SELF-AUDIT FOR COMMUNITY PHARMACIES PROVIDING OTP SERVICE

This resource is a quality improvement tool for community pharmacies providing opioid dependence treatment (ODT) under the NSW Opioid Treatment Program (OTP). It supports pharmacists to self-assess their practice, identify gaps and make improvements where needed.

Complete the self-audit at least once every 6 months. Pharmacies may complete it more frequently where appropriate. Review the relevant evidence or documentation for each item and select Yes, No or N/A. Record any identified gaps in the Quality Improvement Action Plan on page 4.

Completion of the self-audit is included in NSW Pharmacy Incentive Scheme and assists pharmacies when reviewing evidence of quality improvement activities and pharmacy procedures for accreditation purposes.

1. QUALITY MEASURE (Complete separately for each patient audited)

Audit a random sample of patients receiving ODT dose administration at your pharmacy: at least 10% of patients, or 3 patients, whichever is greater. Where appropriate, different pharmacists may complete audits throughout the 6-month period to support shared learning and continuous quality improvement.

Patient identifier:

Date of the audit: Name of the auditing pharmacist:

Review Item	Yes	No	N/A
1. Communication to facilitate initiation or transfer of care			
For initiation at your pharmacy: Relevant dosing arrangements with the prescriber were documented, including the starting dose and first day of dosing.	○	○	○
For transfer of care: The patient's last dose details were confirmed with the previous dosing point and documented before treatment commenced at your pharmacy.	○	○	○
The prescriber's contact details, preferred methods of communication and arrangements for obtaining prescriptions were confirmed with the prescriber.	○	○	○
The pharmacy was confirmed as the nominated dosing point in SafeScript NSW.	○	○	○
2. Prescription validation and dispensing – review the current prescription			
The prescription was received directly from the prescriber and not from the patient.	○	○	○
The prescription was valid, current and met Schedule 8 medicine requirements, with clear instruction including:			
• Patient details	○	○	○
• Prescriber details, including a telephone number	○	○	○
• Medicine, strength and quantity (written in words and numbers for paper prescriptions)	○	○	○
• Adequate directions for use	○	○	○
• Number of repeats and repeat intervals	○	○	○
• Takeaway arrangements	○	○	○
For supply without a prescription in an emergency or other urgent circumstances, the prescription was received within 14 days of supply or, if not received, Pharmaceutical Services Unit (PSU) was notified.	○	○	○
3. Patient identification A clear photograph of the patient was held in the patient's record and readily available for viewing.	○	○	○

Review Item	Yes	No	N/A
4. Dose records The relevant prescription/s was compared with the dosing records for the previous 12 weeks to confirm that:			
Doses supplied or administered were in accordance with the prescriber's directions.	○	○	○
A unique prescription number was recorded in the dispensing software or subsidiary drug register.	○	○	○
All doses supplied or administered were recorded on the day of supply or administration.	○	○	○
Where a dose was not supplied, the reason, any action taken, and application of the missed dose protocol (where required) were documented.	○	○	○
The pharmacist who supplied or administered the dose was recorded.	○	○	○
Where long-acting injectable buprenorphine (LAIB) was administered, administration details, including the date of administration and injection site, were recorded.	○	○	○
5. Authorised treatment changes (e.g. dose adjustments, replacement doses such as lost or vomited doses, and changes to takeaway arrangements)			
Verified that written authorisation for the treatment change, signed and dated by the prescriber, was attached to the prescription.	○	○	○
A new prescription was obtained where changes were made to the medicine, strength, or quantity.	○	○	○
6. Takeaway dose preparation and supply			
Takeaway doses were packaged in child-resistant packaging and correctly labelled, including the date of preparation and intended date of administration.	○	○	○
Where methadone takeaway doses were diluted, the dilution was directed by the prescriber, undertaken in accordance with the product information and clearly indicated on the label.	○	○	○
7. Clinical and patient safety issues			
Where clinical or patient safety issues were identified, communication with the prescriber and any appropriate action taken were documented, including: • Intoxication or withdrawal • Multiple prescribers issuing prescriptions for high-risk medicines • Concomitant use of medicinal cannabis, alcohol, other drugs or medicines of concern • Deviations from the NSW OTP prescribers guide, including reasons • Issues identified during assessment prior to medicine administration, e.g. queries about the dose prescribed • Other patient safety concerns (e.g. personal circumstances affecting attendance or treatment adherence, frequent missed doses).	○	○	○
8. Patient safety advice and harm reduction There was evidence that relevant patient safety advice had been provided to the patient including:			
• Overdose risks and the role of Take Home Naloxone (THN)	○	○	○
• Driving safely and risks associated with sedation or intoxication	○	○	○
• Safe use and storage of takeaway doses	○	○	○
Total number of gaps identified:			

2. PHARMACY PROCEDURES

Review the pharmacy's OTP procedures, record keeping, storage and other regulatory requirements once during each 6-months audit period.

Date of the audit: Name of the auditing pharmacist:

Review Item	Yes	No	N/A
1. Pharmacy proprietor confirmed the pharmacy is **registered as an OTP dosing point** with PSU and notified any changes to the pharmacy name, address or ownership.	○	○	○
2. Documented governance arrangements (guides, workflow or procedures) were in place for the supply of ODT medicines consistent with the OTP Standards and harm reduction support such as supply of THN.	○	○	○
3. Paper prescription for ODT medicines: management and retention			
A system was in place to routinely monitor and follow up on outstanding prescriptions.	○	○	○
Expired or superseded prescriptions were marked as cancelled and separated from current prescriptions.	○	○	○
Paper prescription repeats were retained at the nominated dosing point pharmacy.	○	○	○
Prescriptions were retained for 2 years at the pharmacy where they were dispensed.	○	○	○
4. Schedule 8 medicine record-keeping, storage, stocktake and reconciliation			
The drug register or ODT dosing software was complete, legible and updated at the time of, or on the day of, the transaction.	○	○	○
Any ODT medicine stock discrepancies were documented and appropriately managed.	○	○	○
Stocktakes were completed and recorded at least every 3 months.	○	○	○
ODT medicines were securely stored in a drug safe attached to the premises, with adequate capacity and access controls. Keys or combination codes were managed in accordance with the Medicine Storage Standards.	○	○	○
Where a paper subsidiary drug register was used, it met the requirements of the OTP Standards.	○	○	○
5. Dosing and takeaway preparation			
ODT medicines were prepared, supplied and, where applicable, administered only by pharmacists in a suitable dosing area.	○	○	○
Dosing equipment was appropriately maintained, cleaned and checked for calibration.	○	○	○
Doses prepared in advance were appropriately labelled and securely stored in the drug safe until supplied or administered.	○	○	○
6. An **amenity plan** was documented, reviewed and updated annually in accordance with the OTP Standards, including business continuity and service disruption planning. *Mandatory for pharmacies supplying medicines for ODT under supervised dosing arrangements for 80 or more patients on any given day; recommended for pharmacies below this threshold.*	○	○	○
7. Safe administration of long-acting injectable buprenorphine (LAIB)			
LAIB administration was within the pharmacist's professional scope of practice, with appropriate training and demonstrated competency.	○	○	○
The administration area met the requirements of the OTP Standards.	○	○	○
Total number of gaps identified:			

QUALITY IMPROVEMENT ACTION PLAN

Document any gaps identified during the self-audit and the actions taken or planned to address them. Where further guidance is required, refer to the references below.

Gap/opportunity for improvement	**Action(s)**	
Responsible person	Target completion date	Date completed

Gap/opportunity for improvement	**Action(s)**	
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References:

1. Medicines, Poisons and Therapeutic Goods Act 2022
https://legislation.nsw.gov.au/view/html/inforce/current/act-2022-073

2. Medicines, Poisons and Therapeutic Goods Regulation 2026
https://legislation.nsw.gov.au/view/pdf/asmade/sl-2026-330

3. OTP Standards – NSW Opioid Treatment Program
https://www.health.nsw.gov.au/pharmaceutical/Publications/opioid-treatment-program-standards.pdf

4. OTP Clinical Companion for Community Pharmacists
Opioid Treatment Program Clinical Companion for Community Pharmacists

5. Electronic Drug Register Standards
https://www.health.nsw.gov.au/pharmaceutical/Publications/electronic-drug-register-standards.pdf

6. Medicine Storage Standards
https://www.health.nsw.gov.au/pharmaceutical/Publications/medicine-storage-standards.pdf