Exemptions to the Opioid Agonist Therapy “OAT” Standards During the COVID-19 Pandemic

The provision of medication for Opioid Agonist Therapy (“OAT”) is an essential service. The Saskatchewan College of Pharmacy Professionals (SCPP) along with the College of Physicians and Surgeons of Saskatchewan (CPSS) and the Saskatchewan Registered Nursing Association (SRNA) collective goal remains the safe, accessible, effective and consistent treatment for individuals with opioid use disorder. With the quickly evolving environment in the context of the COVID-19 outbreak, it is crucial to ensure uninterrupted, appropriate access to health care and medications.

Health Canada has provided all Provincial Regulatory Authorities (PRAs) with a Controlled Drugs and Substances Act (CDSA) section 56 exemption. This exemption is in place until September 30, 2020, or the date it is replaced by another exemption or on the date it is revoked.

SCPP established the OAT Standards to ensure pharmacists are providing a consistent practice in terms of the delivery of care to patients who are receiving OAT for substance use disorders.

SCPP, CPSS and SRNA have collaborated on the decisions contained in this document.

Any deviations from the OAT Standards must be documented as to the reason/specific circumstances for the change to the process. It is recommended that “COVID-19 be part of the information documented.

Pharmacists should emphasize the temporary nature of any deviation from the Standards with patients and stress that once the current pandemic risks have subsided, strict adherence to the existing Standards will be resumed.

Practitioners involved in OAT were provided with direction in-line with this communication from CPSS.

When considering OAT take-home doses or deviation from non-standard practices, prescribers are encouraged to be mindful of (not limited to):

- The patient’s risk of taking more medication than prescribed;
- The safe storage of medication;
- The risk of medication diversion;
- The concurrent use of interacting prescribed and non-prescribed substances such as alcohol and other CNS depressants;
- Potential instability due to mental health concerns; and
- The risk of take-home doses to other members in the home.

Practitioners who prescribe OAT will be assessing their patients to determine when the number/amount of take-home doses of methadone and buprenorphine-naloxone may be increased. Pharmacists may see an increase in the length (date range) of prescriptions, an increase in the quantity of take-home doses provided to patients and patients who were on daily witness medications now receiving take-home doses as well as a waiving of witnessing.
ingestion of doses. The time between urine drug screens may also be extended. In circumstances where the usual care of a patient is changed, the practitioner has been advised to document COVID-19 onto the Rx.

Every effort should be made to ensure that patients who are receiving daily observed therapy of HIV or Hepatitis C medications will maintain adherence to therapy if they are not attending the pharmacy every day.

**Buprenorphine/naloxone**

For buprenorphine/naloxone prescriptions the maximum number of take-home doses should not exceed **28 doses** and medication should be blister-packaged (if not already provided in blister-packaging), if packaging options are available. Practitioners have been advised that requests for blister-packaging should be indicated on the prescription. Please see the OAT Standards for more information on blister packaging buprenorphine/naloxone.

**Methadone**

For patients receiving methadone via daily witnessed ingestion, and especially for those with chronic health conditions, practitioners have been advised that take-home doses may be considered once a stable dose is achieved (e.g. not during initiation). The practitioner is asked to consider the benefits and risks of granting take-home doses and is encouraged to provide incremental take-home doses (e.g. 1 to 2 take-home doses per week) where possible. The maximum number of take-home doses should not exceed **14 doses**. Patients receiving a daily methadone dose of ≥120mg, may only receive up to 7 take-home doses.

Patients receiving take-home doses **must** present a locked box at the pharmacy before take-home doses are provided, regardless of the number of take-home doses provided. The patient should be asked if they have a safe place to store their medication before providing take-home doses. Empty take-home dose bottles of methadone **must** be returned to the pharmacy, intact and not tampered with, for proper disposal. We must make every effort to keep our patients and our community safe.

Anytime, but especially when take-home doses are provided, it is essential to highlight the importance of a Take Home Naloxone Kit for patients, social supports and caregivers.

In the interest of infection control, the pharmacist may, with consent from the patient, sign on their behalf for witnessed ingestion and/or pick up of OAT. Returns of methadone bottles must continue to be accepted, but the use of gloves and hand hygiene for handling is strongly advised during regular operations and required during the COVID-19 pandemic. The Harm Reduction Coalition has published information for Safer Drug Use During the COVID-19 Outbreak. Please note the Prescription Quantities Restrictions applicable to Saskatchewan residents.

As per the CDSA section 56 exemption pharmacists may, under specific criteria:

- Extend (a pharmacist may prescribe an interim supply) for a CDSA prescription to a patient while the patient is under their professional treatment at the pharmacy to renew an existing prescription for which the patient has already been diagnosed and for which the patient is already under the care of a practitioner.
- Pharmacists may accept a verbal order for a CDSA medication from an authorized
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practitioner.

• Pharmacists may transfer a prescription for a CDSA medication within Saskatchewan.
• An employee of the pharmacy may deliver a prescription for a CDSA medication.
• In regard to CDSA drugs, the pharmacist, when it is safe to do so, in the best interest of the patient and to prevent the spread of COVID-19 may waive the direct observation of OAT.
• In all of these instances, documentation of the rationale for the decision is required on the patient’s profile or pharmacy record.

Please note that missed dose protocols are to be followed and no doses are to be provided after three (3) consecutive missed doses of methadone or six (6) consecutive missed doses of buprenorphine-naloxone.

Practitioners may institute a direct witness ingestion of methadone and take-home naloxone kits if there is a risk of diversion.

**Delivery of OAT**

Pharmacist must follow the directions as outlined in the [section 56 exemption](#) information provided to you on March 23, 2020.

It is still important even when delivering OAT to ensure the patient is not impaired by another substance or medication which could result in serious harm or an overdose. When providing doses of OAT ensure that the patient’s identity has been confirmed and the patient is not showing signs of intoxication such as slurred speech, gait disturbances or extreme sleepiness or the ability to maintain a coherent conversation.

• Pharmacy staff who deliver controlled substances must adhere to the requirements of social distancing. Arranging payments over the phone prior to the delivery is strongly recommended to decrease the need to exchange money and respect social distancing.
• Pharmacy staff who deliver prescriptions may opt to leave the prescriptions at the door and witness the patient pick up the medication from a distance. The patient should be called when the delivery is made to ensure the correct patient answers the door to pick up, and prescriptions must never be left unattended.
• Pharmacy staff who deliver prescriptions must ensure they:
  o can confirm the identity of the patient or the person responsible for that individual’s care,
  o can ensure the security and integrity of the controlled substances provided to the patient,
  o can ensure the privacy and confidentiality of the patient is maintained at all times,
  o obtain in writing, a note from the pharmacist identifying the name of the individual effecting the delivery, the name and quantity of the controlled substance to be delivered, and the place of delivery, and
  o have a copy of the above note as well as a copy of the [Health Canada Exemption](#) while effecting the delivery.
Transport the medication in a secured container.

The pharmacy staff delivering the medication should be informed that the delivery must be made the same day the medication is provided for delivery and must be returned to the pharmacy if no one was available to accept the delivery. No OAT medications are to remain outside the pharmacy overnight if not delivered to the patient. OAT medications which are not received by the patient (i.e. returned delivery) must be documented on the appropriate records and the practitioner must be notified as per the OAT Standards.

The pharmacy staff delivering the OAT medication must have a copy of the section 56 exemption available and on their person whenever delivery OAT as well as other CDSA medications. They must also have a mechanism to reach the pharmacist for any questions. The pharmacy staff member delivering the medication must ensure it is provided to the patient for whom it is intended or a confirmed agent of the patient if the patient is self-isolating. This will require the pharmacy staff member to identify the patient (photo identification, if and when possible) while keeping in mind social distances (one to two meters) and the need to limit physical and surface contact. The pharmacy staff member delivering the medication is to sign that they have delivered the medication, if possible, in the presence or in a way in which the patient can observe the signature.

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