

Australian Capital Territory

Medicines, Poisons and Therapeutic Goods (Opioid Dependency Treatment (ODT) Contingency Guidelines) Approval 2020

Notifiable instrument NI2020–409

made under the

***Medicines, Poisons and Therapeutic Goods Act 2008*, section 192 (Guidelines about dealings with regulated substances and therapeutic goods)**

1 Name of instrument

This instrument is the *Medicines, Poisons and Therapeutic Goods (Opioid Dependency Treatment (ODT) Contingency Guidelines) Approval 2020*.

2 Commencement

This instrument commences on the day after its notification day.

3 Approval by Chief Health Officer

I approve the Opioid Dependency Treatment (ODT) Contingency Guidelines as set out in Schedule 1.

Dr Kerry Coleman
Chief Health Officer
13 July 2020



ACT Health

Opioid Dependency Treatment (ODT) Contingency Guidelines

For Individuals using Opioid Maintenance Treatment (OMT) during COVID-19 Response



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Who are the guidelines for?

Anyone who is working with people on opioid maintenance treatment (OMT). This includes general practitioners, pharmacists and staff at the Canberra Health Services Alcohol and Drug Service (ADS).

Who compiled these guidelines?

These guidelines were compiled by the ACT Health Directorate (ACTHD) in collaboration with our partners in the community pharmacy sector, the Alcohol and Drug Service at Canberra Health Services, and the alcohol and other drug sector.

Disclaimer

Coronavirus (COVID-19) disease is a rapidly evolving pandemic with national advice and guidance updated regularly. This is an 'organic' document that will be updated in response to changes and identified needs.

Introduction

The purpose of these guidelines is to assist contingency planning for the consequences of the COVID-19 pandemic in relation to people on Opioid Maintenance Treatment (OMT). The aim is to raise awareness of potential problems that may arise and offer guidance as to how these challenges may be mitigated.

The COVID-19 pandemic is a rapidly evolving situation. The Australian Government has already announced (and may announce further) a variety of containment or isolation advisories with implications for staff and people accessing drug treatment services.

Specific service-user populations may be at heightened risk of COVID-19 related illness or complications. Typically, this includes people who are pregnant, people who are 70 years or older; those with chronic medical conditions including immunosuppression and residents of nursing homes or other care facilities. People who use drugs or are on OMT are a particular risk group with very specific needs.

Background

In the ACT, over 1000 people are recipients of Opioid Maintenance Therapy (OMT) at any given point in time.

Interruption to the existing delivery of OMT and associated clinical care as a result of COVID-19 will put people at increased risk of overdose and, in turn, drug-related death. People on OMT needing to self-isolate or quarantine may also be at risk of withdrawal and distress if they are unable to continue their treatment. It is also likely to result in people sourcing illicit drugs as an alternative and thus putting themselves at further increased risk from overdose, blood-borne viruses, related infections and, potentially, increasing their risk of COVID-19 exposure or transmission. It is essential to ensure that adequate OMT service provision is maintained.

Underlying assumptions

Prescriber capacity and availability

Many community prescribers, as well as Canberra Health Services (CHS), have indicated they are well positioned to undertake phone consultations or other telehealth services to ensure continuity of care for this patient group, when in-person or face to face appointments and assessments are not possible.

All facilities already undertaking planning and actions relating to social distancing

Community pharmacies, drug treatment centres, public health facilities and general practitioners (GPs) are already undertaking a range of measures to stop the spread of COVID-19. This includes restricting the number of people in confined spaces, adjusting opening hours, increasingly moving to other appointment models, encouraging the existing community measures of hand hygiene (washing hands and water, use of hand sanitiser) use and physical distancing.

Stock availability

This guideline assumes that stock of OMT medications (methadone and buprenorphine products) continues to be available through routine supply chains.

It is likely that this will be a dynamic situation particularly as it relates to naloxone products. Increased demand for all naloxone products during the COVID-19 response is likely to have an impact on stock availability. The ACT Government will work with the Australian Government and the Therapeutic Goods Administration on monitoring the supply of OMT medications and naloxone. It is expected that there may be increased pressure OMT medication supply during the COVID-19 pandemic.

Pharmacy Disruption to dispensing

Community pharmacy closures or restricted opening hours may occur at some point during the COVID-19 pandemic. In the event of closures, this will lead to disruption in the dispensing of OMT and in the provision of injecting equipment.

Pharmacies are independent businesses who are responsible for their own Business Continuity Plans (BCPs) with the assistance of the Pharmacy Guild of Australia. These BCPs already indicate the likely alternative dosing point for OMT for clients of individual pharmacies.

As part of the COVID-19 response, it is advised that pharmacies collate a list of their OMT clients. The list should include the medication prescribed, the current dose, name of prescriber and existing prescription expiry date as well as current contact details for the patient. Ideally such a list could be quickly updated to include details of the most recent dose collected in order to facilitate transfers to an alternative pharmacy should unexpected pharmacy closures occur.

OMT options to support social distancing

Individual pharmacies and the Alcohol and Drug Service at Canberra Health Services (ADS) are already undertaking appropriate actions to reduce the likelihood of virus transmission at their sites. Measures have included adjusted opening times, restricting the number of individuals inside and the use of specified appointments.

A range of GP prescribers, as well as ADS, already have access to telehealth capability in order to reduce the need for patients to travel, and protect the health of frontline staff, while maintaining robust patient assessment. This will be particularly important if public transport options are reduced.

Options for remote prescribing are permitted under ACT law (including for schedule 8 (controlled) medicines), including telephone, faxed or electronic prescriptions¹. An original written prescription must be sent to the pharmacy within 24 hours for a telephone or faxed prescription.

Prescribing Options

Prescribers should consider increasing the number of unsupervised or 'takeaway doses' for a patient as a social distancing measure. This is particularly true for patients at higher risk of contracting the virus due to pre-existing medical conditions.

¹ Sections 31, 40 and 41 Medicines, Poisons and Therapeutic Goods Regulation 2008.

Category 3A and 3B approval take away limits

Prescribers are authorised to prescribe unsupervised doses up to the limits described for a Category 3A or 3B approval in the [Controlled Medicines Prescribing Standards](#).

Category 3A Approval - Methadone

Length of time in treatment (months)	Methadone	Comments
0-3	0	Exceptional circumstances may allow one dose
3-5	2 per week	Not consecutively
5-7	2 per week	Maximum 2 consecutive
7-9	3 per week	Methadone – maximum 2 consecutive
>9	4 per week	

Category 3B Approval- buprenorphine/suboxone

Length of time in treatment (months)	Buprenorphine / naloxone	Comments
0-1	0	Exceptional circumstances may allow one dose
1-3	2 per week	Not consecutively
3-5	4 per week	Maximum 2 consecutive
5-7	6 per week	
7-9	13 per fortnight	2 weeks unsupervised dosing
9-12	27 per 28 days	4 weeks unsupervised dosing

In accordance with the Controlled Medicines Prescribing Standards, up to one additional take away dose per month is also permitted under a Category 3A or 3B approval, where the person is unable to return to their usual pharmacy for supervised dosing for reasons outside their control.

In addition, up to three additional take away doses are permitted under a Category 3A or 3B approval or an Approval by Drug during a declared public health emergency to enable rapid commencement or continuation of unsupervised doses for a person unable to attend their usual pharmacy for supervised dosing for reasons outside their control. An example is compulsory isolation during the COVID- 19 public health emergency.

The limit of three additional take-aways is intended to authorise the commencement or continuation of take-aways over a weekend. The prescriber will be required to seek Approval by Drug (or an amendment to their existing Approval by Drug) for any additional take-away doses required over the public health emergency period.

Requests for increased takeaways

Prescribers are also able to apply for an *Approval by Drug* to increase the unsupervised doses supplied to the patient beyond Category 3A or 3B approval limits, with the COVID-19 pandemic considered 'special circumstances'. The prescriber must conduct a stability assessment of the client using the [Client Stability Assessment Form](#) and submit to the Health Protection Service (HPS) with the application.

Any increase in unsupervised doses is not without risk, and it is recommended that prescribers and pharmacists consider providing an accompanying supply of naloxone to individuals with the first supply of increased takeaway doses, particularly for methadone.

It is acknowledged that in addition to the risks faced by the patients, prescribers are also subject to increased risk as the responsibility for the provision of unsupervised doses remains within their prescribing. Reduction in supervision, particularly for new OMT patients, or those on higher doses of methadone, increases the risks of adverse outcomes resulting from these prescriptions.

OMT options to support patients under compulsory isolation or quarantine

Current ACT and Australian Government restrictions do not permit patients under self-isolation or quarantine to leave their property. This means that isolated patients are not be able to attend appointments with their prescribers or their usual OMT dosing provider in person. Alternative arrangements to maintain OMT for these patients must be made available.

Where possible, prescribers should ask patients to provide evidence of their need to quarantine. However, non provision of supporting information will not preclude the clients from receiving home delivered OMT for the appropriate quarantine period. Prescribers should identify the date the quarantine period ends as soon as possible and communicate this to the dosing point with any prescription adjustments.

Directly observed doses by pharmacists or registered nurses is best practice, however this may not be possible due to capacity and workplace health and safety issues during the COVID-19 emergency response, particularly as patient numbers in isolation grow. Alternative options are detailed.

Prescribing Options

The patient will need to have all their doses during the quarantine period administered as **unsupervised**. Prescribers may need to apply for approval for an increase in the patient's unsupervised doses, where this is not already authorised by their approval for the patient.

For patients who require quarantine or compulsory isolation, these arrangements will be in place throughout the COVID-19 pandemic response. For patients seeking increased unsupervised doses for physical distancing purposes, it is intended that routine supervised dosing be reinstated when Government restrictions on individual movement are lifted.

CHO Approval Requirements – prescriber specific factors

Hospital in-patients

A prescriber working in a hospital has standing approval to prescribe controlled medicines (including Opioid Maintenance Treatment) for in-patients at that hospital².

Prescribers at certain institutions

A prescriber working at a:

- hospital (for outpatients);
- correctional centre;
- Children and Young People detention place;
- opioid dependency treatment centre operated by the Territory e.g. ADS; or

has interim standing approval to prescribe controlled medicines (including increase takeaways) for a patient of the institution. However, the prescriber must apply for a Chief Health Officer approval within 72 hours of prescribing the controlled medicine for the patient³.

The interim standing approval is also available for a prescriber who prescribes the controlled medicine for a person in police custody.

² Section 555 of Medicines Poisons and Therapeutic Goods Regulation 2008

³ Section 557 of Medicines Poisons and Therapeutic Goods Regulation 2008

General Practitioners

GP or other OMT prescribers will need CHO approval prior to increasing the patient's unsupervised doses (unless the takeaway doses are authorised under a person's Category 3B approval for suboxone).

CHO Approval Requirements – medicine specific factors

Instructions are provided below for prescribers where they need to seek Approval by Drug for an increase in take away doses over the isolation or quarantine period. The approval for increased take away doses relating to COVID-19 pandemic circumstances in most cases will be provided for a maximum of eight weeks per application.

Methadone

- Apply for *Approval by Drug* to authorise up to 14 takeaway doses to be prescribed over the isolation period. Additional approval will be required should quarantine/isolation be required for longer than 14 days.
- Specify the frequency of collection or delivery of take away doses on the application form. Consider up to daily collection or hospital admission for unstable patients.
- A stability assessment form should be submitted with the application.
- Once approval is granted, issue a prescription for the pharmacist or dosing centre specifying the number of takeaways and frequency of collection.

Suboxone- stable patient on treatment 9 months or longer

- Prescribing of 14 take away doses (2 weeks unsupervised dosing) is authorised under Category 3B Approval for stable patients on treatment longer than 9 months.
- Up to 27 take away doses (4 weeks unsupervised dosing) is authorised under a Category 3B approval for stable patients on treatment longer than 12 months.

Suboxone- on treatment for less than 9 months

- Apply for *Approval by Drug* to authorise up to 14 takeaway doses to be prescribed over the isolation period. Additional approval will be required should quarantine/isolation be required for longer than 14 days.
- Specify the frequency of collection or delivery of take away doses on the application form. Consider up to daily collection or hospital admission for unstable patients.
- A stability assessment form should be submitted with the application.
- Once approval is granted, issue a prescription for the pharmacist or dosing centre specifying the number of takeaways and frequency of collection.

Subutex

- Apply for *Approval by Drug* to authorise up to 14 takeaway doses to be prescribed over the isolation period. Additional approval will be required should quarantine/isolation be required for longer than 14 days.
- Specify the frequency of collection or delivery of takeaway doses on the application form. Consider up to daily collection or hospital admission for unstable patients.
- A stability assessment form should be submitted with the application.
- Once approval is granted, issue a prescription for the pharmacist or dosing centre specifying the number of takeaways and frequency of collection.

Naloxone

The provision of naloxone to OMT patients receiving all doses unsupervised is recommended, particularly for patients using methadone. Providing a prescription for this item will ease the financial burden on patients and other treatment providers supporting naloxone provision. Directions Health Services or CAHMA can assist with stock and training material provision. It may be necessary to consider naloxone provision throughout treatment, not exclusively at the commencement of COVID-related unsupervised dosing.

Supply Options

These options will apply to clients dosing at either ADS or in community pharmacies:

Collection by an agent nominated by the patient

OMT unsupervised doses can be collected by an agent of the patient. If considered appropriate by the patient, prescriber and dosing point, this can be a nominated family member or friend over the age of 18, who is likely providing other supports such as grocery shopping to the isolated patient. Amendments to the prescription are not required, but the prescriber should be made aware that an 'agent' is acting on behalf of a patient.

The patient will need to nominate a specific individual, and consent to the collection of OMT doses on their behalf and indicate this in a phone call to the relevant pharmacist or clinic. The nominated agent will need to provide photo identification when doses are collected, and sign for receipt of a specific number of doses.

Agents will need to leave the OMT at the door of isolated individuals and step back at least 2 metres while it is collected by the patient. Agents should call the patient to communicate their medication is at the door and should confirm the patient name during the phone call. Agents will be required to provide written confirmation that doses were collected by the patient back to the centre providing the doses on the same day.

Agents must not leave doses unattended at any time. Should the patient not answer the door, agents should contact the pharmacy immediately, and return the doses to them. A record of doses returned will need to be made at the pharmacy or clinic.

Patients and potential agents will be advised that if any discrepancies arise with the doses delivered on even one occasion which cannot be resolved, an alternative agent will need to be identified for the patient (likely the government-funded option below).

Collection by a Government-funded third party

ACT Health proposes that alternative third parties be made available to assist with OMT dose delivery. This will involve Directions Health Service (Directions) being nominated as the patient's agent, collecting the doses from the relevant pharmacy or clinic, and delivering it to the client's address, accompanied by a second individual. The second individual is intended to be a plain clothed security officer.

The Directions staff member will be subject to the same process as an agent when collecting doses (providing identification and signing for specific number of doses for individual clients).

Agents will need to leave the OMT at the door of the isolated patient and step back at least 2 metres while it is collected by the patient. Agents should call the patient to communicate their medication is at the door. Agents should confirm the patient name. Agents must not leave doses unattended at any time. Should the patient not answer the door, agents should contact the pharmacy immediately, and return the doses to them. A record of doses returned will need to be made at the pharmacy or clinic.

The Directions staff member and the second individual will deliver the doses. Both will sign documentation stating the number of doses that were delivered, confirmed the patient name and that they sighted them being taken into the appropriate premise.

Delivery to patients in residential rehabilitation

If a patient is currently a resident at a rehabilitation facility or other therapeutic community, engagement directly with the facility is also required. Some facilities have capacity for their staff to act as the patient's agent. In this case the relevant facility is nominated as the patient's agent. Should the facility not have capacity, Directions Health Service is able to provide delivery to residential rehabilitation providers.

Risk Identification

Any alternative OMT arrangements carry risks. With increased unsupervised doses available in the community, the potential for both diversion and accidental overdose by patients and third parties increases. Ensuring access to naloxone is recommended, particularly for clients using methadone.

Should patients need training materials regarding take home naloxone, or experience financial difficulty preventing their access to it, they can be referred to the Canberra Alliance for Harm Minimisation and Advocacy (CAHMA) on 02 6253 3643.

For patients who nominate Directions Health Services as their agent, the Directions staff member can provide the Naloxone and training materials on how to use it.

For patients receiving unsupervised doses for the first time, it is recommended they are provided with advice on safe storage in the home and appropriate clinical judgements are made regarding whether dose volume expansion of up to 200mL is required.

All alternative arrangements are still subject to the professional judgement of the prescriber, particularly when considering requests for increased limits of unsupervised doses. The prescriber must conduct a stability assessment of the client using the [Client Stability Assessment Form](#). Clinical judgement or telehealth follow-up is essential for patients with effectively two weeks of unsupervised dosing, who may have contracted COVID-19. It is noted that some of the risks are borne by the prescriber, with the COVID-19 pandemic creating circumstances where patients who would otherwise be assessed as not appropriate for unsupervised dosing need to have them prescribed.

Where prescribers, pharmacists or nurses have specific concerns regarding a patient, they are encouraged to contact that patient in the hours following their dose. Additionally, dose increases are not recommended in the absence of face-to-face review and some supervised dosing. This acknowledges that routine practice during OMT induction is not to prescribe unsupervised doses.

Process Review

As with many contingency arrangements during the COVID-19 pandemic, the options for OMT delivery may need adjustment over time.

Should you have any concerns or suggestions for improvement regarding this document, or the OMT provision contingency process, please email AODPolicy@act.gov.au

These arrangements will continue to apply to individuals who test positive to COVID-19 or have direct contact with a suspected COVID-19 case, however the arrangements for other individuals, particularly regarding physical distancing, are intended to cease when the Government-declared public health emergency is lifted.

Additional Resources

Commonwealth Government – Department of Health

Website: <https://www.health.gov.au/news/health-alerts/novel-coronavirus-2019-ncov-health-alert>

Facebook: <https://www.facebook.com/healthgovau>

ACT Government COVID-19

Website: <https://www.covid19.act.gov.au/>

Facebook: <https://www.facebook.com/ACTHealthDirectorate/>

Pharmaceutical Services Approval by Drug:

<https://www.health.act.gov.au/sites/default/files/2020-02/Medicines%20and%20Poisons%20-%20Application%20for%20approval%20to%20prescribe%20a%20controlled%20medicine.pdf>

ACKNOWLEDGMENT OF COUNTRY

ACT Health acknowledges the Traditional Custodians of the land, the Ngunnawal people. ACT Health respects their continuing culture and connections to the land and the unique contributions they make to the life of this area. ACT Health also acknowledges and welcomes Aboriginal and Torres Strait Islander peoples who are part of the community we serve.

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