OTP Standards

NSW Opioid Treatment Program

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Introduction

The OTP Standards outline the minimum expectations and rules for persons and services providing opioid dependence treatment under the Opioid Treatment Program (OTP). Compliance to the OTP Standards is required under the *Medicines, Poisons and Therapeutic Goods Regulation 2026* (the Regulation).

All health practitioners and staff providing opioid dependence treatment (ODT) are responsible for ensuring they understand the expectations outlined in these standards and current clinical practice guides.

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Glossary of terms

These definitions apply to each section of the OTP Standards for:

Medical Practitioners and Nurse Practitioners providing treatment under the OTP

Pharmacists practising at community pharmacy dosing points

Health Practitioners and other persons at dosing points other than community pharmacy

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Accredited OTP prescriber – A medical practitioner or nurse practitioner who has completed the opioid treatment accreditation course (OTAC) and clinical skills assessment as determined by the NSW Ministry of Health Opioid Pharmacotherapy Accreditation Committee (OPAC).

Addiction medicine specialist – A medical practitioner who holds specialist registration in addiction medicine with the Medical Board of Australia.

Addiction psychiatrist – A medical practitioner who holds specialist registration in psychiatry with the Medical Board of Australia and a Certificate of Advanced Training in Addiction Psychiatry from the Royal Australian and New Zealand College of Psychiatrists.

Bridging – Administration of oxycodone for a limited number of days, as a method of transferring treatment from methadone to buprenorphine in accordance with the NSW Health approved protocol.

Continue treatment – prescribing, supplying or administering to a patient who has been initiated and has reached a stable treatment phase or maintenance dose.

Drug register – a record book that complies with the Regulation, or an electronic form that complies with the Electronic Drug Register Standards.

- **Subsidiary drug register (paper form)** – A bound book which records observed doses and takeaway doses of methadone or buprenorphine supplied to patients, where the total quantity supplied to each patient on any given day is transferred to the drug register daily.

Health Secretary Approval – The Secretary of NSW Health or delegate may issue approvals under the Act and Regulation to prescribe, supply or administer non-standard opioid dependence treatment.

High dose treatment – Treatment with doses above the maximum doses listed below. These do not represent a clinically recommended maximum dose.

i. Methadone 200mg daily

ii. Sublingual buprenorphine 32mg daily

Initiate treatment – commencing treatment for a person not currently being prescribed, supplied or administered opioid dependence treatment. This includes re-initiation if a patient has had a lapse in continuous treatment, requiring dose titration to achieve a stable maintenance dose.

Maintenance / stabilised treatment – ongoing treatment with a medicine, formulation and dose that is effectively managing opioid dependence.

Microdosing – Administration of gradually reducing methadone doses as buprenorphine doses are gradually increased, as a method of transferring treatment from methadone to buprenorphine in accordance with NSW Health approved protocol.

Nominated dosing point – registered pharmacy or other dosing point nominated to provide dosing under the OTP for a person participating in the OTP, as recorded in SafeScript NSW.

Notification – Advice to Pharmaceutical Services Unit of an OTP Registered Prescriber's intent to prescribe, supply or administer medicines under the OTP to an identified individual patient.

ODT dosing software – purpose-built software that supports the administrative and regulatory compliance for pharmacies providing supervised administration services and incorporates a drug

register. Examples include iDose, MethDA, StrongRoom ER, Autodose.

Opioid dependence treatment (ODT) – clinical treatments that may be provided for opioid dependence. This includes both medications (i.e. methadone and buprenorphine) and psychosocial interventions.

Opioid Pharmacotherapy Accreditation Committee (OPAC) – the Committee which assesses and makes decisions on applications for accreditation of medical and nurse practitioners seeking to supply, administer or issue a prescription for buprenorphine or methadone under the OTP. The Committee also provides advice to the Secretary as requested and reports to the Centre for Alcohol and Other Drugs, NSW Ministry of Health.

Original practitioner- has the same meaning as in the Medicines, Poisons and Therapeutic Goods Regulation 2026, being a medical practitioner or nurse practitioner who has an OTP registration and is temporarily unavailable.

OTP clinic - has the same meaning as in the *Medicines, Poisons and Therapeutic Goods* Regulation 2026, and may be either a public OTP clinic or a private OTP clinic.

OTP clinic obtain licence – a licence held by a private OTP clinic for the purpose of obtaining medicines for treatment of patients under the NSW OTP.

OTP Registered Prescriber – medical practitioner or nurse practitioner registered to prescribe, supply or administer medicines under the OTP. Note: all prescribers, whether unaccredited, accredited or specialists must be OTP Registered Prescribers to prescribe, supply or administer medicines for the ODT to a patient under the OTP.

Public OTP clinic – A drug and alcohol treatment service providing ODT controlled by a public health entity as defined in the *Medicines, Poisons and Therapeutic Goods* Act 2022.

Private health facility – means a private health facility licensed under the *Private Health Facilities Act 2007*.

Registration – Initial advice to the Pharmaceutical Services Unit of the intent to prescribe, supply or administer medicines under the OTP by a prescriber or dosing point. Application for OTP registration occurs automatically when a medical practitioner or nurse practitioner makes their first notification.

Replacement practitioner- has the same meaning as in the *Medicines, Poisons and Therapeutic Goods Regulation 2026*, being a practitioner who either practises at the same practice or premises as the original practitioner or is nominated by the original practitioner to carry out the activity.

Takeaway doses – Doses that have been dispensed to a patient to take home and use as directed without being supervised by a clinician. May also be referred to as unsupervised doses.

Treatment – means the prescribing, supply or administration of methadone or buprenorphine for the treatment of opioid dependence under the OTP.

Unaccredited OTP prescriber – A medical practitioner or nurse practitioner where prescribing, supplying or administering Schedule 8 substances is within their scope of practice but who has not completed the opioid treatment accreditation course (OTAC) and clinical skills assessment as determined by the NSW Ministry of Health Opioid Pharmacotherapy Accreditation Committee (OPAC).

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Standards for Medical Practitioners and Nurse Practitioners providing treatment under the OTP

Standards for Medical Practitioners & Nurse Practitioners to treat OTP patients

Under the *Medicines, Poisons and Therapeutic Goods Regulation 2026*:

- a medical practitioner or nurse practitioner who supplies, administers or issues a prescription for buprenorphine or methadone under an OTP registration must carry out the activity in compliance with the OTP Standards
- a medical practitioner or nurse practitioner who supplies, administers or issues a prescription for which an OTP registration is exempted, must supply, administer or issue a prescription in compliance with the provisions of the OTP standards specified in the OTP standards as applying to them.

Unaccredited Medical Practitioners and Nurse Practitioners

1. An unaccredited medical practitioner or nurse practitioner can provide treatment under an OTP Registration for a maximum of 100 patients at any one time, with no more than 10 of these patients receiving methadone.
2. An unaccredited medical practitioner or nurse practitioner must not*:
    a. initiate treatment with methadone under the OTP
    b. initiate treatment under the OTP for a patient under the age of 18 years
    c. initiate treatment under the OTP for a pregnant patient
    d. initiate high dose treatment
    e. transfer a patient from methadone to buprenorphine
    f. supply, administer or issue prescriptions for any other medicine other than methadone and buprenorphine under the OTP.

*in the above situations, patient care should be referred to an addiction medicine specialist, addiction psychiatrist, accredited medical practitioner or accredited nurse practitioner. For (a), (b), (c), and (d) initiation is not allowed; however, continuing treatment following initiation and transfer of care from an accredited prescriber is allowed. For (d) Secretary approval is required to continue treatment.

Accredited Medical Practitioners and Nurse Practitioners

3. All medical practitioners and nurse practitioners working in a public OTP clinic are required to be accredited or working towards accreditation, and can provide treatment under the OTP for a number of patients determined by their local health district's and/or specialty health network's clinical governance framework.
4. An accredited medical practitioner or nurse practitioner working in settings other than a public OTP clinic may provide treatment under the OTP for methadone or buprenorphine for up to a maximum of 250 patients in total.
5. A registrar (trainee) practising under the supervision of an accredited medical practitioner or addiction medicine specialist may only provide treatment under the OTP for methadone or buprenorphine for up to a maximum of 125 patients in total.
6. An accredited medical practitioner or nurse practitioner may transfer a patient from methadone to buprenorphine using the microdosing or bridging methods as outlined in the *Transferring from methadone to buprenorphine: consensus guidance.*
7. An accredited medical practitioner or nurse practitioner must obtain a written second opinion or a documented clinical handover from an Addiction Medicine Specialist or an Addiction Psychiatrist to:

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a. Provide treatment under the OTP for a patient under 18 years of age.

b. Provide treatment under the OTP with a medicine other than buprenorphine or methadone for the OTP, unless for the purpose of bridging.

c. Provide treatment under the OTP with methadone or buprenorphine at high doses.

Addiction Medicine Specialists and Addiction Psychiatrists

8. Addiction Medicine Specialists and Addiction Psychiatrists working in a public OTP clinic or a correctional facility in NSW can provide treatment under the OTP for methadone and buprenorphine for a number of patients determined by their local health districts and/or speciality health network clinical governance frameworks.
9. Addiction Medicine Specialists and Addiction Psychiatrists working in settings other than a public OTP clinic may only supply, administer or issue prescriptions under the OTP for methadone or buprenorphine for up to a maximum of 250 patients in total.
10. Addiction Medicine Specialists and Addiction Psychiatrists initiating treatment under the OTP for medicines other than buprenorphine and methadone for the treatment of opioid dependence** may transfer care to another prescriber with a written clinical handover to support safe ongoing care.
11. Addiction Medicine Specialists and Addiction Psychiatrists initiating treatment under the OTP for a high dose of methadone or buprenorphine** may transfer care to another prescriber with a written clinical handover to support safe ongoing care.
12. Addiction Medicine Specialists and Addiction Psychiatrists may initiate treatment under the OTP for methadone and buprenorphine for patients under 18 years of age. A documented clinical handover is required to transfer care to an accredited medical practitioner to support safe ongoing care.

**must have Health Secretary approval under the *Medicine Poisons and Therapeutic Goods Act 2022.*

General

13. All prescriptions and directions for administration of treatment under the OTP must be forwarded directly to the nominated dosing point and not given to the patient. The number of takeaways must be noted on the relevant prescription.
14. All medical practitioners and nurse practitioners who provide treatment under the OTP must provide safe, high-quality care with reference to current *Safe prescribing of medicines for the management of opioid dependence in NSW: guidance for prescribers*, with provisions in place to support continuity of care, including locum or replacement practitioner arrangements.

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Standards for pharmacists practising at community pharmacy dosing points

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Standards for pharmacists practising at community pharmacy dosing points

Under the *Medicines, Poisons and Therapeutic Goods Regulation 2026*:

- a pharmacist who dispenses buprenorphine or methadone at a pharmacy under an OTP registration must carry out the activity in compliance with the OTP standards.

1. Governance arrangements for the supply of medicines for opioid dependence treatment

A pharmacist supplying medicines for opioid dependence treatment (ODT) under the OTP must have at the pharmacy clearly documented:

a. Procedures to ensure pharmacists are aware of their responsibilities and have the resources to provide safe care and supervised administration (dosing). This includes that only pharmacists prepare, supply, or administer ODT medicines to patients.

b. Processes in place to ensure medicines for opioid dependence are accounted for, including record keeping of the receipt and supply of the medicines that demonstrates identification of the pharmacist making the record and the person receiving the medicines, using a compliant subsidiary drug register or ODT dosing software.

c. Procedures in place to ensure secure storage in accordance with the Medicines Storage Standards and quality assurance of medicines for opioid dependence, including maintaining Schedule 8 compliant cold-chain processes for long-acting buprenorphine injections (LAIB) if required.

d. Procedures for managing and documenting clinical interventions and communication with other providers involved in the patient's care.

e. Procedures in place for the maintenance of dosing equipment as per the operational protocols of the equipment used.

f. Procedures for providing takeaway doses, including Schedule 8 labelling and child-resistant packaging requirements.

g. Staff training records maintained to confirm staff are adequately trained to provide safe and high-quality services, in line with the *Safe prescribing of medicines for the management of opioid dependence in NSW: guidance for prescribers* and *Community Pharmacy Clinical Companion*.

2. Pharmaceutical Benefits Scheme (PBS) requirement and Pharmacy Council Registration

The pharmacist(s) proprietor of a registered OTP pharmacy must:

a. Ensure that the pharmacy is, and remains, approved for the purpose of supplying pharmaceutical benefits from the premises in accordance with section 90 of the *National Health Act 1953* (a 'PBS pharmacy').

b. Notify the Pharmaceutical Services Unit of changes to the pharmacy name, address or ownership, as registered with the Pharmacy Council of NSW.

3. Amenity considerations

The pharmacist(s) proprietor of a registered OTP pharmacy supplying medicines for ODT under supervised dosing arrangements for 80 or more patients on any given day must implement an amenity plan to be complied with by all pharmacists involved in ODT medicines supply at the site.

The amenity plan must be documented, reviewed and updated annually, and must include:

a. strategies to support patient flow and timely access to treatment

b. a daily dosing plan, aligning care provision with safe and sustainable pharmacy practice

c. a plan that ensures business continuity, storage capacity, security, and an adequate number

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of staff allocated to deliver OTP services

d. a signed declaration by the proprietor pharmacist(s) that commits to adequate daily staffing in accordance with the daily dosing plan.

For pharmacies dosing less than 80 patients per day, the above amenity considerations are recommended.

4. Safe administration of long-acting injectable buprenorphine

Pharmacists providing administration of long-acting buprenorphine (LAIB) injections on the prescription from a medical practitioner or nurse practitioner must ensure that administration of LAIB injections is within their professional scope of practice including appropriate training and demonstrated competency.

Administration by a pharmacist may be provided at a community pharmacy. This requires an administration area that is a dedicated space or existing room for the purpose of providing medicines by injection and:

a. is not used as a dispensary, storeroom, or staff room

b. is a professional and functional space that is safe, clean and tidy and allows for auditory and visual privacy

c. the space, and entry and exit from the space should avoid risks for access to any scheduled medicines, dispensary, compounding materials, or patient records

d. has adequate lighting and maintained at a comfortable ambient temperature

e. has ready access to a hand washing facility and/or hand sanitisation facility

f. has sufficient bench space (with an impervious surface), a minimum of 2 chairs (the one for the patient cannot be a stool or on wheels)

g. has equipment to perform first aid treatment and has documented CPR procedures

h. has space to allow the pharmacist or other trained person adequate space to manoeuvre and perform first aid treatment and CPR

i. has unhindered and easy access to the area for emergency services.

5. Dispensing and retaining prescriptions

Pharmacists must only dispense a prescription for ODT medicines from a pharmacy that is the nominated dosing point for the patient. This applies to physical and e-prescriptions, and any prescription repeats. Pharmacists must retain physical prescription repeats at the nominated dosing point pharmacy.

Supply of ODT medicines must be in accordance with prescriptions and directions that have been provided directly from the prescriber, and not the patient.

6. Recording the supply and administration of medicines

On supply or administration of medicines under the OTP to a patient, a pharmacist must record this supply in a compliant drug register. The core requirements for the drug register are outlined in the Regulations. In addition, the drug register or subsidiary drug register must also capture:

a. The quantity of observed doses

b. The number and quantity of take away doses

c. The day or days for which any take away doses are supplied.

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7. Subsidiary drug register (paper form)

On supply or administration of medicines under the OTP to a patient, a pharmacist may keep records using a subsidiary drug register in paper form in addition to keeping a compliant drug register.

Below are the minimum mandatory requirements for a subsidiary drug register:

- Separate subsidiary drug register books should be used for *Aspen Methadone Syrup* oral liquid, *Biodone Forte* oral liquid, *Subutex* tablets and *Suboxone* films.
- The book must be in bound form with the pages numbered consecutively.
- The cover of the book must describe its contents and indicate the period covered.
- Each page must have a clear heading and be ruled up in a consistent fashion with a heading for each column/line, as applicable.
- The subsidiary drug register must include the patient's name, prescription number, the name of the prescriber, the actual quantity dispensed to each patient on that particular day (including takeaways), the date each dose is supplied and an indication of the days for which takeaway doses have been supplied.
- A system must be put in place to identify the pharmacist responsible for dispensing each dose.
- A pharmacist must reconcile the doses supplied each day and document the quantity of drug supplied. The pharmacist that conducts this reconcilliation must sign the relevant entry in the subsidiary drug register and make a corresponding entry in the main drug register.
- Together, the subsidiary register and the main drug register must provide a clear history of methadone usage (by patient and quantity) and must reflect the actual balance of methadone or buprenorphine held.

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Standards for all health practitioners and other persons at dosing points other than community pharmacy

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Standards for Health Practitioners and other persons at dosing points other than Community Pharmacy

Under the *Medicines, Poisons and Therapeutic Goods Regulation 2026* ('Regulation'):

- a medical practitioner or nurse practitioner who supplies or administers buprenorphine or methadone under an OTP registration must carry out the activity in compliance with the OTP standards
- a medical practitioner or nurse practitioner carrying out an activity for which an OTP registration is exempted under the Regulation, must carry out the activity in compliance with the OTP standards. This includes:
    - treatment of a patient admitted to, or receiving or emergency treatment at, a public health entity or private health facility
    - continuation of treatment of a patient by a replacement practitioner on behalf of the original practitioner
    - continuation of treatment of an inmate in a correctional centre or within 28 days of the inmate's release.
- a provider under the OTP who is the holder of an obtain licence must ensure the OTP clinic is operated in compliance with the OTP standards
- a public health entity operating a public OTP clinic must ensure the OTP clinic is operated in compliance with the OTP standards

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Scope:

This standard applies to all persons supplying, administering or issuing a prescription for OTP medicines under the Regulation. The locations where OTP activities take place may include OTP public clinics and Local Health District public hospitals (including Hospital in the home), private hospitals, GP clinics, private OTP clinics, and Aboriginal Medical Services sites.

1. Governance arrangements for the supply of medicines for opioid dependence treatment

The obtain licence holder at an OTP clinic, the chief executive of a public health entity operating an OTP clinic, or the medical practitioner or nurse practitioner providing ODT medicines in private practice, must ensure the dosing point holds current accreditation in accordance with the National Quality Framework for Drug and Alcohol Treatment, and have documented:

a. Processes to ensure medicines for opioid dependence are accounted for, including record keeping of the receipt and supply of the substances that demonstrates identification of the authorised person and witness making the record, and the person receiving the medicines, using a compliant drug register.

b. Procedures in place to ensure secure storage in accordance with the Medicines Storage Standards and quality assurance of medicines for opioid dependence, including maintaining Schedule 8 compliant cold-chain processes for long-acting buprenorphine injections (LAIB) if required.

c. Processes, procedures and clinical governance frameworks established to ensure safe and high quality provision of ODT, ensuring staff:
    - are aware of their responsibilities and have the resources to provide safe care
    - are qualified to supervise administration (dosing) of medicines for opioid dependence
    - provide unsupervised doses that meet labelling and packaging requirements for Schedule 8 medicines in accordance with the Regulation.

d. Procedures in place for the maintenance of dosing equipment as per the operational protocols of

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the equipment used.

e. Incident reporting and complaints management procedures and records.

f. Business continuity and amenity plan, reviewed regularly and updated annually to support:

- strategies to support patient flow and timely access to treatment
- daily dosing plans, aligning care provision with adequate staffing
- storage capacity, security, ingress / egress and emergency protocols
- locum arrangements and local health district contacts.

2. Safe administration of long-acting buprenorphine injections

Health practitioners must only administer long-acting buprenorphine injections under the written direction of a medical practitioner or nurse practitioner if it is within their professional scope of practice, including appropriate training and demonstrated competency.

The administration area must be a dedicated space or existing room for the purpose of providing medicines by injection and:

a. is not used as a storeroom or staff room.

b. is a professional and functional space that is safe, clean and tidy, and allows for auditory and visual privacy.

c. the space, and entry and exit from the space should avoid risks for access to any scheduled medicines or patient records.

d. has adequate lighting and is maintained at a comfortable ambient temperature.

e. has ready access to a hand-washing facility and/or hand sanitisation facility.

f. has sufficient bench space (with an impervious surface), a minimum of 2 chairs (the one for the patient cannot be a stool or on wheels).

g. has equipment to perform first aid treatment and has documented CPR procedures.

h. has adequate space to allow the health practitioner or other trained person to manoeuvre and perform first aid treatment and CPR.

i. has unhindered and easy access to the area for emergency services.

3. Retaining prescriptions or directions for administration

The obtain licence holder at an OTP clinic or the chief executive of the public health entity operating a public OTP clinic are responsible for ensuring that staff:

- retain and store any prescriptions or other documents used as directions for administration of treatment under the OTP
- ensure that prescriptions, or other documents used as directions for administration, are received directly from the prescriber rather than from the patient.

Medical Practitioners and Nurse Practitioners at dosing points other than OTP clinics must ensure that they retain and store any prescriptions or other documents used as directions of administration of treatment under the OTP.

4. **Recording the supply and administration of medicines**

Following the supply or administration of methadone, buprenorphine or other prescribed medicine to a patient for the purposes of the OTP, a health practitioner at the dosing point must record in a compliant drug register or ODT dosing software:

a. The date on which the supply or administration occurred.

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b. The amount of medicine type and amount supplied or administered to the patient on that day.
c. The number of takeaway doses supplied to the patient on that day (if applicable).
d. The day or days on which any supplied takeaway doses are to be consumed (if applicable).
e. The amount of medicine supplied which are to be consumed as takeaway doses (if applicable).

The drug register should accurately reflect the current balance of stock on hand.

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