 Making progress & meeting stability criteria	Up to 6/week (1 attendance /week) Increase no faster than 1 USD extra per 4 weeks continued stability	2/week (or at least 1 attendance /week)	3/week (4 attendances /week)
>12 Making progress & meeting stability criteria	Up to 13/fortnight (1 attendance/fortnight) Increase no faster than 1 USD extra per 4 weeks continued stability	Up to 6 (alt day), 7 (on 4 day a week dosing), or 5 (on 3 day a week dosing) consecutive, (or at least 1 attendance) each fortnight. Increase no faster than 1 USD extra per 8 weeks continued stability	4/week (3 attendances /week)

¹ Alternate day dosing includes four (4) day a week and three (3) day a week dosing arrangements.

- Where buprenorphine without naloxone is being prescribed because buprenorphine/naloxone is medically contraindicated (e.g. pregnancy, allergy), takeaway unsupervised doses of buprenorphine can be provided at the same rate of increase as for buprenorphine/naloxone, but may be limited to a maximum of four (4) days of unsupervised dosing /week.
- Takeaway USD may be provided for public holidays for all patients where there is no reasonable alternative (e.g. double or triple dosing with buprenorphine preparations).
- There are special arrangements for takeaway USD in the case of a cyclone or disaster.
- Earlier Suboxone takeaway USD, within the first 2 months, with a faster rate of increase to only 1 dosing attendance/week may be considered for patients whose problem opioid use has involved only excess oral codeine medications, particularly to facilitate work.

4.29 Packaging and labelling of takeaway USD

Packaging and labelling of takeaway USD is normally only undertaken by pharmacists. Registered nurses at Tobacco Alcohol and Other Drugs Service (TADS) in Darwin and Alcohol and Drugs Service Central Australia (ADSCA) in Alice Springs are also approved by the CHO.

The label for takeaway USD of buprenorphine and buprenorphine/naloxone and methadone must contain:

- the name, strength and dose form of the substance;
- the quantity contained in the container;
- specific instructions for the use and dose of the substance (for example, "take as directed" is not sufficient);
- the name of the person;
- the name, address and telephone number of the person or health care facility supplying the substance;
- a warning concerning drowsiness and the concurrent use of alcohol or other sedating medication; and
- a warning to keep out of the reach of children.

Takeaway USDs of methadone liquid must be supplied in the following fashion:

- child resistant containers must be used;
- separate containers must be used for each individual day (i.e. two days doses may not be supplied in one container);
- containers may not be re-used for that purpose; and
- each individual day's dose must be **diluted with water** such that there is a minimum volume of **200mL** of fluid in the container.

4.30 Missed doses

An authorised health practitioner may describe on a prescription for a restricted S8 substance the actions to be taken by a dispensing pharmacist or nurse in case of missed doses.

Alternatively, an authorised health practitioner may, for the use of a registered nurse who is the subject on an authorisation under section 250 of the Act, establish a 'Scheduled Substance Treatment Protocol' (as per section 254 of the Act), which describes the actions to be taken in case of missed doses. This protocol must be approved for use by the CHO. It may be submitted to the CHO via Medicine & Poisons Control. Please refer to Enquiries (page 4) for details.

In the absence of either of the above, if a patient misses dosing for the equivalent of two (2) consecutive days of medication, the prescription becomes invalid and the medication may not be dispensed. The patient must be referred to the authorised health practitioner for review and renewal of the prescription or as per section 61 of the Act, a telephone order may be accepted from the authorised health practitioner.

If a patient misses doses on more than four (4) days over a month, the dispensing pharmacist or nurse must inform the prescribing medical practitioner.

4.31 Pharmacists and other health practitioners dispensing Opioid Substitution Treatment

This section applies to pharmacists, medical practitioners, and nurses who are supplying buprenorphine, buprenorphine/naloxone or methadone to the patient on the direction of a prescriber who is authorised under the Act to prescribe these restricted S8 substances ('authorised health practitioner').

Dosing points may include pharmacies (community and hospital), correctional services health centres, Tobacco Alcohol and Other Drugs Service (TADS) in Darwin, Alcohol and Drugs Service Central Australia (ADSCA) in Alice Springs, and hospitals.

The authorised health practitioner should inform the pharmacist or other health practitioner of any concerns regarding the patient that are relevant for dosing safety.

Any situation where a pharmacist or health practitioner holds any concern about a patient should be promptly reported to the authorised health practitioner.

Intoxicated presentations

If a patient presents for dosing and appears to be intoxicated, the dose should be withheld and the authorised health practitioner must be informed.

Vomiting after a dose/vomited dose

No doses are to be replaced without direction from the authorised health practitioner, whether or not the event was witnessed by the pharmacist or health practitioner. Any vomiting shortly after a dose must be reported to the authorised health practitioner who will need to assess the situation, e.g. pregnancy, cause of the vomiting etc., and may require the patient to present for clinical review.

Vomiting - Methadone

If vomiting has occurred more than 20 minutes after the dose, the patient can be reassured that all of the dose has been absorbed.

Vomiting - Buprenorphine and buprenorphine/naloxone

The patient can be reassured that buprenorphine is rapidly absorbed via the buccal and sublingual mucosa and there is no need for any replacement.

Missed doses

All missed doses must be notified to the authorised health practitioner.

If a patient misses dosing such that two (2) consecutive days of medication have been missed, no dose should be provided, and the patient referred to the authorised health practitioner. An authorised health practitioner may provide a written direction on a prescription regarding a dose to be prescribed if a patient on alternate day or third day dosing presents on a non-dosing day after missing the prior medication dose and is assessed by the pharmacist or health practitioner as safe to receive a dose of the medication.

Lost/stolen/spilt doses

Lost or stolen doses represent a significant risk to the community.

No doses reportedly lost by the patient or stolen from the patient are to be replaced without direction from the authorised health practitioner.

No doses reportedly spilt by the patient are to be replaced without direction from the authorised health practitioner.

Prescription expiry

Patients must not be given S8 medication after a prescription has expired unless directed to do so by the authorised health practitioner.

Please Note: Section 16 of the Act applies both the Schedules and Appendices of the "Schedule for the Uniform Scheduling of Medicines and Poisons" (SUSMP) also known as the Poisons Standard. Appendix K – Drugs Required to be Labelled with a Sedation Warning, and Appendix L – Requirements for Dispensing Labels for Human and Veterinary Medicines applies to all medicines in S4 and S8 supplied to a patient.

Resources

Further resources are available at: www.health.nt.gov.au/poisonscontrol

References

National Health Act 1953 available from:

<http://www.comlaw.gov.au/Details/C2013C00083>

National Health (Collaborative arrangements for nurse practitioners) Determination 2010 – available from the Federal Register of Legislative Instruments F2010L02107

National Health (Collaborative arrangements for midwives) Determination 2010 as amended 1 September 2013 – available from the Federal Register of Legislative Instruments F2013C00882

National Nursing & Midwifery Board registration standards for nurse practitioners and eligible midwives available from:

<http://www.nursingmidwiferyboard.gov.au/Registration-Standards.aspx>

Medicines, Poisons and Therapeutic Goods Act 2012 available from:

http://www.health.nt.gov.au/Environmental_Health/Poisons_Control/index.aspx

Medicines, Poisons and Therapeutic Goods Regulations 2014 available from:

http://www.health.nt.gov.au/Environmental_Health/Poisons_Control/index.aspx

NOTIFICATION OF SUPPLY OF AN UNRESTRICTED SCHEDULE 8 SUBSTANCEMedicines & Poisons Control ~ Phone: 8922 7341 Fax: 8922 7200 Email: poisonscontrol@nt.gov.au**PATIENT DETAILS***Please Note: Please print clearly*

Surname: Given Names:

Alias: Date of Birth: / / Sex: M ☐ F ☐

Name of Parent or Guardian (if child under 18):

↳ Relationship to Patient:

Residential Address:

Medicare Card No.: Health Care Card No.:

SCHEDULE 8 SUBSTANCE

Name and Dose of Substance:

Date of First Dose: / / Duration of Prescription:

Likely Duration of Need for S8 Medication:

Clinical Indication: Palliative Care: Y ☐ N ☐**REASON FOR NOTIFICATION**Supply / Intention to Supply for More Than 8 Weeks ☐ High Initial Dose ☐Replace Lost / Stolen Medication ☐ High Ongoing Dose ☐Previous Supply Consumed Earlier Than Intended ☐ Dose Rate Increase ☐Continuing Supply Initiated by Other Medical Practitioner ☐ Other (Specify below) ☐

Other Reason:

HAS THE PATIENT: Please Note: Further details & copies of correspondence may be required by the Chief Health Officer.Had a specialist assessment? Pain ... ☐ Alcohol & Other Drugs ☐ Other ☐

↳ Dates of Most Recent Specialist Assessments:

↳ Name and Contact Info. of Specialist:

Had Previous Treatment for Opiate Dependency? Y ☐ N ☐Had Previous Treatment for Other Drug or Alcohol Dependency? Y ☐ N ☐Ever Injected Drugs? Y ☐ N ☐Ever Been Under the Care of an Alcohol & Other Drugs Program in the NT or Elsewhere? Y ☐ N ☐**PRESCRIBER DETAILS***Please Note: Nurse Practitioners must attach details of collaborative arrangement with Medical Practitioner.*

Prescriber Name: Prescriber No.:

Practice Address:

Phone No.: Fax No.:

Prescriber Signature: _____ Date Signed: / /

APPLICATION FOR AUTHORITY TO PRESCRIBE A RESTRICTED S8 PSYCHOSTIMULANT MEDICATION

Medicines & Poisons Control ~ Phone: 8922 7341 Fax: 8922 7200 Email: poisonscontrol@nt.gov.au

PATIENT DETAILS

Please Note: Please print clearly

Surname: Given Names:
 Alias: Date of Birth: / / Sex: M ☐ F ☐
 Name of Parent or Guardian (if child under 18):
 ↳ Relationship to Patient:
 Residential Address:
 Medicare Card No.: Health Care Card No.:
 HRN No.:

MEDICATION

Dexamphetamine ☐ Dose of Substance:
 Methylphenidate ☐ Dose of Substance:
 Lisdexamfetamine ☐ Dose of Substance:

DIAGNOSIS

Narcolepsy ☐ Attention Deficit Disorder ☐
 Idiopathic Hypersomnolence ☐ Adult Attention Deficit Disorder ☐

PRESCRIBER DETAILS

Prescriber Name: Prescriber No.:
 Practice Address:
 Phone No.: Fax No.:
 Category: Paediatrician ☐ Neurologist ☐ Psychiatrist ☐ Physician ☐
 Registrar ☐ General Prac. ☐ Nurse Prac. ☐
 Prescriber Signature: _____ Date Signed: / /

*A General Practitioner or Nurse Practitioner may only co-prescribe with a Specialist Neurologist / Psychiatrist / Physician or Registrar-in-training. A second specialist opinion is needed for clients less than 4 years of age. Nurse Practitioners must attach details of collaborative arrangement with Medical Practitioner.

SPECIALIST INITIATING OR REVIEWING PATIENT Date of Last Review: / /

Specialist Name:
 Practice Address:
 Phone No.: Fax No.:
 Category: Paediatrician ☐ Neurologist ☐ Psychiatrist ☐ Physician ☐
 Registrar ☐

Interstate / International Specialist? Y ☐ N ☐

↳ Prescriber has personally verified decision to prescribe with specialist? (Required): Y ☐ N ☐

Please Note: International visitors residing for less than 3 months can only be approved a maximum 1 script with 1 repeat.

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Photo Here

APPENDIX C

APPLICATION FOR AUTHORITY TO PRESCRIBE A RESTRICTED S8 SUBSTANCE
FOR THE TREATMENT OF ADDICTION

Medicines & Poisons Control ~ Phone: 8922 7341 Fax: 8922 7200 Email: poisonscontrol@nt.gov.au

PATIENT DETAILS

Please Note: Please print clearly

Surname: Given Names:
Alias: Date of Birth:/...../..... Sex: M ☐ F ☐
Residential Address:
Medicare Card No.: Health Care Card No.:
HRN No.:
Indigenous Status: Aboriginal ☐ Torres Strait Islander ☐ Not Disclosed ☐

SCHEDULE 8 SUBSTANCE

Agreed Treatment Plan: Maintenance (24 months authority) ☐ Withdrawal (3 weeks authority) ☐

Name of Substance: ☐ Buprenorphine (s/l) ☐ Methadone (liquid)
☐ Buprenorphine/naloxone (s/l) ☐ Other:
☐

Pharmacy Name: Initial dose (mg):
Date of First Dose:/...../.....

If an Amendment: Withdrawal to Maintenance ☐ Maintenance to Withdrawal ☐
Methadone to Buprenorphine ☐ Buprenorphine to Methadone ☐
Change of Buprenorphine Form ☐

If a Transfer patient: Transfer from within the NT ☐ Transfer from Interstate ☐



Name of Former Prescriber:

REASON FOR CESSATION

Please Note: Please tick only one

Mutual agreement (program incomplete) ☐ Transfer interstate (specify state) ☐
Left against medical advice ☐ Transfer to another NT prescriber ☐
Request by Medical Officer ☐ Completed program ☐
Ceased to pick up dose ☐ Hospitalisation ☐
Imprisonment ☐ Referred to non-drug treatment ☐
Deceased ☐ Other (please specify): ☐

PRESCRIBER DETAILS

Please Note: Nurse Practitioners must attach details of collaborative arrangement with Medical Practitioner.

Prescriber Name: Prescriber No.:
Practice Address:
Phone No.: Fax No.:
Prescriber Signature: Date Signed:/...../.....
Supervising Prescriber Name (if applicable):
Phone No.: Address:

CLINICAL ASSESSMENT FOR THE LEVEL OF SUPERVISED DOSING**Medicines & Poisons Control ~ Phone: 8922 7341 Fax: 8922 7200 Email: poisonscontrol@nt.gov.au****PATIENT DETAILS***Please Note: Work through these with the client and include in the client file/records.*

Surname: Given Names:

Current Medication: Date of Birth:/...../..... Sex: M ☐ F ☐

Dose: No. of Takeaways:

HRN No.: Review Date:/...../.....

TYPE	SCENARIO	HIGH	MED	LOW
Attendance at medical / case manager reviews	Regular attendance			☐
	Occasional DNAs ¹ (e.g. misses 1 in 4 appointments)		☐	
	Regular DNAs (e.g. routinely misses ≥ 2 in 4 appointments)	☐		
Provision of Urine Drug Screens (UDS)	Provided on request			☐
	Not provided on request	☐		
Heroin & other opioid use	Nil additional opioid use			☐
	Infrequent additional opioid use		☐	
	Regular additional use (e.g. 1-2 times / week)	☐		
Benzodiazepine use	No Benzodiazepine use			☐
	Prescribed & stable ² use		☐	
	High dose ³ and harmful use ⁴ , abuse or dependence ⁵	☐		
Alcohol use	Low risk levels of alcohol use ⁶			☐
	Infrequent risky / high risk levels of alcohol use		☐	
	Harmful use, alcohol abuse or dependence	☐		
Stimulant use	Nil			☐
	Infrequent use		☐	
	Regular use	☐		
Mental state assessment	Nil concerns			☐
	Concerns regarding risk to self or others	☐		
Medical co-morbidity	Nil concerns			☐
	Concerns regarding medical condition (severe liver/respiratory disease)	☐		
Stable accommodation	Yes			☐
	No	☐		
Evidence of recent injecting sites	No recent IV sites			☐
	Evidence of recent IV sites	☐		
Missed doses	Dosing point not contacted	☐		
	No missed doses in past 4 weeks			☐
	Occasional missed doses (≤ 1 per week)		☐	
	Regular missed doses (≥ 2 per week)	☐		
Intoxicated presentations at dispensing point or clinic / overdoses	Nil within past 2 months			☐
	Recent within past 2 months		☐	
	Recent within past month	☐		
Concerns re: abuse/diversion of take-away doses	Nil concerns			☐
	Poor ability to "control" large supplies of medications (e.g. using take-away doses in advance)		☐	
	Recent history of abuse (e.g. injecting medications, double dosing, diversion to others)	☐		

Consider these scenarios and their given supervision level, and adjust according to clinical opinion. The overall pattern becomes a recommended level of supervised dosing.

¹ Did Not Attend (DNA): A failure to attend a scheduled appointment without advance notice / justification acceptable to the Medical Officer.² Low dose BZD use is defined as equivalent to <30mg diazepam / day. High dose > 30mg diazepam.³ Stable use: no additional use to amounts prescribed, no binges, intoxicated presentations or recent overdoses.⁴ ICD 10 diagnosis of harmful use.⁵ DSM IV diagnosis of abuse and dependence.⁶ Refer to *Australian Alcohol Guidelines* for risk levels and alcohol use.

APPLICATION FOR VARIATION TO REGULAR OPIOID SUBSTITUTION THERAPY (OST) TAKEAWAY UNSUPERVISED DOSES (USD): BUPRENORPHINE/NALOXONE

Medicines & Poisons Control ~ Phone: 8922 7341 Fax: 8922 7200 Email: poisonscontrol@nt.gov.au

This form relates only to applications for approval for variations to regular pharmacotherapy takeaway USD for stable patients on buprenorphine/naloxone (Suboxone) treatment.

Rationale

For safety reasons, opioid substitution therapy (OST) is based on the principle of supervised dosing with takeaway unsupervised doses (USD) as a privilege for a stable patient who has made significant progress in reducing or eliminating illicit opioid use, and to facilitate life activities such as employment or study.

NT legislation provides for patients on buprenorphine/naloxone OST on daily dosing to be prescribed takeaway USD up to a maximum of three per week, and on alternate daily dosing no more than one takeaway dose per week. This number can only be exceeded through application to the CLAC for special authorisation.

Clinical experience with buprenorphine/naloxone indicates greatly reduced potential for risks of self-administration by injection, diversion, overdose/death of the patient or others, with potential for more clients on buprenorphine/naloxone to safely be prescribed more takeaway USD. Stable patients on buprenorphine/naloxone may therefore graduate to dosing once a fortnight after a period of proven stability on OST.

In the case of continuing illicit cannabis use, increased takeaway USD may be considered to enable employment commitments. Extended Suboxone provisions however will be limited to one observed dose each week rather than one per fortnight.

DAILY DOSING: patients who demonstrate continuing long term stability may gradually increase prescribed takeaway USD to a maximum of 13/fortnight - i.e. attending the pharmacy or dosing point for dosing once a fortnight.

ALTERNATE DAY DOSING (includes 4 day a week dosing): patients who demonstrate continuing long term stability may gradually increase prescribed takeaway USD to a number that requires attendance at the pharmacy or dosing point for dosing once a fortnight.

Assessment

For authorisation of EACH takeaway USD increase by the CLAC, the following criteria **MUST** be confirmed by the applying prescriber on the application form overleaf. Where there is a variation from the criteria the applying doctor must attach a letter to justify their application in writing. The application should be faxed to 8922 7200 or emailed to poisonscontrol@nt.gov.au allowing at least 5 working days for approval

Clients must meet the following requirements:

- For clients on daily dosing, client has received the current number of takeaway USD for at least 4 weeks.
- For clients on alternate day dosing, client has received the current number of takeaway USD for at least 8 weeks.
- Since the previous takeaway USD increase, there is continued evidence of:
 - No injecting or using other opioids or illicit drugs
 - No unsanctioned benzodiazepines or stimulants
 - At least 2 Urine Drug Screens (USD) free of other opioids, unsanctioned psychoactive medication or illicit drugs
 - No problem with alcohol consumption
 - No diverted pharmacotherapy doses
 - No episodes of intoxication
 - No concern about behaviour, mood and social functioning
- Client has not missed more than 2 daily or 1 alternate day doses within the past 3 months.
- Client has continued stable on the pharmacotherapy program, is reliably keeping review appointments, and fulfils the conditions of any contract relating to management.
- Client has continued stable mental health, no physical health conditions or other medications reducing safety.
- Client has continued adequate safe packaging & storage arrangements for takeaway dose.

APPLICATION FOR VARIATION TO REGULAR OPIOID SUBSTITUTION THERAPY (OST) TAKEAWAY UNSUPERVISED DOSES (USD): BUPRENORPHINE/NALOXONE

Medicines & Poisons Control ~ Phone: 8922 7341 Fax: 8922 7200 Email: poisonscontrol@nt.gov.au

PATIENT DETAILS

Surname: Given Names:

Current Medication: Date of Birth: / / Sex: M ☐ F ☐

For this patient whom I have been treating with buprenorphine-naloxone since (Date of commencement) and who has been onmg daily/alternate daily since (Date of dose commencement), I confirm the following:

- Patient has been receiving (No. doses) number of takeaway doses since (Date of takeaway commencement)
- Since this date, there has been continued evidence of:
 - No injecting or using of opioids or illicit drugs.....
 - No unsanctioned benzodiazepines or stimulants
 - At least two consecutive Urine Drug Screens (UDS) are free of other opioids, unsanctioned psychoactive medications, or illicit drugs, or undeclared cannabis use
 - No problem with alcohol consumption.....
 - No episodes of intoxication
 - No diverted pharmacotherapy doses
 - No concern about behaviour, mood or social functioning
- Patient has not missed more than 2 daily or 1 alternate day doses within the past 3 months
- Patient keeps review appointments, fulfils conditions of any contract relating to management
- Patient has continuous stable mental health, with no physical health conditions or other medication that reduce safety.....
- Patient maintains safe storage for takeaway doses regarding children and other adults

AND, I consider that the patient can safely care for and use (No. doses) ... takeaway buprenorphine/naloxone buccal film doses of (Dose) mg daily / alternate daily on a regular basis.

PRESCRIBER DETAILS

Please Note: Nurse Practitioners must attach details of collaborative arrangement with Medical Practitioner.

Prescriber Name: Prescriber No.:

Practice Address:

Phone No.: Fax No.:

Prescriber Signature: Date Signed: / /

APPLICATION FOR VARIATION TO REGULAR OPIOID SUBSTITUTION THERAPY (OST) TAKEAWAY UNSUPERVISED DOSES (USD): METHADONE AND BUPRENORPHINE

Medicines & Poisons Control ~ Phone: 8922 7341 Fax: 8922 7200 Email: poisonscontrol@nt.gov.au

Rationale

For safety reasons, opioid substitution therapy (OST) is based on the principle of supervised dosing with takeaway unsupervised doses (USD) as a privilege for a stable patient who has made significant progress in reducing or eliminating illicit opioid use, and to facilitate life activities such as employment or study.

NT legislation provides for patients on buprenorphine/naloxone OST on daily dosing to be prescribed takeaway USD up to a maximum of three per week, and on alternate daily dosing no more than one takeaway dose per week. This number can only be exceeded through application to the CLAC for special authorisation.

Clinical experience with buprenorphine/naloxone indicates greatly reduced potential for risks of self-administration by injection, diversion, overdose/death of the patient or others, with potential for more clients on buprenorphine/naloxone to safely be prescribed more takeaway USDs. Stable patients on buprenorphine/naloxone may therefore graduate to dosing once a fortnight after a period of proven stability on OST.

In the case of continuing illicit cannabis use, increased takeaway USD may be considered to enable employment commitments. Extended Suboxone provisions however will be limited to one observed dose each week rather than one per fortnight.

DAILY DOSING: patients who demonstrate continuing long term stability may gradually increase prescribed takeaway USD to a maximum of 13 per fortnight - i.e. attending the pharmacy or dosing point for dosing once a fortnight.

ALTERNATE DAY DOSING (includes 4 days a week dosing): patients who demonstrate continuing long term stability may gradually increase prescribed takeaway USD to a number that requires attendance at the pharmacy or dosing point for dosing once a fortnight.

Assessment

For authorisation of EACH takeaway USD increase by the CLAC, the following criteria **MUST** be confirmed by the applying prescriber on the application form overleaf. Where there is a variation from the criteria the applying doctor must attach a letter to justify their application in writing. The application should be faxed to 8922 7200 or emailed to poisonscontrol@nt.gov.au allowing at least 5 working days for approval

Clients must meet the following requirements:

- For clients on daily dosing, client has received the current number of takeaway USD for at least 4 weeks.
- For clients on alternate day dosing, client has received the current number of takeaway USD for at least 8 weeks.
- Since the previous takeaway USD increase, there is continued evidence of:
 - No injecting or using other opioids or illicit drugs
 - No unsanctioned benzodiazepines or stimulants
 - At least 2 Urine Drug Screens (USD) free of other opioids, unsanctioned psychoactive medication or illicit drugs
 - No problem with alcohol consumption
 - No diverted pharmacotherapy doses
 - No episodes of intoxication
 - No concern about behaviour, mood and social functioning
- Client has not missed more than 2 daily or 1 alternate day doses within the past 3 months.
- Client has continued stable on the pharmacotherapy program, is reliably keeping review appointments, and fulfils the conditions of any contract relating to management.
- Client has continued stable mental health, no physical health conditions or other medications reducing safety.
- Client has continued adequate safe packaging & storage arrangements for takeaway dose.

APPLICATION FOR VARIATION TO REGULAR OPIOID SUBSTITUTION THERAPY (OST) TAKEAWAY UNSUPERVISED DOSES (USD): METHADONE AND BUPRENORPHINE

Medicines & Poisons Control ~ Phone: 8922 7341 Fax: 8922 7200 Email: poisonscontrol@nt.gov.au

PATIENT DETAILS

Surname: Given Names:

Current Medication: Date of Birth: / / Sex: M ☐ F ☐

For this patient whom I have been treating with since (Medicine) and who has been on mg (Date of commencement) daily/alternate daily since (Dose), I confirm the following: (Date of dose commencement)

- Patient has been receiving number of takeaway doses since (No. doses) (Date of takeaway commencement)
- Since this date, there has been continued evidence of:
 - No injecting or using of opioids or illicit drugs.....
 - No unsanctioned benzodiazepines or stimulants
 - At least two consecutive Urine Drug Screens (UDS) are free of other opioids, unsanctioned psychoactive medications, or illicit drugs, or undeclared cannabis use
 - No problem with alcohol consumption.....
 - No episodes of intoxication
 - No diverted pharmacotherapy doses
 - No concern about behaviour, mood or social functioning
- Patient has not missed more than 2 daily or 1 alternate day doses within the past 3 months
- Patient keeps review appointments, fulfils conditions of any contract relating to management
- Patient has continuous stable mental health, with no physical health conditions or other medication that reduce safety.....
- Patient maintains safe storage for takeaway doses regarding children and other adults

AND, I consider that the patient can safely care for and use (No. doses) takeaway (Medicine) doses of mg daily / alternate daily on a regular basis. (Dose)

PRESCRIBER DETAILS

Please Note: Nurse Practitioners must attach details of collaborative arrangement with Medical Practitioner.

Prescriber Name: Prescriber No.:

Practice Address:

Phone No.: Fax No.:

Prescriber Signature: Date Signed: / /

APPLICATIONS FOR OPIOID SUBSTITUTION THERAPY (OST) TAKEAWAY UNSUPERVISED DOSES (USD) FOR TRAVEL

Medicines & Poisons Control ~ Phone: 8922 7341 Fax: 8922 7200 Email: poisonscontrol@nt.gov.au

APPENDIX B

The CLAC may recommend approval of an application for takeaway USD above the regular takeaway allowance for stable patients for travel purposes, or for less stable patients in a crisis, if it is not possible or considered to be practical for a patient to be transferred to a local prescriber and/or dispensing pharmacy.

Other Australia Jurisdictions

Some Australia jurisdictions make legal provision for arrangements to be made for a limited period of dispensing on an NT OST prescription, including approval of a suitable takeaway USD regime. Advance notification, arrangements and/or paperwork is generally required, and prescribers must check with the relevant jurisdictional authority or authorities.

Please see the [Medicines & Poisons Control](#) website for a list of Interstate Health Department contact phone numbers.

NT CLAC Applications

Applications to the CLAC should be faxed to 8922 7200 or emailed to poisonscontrol@nt.gov.au allowing at least 5 working days for approval.

Applications are to be in writing. They should be signed by the prescriber, and provide the following information:

- Details of the prescriber: name; contact email/fax
- Details of the patient: name; DOB; address
- Details of patient's OST:
 - Medication name & dose
 - Current takeaway USD allowance & date since that allowance has been prescribed
 - Total period of time on the program/start date
- Details of planned travel:
 - Reason (e.g. work, holiday, visit family, family illness, crisis etc.)
 - Dates (may be approximate if final booking dependent on approval)
 - Destinations (e.g. NT town/area/aboriginal community; interstate town/area; overseas country/countries)
- Details of patient stability and safety:
 - Attach the form provided, with explanation of any areas unable to be confirmed
- Confirmation that the prescriber has sighted/will check any travel tickets/documentation (conditional approval can be granted subject to the prescriber sighting documentation)
- Any previous CLAC approval for such requests with safe outcome
 - Number of USD approved & date(s)
- An indication from the prescriber on the level of support from the prescriber for the application, or whether the prescriber is seeking advice from the CLAC at the request of the patient
- Any other information in support of the application