GUIDE TO POISONS AND THERAPEUTIC GOODS LEGISLATION FOR MEDICAL, NURSE AND MIDWIFE PRACTITIONERS AND DENTISTS

This Guide is a summary only and should be used in conjunction with the *Poisons and Therapeutic Goods Act 1966*, the *Poisons and Therapeutic Goods Regulation 2008* (available on the Internet at www.legislation.nsw.gov.au) and the NSW Poisons List.

Further information may be obtained from the Duty Pharmaceutical Officer, Pharmaceutical Services, via email: MOH-PharmaceuticalServices@health.nsw.gov.au, or via phone: (02) 9391 9944 or fax: (02) 9424 5860.

NOTE: In this guide **authorised practitioner** refers to: a medical practitioner; a dentist; a veterinary practitioner; a nurse practitioner; a midwife practitioner; an optometrist

NOTE: This guide was updated in November 2023 to reflect changes in policy relating to prescribing psychostimulant medicines for the treatment of ADHD. For more information see: https://www.health.nsw.gov.au/pharmaceutical/Pages/default.aspx

A more detailed review of the information in this guide is currently under development and will be published in 2024.

THE POISONS LIST

Schedules 1 to 10 of the current Poisons Standard published by the Commonwealth under the *Therapeutic Goods Act 1989* are adopted as the Poisons List in NSW (available at: http://www.tga.gov.au/publication/poisons-standard-susmp). Schedule 1 is intentionally blank.

The following is a summary of the nature of the substances in each schedule. The requirements for the storage, supply, labelling, recording, etc. for Schedule 4 and 8 substances are detailed later in this Guide.

Schedule 2 – Pharmacy medicine

Substances which are dangerous to life if misused or carelessly handled but which should be available to the public for therapeutic use or other purposes without undue restriction and may be supplied only by authorised practitioners, pharmacists or persons licensed as "Poisons Licence Holders".

Schedule 3 – Pharmacist only medicine

Substances which are for therapeutic use and:

(i) about which personal advice may be required by the user in respect of their dosage, frequency of administration and general toxicity;

(ii) with which excessive unsupervised medication is unlikely; or

(iii) which may be required for use urgently so that their supply only on the prescription of an authorised practitioner would be likely to cause hardship.

Schedule 3 substances may be supplied only by authorised practitioners or pharmacists. Where such substances are supplied by a pharmacist, they must be personally handed to the patient by the pharmacist and give the person an opportunity to seek advice as to the use of the substance. Other conditions apply to certain substances.

Schedule 4 – Prescription only medicines (Restricted Substances)

Referred to as Restricted Substances in NSW, the use or supply of which should be by or on the order of persons permitted by State or Territory legislation to prescribe (referred to as "authorised practitioners" in NSW) and should be available from a pharmacist on prescription.

Schedule 5 - Caution

Poisonous substances of a dangerous nature commonly used for domestic purposes which should be readily available to the public but which require caution in their handling, use and storage.

Schedule 6 - Poison

Substances with a moderate potential for causing harm, the extent of which can be reduced using distinctive packaging with strong warnings and safety directions on the label.

Schedule 7 – Dangerous poison

Substances of exceptional danger which require special precautions in their manufacture, packaging, storage and/or use. These poisons should be available only to specialised or authorised users who have the skills necessary to handle them safely. Special regulations restricting their availability, possession, storage or use may apply.

Schedule 8 - Controlled drug (Drugs of Addiction)

Substances which are addiction producing or potentially addiction producing. Possession, supply, prescribing and use are strictly limited.

Schedule 9 (Prohibited substance)

Substances which may be abused or misused and have no legitimate therapeutic use and are prohibited except for scientific research.

Schedule 10 Substances of such danger to health as to warrant prohibition of supply and use

Substances prohibited because of their known dangerous properties.

Other controls

Provision is also made for substances to be rigidly controlled by subjecting their use or supply to special authority.

The majority of preparations available only on medical, nurse practitioner or dental

authority fall into one of the following categories:

A. RESTRICTED SUBSTANCES (Schedule 4)

B. RESTRICTED SUBSTANCES ON SPECIAL AUTHORITY

C. DRUGS OF ADDICTION (Schedule 8)

A. RESTRICTED SUBSTANCES (Schedule 4)

A1. Acquisition

Restricted substances may be obtained by a medical practitioner, nurse or dentist:

(i) from a licensed wholesaler; or

(ii) from a pharmacy for emergency use on a signed and dated order (on the letterhead) of the medical practitioner, nurse practitioner or dentist.

A2. Storage

Must be stored in a part of the premises which is partitioned off or otherwise separated from the remainder of the premises and to which the public is not permitted to have access (e.g. a cupboard or drawer in a practice).

A3. Prescriptions

A prescription for a restricted substance is issued by an authorised prescriber. It is valid for 12 months from the date of writing, except in the case of a prescription for an Appendix D substance (see A7), which is valid for 6 months only.

Information on valid prescription formats including electronic prescribing and non-handwritten (computer generated), is available at:

https://www.health.nsw.gov.au/pharmaceutical/Pages/legal-form-prescription.aspx

A prescription must bear the following particulars:

(a) the date on which it is issued;

(b) the patient's name, date of birth and address;

(c) the name, strength and quantity of the restricted substance;

(d) the number of repeats if the prescription is to be dispensed more than once;

(e) in the case of prescriptions for anabolic/androgenic steroidal agents, amylobarbitone/pentobarbitone injections, the time interval between any repeat dispensing ordered.

(f) adequate directions for use; and

(g) the signature of the prescriber.

The prescription must also show:

- the prescriber's name and designation, and
- the address and telephone number of the premises or hospital where the prescription is issued

These particulars may be pre-printed.

A prescription written by a dentist must be endorsed with the words "For dental treatment only" and if written by an optometrist, the words “For optometrical treatment only".

Where, in the case of an emergency, a direction, either by telephone, email or facsimile, is given for the supply of a restricted substance, a prescription, endorsed with “emergency prescription under clause 36” or words that that effect, must be written within 24 hours and forwarded within 7 days to the pharmacist.

Where a prescriber wishes to exercise some control over the frequency at which repeats on a prescription are dispensed, an interval between repeat dispensing, even when this is not obligatory, may be written on the prescription, e.g. repeat twice at 10 day intervals. There is then an obligation on the pharmacist dispensing a repeat to ensure that at least that period of time has elapsed since the prescription was last dispensed.

It should be noted that all prescriptions for anabolic/androgenic steroidal agents and amylobarbitone/pentobarbitone injections must be retained at the pharmacy dispensing the original prescription. Where repeats are ordered, the patient will therefore be required to return to the pharmacy at which the prescription was originally dispensed to obtain the repeats.

A4 Prescribing on a medication chart for residential care facility patients

A chart compliant with the format of the National Residential Medication Chart and the Commonwealth *National Health (Residential Medication Chart) Determination 2012*, hereinafter called a “compliant RMC”, can be used in NSW Residential Care Facilities (RCFs).

Compliant RMCs permit both the prescribing and dispensing of Pharmaceutical Benefits Scheme (PBS) medications and non-PBS medications, with some exceptions.

In NSW, only a medical practitioner may use a compliant RMC to prescribe unscheduled, Schedule 2, Schedule 3 and most Schedule 4 medications.

A compliant RMC does NOT constitute a legal prescription for the following medications:

- Schedule 8 medications,
- anabolic-androgenic steroids,
- amylobarbitone or pentobarbitone injections, and
- clomiphene, cyclofenil, dinoprost, dinoprostone, acitretin, etretinate, or isotretinoin.

Schedule 8 medications and the above Schedule 4 medications may only be prescribed and will only be accepted for dispensing by pharmacists, on the presentation of a valid prescription (see Sections A3, A7 and C4 in this Guide) and Supply of prescription medicines (see https://www.health.nsw.gov.au/pharmaceutical/Pages/legal-form-

prescription.aspx).

A compliant RMC is valid as a prescription for dispensing only when: -

a) The duplicate copy is complete, clear and legible, and
b) The resident's name and address are included, and
c) The name, address and telephone number of the RCF are included, and
d) The prescriber's name and designation are included, and
e) The medication is ordered only by a medical practitioner, and
f) The order is for an unscheduled, Schedule 2, Schedule 3 or Schedule 4 medication, other than

- anabolic-androgenic steroids, or
- amylobarbitone or pentobarbitone injections, or
- clomiphene, cyclofenil, dinoprost, dinoprostone, acitretin, etretinate, or isotretinoin, and

g) The relevant 'Medicine' order section of the compliant RMC has been handwritten by the medical practitioner with:

(i) The date of prescribing, and
(ii) The name and form (if not readily apparent) of the medication, and
(iii) The strength (if not readily apparent) of the medication, and
(iv) The route of administration (if not readily apparent) of the medication, and
(v) Adequate directions for use (Note: This may include a dose with the daily frequency, or the times during the day, for administration of the medication), and
(vi) The period during which the medication is be used or administered, being a period that ends on a date that is no more than 4 months from the date of first use of the relevant compliant RMC for the patient (Note: This may be achieved with a start date and stop date for the administration of the medication), and
(vii) The prescriber's name and signature.

Further information about compliant RMCs is available from the Australian Commission on Safety and Quality in Health Care, which has published guidance material at https://www.safetyandquality.gov.au/our-work/medication-safety/national-residential-medication-chart and includes the 'NRMC guidelines for prescribers' https://www.safetyandquality.gov.au/publications-and-resources/resource-library/national-residential-medication-chart-user-guide-prescribers

A5. Prescribing and Supply to be within Therapeutic Standards.

A medical practitioner, nurse practitioner or dentist must not issue a prescription for, or supply, a restricted substance in a quantity, or for a purpose, that does not accord with recognised therapeutic standards of what is appropriate in the circumstances.

A6. Supply.

Where a medical practitioner, nurse practitioner or dentist supplies a restricted substance, including clinical samples, a record must be made showing:

(a) the date on which the medicine was supplied;

(b) the name, date of birth and address of the patient; and

(c) the name, strength and quantity of the restricted substance supplied.

This record must be kept at the prescriber's practice, office or hospital and be made available for inspection if required.

The label on the container of any restricted substance supplied must include:

(a) the words "KEEP OUT OF REACH OF CHILDREN" in red on a white background;

(b) where the medicine is for external use, the word "POISON" or the words "FOR EXTERNAL USE" in red on a white background;

(c) the approved name, strength and quantity of the medicine and (unless the medicine is a preparation compounded extemporaneously to the prescriber's own formula) its proprietary name also;

(d) adequate directions for use, which should be as explicit as possible;

(e) the patient's name;

(f) the name and address of the medical practitioner, nurse practitioner, or dentist; and

(g) any necessary or appropriate warnings about the risk of impairment of driving ability or the concurrent consumption of alcohol associated with the medicine.

A7. Appendix D Substances.

For a detailed guide to Schedule 4 Appendix D drugs known in NSW as prescribed restricted substances, including a full list of the substances, please visit:

https://www.health.nsw.gov.au/pharmaceutical/Pages/sch4d.aspx

Some restricted substances which may be liable for misuse or abuse or cause dependence are listed in Appendix D of the *Poisons and Therapeutic Goods Regulation 2008*. A medical practitioner, nurse practitioner or dentist must immediately report the loss or theft of an Appendix D substance to Pharmaceutical Services by completing the online 'Notification of Loss or Theft of Accountable Drugs (S8 and S4D substances)' located on the Internet at:

http://www.health.nsw.gov.au/pharmaceutical/Pages/lost-stolen-drugs.aspx

and, in the case of theft, to the Police.

There is an obligation on a patient requesting a medical practitioner, nurse practitioner or dentist to supply or prescribe an Appendix D substance, to disclose the amount of that substance or any other Appendix D substance(s) that they have been prescribed or supplied with over the last 2 months. **When such a request is made, if the information is not voluntarily disclosed by the patient, it is**

appropriate to ask them directly and, in any case, record the response on the patient's file. Safescript NSW may also be accessed by the health practitioner to view the patient's prescribed and dispensed monitored medicines to guide the appropriate management of the patient.

Each time a medical practitioner, nurse practitioner, or dentist prescribes an Appendix D substance they must make a record of:

- the date of the prescription
- the patient's name, date of birth and address
- the name, strength and quantity of the substance
- the number of repeats (if any) and repeat intervals, see A3(e)
- the directions for use (as written on the prescription)

This record, which would normally be made in the patient's file, must be kept at the prescriber's surgery, office or hospital and made available for inspection if required.

Unauthorised possession of an Appendix D substance is an offence.

Persons authorised to have possession of Appendix D substances include "authorised practitioners", pharmacists, a nurse in charge of a ward in a public hospital, licensed wholesalers and a person for whom a prescription for that substance has been issued by an "authorised practitioner".

B. RESTRICTED SUBSTANCES ON SPECIAL AUTHORITY

The substances listed below may be prescribed only by medical practitioners having the prior authority of the NSW Ministry of Health. However, certain specialist medical practitioners are authorised under a class authority (see https://www.health.nsw.gov.au/pharmaceutical/Documents/authority-certainrestrictedsubstances-class.PDF) to prescribe the following drugs for any of their patients.

The drugs concerned and a summary of the specialities authorised are:

- **acitretin, etretinate, isotretinoin for oral use** - A medical practitioner registered in the specialty of dermatology
- **clomiphene, cyclofenil** - A medical practitioner registered in the specialty of obstetrics and gynaecology or physician in the field of specialty practice of endocrinology
- **dinoprost, dinoprostone** - A medical practitioner registered in the specialty of obstetrics and gynaecology

○ **follitropin beta, luteinising hormone, urofollitropin (human FSH)**	-	A medical practitioner registered in the specialty of obstetrics and gynaecology or physician in the field of specialty practice of endocrinology.
○ **tretinoin for oral use**	-	A medical practitioner registered in the specialty of dermatology or physician in the field of specialty practice of haematology
○ **hydroxychloroquine**	-	A medical practitioner registered in the specialty of: dermatology, intensive care medicine, paediatrics and child health, emergency medicine, or a medical practitioner practicing in a public hospital A medical practitioner practicing in general practice for the purpose of continuing treatment initiated by a physician listed in above point. A dentist registered in the specialty of oral medicine.

The medical practitioner must indicate clearly on the prescription:

- their qualification, and
- the words "ISSUED UNDER CLAUSE 37 OF THE POISONS AND THERAPEUTIC GOODS REGULATION 2008" or words to that effect (for example "Clause 37").

Practitioners, who were previously individually authorised, may continue to use their current CL….., RA……, (as the case may be) endorsement in lieu of the above.

C. DRUGS OF ADDICTION (Schedule 8)

C1. Acquisition.

Drugs of addiction may be obtained by a medical practitioner, nurse practitioner or dentist:

(i) from a licensed manufacturer or wholesaler on a signed and dated order (on the letterhead) of the medical practitioner, nurse practitioner or dentist;

(ii) from a pharmacy for emergency use on a signed and dated order (on the letterhead) of the medical practitioner, nurse practitioner or dentist.

C2. Storage.

Must be kept apart from all other goods (other than cash or documents) in a safe,

cupboard, or drawer in a cabinet, which is **securely attached to a part of the premises** and which is **kept locked** when the drugs are not in immediate use. Emergency supplies may be carried in a bag, provided the bag is left in a locked room, locked cupboard, or locked vehicle when not in immediate use. A room etc. is not "locked" if the key is left in the lock or is otherwise readily accessible to anybody.

For storage of S8 medicines requiring refrigeration see https://www.health.nsw.gov.au/pharmaceutical/Pages/refrigeration-s8s.aspx

C3. Accountability.

A RECORD MUST BE MADE IN A DRUG REGISTER OF ALL DRUGS OF ADDICTION OBTAINED, SUPPLIED OR ADMINISTERED, irrespective of whether such drugs were obtained from a wholesaler, or from a pharmacist on an order for emergency use, or on a prescription written for a patient and held by the medical practitioner, nurse practitioner or dentist on behalf of the patient.

The record must be entered in the register in ink on the day on which the transaction takes place. A separate page must be used for each kind of drug of addiction and for each strength of the drug. No alteration may be made in the register, but any mistake may be corrected by a marginal or footnote, initialled and dated. The register must be kept on the premises in which the drugs of addiction are stored, it must be retained for a period of two years from the date of the last entry and made available for inspection if required. Details to be entered include:

(i) the date of the entry;

(ii) the name and address of the supplier (in the case of receipt) or the patient (in the case of administration or supply);

(iii) the quantity received, supplied or administered and the balance held after the transaction; and

(iv) the signature of the medical practitioner/nurse practitioner/dentist.

A drug register may be purchased from Finsbury Green (email: nswhealth@finsbury.com.au).
Alternatively, a bound exercise book in which the pages are numbered consecutively and which has columns ruled as shown below, could be used. Each preparation of a drug of addiction and each strength must be listed on a separate page.

Drug Name, Form and Strength .....

DATE	NAME & ADDRESS OF PERSON SUPPLIED OR FROM WHOM RECEIVED	QTY IN	QTY OUT	BALANCE	NAME OF AUTHORITY	SIGNATURE OF PERSON PRESCRIBING, SUPPLYING OR ADMINISTERING

For information on electronic drug registers see: https://www.health.nsw.gov.au/pharmaceutical/Pages/electronic-drug-register.aspx

Twice a year, during **March and September**, every person who is required to keep a drug register must carry out a **full stock check** of all drugs of addiction in their possession. Immediately under the last entry for each drug, they should write the date on which the check was done, the words "Balance on hand", the quantity actually held, and they should sign the entry. Any person who assumes control of a practice for one month or more should immediately perform a similar stock check irrespective of the time of year.

If **a drug register is lost or destroyed**, the medical practitioner, nurse practitioner, or dentist must immediately notify the Ministry of Health **in writing** of the fact and of the circumstances. The notification should be sent by email to MOH-PharmaceuticalServices@health.nsw.gov.au or sent by mail, addressed to:

Director
Pharmaceutical Services Unit
NSW Ministry of Health
Locked Mail Bag 2030
St Leonards NSW 1590

or may be faxed to (02) 9424 5860.

For advice, telephone the Duty Pharmaceutical Officer on (02) 9391 9944.

A drug register must be kept for 2 years from the date of the last entry made in it.

If a medical practitioner, nurse practitioner, or dentist **loses (or has stolen from them)** a drug of addiction, they must immediately notify Pharmaceutical Services by completing the online 'Notification of Loss or Theft of Accountable Drugs (S8 and S4D substances)' located at:

http://www.health.nsw.gov.au/pharmaceutical/Pages/lost-stolen-drugs.aspx

and enter the relevant details in the drug register.

The police should also be notified where theft has occurred.

C4. Prescriptions

A prescription for the supply of a drug of addiction may be issued:

(i) by a medical practitioner or a nurse practitioner only for use in the course of medical treatment; **or**

(ii) by a dentist for use in the course of dental treatment for a period not exceeding one month's continuous treatment of a patient

(a) in a hospital, with any drug of addiction; or

(b) not in a hospital, with only pentazocine or any drug of addiction appearing at that time on the list of preparations in the current Schedule of Pharmaceutical Benefits, issued by the Commonwealth Department of Health, which may be prescribed by dentists.

A prescription for a drug of addiction written by a medical practitioner, nurse practitioner, or dentist is **valid for a maximum of 6 months** from the date of writing, even if repeats are ordered.

There are a range of prescription formats available. Refer to Supply of prescription medicines (see https://www.health.nsw.gov.au/pharmaceutical/Pages/legal-form-prescription.aspx) for more information

A prescription must include:

(a) the date on which it was written;

(b) the patient's name, date of birth and address;

(c) the name and strength of the drug of addiction;

(d) the quantity to be dispensed, **in both words and figures**;

(e) if the prescription is to be dispensed more than once, the number of repeats and the minimum time **interval** between repeat dispensing;

(f) **adequate** directions for use; and

(g) the signature of the prescriber.

Handwritten prescriptions must include (a) – (g) in ink in the prescriber's legible handwriting.

For **computer generated prescriptions** the details (c) - (g) above **must also** be handwritten by the prescriber. Where the prescription is in duplicate, the handwritten part must be on the duplicate copy, to be retained by the pharmacist. For more information see Criteria for Issuing Non-Handwritten (Computer-Generated) Prescriptions (TG 184) at https://www.health.nsw.gov.au/pharmaceutical/Documents/prescriptions-nonhandwritten.pdf.

For **electronic conformant prescriptions** see Electronic prescribing - , see Information for community pharmacists (https://www.health.nsw.gov.au/pharmaceutical/Pages/electronic-prescribing.aspx#bookmark4

The prescription must show the prescriber's name and designation and the address and telephone number of the practice (or if issued at a hospital, the name, address and telephone number of the hospital). These particulars may be pre-printed.

A prescription written by a dentist must be endorsed with the words “For dental treatment only” which may be pre-printed on the form.

A separate prescription form is required for **each** preparation containing a drug of addiction. **No other item** may be written on the **same** form (including no other preparation containing a drug of addiction).

A medical practitioner, nurse practitioner or dentist must confirm any dose of a drug of addiction that could be regarded as being **dangerous or unusual** by

underlining the dose and initialling in the margin on a paper based prescription.

For electronic conformant prescriptions, prescribers do not need to comply with the following paper prescription requirements:

- any handwriting and hand signature on the prescription,
- underlining and initialling of any dose that could be regarded as dangerous or unusual,
- include the quantity to be dispensed written in words as well as figures.

Each time a medical practitioner, nurse practitioner, or dentist prescribes a drug of addiction**,** they must **make a record** (in the patient's file kept at the practice, office or hospital) of:

- date of the prescription
- patient's name, date of birth and address
- drug name, strength and quantity
- number of repeats (if any) and intervals, and
- directions for use, as written on the prescription

Where, in the case of **an emergency**, a medical practitioner, nurse practitioner, or dentist directs the supply of a drug of addiction either by telephone, electronic mail message or facsimile, a prescription, endorsed to show that it is issued as confirmation of such a direction, must be written forthwith and forwarded to the pharmacist within 24 hours. (Note: A facsimile or electronic mail message still has to be followed up by a prescription).

With the exception of electronic conformant prescriptions, prescriptions for which repeats are ordered must be **retained at the pharmacy** dispensing the original prescription. Patients who require repeat dispensing, where ordered, will therefore be required to return to the pharmacy at which the prescription was originally dispensed.

PRESCRIPTION PADS AND STATIONERY FOR COMPUTER GENERATED PRESCRIPTIONS ARE FREQUENTLY STOLEN. It is advisable to have only one pad and limited stationery in use at any time and to **keep the remainder in a locked cupboard**. If a loss is discovered or forgeries are detected, the police should be notified immediately. Arrangements can be made to alert pharmacists by completing the online 'Notification of Lost, Stolen, or Forged Prescription' located at:

http://www.health.nsw.gov.au/pharmaceutical/Documents/notification-form.pdf

NOTE: It is obligatory under the Poisons and Therapeutic Goods Regulation 2008 for a pharmacist to contact the prescriber to confirm the validity of a prescription for any drug of addiction unless the pharmacist knows the patient or is familiar with the prescriber's handwriting or the prescription is in an electronic conformant format. Prescribers may therefore expect phone calls from pharmacists carrying out their obligations in this regard or **in relation to paper prescriptions whose validity is otherwise doubtful.**

C5. Prescribing and Supply to be within Therapeutic Standards

A medical practitioner, nurse practitioner, or dentist must not issue a prescription for, or supply, a drug of addiction in a quantity, or for a purpose, that does not accord with recognised therapeutic standards of what is appropriate in the circumstances.

C6 Authority Requirements

An authority that is required under the provisions of the *Poisons and Therapeutic Goods Act 1966* is distinct from, and independent of, any authority under the Pharmaceutical Benefits Scheme which is only for the subsidy of the cost of the medication to the patient.

An authority is required to prescribe or supply a drug of addiction under the NSW Poisons and Therapeutic Goods legislation, **only in** the circumstances described below.

(i) The Treatment of Drug Dependent Persons

A drug dependent person* may **not** be supplied with any drug of addiction or a prescription for a drug of addiction without the **prior written authority** of the NSW Ministry of Health, except for treatment of the person as an in-patient in a hospital for a period not exceeding 14 consecutive days following admission.

Defined under section 27 of *Poisons and Therapeutic Good Act 1966, a* **drug dependent person** means a person who has acquired, as a result of repeated administration of:
(a) a drug of addiction, or
(b) a prohibited drug within the meaning of the *Drug Misuse and Trafficking Act 1985*
an overwhelming desire for the continued administration of such a drug.

(ii) The Treatment of Non - Drug Dependent Persons

An **authority** from the NSW Ministry of Health is required in the following situations:

- To prescribe or supply any of the following drugs of addiction for continuous or ongoing treatment of more than 2 months:
    - any drug of addiction intended for administration by injection
    - any drug of addiction for inhalation, or for spray or application to mucous membranes
    - alprazolam

- flunitrazepam
- dextromoramide
- buprenorphine (except transdermal preparations)
- hydromorphone
- methadone

- Before prescribing:
    - *psychostimulants such as dexamfetamine, methylphenidate, and lisdexamfetamine
    - any compounded S8 drug
    - psilocybine
    - MDMA

*Psychiatrists, paediatricians and neurologists are authorised under a class authority from NSW Health to prescribe or supply psychostimulant medication to a non-drug dependent person for the treatment of ADHD up to a maximum daily dose of:

- dexamfetamine 50mg
- lisdexamfetamine 70mg
- methylphenidate 108mg

See also Prescribe a psychostimulant medication at https://www.health.nsw.gov.au/pharmaceutical/doctors/Pages/prescribe-psychostimulant.aspx

How to apply for an Authority to prescribe or supply a Schedule 8 (drug of addiction)

Psychostimulant medications

Applications for an authority to prescribe or supply a psychostimulant medication should be submitted via SafeScript NSW (https://www.safescript.health.nsw.gov.au/health-practitioners). If unable to access SafeScript NSW you can submit an Application for authority to prescribe or supply a S8 psychostimulant (see: https://www.health.nsw.gov.au/pharmaceutical/doctors/pages/application-forms.aspx) to NSW Health.

Applications via the SafeScript NSW portal allows prescribers to receive instant approvals in many cases and monitor their application progress.

Application forms to prescribe other S8 medications

Application forms are specific to the drug and indication.

Some Schedule 8 medications can only be prescribed by a specialist or by a general practitioner under shared care arrangements. Refer to the application form for any required supporting documentation.

For further information see NSW Health – Application Forms for Authority to Prescribe or Supply, or contact the Approvals Management Section, Pharmaceutical Services at email: MOH-S8Auth@health.nsw.gov.au or during office hours on (02) 9424 5923.

(iii) Psychostimulants (dexamfetamine, lisdexamfetamine and methylphenidate)

For further information see Prescribe a psychostimulant medicine at https://www.health.nsw.gov.au/pharmaceutical/doctors/Pages/prescribe-psychostimulant.aspx

The psychostimulant medicines dexamfetamine, lisdexamfetamine, and methylphenidate may be prescribed only:

(1) by psychiatrists, paediatricians and neurologists who are authorised under a class authority from NSW Health to prescribe or supply psychostimulant medication for the treatment of ADHD in a non-drug dependent person. The class authority can be used to prescribe up to a maximum daily dose of:

- dexamfetamine 50mg
- lisdexamfetamine 70mg
- methylphenidate 108mg

(2) by all other prescribers, or by psychiatrists, paediatricians and neurologists for an indication other than ADHD, or for drug dependent patients with the **prior authority** of the NSW Ministry of Health, issued following receipt of a written application. Applications can be made online via SafeScript NSW (see https://hp.safescript.health.nsw.gov.au/) or via submission of an application form to NSW Health, see https://www.health.nsw.gov.au/pharmaceutical/doctors/pages/application-forms.aspx

All prescriptions for psychostimulants must be endorsed with one of the following:

- CA2023 – for use by psychiatrists, paediatricians and neurologists prescribing under the conditions of the class authority (https://www.health.nsw.gov.au/pharmaceutical/Documents/authority-class-of-persons.pdf) .
- A^{xxxxxxx} OR AU^{xxxxxxx} - unique number that may be specific for a prescriber OR specific for a patient
- CNS^{xxxxxxx} OR S28c^{xxxxxxx} - unique prescriber approval previously issued to a prescriber by the Ministry of Health)**

* This authority/approval is distinct from, and independent of, any authority from Services Australia, which is for the purpose of subsidising the cost of medicines for patients under the Pharmaceutical Benefits Scheme (PBS). For more information see Authority PBS Prescription.

** From 13 November 2023, CNS or S28C authority holders that are:

- psychiatrists, paediatricians, or neurologists must start using the class authority

where applicable or otherwise apply for individual patient approval

- medical practitioners who have been issued an alternative authority with reference number prefix "A^{xxxxxxx}", must start using this number to endorse prescriptions for psychostimulants. The conditions stated in that authority must be followed.

NOTE: Current prescriptions endorsed with reference number “CNS" or “S28c" will remain valid for dispensing until 30 June 2024, unless expired.

Prescribers are reminded that a prescription for the above drugs cannot be dispensed by a pharmacist unless the prescription is endorsed with one of these numbers. These requirements apply to all prescriptions for psychostimulants irrespective of whether they are PBS or non-PBS (private) prescriptions.

(iv) Unregistered Schedule 8 medicines

Unregistered medicines are not assessed for quality, safety or efficacy by the Therapeutic Goods Administration (TGA). To prescribe an unregistered medicine in Australia, a prescriber must obtain an approval to supply an unregistered good issued by the TGA under the Commonwealth’s *Therapeutic Goods Act 1989* under the:

- Special Access Scheme, or
- Authorised Prescriber Scheme, or
- Clinical Trial Schemes.

Under the NSW *Poisons and Therapeutic Goods Act 1966*, an authority (NSW authority) is required to prescribe and supply an unregistered Schedule 8 medicine:

- to a drug dependent person (see section C.1)
- that is a compounded medicine, or
- for a clinical trial.

Please contact the Approvals Management Section, Pharmaceutical Services on (02) 9424 5921 (for methadone or buprenorphine under the NSW Opioid Treatment Program) or (02) 9424 5923 (for other drugs of addiction) for clarification of any authority requirements.

C7. Possession. Unauthorised possession of a drug of addiction is an offence.

Medical practitioners, nurse practitioners and dentists are authorised to be in possession of drugs of addiction for use in connection with their profession.

A person for whom a prescription for a drug of addiction has been issued by a medical practitioner, nurse practitioner, or dentist is also authorised to have possession to the extent covered by the prescription(s).

C8. Destruction.

A drug of addiction in the possession of a medical practitioner, nurse practitioner or dentist for use in connection with their profession and which has become unusable, may legally be destroyed:

(i) by a community (retail) pharmacist (in the presence of the medical practitioner,

nurse practitioner, or dentist ("practitioner"), either at the pharmacy or the practitioner's practice premises) who must record the destruction in the practitioner's drug register. The entry must show the date, the name, professional registration number and signature of the pharmacist and the name and signature of the practitioner, or

(ii) by or under the direct personal supervision of a police officer, or by a person authorised by the NSW Ministry of Health to do so.

C9. **Self-Administration of Drugs of Addiction.** A medical practitioner or dentist may not self-administer a drug of addiction other than for the **purpose of medical or dental treatment**, respectively and only for a period of **not more than 7 days** (unless they hold an authority to do so from the NSW Ministry of Health or it is prescribed for them by another practitioner).

FURTHER INFORMATION

Further information may be obtained at http://www.health.nsw.gov.au/pharmaceutical. Further queries can be directed to email MOH-PharmaceuticalServices@health.nsw.gov.au, or by contacting the Duty Pharmaceutical Officer during office hours on (02) 9391 9944.

This document has been produced by:

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