



Pharmacy Programs  
Administrator

# PROGRAM RULES

## Opioid Dependence Treatment (ODT) Community Pharmacy Program

December 2023



Australian Government  
Department of Health and Aged Care

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## TABLE OF CONTENTS

<b>1</b>	<b>INTRODUCTION</b> .....	<b>1</b>
<b>2</b>	<b>BACKGROUND</b> .....	<b>1</b>
<b>3</b>	<b>DEFINITIONS</b> .....	<b>2</b>
<b>4</b>	<b>ELIGIBILITY</b> .....	<b>2</b>
	4.1 Service Provider Eligibility Criteria.....	2
	4.2 Patient Eligibility Criteria.....	3
	4.3 Patient Consent.....	3
<b>5</b>	<b>ODT COMMUNITY PHARMACY PROGRAM CLAIMING AND PAYMENTS</b> .....	<b>4</b>
	5.1 ODT Staged Supply Community Pharmacy Service Claiming and Payments .....	4
	5.2 ODT Injection Community Pharmacy Service Claiming and Payments.....	6
	5.3 Claim Lodgement .....	6
	5.4 Supporting Documentation .....	7
<b>6</b>	<b>PATIENT FEES</b> .....	<b>7</b>
<b>7</b>	<b>AUDIT AND COMPLIANCE REQUIREMENTS</b> .....	<b>8</b>
<b>8</b>	<b>RESOURCES</b> .....	<b>8</b>
	<b>APPENDIX A OPIOID DEPENDENCE TREATMENT (ODT) COMMUNITY PHARMACY PROGRAM SERVICE INFORMATION STATEMENT AND CONSENT FORM</b> .....	<b>9</b>

## LIST OF TABLES

Table 5-1: Provision of ODT Staged Supply Service Fee .....	5
Table 5-2: In-pharmacy administration of Injection Service fee .....	6

## OPIOID DEPENDENCE TREATMENT (ODT) COMMUNITY PHARMACY PROGRAM

**Participating Service Providers must agree to accept the payment received under this Program as full payment (see section 6, Patient fees) and provide all aspects of the Program at no cost to participating patients, other than a patient PBS medication co-payment (if applicable).**

### 1 INTRODUCTION

This document outlines the Program Rules governing the Opioid Dependence Treatment (ODT) Community Pharmacy Program. This document must be read in conjunction with the *Pharmacy Programs Administrator (PPA) General Terms and Conditions* (General Terms), relevant Professional Standards and Pharmacy Board Guidelines. Definitions in the General Terms apply in these Program Rules.

### 2 BACKGROUND

In the 2023-24 Budget the Australian Government committed \$377.3 million over 4 years from 2023-24 (and \$98.4 million ongoing) to reforming ODT access.

This funding supports the ODT Community Pharmacy Program which aims to deliver a nationally consistent approach for patients requiring ODT services provided by eligible Pharmaceutical Benefits Scheme (PBS) community pharmacies.

**The Program is designed to improve access to and affordability of ODT within the community pharmacy sector, by supporting the delivery of pharmacy services for people in treatment programs for opioid dependence.**

Supplying patients with methadone liquid, buprenorphine sublingual tablets and buprenorphine + naloxone sublingual films often require more frequent activities relating to in-pharmacy and take-away dosing. Therefore, the ODT Community Pharmacy Program has been established to introduce nationally consistent payment arrangements for ODT staged supply services provided by Section 90 (s90) community pharmacies.

In addition, subject to their respective state and territory policies and regulations, s90 community pharmacies can receive a fee for on-site pharmacist administration of injectable buprenorphine.

The following medicines listed on the Section 100 Highly Specialised Drugs Program (Community Access) of the Schedule of Pharmaceutical Benefits (the PBS Schedule) for the treatment of opioid dependence from 1 July 2023 are eligible for payments under this program:

- methadone oral liquid
- buprenorphine sublingual tablets
- buprenorphine + naloxone sublingual films
- long-acting injectable buprenorphine products.

## OPIOID DEPENDENCE TREATMENT (ODT) COMMUNITY PHARMACY PROGRAM

### 3 DEFINITIONS

**Community Pharmacy** means a pharmacy approved to dispense pharmaceutical benefits as defined in Section 90 of the National Health Act 1953.

**In-Pharmacy Dosing** means provision of a supervised dose of an oral or sublingual ODT medicine within the pharmacy.

**Opioid Dependence Treatment** (ODT) also known as Opioid Substitution Treatment (OST) or Opioid Replacement Therapy (ORT).

**PBS** means the Pharmaceutical Benefits Scheme.

**Service Provider** means the entity providing services (e.g. a s90 Community Pharmacy) nominated in the Pharmacy Programs Administrator Portal, which at all times meets the Eligibility Criteria set out in the ODT Community Pharmacy Program Rules.

**Services** means services, tasks and obligations described in the relevant Program Rules.

**Take-away Dosing** means a dose provided to the patient to take outside of the pharmacy setting i.e. the patient was not supervised by the pharmacist while taking the oral or sublingual ODT medicine. Also known as take-home dosing.

### 4 ELIGIBILITY

#### 4.1 Service Provider Eligibility Criteria

To be eligible to become an Approved ODT Community Pharmacy Service Provider and participate in the ODT Community Pharmacy Program, a Community Pharmacy must meet the following criteria and is required to confirm its compliance with these and other criteria upon program registration:

- Be approved to dispense pharmaceutical benefits as part of the Pharmaceutical Benefits Scheme (PBS) defined in Section 90 of the *National Health Act 1953* (i.e. a Section 90 Community Pharmacy. Hospitals are not eligible under this program)
- Be approved by their relevant State/Territory to supply/administer the relevant ODT medications to patients
- Consent to share their contact information and supply data with their relevant State/Territory
- Undertake ODT Community Pharmacy Services in accordance with the PPA General Terms and Conditions (available [here](#)) and the ODT Community Pharmacy Program Rules, including those related to patient eligibility
- Provide/administer ODT Community Pharmacy Services in accordance with relevant Professional Standards and Guidelines
- Provide/administer ODT Community Pharmacy Services in accordance with relevant State/Territory requirements
- Obtain appropriate written consent for provision/administration of the service and provision of patient data to the PPA/Department of Health and Aged Care (the Department). Please note that State/Territory consent forms are not sufficient as they do not include consent for data to be provided to the PPA/Department. A consent form is available [here](#) and at Appendix A of this document

## OPIOID DEPENDENCE TREATMENT (ODT) COMMUNITY PHARMACY PROGRAM

- Ensure that the preparation and supply of the instalment occurs in an area which accords with legislative requirements for dispensing medications
- Comply with legislative requirements in relation to storage of and staff access to medicines that are held in the pharmacy, including ensuring that the area where the medicines are stored is not accessible to the public
- **Provide all aspects of the ODT Community Pharmacy Service at no cost to participating patients (other than a patient PBS medication co-payment, if applicable).**

### 4.2 Patient Eligibility Criteria

To be eligible for an ODT Community Pharmacy Service funded under the Program, the patient must:

- Be a Medicare and/or Department of Veterans' Affairs (DVA) cardholder
- Have been prescribed one or more medicines for opioid dependence treatment listed on the Section 100 Highly Specialised Drugs Program (Community Access)
- Be enrolled in a state or territory ODT program and receiving ODT medicines from a s90 approved Community Pharmacy.

Eligible patients cannot be levied with additional Patient charges, other than a patient PBS medication co-payment (if applicable), see section 6, Patient fees.

Where a patient does not meet the eligibility criteria (above), the Service Provider may offer the service at the patient's own cost providing that by doing so they are still meeting their relevant State or Territory requirements. A lack of eligibility for funding under this Program does not invalidate a prescriber's request to provide ODT medicines to patients.

### 4.3 Patient Consent

Service Providers must obtain appropriate written consent from the patient or the patient's carer prior to providing an ODT Community Pharmacy Service – note that this consent relates to patient access to this program and associated reporting and claiming, not the dispensing of the medication itself. Informed patient consent is required that covers both the provision of:

- The service (e.g. staged supply instalments of oral/sublingual ODT medicines or administration of a buprenorphine injection)
- Identifying information to the PPA and Department to allow for the claim to be processed and paid.

A consent form, which includes information that explains this to patients is available at Appendix A of this document and can be found online [here](#).

## 5 ODT COMMUNITY PHARMACY PROGRAM CLAIMING AND PAYMENTS

To be eligible to claim for ODT Community Pharmacy Services under this Program, Service Providers must collect information and submit it via the PPA Portal. Approved Service Providers can claim the following payments under the Program:

- ODT Staged Supply Community Pharmacy Service Claims
- ODT Injection Community Pharmacy Service Claims.

### 5.1 ODT Staged Supply Community Pharmacy Service Claiming and Payments

#### Claiming

Approved Service Providers (i.e. pharmacies that at all times meet the Eligibility Criteria set out in these ODT Community Pharmacy Program Rules) will be able to claim a **daily fee per patient** for activities associated with the staged supply of eligible ODT medicines (i.e., for in-pharmacy and take-away dosing preparation including consumables). Eligible ODT medicines are:

- methadone oral liquid
- buprenorphine sublingual tablets
- buprenorphine + naloxone sublingual films.

Long-acting injectable buprenorphine products are excluded from ODT Staged Supply Community Pharmacy claims and, where administered to the patient by the Service Provider, should instead be submitted as an ODT Injection Community Pharmacy Service claim (see section 5.2).

Service Providers can claim for all eligible patients for which they are providing ODT Staged Supply services i.e. there are no caps on the number of eligible patients for which a Service Provider can claim each month. Whilst no Service Provider caps apply under the ODT Community Pharmacy Program, Service Providers must continue to comply with any State/Territory limits placed upon the number of patients they can service.

#### Claiming Timeframes

Service Providers must submit eligible ODT Staged Supply Service claims via the PPA Portal:

- On a monthly basis in arrears
- By the end of the next calendar month (e.g. services provided in November must be claimed by 31 December)
- As one monthly claim per eligible patient.

Claims that are outside this timeframe or are incomplete cannot be submitted and will not be paid.

#### Payment

Approved Service Providers can claim the following ODT Staged Supply Service payments under the Program. These payments are GST Exempt.

**OPIOID DEPENDENCE TREATMENT (ODT) COMMUNITY PHARMACY PROGRAM**
**Table 5-1: Provision of ODT Staged Supply Service Fee**

Description	Fee (per patient, per dosing day)
Provision of in-pharmacy or take-away ODT Staged Supply Service (per dosing day per ODT patient):	
<i>Dose management fee (staged supply fee)</i>	<i>\$4.69</i>
<i>Consumable allowance fee</i>	<i>\$0.97</i>
<b><i>Total fee (per dosing day per ODT patient)</i></b>	<b><i>\$5.66</i></b>

*ODT Staged Supply Services include ODT doses administered to patients in-pharmacy and as take-away doses.*

Please note split doses, double/triple doses or additional doses provided to a patient on a given day should only be recorded as one dosing day for claiming purposes. Where a dose has been prepared but has not been collected by a patient, this dose can still be recorded and claimed as an in-store or take-away dosing day, depending on the dose type prepared.

**No additional patient charges may be levied for participating patients who are funded through the ODT Community Pharmacy Program**, however patients will still be required to pay the PBS co-payment for the medicine (if applicable). Service Providers must declare upon program registration and at the lodgement of each claim that no such fees have been levied.

## OPIOID DEPENDENCE TREATMENT (ODT) COMMUNITY PHARMACY PROGRAM

### 5.2 ODT Injection Community Pharmacy Service Claiming and Payments

#### Claiming

Subject to state and territory guidelines and regulations, approved Service Providers can submit payment claims for **in-pharmacy** administration of buprenorphine injections (weekly and monthly), where these injections are provided by an appropriately qualified pharmacist.

Service Providers may claim a fee for each eligible long-acting buprenorphine (weekly or monthly) injection provided under the ODT Community Pharmacy Program.

Service Providers can claim for all eligible patients they have administered long-acting injectable buprenorphine to, i.e. there are no caps on the number of eligible patients for which a Service Provider can claim each month. Whilst no Service Provider caps apply under the ODT Community Pharmacy Program, Service Providers must continue to comply with any State/Territory limits placed upon the number of patients they can service.

**Claiming Timeframes** Service Providers must submit eligible ODT Injection claims via the PPA Portal:

- By the end of the next calendar month (e.g. services provided in November must be claimed by 31 December)
- Each injection must be submitted as a separate claim.

ODT injections can be claimed as soon as the injection has been administered - you do not need to wait to submit these on a monthly basis.

Claims that are outside this timeframe or are incomplete cannot be submitted and will not be paid.

#### Payment

Approved Service Providers can claim the following Injectable ODT Services payments under the Program. These payments are GST Exempt.

**Table 5-2: In-pharmacy administration of Injection Service fee**

Description	Fee (per injection)
In-pharmacy administration of ODT Injection Service	\$22.15

**No additional patient charges may be levied for participating patients who are funded through the ODT Community Pharmacy Program**, however patients will still be required to pay the PBS co-payment for the medicine (if applicable). Service Providers must declare upon program registration and at the lodgement of each claim that no such fees have been levied.

### 5.3 Claim Lodgement

The following information must be provided to the Pharmacy Programs Administrator in order to claim a payment under this Program:

- a. Patient Medicare Number or DVA Number



## OPIOID DEPENDENCE TREATMENT (ODT) COMMUNITY PHARMACY PROGRAM

- b. Patient name
- c. Patient date of birth
- d. Consent for service provision and data collection
- e. Claim period/service date
- f. ODT Staged Supply Community Pharmacy Service claim only:
  - i. The number of days the patient had in-pharmacy or take-away ODT doses during the month (noting split doses, double/triple doses or additional doses given to a patient on a given day should only be counted as one day)
- g. Medication supplied
- h. Injectable claim only:
  - i. Pharmacist name
  - ii. Pharmacist AHPRA number
- i. Claim declaration.

### 5.4 Supporting Documentation

The following information must be retained by the ODT Community Pharmacy Service Provider for seven years to support any claim for payment made under these Program Rules:

- a. S90 number at the time of the provision of the ODT Community Pharmacy Service
- b. Proof of relevant State/Territory approval to provide ODT services
- c. Proof patient was prescribed ODT program medicine/s
- d. Registered Pharmacist Identifier (e.g. AHPRA registration number)
- e. Copy of the patient consent form
- f. Patient's Medicare/DVA Card number
- g. Date(s) of provision of medicine instalments as a part of the ODT Community Pharmacy Service, e.g. dosing pick-up sheets, dispensing records recorded in software etc.

Supporting documentation can be electronic or hard copy.

## 6 PATIENT FEES

No additional Patient charges may be levied for participating patients who have received their ODT medications through the PBS or are funded through the ODT Community Pharmacy Program, other than a patient PBS medication co-payment (if applicable).

Participating Service Providers must declare upon program registration and at the lodgement of each claim that no such fees have been levied.

This includes any patients who have had their ODT medicines dispensed under the PBS Section 100 HSD arrangements and are otherwise eligible to participate in the ODT Community Pharmacy Program, but have elected not to sign a consent form, which prevents the Service Provider from submitting a service claim through the PPA.

## 7 AUDIT AND COMPLIANCE REQUIREMENTS

Service Providers must retain full and true records (including all patient consent forms) in relation to the provision of services for not less than seven years after the claim for payment. Such records must be kept in a manner that permits them to be conveniently and properly audited, and enables the amounts claimed as well as the services provided under the General Terms and these Program Rules to be determined. Service Providers may be subject to audits by the Department (or its representative) to ensure that the General Terms and these Program Rules have been complied with and must provide all and any records requested as part of such audit(s).

Service Providers must also ensure that they are using current documents when obtaining information or consent from patients. Service Providers that wrongfully or incorrectly receive funding and/or do not meet the requirements set out in the General Terms and these Program Rules may be subject to compliance action (as determined by the Department or PPA) and repayment may be required. Under section 137.1 of the Criminal Code, giving false and misleading information is a serious offence. If an audit/compliance action is to be conducted, Service Providers will be required to produce documentation within a specified time frame.

Service Providers should also note that in addition to compliance action, as per the General Terms, participation can be terminated by notice if:

- a. You have failed to carry out the Services
- b. You have failed to comply with the relevant Program Rules
- c. The PPA considers that any statement made by You is incorrect, misleading or incomplete in a way which would have affected Your eligibility to participate in this program and other programs administered by the PPA
- d. The PPA considers that You will be unable to perform Your Services under these General Terms
- e. The Australian Government terminates or reduces the scope of its agreement with the PPA in relation to the Programs or suspends the PPA's performance of the same
- f. The Australian Government cancels Your participation in this program and/or one or more 7CPA Programs as outlined in the relevant Program Rules.

## 8 RESOURCES

ODT Community Pharmacy Program resources are available for download at [www.ppaonline.com.au](http://www.ppaonline.com.au).

**Additional information regarding the prescribing and supply of ODT medicines under the Section 100 HSD Program (community access) and the PBS can be found below.**

*Please note that the PPA are unable to assist with queries relating to the prescribing and supply of ODT medicines under the PBS.*

[Pharmaceutical Benefits Scheme \(PBS\) | Opioid Dependence Treatment Program](#)

[Pharmaceutical Benefits Scheme \(PBS\) | Section 100 – Highly Specialised Drugs Program](#)

## OPIOID DEPENDENCE TREATMENT (ODT) COMMUNITY PHARMACY PROGRAM

### APPENDIX A OPIOID DEPENDENCE TREATMENT (ODT) COMMUNITY PHARMACY PROGRAM SERVICE INFORMATION STATEMENT AND CONSENT FORM

#### INFORMATION STATEMENT

**You have been prescribed one or more opioid dependence treatment medicines that are available on the Pharmaceutical Benefits Scheme (PBS), for dispensing at your community pharmacy.**

Under this program, opioid medicines that are listed on the Section 100 Highly Specialised Drugs Program (Community Access) will be dispensed by your pharmacy under the PBS. This means you will need to pay a PBS co-payment towards your medicine (this amount varies depending on whether you hold a concession card and/or if you have reached the PBS Safety Net threshold) and the amount you pay will count towards your PBS Safety Net record.

The Australian Government will pay your pharmacy for the staged supply provision/administration of your ODT Community Pharmacy Service medicines.

**Any additional patient fees are not permitted under this program, so the most you should pay is the general or concessional PBS co-payment amount for the medicine itself.**

In order to receive this service, you need to:

- Have a valid Medicare and/or Department of Veterans' Affairs (DVA) card
- Have been enrolled in a state or territory ODT program and receiving ODT medicines from your community pharmacy.

Under this service your pharmacist will:

- Assess your eligibility to receive the service
- Obtain informed consent from you to receive the service
- Collect personal and sensitive information from you to enable the pharmacy to claim a payment for delivery of this service
- Provide these PBS medicines to you in instalments (i.e. dosing in the pharmacy or take-aways), or as an injection.



**CONTACT THE SUPPORT CENTRE:** 1800 951 285 | [support@ppaonline.com.au](mailto:support@ppaonline.com.au)

## OPIOID DEPENDENCE TREATMENT (ODT) COMMUNITY PHARMACY PROGRAM

### Australian Privacy Principle 5 Notification under the *Privacy Act 1988*

Your personal information is protected by law, including the *Privacy Act 1988*.

### Collection of personal information to allow payment to your pharmacist

The Department and the Pharmacy Programs Administrator (PPA) are collecting your personal information to verify your eligibility to receive ODT Community Pharmacy Services and enable the pharmacy to claim a payment for the delivery of the service to you.

Personal information, such as your Medicare/DVA number and the medications you are taking will be collected by your pharmacist and disclosed for this purpose.

If you consent to receive these funded services by completing and signing the consent form, your personal information will be collected for this purpose.

### Further Information

The Department is unlikely to disclose your personal information to overseas recipients.

The Department can be contacted by telephone on (02) 6289 1555 or free call 1800 020 103 or by using the online enquiries form at [www.health.gov.au](http://www.health.gov.au).

The PPA can be contacted by telephone on 1800 951 285 or email at [support@ppaonline.com.au](mailto:support@ppaonline.com.au).

The Department has a privacy policy which you can read at <https://www.health.gov.au/resources/publications/privacy-policy>.

The PPA has a privacy policy which you can read at [www.ppaonline.com.au/privacy-policy](http://www.ppaonline.com.au/privacy-policy).

You can obtain copies of these privacy policies by using the contact details set out above. The privacy policies contain information about:

- How you may access the personal information the Department or PPA holds about you and how you can seek correction of it
- How you may complain about a breach of the Australian Privacy Principles and how complaints are dealt with.

## OPIOID DEPENDENCE TREATMENT (ODT) COMMUNITY PHARMACY PROGRAM

### ACKNOWLEDGEMENT

I have been provided (verbally or in writing), the contents of the ODT Community Pharmacy Program Information Statement and understand the services and what I am consenting to.

### CONSENT

- I consent to receive ODT Community Pharmacy Services and in doing so I consent to the collection of my personal information by the Pharmacy Programs Administrator and the Australian Government Department of Health and Aged Care and to enable the pharmacy to claim a payment for delivery of that service.

<b>Signature</b>		<b>Date</b>	
<b>Print name</b>			

If you are signing on behalf of the Participant, please indicate your relationship to the Participant:

- Parent or guardian of child
- Other – Please tick applicable category below:
- Enduring Guardian, recognised by a relevant State or Territory law
  - Enduring Power of Attorney, recognised by a relevant State or Territory law
  - A person recognised by a relevant State or Territory law
  - A person who has been nominated in writing by the Participant while the Participant was capable of giving consent.

*This program is funded by the Australian Government.*



**CONTACT THE SUPPORT CENTRE:** 1800 951 285 | [support@ppaonline.com.au](mailto:support@ppaonline.com.au)