Regulatory advice for community pharmacists during COVID-19

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**Purpose**

This publication provides regulatory advice and information to community pharmacies relating to business continuity and medication supplies, to enable safe and lawful practices during 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 in 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 is 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.

During the current crisis, community pharmacies are 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 during the COVID-19 pandemic.

Issues covered by this document include:

- Supply limits on medicines to prevent shortages
- Prescribing and dispensing options during COVID-19
- 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 requirements for possible pharmacy closure in the event of pharmacist staff isolation.

Recommendations for a safe pharmacy environment and minimising staff and patient exposure to COVID-19 are covered elsewhere and are not specifically addressed in this document.
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 response to extreme demand due to the COVID-19 pandemic and to ensure equitable access to medicines for all consumers.

Limits and supply conditions are imposed through various regulatory mechanisms and are anticipated to be added, extended or modified in response to changing demand and critical shortages.

As at 23 April 2020, limits and conditions are detailed below.

1.1 Prescription medicines

- Pharmacists may only dispense ONE months’ supply at the prescribed dose for specified medicines
- Critical medicines affected by this limit are listed on the Therapeutic Goods Administration (TGA) website.

It is recommended that other prescription medicines also be limited to ONE months’ supply or, where applicable, one standard pack (for example, oral contraceptives).

For PBS medicines, dispensing multiple repeats at one time is permitted only for valid, Regulation 49 (previously called Regulation 24) prescriptions, endorsed by the prescriber themselves. Regulation 49 must be used sparingly and only in exceptional circumstances in accordance with the legislated criteria. In case of any doubt, pharmacists should discuss this with the prescriber.

For S8 medicines, pharmacists must adhere to the stated minimum repeat interval, specified on the prescription.

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 and have not been previously prescribed hydroxychloroquine by an AHPRA registered prescriber must also have treatment initiated by a specialist in Australia.

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 to:
  - a person with evidence of a medically diagnosed lung condition
  - 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, evidence of medically diagnosed lung condition 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 Paediatric paracetamol formulations
- Only one product and one unit should be supplied per customer.

1.2.3 Other OTC medicines
- Pharmacists should limit supply of critical Schedule 3 products to one supply per customer where ever possible.
- This includes GTN spray, adrenaline auto-injectors and naloxone.

A comprehensive list of prescription and OTC medicines that have enforced limits on their supply can be found at the [TGA website](https://www.tga.gov.au)

2 Dispensing options during COVID-19
There are a number of options available to pharmacists in situations where the patient does not have a valid paper-based original prescription or repeats. These include:
- the normal option for dispensing scheduled medicines in an emergency as per the WA Medicines and Poisons Regulations 2016
- digital images of prescriptions written during a telehealth consultation
- continued dispensing

These options are summarised in the following table and described in more detail on pages 5 to 7.

<table>
<thead>
<tr>
<th>Dispensing option</th>
<th>Schedule 4</th>
<th>Schedule 8</th>
<th>Original Rx required</th>
<th>Rx requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1</strong> Normal emergency supply with no confirmation by prescriber. Can still occur during COVID-19.</td>
<td>3 days’ supply maximum</td>
<td>Not allowed</td>
<td>Not required</td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>2</strong> Normal emergency direction to supply <em>directly from prescriber</em> by fax, phone or email. Can still occur during COVID-19. <strong>See also option 3.</strong></td>
<td>Yes, supply quantity prescribed (i.e. quantity directed to supply by prescriber)</td>
<td>Yes, supply quantity prescribed once confirmed with prescriber. Do not dispense if unable to confirm with prescriber.</td>
<td>Yes for S4 and S8 Prescriber must send Rx within 24 hours and mark Rx that it is a confirmation of direction to supply. <strong>See also option 3.</strong></td>
<td>Normal as per Regulation 10 of WA Medicines and Poisons Regulations 2016</td>
</tr>
<tr>
<td>Notify Department if Rx not received by pharmacy?</td>
<td>No</td>
<td>Yes</td>
<td>Yes for S8 if Rx not received within 5 working days</td>
<td></td>
</tr>
</tbody>
</table>

[TGA website](https://www.tga.gov.au)
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.

2.1 WA legislation: normal supply of medicines in an emergency

The Medicines and Poisons Regulations 2016 already allow pharmacists to supply an emergency three day supply of a Schedule 4 medicine. A 3 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.

The Medicines and Poisons Regulations 2016 also already allow pharmacists to 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 sent by email or via a text message or a scan 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 supplied.

Where a prescriber directs a pharmacist to supply a prescription for a Schedule 4 or 8 medicines in this manner, the prescriber must dispatch a prescription directly to the dispensing pharmacy within 24 hours.

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 the supply.

See Section 2.2 below for variations to the usual emergency supply processes when a digital image of a prescription, written during a telehealth consultation, is sent to the pharmacy by the prescriber.
2.2 Digital images to supply PBS medicines in support of Telehealth Services

To complement the new temporary Medicare Benefits Schedule (MBS) Telehealth Services, the PBS now allows prescribers to provide a digital image (via fax, email or text message) of a prescription to a pharmacist to dispense.

In line with PBS changes, an emergency notice issued under the WA Public Health Act 2016 also allows dispensing to occur following receipt of a digital image of a prescription from a prescriber. The authorisation document can be found at: [www.wa.gov.au/government/publications/authorisation-prescribe-or-supply-poison](http://www.wa.gov.au/government/publications/authorisation-prescribe-or-supply-poison)

If the digital image prescription is for a Schedule 4 medicine, both Commonwealth and Western Australian requirements mean prescribers do not have to send a hard copy of the prescription to pharmacies.

All repeats ordered on a digital image of a prescription must be retained by the pharmacy.

If the digital image prescription is for a Schedule 8 medicine, WA legislation requires prescribers send hard copies of the prescriptions to pharmacies within five working days.

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

Both prescribers and pharmacists are required to retain copies of the fax, email or text message of digital images of prescriptions for Schedule 4 medicines for two years.

Where a prescriber has transmitted a digital image of a prescription for a Schedule 8 medicine to a pharmacist, the pharmacist must keep the digital image until the hard-copy prescription is received.

This means the only changes from the usual ‘emergency supply’ requirements for Schedule 8 prescriptions are that the time for the prescriber to dispatch, and the time for the pharmacist to receive, the hard-copy prescription have been extended.

2.3 Continued dispensing

2.3.1 Continued dispensing and WA legislation

In line with Commonwealth changes, an emergency notice issued under the WA Public Health Act 2016 now allows pharmacists to provide an additional supply of S4 medicines for patients who require ongoing treatment and who are unable to obtain a prescription from their doctor.

This applies to all S4 medicines.

Continued dispensing is not applicable to S8 medicines.

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.

The supply is to be for one standard PBS supply quantity or in the case of a non-PBS medicine, the smallest generally available standard pack size.

At this time, 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.

Continued dispensing is not suitable for acute or short term therapy, antibiotics or other situations where treatment is not continuous.
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. Early supply is not appropriate, simply due to a State of Emergency and particular care should be taken with benzodiazepines and other similar medicines.

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.

Further information is available at ww2.health.wa.gov.au/Articles/A_E/Coronavirus/COVID19-information-for-health-professionals

2.3.2 Continued dispensing and the PBS
The Commonwealth Government has expanded the number of medicines for which continued dispensing is applicable under the PBS, during COVID-19.

A list of these medicines can be found at: National Health Continued Dispensing Emergency Measures

Information on the PBS requirements for continued dispensing can be found at: Education guide- Continued Dispensing Initiative- PBS requirements

Frequently asked questions regarding the PBS can be found at: FAQ for PBS continued dispensing

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

Continued dispensing is based on a prescription written previously by an Australian Registered health practitioner with prescribing rights.

2.3.4 Continued dispensing - differences between the PBS and WA legislation

- Schedule 8 medicines: the PBS allows for the continued dispensing of Schedule 8 medicines, WA legislation does not; therefore Schedule 8 medicines cannot be supplied via continued dispensing arrangements in WA.

- Quantity: the PBS allows for increased quantities to be continually dispensed if the patient has previously had an authority prescription; however WA legislation limits the quantity to a standard PBS quantity.

- The PBS has a specific list of medicines that can be dispensed via continued dispensing, WA legislation allows continued dispensing for all Schedule 4 medicines, which means continued dispensing is applicable to non-PBS medicines in WA.
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 COVID-19, 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 COVID-19 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, 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 TGA has issued exemptions from certain TGA regulations for specific formulations of hand sanitisers during COVID-19. Hand sanitisers do not usually contain ingredients that are scheduled medicines.

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

Further information is available on the TGA website at: www.tga.gov.au/hand-sanitisers-and-covid-19

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. Further information is available on the ATO website at: www.ato.gov.au/Business/Excise-and-excise-equivalent-goods/Alcohol-excise

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

3.4 Vaccination by pharmacists
When vaccines are being administered (including during the period of post-vaccination monitoring), at least one pharmacist or other staff member, who is currently competent to provide CPR and first aid, must be present and available.

St John Ambulance is offering CPR refresher courses for pharmacy staff. Bookings can be made:
- Via the St John Corporate Team: corporate@stjohnwa.com.au

The email request should have an email address from the pharmacy or email signature that indicates it is not from an individual person as places are being prioritised for essential workforce / healthcare workers.
Call St John Ambulance on 08 9334 1233 and indicate that the booking is for pharmacy staff.

4 Community Program for Opioid Pharmacy therapy (CPOP)

4.1 General Recommendations
To improve pharmacist and patient safety during the COVID-19 State of Emergency, 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.

THN is available free of charge through pharmacies registered in the THN Pilot Program. Registration for the program is via the Mental Health Commission website and additional information is available at Australian Health Department website.

4.2 Dosing
Methadone and buprenorphine in CPOP may still 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 in home isolation, arrangements will be considered on a case by case basis, consistent with the individual risk involved. 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.

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 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.

6.1 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.

6.2 Repeat prescription transfers

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

6.2.1 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.

6.2.2 Schedule 8 medicines

Repeat prescriptions for Schedule 8 medicines must remain on the premises of the pharmacy which first dispensed them.

For patients that require supply while a pharmacy is temporarily closed:

- arrange for transfer of repeat prescriptions to another pharmacy 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.

Schedule 8 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.

Continued dispensing arrangements do not apply to Schedule 8 medicines. Where required, patients can obtain a new prescription from a prescriber under emergency provisions and the prescriber may email, phone or fax the prescription to the pharmacy, prior to sending the original.

6.3 Staged-supply
Staged-supply arrangements should continue without amendment, unless the prescriber has been contacted and approved other arrangements. For staged-supply patients, in isolation with COVID-19, 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.

6.4 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.

Pharmacist 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.

6.5 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
7 Further Information

Australian Government Department of Health

Government of Western Australia Department of Health
ww2.health.wa.gov.au/Articles/A_E/Coronavirus

Therapeutic Goods Administration

International Pharmaceutical Federation

Pharmaceutical Society of Australia
www.psa.org.au/coronavirus

Pharmacy Guild of Australia

Society of Hospital Pharmacists of Australia
www.shpa.org.au/covid-19
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