



Government of **Western Australia**
Department of **Health**

Regulatory advice for community pharmacists during COVID-19

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Purpose

This publication provides updated regulatory advice and information to community pharmacies relating to business continuity and medication supplies, to enable safe and lawful practices during the current phase of the COVID-19 pandemic.

This advice is relevant to all community pharmacies in Western Australia. The Department of Health recognises that every community pharmacy is slightly different and there may be some need to adapt and implement this advice by taking individual circumstances into account.

This advice does not replace the need for pharmacists and community pharmacies to exercise professional judgement and comply with relevant laws and professional standards.

The Pharmaceutical Society of Australia (PSA) and The Pharmacy Guild of Australia (PGA) have produced other COVID-19 information for community pharmacy, including detailed operational information and resources which are available on their websites.

Background

Community pharmacies are an essential public service; providing readily accessible healthcare advice and supply of prescription and other medicines to the broader population.

Community pharmacists are often the first professional point of contact within the health system for people seeking information about health-related concerns.

Community pharmacies are considered to be an essential health service, required to be available to the public and needing to ensure ongoing provision of business as usual (BAU) medication management services.

Issues covered by this document include:

- Supply limits on medicines to minimise the risk of shortages,
- Prescribing and dispensing options during the current phase of the COVID-19 pandemic,
- Variations to other pharmacy practices including: signing of prescriptions, hand sanitisers and vaccinations by pharmacists,
- Ongoing safe management of Community Program for Opioid Pharmacotherapy (CPOP) clients and
- Planning for possible pharmacy closure in the event of pharmacist staff isolation.

1 Supply limits on medicines

Various measures have been introduced to impose limits on supply quantities of prescription and over-the-counter (OTC) medicines. These measures were instituted in March 2020, in response to extreme demand experienced at the start of the COVID-19 pandemic, to ensure equitable access to medicines for all consumers. There remains potential for sporadic increased demand and supply chain disruptions.

Limits and conditions, as at July 2022, are detailed below.

1.1 Prescription medicines

- For most prescription medicines it is recommended, pharmacists only dispense one month's supply at the prescribed dose, or where applicable, one standard pack..
- There are certain critical medicines where interrupted supply can result in serious health consequences. Dispensing of these should be limited to one month's supply at the prescribed dose. A list of critical medicines is found at: [Limits on dispensing and sales of prescription and over-the-counter medicines | TGA](#)

For Pharmaceutical Benefits Scheme (PBS) medicines, dispensing multiple repeats at one time is only permitted for valid, Regulation 49 (previously called Regulation 24) prescriptions, where the prescription has been endorsed by the prescriber.

For S8 medicines, pharmacists must adhere to the stated minimum repeat interval, specified on the prescription. A pharmacist cannot supply a repeat of an S8 medicine earlier than specified unless they have been directed to do so by the health practitioner who wrote the original prescription.

In addition, the Therapeutic Goods Administration (TGA) [Medicine shortages](#) database lists national shortages of medicines, which have been reported by pharmaceutical sponsors.

1.1.1 Hydroxychloroquine

- For patients commencing hydroxychloroquine, treatment must be initiated by a specialist medical practitioner such as a:
 - dermatologist
 - physician
 - paediatrician/child-health specialist
 - dental practitioner with specialist 'oral medicine' registration.
- For patients already under treatment with hydroxychloroquine, there is no change, and the usual prescriber (including general practitioners) can continue to write prescriptions.
- Overseas patients, who have been prescribed hydroxychloroquine overseas but who have not previously been prescribed hydroxychloroquine by an AHPRA registered prescriber, must also have treatment initiated by a specialist in Australia.

1.1.2 Ivermectin (oral)

- General practitioners can only prescribe oral ivermectin for the TGA approved indications: onchocerciasis (river blindness), strongyloidiasis (intestinal roundworm) and severe scabies. These indications are all eligible to be prescribed as a PBS streamlined authority item.
- Specialist medical practitioners in the following classes can prescribe for any indication:
 - Dermatologists
 - Gastroenterologists and hepatologists (including paediatric)
 - Infectious diseases physicians (including paediatric).

1.2 Over the counter medicines

1.2.1 Salbutamol inhalers (when supplied as a Schedule 3 product)

- a maximum supply of one unit, per purchase, per person.
- pharmacists are encouraged to make a record of over the counter supply, as this creates evidence of previous supply.
- supply is restricted, through the current Schedule 3 entry, to:
 - a person who requires salbutamol for the relief of bronchospasm due to asthma or chronic obstructive pulmonary disease or for acute prophylaxis against exercise-induced asthma or other stimuli known to induce bronchospasm or
 - a person where the pharmacy has a record of previous supply to the person
 - a health professional with authorisation to use and supply salbutamol in the practice of their profession (such as a PBS Doctor's Bag Order) or
 - supply for use in first aid at a school, child-care centre or similar institution.

Pharmacists are expected to use professional judgement; however, suitable evidence to support a decision to supply could include sighting an asthma management plan, dispensing history, old prescription, doctor's letter or hospital discharge or provision of a suitable clinical history.

1.2.2 Other OTC medicines

- Pharmacists should limit supply of critical Schedule 3 products to one unit per purchase, wherever possible.
- This includes paracetamol products for children, GTN spray, adrenaline auto-injectors and naloxone.

The list of over the counter medicines where interrupted supply could result in serious health consequences and supply is limited to one unit per purchase is found at [Limits on dispensing and sales of prescription and over-the-counter medicines | TGA](#)

2 Urgent supply when the patient does not have a valid prescription

With isolation required for people who have COVID-19 infection and, in some circumstances, for people who are close contacts of a COVID-19 case, there will be situations where a patient may be unable to obtain a prescription in a timely manner.

The Medicines and Poisons Regulations 2016 include a number of mechanisms by which a pharmacist may be able to supply a Schedule 4 or Schedule 8 medicine without the patient first presenting a prescription.

2.1 Three day supply initiated by pharmacist

The Regulations allow pharmacists to supply an emergency three day supply of a Schedule 4 medicine.

A three day supply can only be provided if:

- the pharmacist is satisfied that the patient is already under treatment with the medicine,
- the patient cannot obtain a prescription and
- interruption of treatment is likely to cause harm.

In this case, no prescription or confirmation by a prescriber is required.

2.2 Direction from a prescriber, in an emergency

Pharmacists can supply a quantity of both a Schedule 4 and Schedule 8 medicine where the prescriber has directed the pharmacist to do so orally, by telephone or by 'other electronic means'. The term 'other electronic means' includes options such as a fax, a photo of the prescription sent by email or via a text message or a scan of the prescription sent by email or via a text message.

This type of emergency supply is only applicable where the fax, photo or scan is sent to the pharmacy by the prescriber. If the fax, photo or scan is sent to the pharmacy by the patient, the patient must present the original prescription (or repeat authorisation) before the medicine can be provided to the patient.

Where a prescriber directs a pharmacist to supply a prescription for a Schedule 4 or 8 medicine in this manner, the prescriber must dispatch a covering prescription directly to the dispensing pharmacy within 24 hours. The covering prescription must not be provided to the patient and the obligation to supply the covering prescription is with the prescriber.

The pharmacist is required to notify the Department if the prescription for the Schedule 8 medicine has not been received within five working days of making the supply.

As in normal circumstances, if a pharmacist is presented with an original prescription for a Schedule 8 medicine and is unable to confirm that the prescription is authentic, up to 2 days' supply can be provided to the patient.

2.3 Continued dispensing

The term 'continued dispensing' refers to the provision of one additional supply of certain Pharmaceutical Benefits Scheme (PBS) medicines where the patient is already under chronic therapy with the medicine but where it is not practical for the patient to obtain a new ongoing prescription for their medically necessary treatment.

Since 2012, continued dispensing arrangements have existed for oral contraceptives and HMGCoA reductase inhibitors ('statins').

Early in the COVID-19 pandemic, continued dispensing was expanded to cover a significantly greater range of Schedule 4 medicines. However, those arrangements ceased at the end of June 2022 and, from 1 July 2022, have been replaced by a more limited ongoing arrangement.

Continued dispensing is **not** applicable to any Schedule 8 medicines.

The Commonwealth Government has issued a determination under the *National Health Act 1953*, which includes PBS items for chronic treatment of various cardiac and respiratory conditions as well as diabetes and HIV. This regulatory instrument is available on the Federal Register of Legislation website at: [National Health \(Continued Dispensing\) Determination 2022](#).

A list of PBS medicines that may be supplied via continued dispensing arrangements is found in Schedule 1 of the [National Health \(Continued Dispensing\) Determination 2022](#)

Under the WA legislation, a Structured Administration and Supply Arrangement (SASA) issued by the Chief Executive Officer (or delegate) of the Department of Health is used to provide regulatory support for continued dispensing arrangements. The [Pharmacists - Continued Dispensing SASA](#) allows pharmacists to supply the same PBS items as the Commonwealth Government instrument.

Supply is subject to the pharmacist being adequately satisfied that:

- the patient is already under chronic, continuous treatment with the medicine
- resupply is urgent and medically necessary and
- it is not practical for the patient to obtain a prescription.

Continued dispensing provisions are only accessible once in a 12 month period. After accessing a continued dispensing supply, patients will need to return to a prescriber, for prescriptions to authorise ongoing supply.

Pharmacists are expected to use professional judgement. It is suggested that the pharmacist review and verify prior dispensing history on record at the pharmacy.

If the patient is not a usual customer of the pharmacy, then provision of the most recent, labelled medicines package may be suitable. Any used packaging used for this purpose should not be returned to the patient.

In all cases, pharmacists should check the most recent date of supply. Access to continued dispensing is only suitable where the patient has exhausted, or is about to exhaust, their supply. This should be based on the prior date of supply.

Continued dispensing provisions are not a substitute for appropriate medical review. Pharmacists are encouraged to remind patients that telehealth services may be available for medical review.

Usual dispensing records must be made and supplied medicines must be labelled as usual.

Continued dispensing does not apply to prescriptions written by an overseas medical practitioner.

If a continued dispensing supply is made, pharmacists must advise the patient's most recent prescriber that this has occurred. This is both a PBS requirement and a condition of the SASA.

2.4 Cessation of 'digital image' provisions

Early in the COVID-19 pandemic, the Commonwealth Government issued a legislative instrument to allow pharmacists to dispense PBS medicines following receipt of a 'digital image' of a paper-based prescription. This was intended to complement the newly initiated Medicare Benefits Schedule (MBS) Telehealth Services and recognised the limited availability of electronic prescriptions at the time.

In line with the Commonwealth 'digital image' arrangement, an authorisation was issued under the *WA Public Health Act 2016*. This mechanism to authorise use of 'digital image' prescriptions could be used because the COVID-19 Public Health State of Emergency had been declared.

These emergency arrangements meant that prescribers did not have to send the original paper-based prescription from which the 'digital image' was taken to the supplying pharmacy.

The regulatory allowances for use of 'digital image' prescriptions **ceased** on 31 March 2022. This means that, from 1 April 2022, if a prescriber uses of a 'digital image' of a paper-based prescription to direct a pharmacist to make an emergency supply, the prescriber must also send the original paper-based prescription directly to the pharmacy (see Section 2.2).

3 Variations to other community pharmacy practices during COVID-19

3.1 Signing for receipt of a medicine

The PBS requirement that patients or their agents sign for the receipt of a PBS medicine, does not apply during the current phase of the COVID-19 pandemic, where it is not practicable for them to sign the prescription.

The Medicines and Poisons Regulations 2016 do not specify that the receipt of medicines is required by signing the prescription.

3.1.1 Signing prescriptions for medicines in Schedule 8

Whilst PBS prescriptions do not have to be signed for during the current phase of the COVID-19 pandemic and the WA legislation does not specify that prescriptions are signed for, pharmacists may believe that signing a prescription for receipt of a Schedule 8 medicine is required in certain circumstances.

If a patient refuses to sign for the receipt of a Schedule 8 medicine when requested, it is recommended that the pharmacist records this on the prescription.

3.2 Hand sanitisers

Hand sanitisers are regulated as cosmetics or as therapeutic goods, depending on the claims made for the sanitiser. The exemptions from certain regulations issued by the TGA for specific formulations of hand sanitisers during COVID-19 continues.

Hand sanitisers do not usually contain ingredients that are scheduled substances.

There are strict labelling requirements including the requirement for a 'Keep out of reach of children' statement.

Further information [about hand sanitisers](#) is available on the TGA website.

3.3 Ethanol

The WA Medicines and Poisons legislation does not cover the use or sale of ethanol. However, because the ethanol purchased by pharmacies is not denatured and there is no excise paid on it (regulated by the Australian Taxation Office, ATO), it cannot be sold to the public. Alcohol purchased by pharmacies for use in compounding is classified as 'concessional spirit' by the ATO. Further information is available [on the ATO website](#).

Pharmacists cannot supply neat ethanol or ethanol diluted with water without other excipients or additives, but they can use ethanol to compound other products.

4 Community Program for Opioid Pharmacy therapy (CPOP)

4.1 General Recommendations

The general recommendations to improve pharmacist and patient safety during the COVID-19 State of Emergency, continues during this phase. CPOP pharmacists are recommended to:

- organise and stagger dosing attendance times for clients;
- ensure clients comply with social distancing requirements; and
- provide naloxone to all clients, particularly those accessing take away doses.

Naloxone can be provided over the counter, via prescription or through the 'Take Home Naloxone' (THN) Program.

The THN Program moved from being a pilot program to an ongoing national program from 1 July 2022. THN is available free of charge through pharmacies registered in the THN Program. For pharmacies, the THN Program is managed via the [Pharmacy Programs Administrator](#).

4.2 Dosing

Methadone and buprenorphine in CPOP may only be supplied by an approved pharmacy and on the prescription of an approved CPOP prescriber. CPOP Pharmacies must continue to observe the [CPOP Clinical Policies and Procedure](#) (the WA Policies) manual at all times. All patients continue to require approval to enter into the CPOP program and prescriptions must have a HDWA number to confirm this approval.

However, during the COVID-19 State of Emergency, existing CPOP clients may have their therapy modified, to reduce the frequency of pharmacy attendance. In these cases, modifications to any prescribed treatment must:

- be made by an approved CPOP prescriber;
- be part of instructions on a valid prescription; and
- **not** be initiated by the patient or pharmacist.

Approved prescribers may consider modification of therapy, where safe to do so, on a case by case basis. This may occur in a number of ways, such as:

- transfer from methadone to buprenorphine;
- extending buprenorphine dosing intervals (i.e. daily to second or third daily);
- increasing takeaway doses to the maximum number provided for in the WA Policies;
- transfer to depot buprenorphine formulations.

In all cases, adjustment must be authorised by the prescriber and a replacement, compliant CPOP prescription received by the pharmacy.

Pharmacists are not permitted to dose at or deliver takeaway doses to a patient's residence due to safety considerations.

Depot buprenorphine is only to be prescribed by approved specialist prescribers and supplied by pharmacies individually approved by the Department of Health for this purpose.

For CPOP patients diagnosed with COVID-19 and who are in home isolation, arrangements will be considered on a case by case basis, consistent with the individual risk involved. Unless specifically approved in relation to an individual client, pharmacies may **not** supply to third parties or home deliver CPOP therapy. All exceptional arrangements of this nature require approval of the prescriber **and** the Community Pharmacotherapy Program (CPP) or Department of Health. (see also Sections 4.3.1 and 4.3.2)

4.3 Extraordinary arrangements

4.3.1 Additional takeaway doses

The CPOP Clinical Review Committee (CPOP CRC) or Next Step prescribers *may* provide approval for supply of additional takeaways outside the standard WA Schedule.

If this occurs, the pharmacy will be advised formally by the CPOP CRC or the Next Step prescriber for record keeping and accountability purposes.

4.3.2 Collection of takeaways by a third party

The CPOP CRC *may* provide approval for collection of takeaway doses to an approved person nominated by a CPOP prescriber.

The number of doses approved for collection will be determined on a case-by-case basis.

If this occurs, the pharmacy will be advised formally by the CPOP CRC for record keeping and accountability purposes.

The nominated person must show photographic identification and sign a collection agreement at the time of collection.

4.3.3 Closure of CPOP Pharmacy

Pharmacies should consider this possibility and develop a contingency plan, in advance, for management of CPOP clients.

For any CPOP pharmacy considering the need for temporary closure due to COVID-19, arrangements must be made for all CPOP clients prior to closure. Affected pharmacies should, as soon as possible, make contact with the:

- Community Pharmacotherapy Program (CPP) on 08 9219 1913; and
- Department of Health on 08 9222 6812.

Copies of all current patient prescriptions and dosing histories must be forwarded to CPP to assist with client relocation.

A notice should be attached to the pharmacy shopfront advising CPOP clients to call their prescriber or the CPP for assistance.

See also Section 6: Pharmacy Closures

5 Medication supply and delivery practices

5.1 Sending medicines via post or courier

Schedule 4 (S4) medicines which have been prescribed, dispensed and labelled for a patient can be sent to patients via post or courier. This is not restricted under Western Australian law, however Australia Post regulations may apply. The [Australia Post - Dangerous and prohibited goods and packaging guide](#) requires that the quantity sent “does not exceed the maximum quantity that may be dispensed at one time” and have special packaging requirements for tablets, liquids, pastes and powders.

In the case of Schedule 8 medicines delivered by post or courier, items should be packaged in a way that means the contents are securely wrapped and not readily identifiable during transit. It is recommended that the sender obtain a receipt from the carrier and require the carrier to obtain a receipt from the addressee and deliver this to the sender.

Schedule 2, Schedule 3 and unscheduled medicines can be sent to the patient by post or courier or other carrier. For S3 medicines, pharmacists must continue to meet normal standards relating to determining therapeutic need prior to supply. Quantities of S3 medicines supplied must be reasonable for the therapeutic need.

Regardless of the mode of delivery, pharmacists should consider their ongoing professional responsibilities to ensure quality use of medicines and patient safety, including that adequate counselling is provided to the patient in relation to any medication supplied.

6 Pharmacy participation in COVID-19 vaccine rollout

In late January 2021, the Commonwealth Government announced that community pharmacies were eligible to be vaccination sites for the COVID-19 vaccine rollout from Phase 2A (May 2021 onwards). Since the COVID-19 vaccine rollout commenced, over 7.5 million vaccine doses have been administered in community pharmacies across Australia.

Only pharmacies approved by the Commonwealth Department of Health, via the Pharmacy Programs Administrator (PPA), are eligible to participate in the COVID-19 Vaccination in Community Pharmacy (CVCP) Program.

Further information about the CVCP Program is available from the [Pharmacy Programs Administrator \(PPA\)](#).

To provide the necessary regulatory support in WA, a [Structured Administration and Supply Arrangement \(SASA\)](#) has been issued authorising suitably trained pharmacists to initiate administration of COVID-19 vaccine products provided the pharmacy has been approved to participate in the CVCP Program.

7 Pharmacy Closures

In the event a sole pharmacist is in isolation due to COVID-19 and the pharmacy is unable to source a locum pharmacist, the pharmacy must continue to comply with regulations on supply and storage of medicines.

7.1 Pre-planning

Pharmacies are encouraged to plan ahead of time for the possibility of a temporary closure by:

- identifying and reviewing availability of locum arrangements
- checking in advance regarding patient preferences for transferring repeat prescriptions to another pharmacy
- contacting other local pharmacies to organise and share plans regarding assistance, emergency script transfers and other professional services
- preparing signage to notify patients of any arrangements in place
- considering arrangements for patients to contact pharmacy staff and receive advice on supply alternatives in the event of a sudden closure and
- considering continuity of care for patients receiving pharmacy services that are not readily transferrable elsewhere.

Arrangements for continuity of care for patients should be considered, planned and clearly communicated for patients:

- with prescriptions on file, including for Schedule 8 medicines
- receiving opioid substitution therapy (CPOP)
- on staged-supply arrangements
- receiving dose administration aids (DAA) and
- who have delivery arrangements in place.

7.2 Repeat prescription transfers

The following options can be considered for prescription transfers for any pharmacy that is required to close temporarily.

7.2.1 Schedule 4 medicines

Prescriptions can be:

- delivered to a different pharmacy in advance, according to patient preference
- sent to the patient's home, by post or other means
- individually sent, as requested, by courier or delivery service, to another pharmacy for dispensing and delivery to the patient.

7.2.2 Schedule 8 medicines

Repeat prescriptions for paper-based Schedule 8 (S8) medicines must remain on the premises of the pharmacy which first dispensed them. For fully electronic S8 prescriptions, repeats can be dispensed at any pharmacy and the patient should be provided with their token to allow them to access their next S8 repeat.

For patients that require supply while a pharmacy is temporarily closed, transfer of repeat prescriptions to another pharmacy should be arranged via the [normal process](#).

Information supplied to MPRB should include:

- patient name, address and date of birth
- medicine name, form, strength and quantity
- dispensing interval

- date of transfer and
- name and address of receiving pharmacy.

Where multiple transfers are involved, this information can be provided in a spreadsheet format.

Paper-based S8 repeats must not be returned to patient. The repeats must be posted or hand delivered to the new pharmacy and the pharmacy should be alerted to expect the transfer. For prescriptions transferred, the last date of supply must be clearly visible to the receiving pharmacy.

7.3 Staged-supply

Staged-supply arrangements must continue without amendment, unless the prescriber has been contacted and approved other arrangements. For staged-supply patients, who are in isolation or quarantine, the prescriber must be contacted before modifying supply arrangements.

For Schedule 8 medicines, many staged-supply arrangements are a prescribing condition imposed by the Department of Health. Staged supply medications may be home delivered.

If transferring a staged-supply prescription to another pharmacy:

- transfer the prescription as above
- communicate any staged-supply restrictions to the receiving pharmacy
- ensure the record of supply and the date of last supply are clear and provided to the receiving pharmacist.

7.4 Security

Pharmacists are reminded that all standard after-hours security arrangements must be in place for any pharmacy required to close temporarily, including alarms and monitoring.

Pharmacists are not authorised to take medicines home, dispense medicines from another site that is not the registered pharmacy premises, or conduct pharmacy practice from a mobile site.

Pharmacies may not dispense prescription medicines or supply Schedule 3 medicines, without the pharmacist present at the pharmacy.

In the absence of the pharmacist, non-pharmacist staff are permitted to enter the premises and conduct administrative and other non-dispensing activities, such as assisting with script transfers, at the direction of the pharmacist in charge. In these cases;

- there must be no public access to medicines (i.e. pharmacy is not open to the public)
- the staff may not dispense or supply medicines and
- the staff may not have any access to Schedule 8 medicines.

Such arrangements are subject to the discretion and direction of the responsible pharmacist.

7.5 Temporary closure checklist

- Ensure ongoing security arrangements for storage of medicines
- Place signage for customers
- Advise local prescribers and nearby pharmacies
- Make arrangements for transfer of prescriptions on file
- Advise CPOP program and make arrangements for CPOP clients
- Contact aged care facilities or other contracted services
- Advise other authorities –
 - [Pharmacy Registration Board](#)
 - [Medicines and Poisons Regulation Branch](#) and
 - [Pharmaceutical Benefits Scheme](#).

8 Further Information

Australian Government Department of Health

www.health.gov.au/news/health-alerts/novel-coronavirus-2019-ncov-health-alert/coronavirus-covid-19-resources

Government of Western Australia Department of Health

ww2.health.wa.gov.au/Articles/A_E/Coronavirus

Therapeutic Goods Administration

www.tga.gov.au/behind-news/coronavirus-covid-19-information-medicines-and-medical-devices

Pharmaceutical Society of Australia

www.psa.org.au/coronavirus

Pharmacy Guild of Australia

www.guild.org.au/resources/business-operations/COVID-19-Information

Society of Hospital Pharmacists of Australia

[COVID-19 information hub - The Society of Hospital Pharmacists of Australia \(shpa.org.au\)](http://www.shpa.org.au/COVID-19-information-hub)

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