College of Pharmacists of British Columbia

Board Teleconference
April 6, 2020
MINUTES

Members Present:
Christine Antler, Chair, District 2
Anca Cvaci, Vice-Chair, District 6
Alex Dar Santos, District 1
Andrea Silver, District 3
Steven Hopp, District 4
Michael Ortynsky, District 5
Claire Ishoy, District 7
Bal Dhillon, District 8
Tracey Hagkull, Government Appointee
Anne Peterson, Government Appointee
Katie Skelton, Government Appointee
Justin Thind, Government Appointee

Staff:
Bob Nakagawa, Registrar
David Pavan, Deputy Registrar
Ashifa Keshavji, Director of Practice Reviews and Quality Assurance
Doreen Leong, Director of Registration and Licensure
Mary O'Callaghan, Chief Operating Officer
Anu Sharma, Acting Director of Policy and Legislation
Gillian Vrooman, Director of Communications and Engagement
Kimberly Hilchie, Pharmacy Policy Consultant
Stephanie Kwok, Executive Assistant

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1. **WELCOME & CALL TO ORDER**
   Chair Antler called the meeting to order at 4:35pm on April 6, 2020.

   Chair Antler acknowledged the Coast Salish People on whose unceded traditional territories the meeting is being chaired from, the Coast Salish, Squamish and Tsleil-Waututh First Nations. She also recognized that attendees of the teleconference are joining the call from other First Nations territories across BC.

2. **CHAIR'S UPDATES**
   Chair Antler reported that the regular April Board meeting will take place on Microsoft Teams.

   As per feedback from the Board meeting evaluation survey and discussion from the April 2nd Governance Committee meeting, Chair Antler provided clarity on factors that determine what items go on the Committee of the Whole meeting agenda and Board meeting agenda.

College of Pharmacists of British Columbia

Board members may request through the Chair to have items added to the meeting agenda, given that staff have adequate time to prepare and present the briefing materials to the Board for review.

3. REGISTRAR'S UPDATES

Registrar Nakagawa provided an update on April Board meeting logistics. Briefing materials will be available for Board review soon.

He spoke about the HPA Bylaw amendments related to temporary Registration approved at the last Board meeting. Based on legal advice and conversations subsequent to Board approval, the College has rescinded the waiver for professional liability insurance for temporary limited pharmacist registration and temporary student registration as these registrants perform pharmacy services under the direct supervision of a full Pharmacist. Liability insurance will be required for those individuals going on temporary registration.

He reported on his follow-up conversations with the Ministry of Health regarding the 30 day supply issue. The Assistant Deputy Minister of Pharmaceutical Services Division confirmed that the policy has not been adopted by Pharmacare.

4. LEGISLATIVE UPDATES

The Legislation and Policy team is currently reviewing various bylaws and policies including PPP-58 Adaptation Policy and electronic transmission of prescription.

5. AMENDMENTS TO PPP-71 DELIVERY OF OPIOID AGONIST TREATMENT (APPENDIX 1)

Anu Sharma, Acting Director of Policy and Legislation provided an overview of Health Canada's temporary exemptions under the *Controlled Drugs and Substances Act* and its regulation to support delivery of opioid agonist treatment to patients.

The Board had a fulsome discussion about the risks and implications associated with the amendments to PPP-71.

It was moved and seconded that the Board:
Approve amendments to Professional Practice Policy 71 ("PPP-71") – Delivery of Opioid Agonist Treatment, as circulated, to be effective immediately.

CARRIED

OTHER BUSINESS

Steven Hopp, District 4 Board member spoke about his perspective on changes that the Board and College should consider bringing forward to ensure that the people in BC will receive the best pharmacy care during these unprecedented times.

ADJOURNMENT

Chair Antler adjourned the meeting at 5:57pm on April 6, 2020.

College of Pharmacists of British Columbia

BOARD MEETING
April 6, 2020

Amendments to Professional Practice Policy 71 – Delivery of Opioid Agonist Treatment

DECISION REQUIRED

Recommended Board Motions:

1. Approve amendments to *Professional Practice Policy 71* ("PPP-71") – *Delivery of Opioid Agonist Treatment*, as circulated, to be effective immediately.

Purpose

To propose the following policy changes:

- Amendments to *PPP-71 Delivery of Opioid Agonist Treatment*

Background

On March 11, 2020, the World Health Organization declared the novel coronavirus, COVID-19, a pandemic, citing concern over alarming levels of spread and severity across the globe. The novel coronavirus has caused a global outbreak of respiratory infections since its discovery in December 2019.

At the February 14, 2020, meeting of the Board, the Board approved amendments to *Professional Practice Policy (PPP) 71 – Delivery of Opioid Agonist* and consequential amendments to *PPP-66 Opioid Agonist Treatment* and associated Policy Guides to be effective April 1, 2020 (see Appendix 1). In light of the risk of a widespread COVID-19 outbreak in British Columbia, the effective date of *PPP-71 Delivery of Opioid Agonist Treatment* was amended by the Board to be effective immediately on March 17, 2020, with the intent to support delivery of opioid agonist treatment to patients (see Appendix 2).

In the context of the COVID-19 outbreak and implementation of prevention and control measures across the country, it is important to maintain Canadians' access to controlled substances when needed for medical treatments, including OAT. To support access, Health Canada has provided a temporary exemption under the *Controlled Drugs and Substances Act*

("CDSA") and its Regulations to support access (see Appendix 3). If permitted within provincial scopes of practice, the exemptions:

- permit pharmacists to extend prescriptions;
- permit pharmacists to transfer prescriptions to other pharmacists;
- permit prescribers to issue verbal orders (i.e., over the phone) to extend or refill a prescription; and
- permit pharmacy employees to deliver prescriptions of controlled substances to patient's homes or other locations where they may be (i.e. self isolating).

The situation regarding COVID-19 continues to evolve here in BC, Canada and other jurisdictions in the world. The College of Pharmacists of BC is working closely with the Ministry of Health and other partners to support the response to this new illness as part of BC's health system.

Due to significant increased demand for OAT delivery services, including for patients who must self-isolate, pharmacists are having difficulty meeting the increased needs for delivery of OAT. The College staff have been working with the Ministry of Health and other partners to identify potential solutions, including considering the use of both regulated health professionals and pharmacy employees to help ensure patients receive their OAT doses.

Discussion

In response to increased demand for OAT delivery services, and Health Canada's temporary exemption to the CDSA, College staff conducted a jurisdictional scan of pharmacy regulatory authorities (PRAs) across Canada, and identified PRAs that have broadened their policies to allow for delivery of OAT by non-pharmacists, including unregulated pharmacy employees. Guidance has been provided by the Centre for Addition and Mental Health (Ontario) and the Nova Scotia College of Pharmacists (see Appendices 4 and 5, respectively). Elements from the recommendations of both of these guidance documents were considered in developing temporary amendments to *PPP-71 Opioid Agonist Treatment* in light of the COVID-19 public health emergency.

To improve access to OAT treatment for patients that require OAT delivery, temporary amendments are proposed to *PPP-71 Delivery of Opioid Agonist Treatment* to align with Health Canada's temporary exemption to the CDSA (see Appendix 6). Amendments include:

1. **Allowing a pharmacist to authorize a regulated health professional with the appropriate scope and competence to deliver an OAT drug to a patient.**

A pharmacist may authorize a regulated health professional to deliver OAT, if they have the scope and competence to assess the patient and witness the ingestion of OAT (where required). Allowing pharmacists to provide this authorization aligns with the Health Canada

temporary exemption to the CDSA. The temporary exemption currently states that "individuals delivering a controlled substance on behalf of a pharmacist are exempt from section 5 of the CDSA," and thus the delivery exemption itself is not explicitly limited to pharmacy employees.

2. Allowing a pharmacist to authorize a pharmacy employee to deliver OAT to a patient on the pharmacist's behalf.

This aligns with the Health Canada temporary exemption to the CDSA.

The authorization of a pharmacy employee should be reserved for exceptional circumstances where it is not possible for a pharmacist or regulated health professional to deliver the OAT drug. The pharmacist must ensure that the pharmacy employee authorized to deliver the OAT drug has the appropriate knowledge and competence to provide witnessed ingestion (where applicable), and to recognize when it may be unsafe to provide the dose to the patient. *PPP-66 Opioid Agonist Treatment* Policy Guides require that patient to be assessed prior to releasing an OAT dose, and so where possible, a pharmacist should assess the patient by phone or other virtual means before the pharmacy employee releases the dose.

3. Requirement to document the signature and name of the person delivering the OAT drug.

In addition to the documentation requirements outlined in *PPP-71 Delivery of Opioid Agonist Treatment* and the *PPP-66 Opioid Agonist Treatment* Policy Guides, for each delivery, the signature and name of the person authorized to deliver the OAT drug must be documented and retained in the patient record.

4. Additional requirements as set out by the Health Canada's temporary exemption to the CDSA.

There are additional requirements set out by the Health Canada temporary exemption to the CDSA for delivery of controlled substances by individuals on behalf as pharmacists. It is expected that these requirements also be met:

(C) Any individual who delivers a controlled substance on behalf of a pharmacist must

1. Deliver the controlled substance to the individual identified in the prescription (or to a person responsible for that individual's care);
2. 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,
3. Have the above note as well as a copy of this exemption while effecting the delivery.

Guiding Questions

When reviewing the proposed amendments, the Board is asked to consider:

- Do the proposed amendments address the exemption issued by Health Canada on the delivery of controlled substances?
- Is there anything unclear, ambiguous, or unnecessary in the draft proposed amendments?
- Is there anything missing from the draft proposed amendments?

Next Steps

The Board has the authority to amend PPPs. As such, if approved by the Board, the proposed amendments to *PPP-71 Delivery of Opioid Agonist Treatment* would come into effect immediately.

Recommendation

The Legislation Review Committee recommends that the Board approve the proposed amendments to *PPP-71 Delivery of Opioid Agonist Treatment* effective immediately.

Appendix	
1	February 2020 Board Meeting PPP-71 Amendments Briefing Note (without appendices)
2	March 17 2020 Board Meeting PPP-71 In-Force Date Change Briefing Note
3	Letter and attachments from Michelle Boudreau, Director General, Controlled Substances Directorate, Health Canada dated March 19, 2020
4	Centre for Addiction and Mental Health, Early Guidance for Pharmacists in Managing Opioid Agonist Treatment during the COVID-19 Pandemic
5	Nova Scotia College of Pharmacists, Opioid Agonist Maintenance Treatment (OAMT) Services During the COVID–19 Pandemic (March 2020)
6	Amendments to *PPP-71 Delivery of Opioid Agonist Treatment* (track changes and clean)

Appendix 1

College of Pharmacists of British Columbia

BOARD MEETING
February 14, 2020

7. Legislation Review Committee
b) Amendments to Professional Practice Policy 71 – Delivery of Methadone for Maintenance

DECISION REQUIRED

Recommended Board Motions:

1. Approve amendments to *Professional Practice Policy 71* ("PPP-71") – *Delivery of Methadone for Maintenance*, as circulated, to be effective April 1, 2020.

2. Approve consequential amendments to the following Professional Practice Policy ("PPP") and associated Policy Guides as circulated, to be effective April 1, 2020:

    a. *PPP-66 Opioid Agonist Treatment*
    b. PPP-66 Policy Guide Buprenorphine/Naloxone Maintenance Treatment
    c. PPP-66 Policy Guide Methadone Maintenance Treatment
    d. PPP-66 Policy Guide Slow Release Oral Morphine Maintenance Treatment

Purpose

To propose the following policy changes:

- Amendments to *PPP-71 Delivery of Methadone for Maintenance*
- Consequential amendments to *PPP-66 Opioid Agonist Treatment* and associated Policy Guides

Background

Developed in 2013, *PPP-71 Delivery of Methadone for Maintenance* currently permits pharmacists working in community pharmacies to deliver methadone for maintenance to a patient's home only if the physician authorizes the delivery due to the patient's immobility. At the time it was developed, it was understood that federal legislation did not support the delivery of methadone by pharmacists. However, *PPP-71 Delivery of Methadone for Maintenance* was established to create a way to ensure best patient health outcomes and continuity of care, when patients have restrictions in mobility that would require the delivery of methadone for maintenance.

In September 2018, Health Canada released the Transportation of Controlled Substances in Canada policy position ("policy position"), which states pharmacists are permitted to transport controlled substances to a patient with an appropriate prescription.[1] In addition, the clinical guidelines and requirements for opioid agonist treatment ("OAT") have changed since 2013. The College of Pharmacists of BC ("the College") now has policies setting requirements for dispensing two other OAT drugs (i.e., buprenorphine/naloxone and slow release oral morphine). However, the College has not established provisions regarding pharmacist transportation of those drugs. Further, federal requirements have been amended to authorize nurse practitioners to prescribe OAT. In light of these changes, amendments to *PPP-71 Delivery of Methadone for Maintenance* are proposed.

Discussion

Consultations with internal and external stakeholders were held throughout the process of developing amendments to this policy (see Appendix 1). Additionally, the policies and positions of other pharmacy regulatory authorities on OAT delivery were sought out and reviewed to inform the proposed amendments (see Appendix 2). Taking these into consideration, proposed amendments to the policy were made, and include those listed below.

1. **Policy broadened to include buprenorphine/naloxone and slow release oral morphine in addition to methadone.**
   Since the implementation of *PPP-71 Delivery of Methadone for Maintenance* in 2013, the College released guidelines for providing services related to buprenorphine/naloxone and slow release oral morphine. Previously there were no established provisions for the transportation of these drugs. The policy is proposed to apply broadly to all three oral OAT drugs. To improve alignment with this proposed policy change, the proposed title of the PPP is *"PPP-71 Delivery of Opioid Agonist Treatment"*.

2. **Delivery location is no longer restricted to a patient's home address, but will now be permitted at a location that is safe for both the patient and the pharmacist, is private, maintains confidentiality of the patient, and has a verifiable address.**
   The requirement for delivery to a patient's home address was removed, and new principle-based criteria for delivery locations were implemented to allow for more flexibility in delivery location. Several other pharmacy regulatory authorities do not restrict the delivery of OAT to a patient's home address, and removal of this restriction was broadly supported by external stakeholders as it supports access to treatment.

[1] https://www.canada.ca/en/health-canada/services/health-concerns/controlled-substances-precursor-chemicals/policy-regulations/policy-documents/transportation-of-controlled-substances-in-canada.html

3. **Reason for delivery is no longer restricted to immobility or extraordinary circumstances, and a pharmacist may provide delivery if it is safe, appropriate and in the best interest of the patient to do so.**
   The release of Health Canada's policy position has led to the reassessment of many aspects of *PPP-71 Delivery of Methadone for Maintenance*, which was initially put in place as an exception to federal legislation. Now that delivery of controlled substances is no longer interpreted to be an exception to the rule, the necessity of restrictions placed on delivery were re-examined. Removal of restriction on reason for delivery was widely supported during internal and external stakeholder consultations. A requirement that the pharmacist ensure delivery is safe, appropriate and in the best interest of the patient, and a requirement to document their rationale are proposed in the policy amendments for patient safety.

4. **Delivery no longer requires physician authorization, and a pharmacist may use their professional judgement to decide to deliver OAT to a patient.**
   As described above, the Health Canada policy position states that delivery of controlled substances by a pharmacist directly to a patient with a valid prescription is permitted. Because of the proposed amendment to no longer restrict delivery to patients who are immobile, a physician assessment and authorization for delivery would no longer be required. Community pharmacists are able to assess patients and determine if delivery is safe, appropriate and in their best interest. It is proposed that pharmacists be required to notify the prescriber that they have decided to initiate or stop delivery. Prescribers indicated that this was important information for them to know, to ensure the circle of care is informed of the treatment plan.

   A proposed provision was added stating that if a prescriber indicates that delivery is not permitted, the pharmacist must not initiate delivery to that patient, which aligns with the proposed changes to the Controlled Prescription Program form, as well as requests from prescribers (see Appendix 4).

5. **New safety provisions included in the policy.**
   In addition to the proposed requirement to deliver to a location that is safe for both the patient and the pharmacist, a provision has been proposed that allows a pharmacist to refuse to deliver OAT if there is concern for the safety of the patient, the pharmacist, or the public. Additionally, it is proposed that pharmacy managers must have written policies and procedures in place to ensure the safety and security of the patient, pharmacist and drug during the delivery. These provisions are recommended keeping in mind that the pharmacist providing the delivery will also be performing a patient assessment and witnessed ingestion at a patient's location, outside of the traditional pharmacy setting. Additionally, pharmacists would be transporting controlled substances which may be targets of theft, and adequate security measures should be put in place.

Additional proposed amendments to the policy include a strengthened recommendation for pharmacists to refer a patient to another pharmacy if providing delivery service is not feasible within the services and resources of the pharmacy, and clarification that due to the requirement for patient assessment prior to releasing the OAT drug, only a pharmacist (e.g., not a pharmacy technician or courier) may deliver OAT. *PPP-66 Opioid Agonist Treatment* and associated Policy Guides are referenced in the updated policy, as all the requirements in these still apply when OAT is delivered.

The internal and external stakeholder consultations revealed areas of the policy that required further clarification. Several groups provided feedback, requesting information on how other health care practitioners fit into this policy. At this time, models of delivery that include other health care providers are considered outside of the scope of this policy. It has been clarified in the policy preamble that this policy applies only to pharmacists delivering OAT directly to a patient, as specified by the Health Canada policy position.

During consultations, requiring documentation in PharmaNet that the OAT drug was delivered was discussed. Documenting this information the 'sig field' in PharmaNet was considered as an option, but limitations were identified, including that the 'sig field' is only able to display a limited number of characters. Another possibility discussed was using product identification numbers (PINS) to indicate when an OAT drug is delivered, similar to the existing practice for methadone when prescribed for OAT; however, currently no PINS for delivery of buprenorphine/naloxone or slow release oral morphine exist. Given the limitations with the 'sig field' and because information on whether or not the OAT drug was delivered would be available by calling the pharmacy as the proposed amendments to the policy include documenting the delivery date, time and address for each delivery in the patient record, no additional requirements to document that the OAT drug is delivered in PharmaNet are proposed.

In recognition that having delivery information available in PharmaNet for <u>all</u> forms of OAT may be valuable as patients move through different care settings, discussions on developing delivery PINS for buprenorphine/naloxone and slow release oral morphine with the Ministry of Health will be further pursued.

Lastly, due to the proposed changes to *PPP-71 Delivery of Methadone for Maintenance* and the Controlled Prescription Program duplicate forms, consequential amendments are proposed to *PPP-66 Opioid Agonist Treatment* and associated Policy Guides (see Appendix 5). Additional proposed amendments stemming from recent PPP changes as part of the *Pharmacy Operations and Drug Scheduling Act* Modernization Phase Two project have also been included in these proposed consequential amendments.

Next Steps

The Board has the authority to amend PPPs. As such, if approved by the Board, the proposed amendments to *PPP-71 Delivery of Methadone for Maintenance* and the consequential amendments to *PPP-66 Opioid Agonist Treatment* and associated Policy Guides would come into effect on April 1, 2020. Allowing these amendments to come into force on this date will enable the implementation plan, and ensure necessary communication of changes to stakeholders.

Recommendation

The Legislation Review Committee recommends that the Board approve the proposed amendments to *PPP-71 Delivery of Methadone for Maintenance* and the consequential amendments to *PPP-66 Opioid Agonist Treatment* and associated Policy Guides, to be effective April 1, 2020.

Appendix	
1	List of Stakeholders Consulted
2	Jurisdictional Scan Summary
3	Amendments to *PPP-71 Delivery of Methadone for Maintenance* (track changes and clean)
4	Amendments to the Controlled Prescription Program Forms Briefing Note (Feb 14, 2020)
5	Consequential amendments PPP-66 & Policy Guides (track changes)

Appendix 2

College of Pharmacists of British Columbia

Amendments to the Effective Date of Professional Practice Policy 71 – Delivery of Opioid Agonist Treatment and Consequential Amendments to Professional Practice Policy 66 – Opioid Agonist Treatment and associated Policy Guides

DECISION REQUIRED

Recommended Board Resolutions:

1. Be it resolved that the Board amend the effective date of the previously approved amendments to *Professional Practice Policy 71* ("PPP-71") – *Delivery of Opioid Agonist Treatment*, as circulated, to be effective immediately upon approval of the Board.

2. Be it resolved that the Board amend the effective date of the previously approved consequential amendments to the following Professional Practice Policy ("PPP") and associated Policy Guides as circulated, to be effective immediately upon approval of the Board:

    a. *PPP-66 Opioid Agonist Treatment*
    b. PPP-66 Policy Guide Buprenorphine/Naloxone Maintenance Treatment
    c. PPP-66 Policy Guide Methadone Maintenance Treatment
    d. PPP-66 Policy Guide Slow Release Oral Morphine Maintenance Treatment

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Purpose

To request that the Board of the College of Pharmacists of British Columbia ("the Board") amend the effective date of the previously approved amendments to *PPP-71 Delivery of Opioid Agonist Treatment* and consequential amendments to the following PPP and associated Policy Guides, to be effective immediately upon approval of the Board:

a. *PPP-66 Opioid Agonist Treatment*
b. PPP-66 Policy Guide Buprenorphine/Naloxone Maintenance Treatment
c. PPP-66 Policy Guide Methadone Maintenance Treatment
d. PPP-66 Policy Guide Slow Release Oral Morphine Maintenance Treatment

Appendix 2

Background

At the February 14, 2020, meeting of the Board, the Board approved amendments to *Professional Practice Policy (PPP) 71 – Delivery of Opioid Agonist* and consequential amendments to *PPP-66 Opioid Agonist Treatment* and associated Policy Guides effective April 1, 2020 (see Appendix 1). The decision to allow these amendments to come into force on this date was to enable the implementation plan, and ensure necessary communication of changes to stakeholders.

On March 11, 2020, the World Health Organization declared the novel coronavirus, COVID-19, a pandemic, citing concern over alarming levels of spread and severity across the globe. The novel coronavirus has caused a global outbreak of respiratory infections since its discovery in December 2019.

The situation regarding COVID-19 continues to evolve here in BC, Canada and other jurisdictions in the world. The College of Pharmacists of BC is working closely with the Ministry of Health and other partners to support the response to this new illness as part of BC's health system.

Discussion

Recent consultations with the BC Centre on Substance Use, BC College of Nursing Professionals, College of Physicians and Surgeons of BC, First Nations Health Authority, Ministry of Health, and Office of the Provincial Health Officer have indicated that in light of the risk of a widespread COVID-19 outbreak in British Columbia, the effective date of *PPP-71 Delivery of Opioid Agonist Treatment* should be amended to be effective as soon as possible. This will support delivery of opioid agonist treatment to patients.

Communication of the changes to stakeholders will be expedited to facilitate implementation of the amendments to *PPP-71 Delivery of Opioid Agonist Treatment*, *PPP-66 Opioid Agonist Treatment* and associated Policy Guides. Additionally, guidance on how to use the existing Controlled Prescription Program forms with the new PPP-71 amendments will be provided.

Next Steps

The Board has the authority to amend PPPs. As such, if approved by the Board, the effective date of the previously approved amendments to *PPP-71 Delivery of Opioid Agonist Treatment* and the consequential amendments to *PPP-66 Opioid Agonist Treatment* and associated Policy Guides would come into effect immediately.

Recommendation

The Legislation Review Committee recommends that the Board amend the effective date of the previously approved amendments to *PPP-71 Delivery of Opioid Agonist Treatment* and the previously approved consequential amendments to *PPP-66 Opioid Agonist Treatment* and associated Policy Guides, to be effective immediately, by signing the attached Resolution (Appendix 2).

Appendix	
1	February 2020 Board Briefing Materials
2	Board Resolution Signature Page

Appendix 3

Health Canada Santé Canada

March 19, 2020

To maintain Canadians' access to controlled substances for medical treatments (e.g., treatment of substance use disorders and chronic pain), while they adhere to social distancing guidance from public health officials or if they need to self-isolate, Health Canada has issued the attached exemptions for prescriptions of controlled substances under the *Controlled Drugs and Substances Act* (CDSA) and its Regulations. If permitted within the applicable provincial/territorial scopes of practice, the exemptions:

- permit pharmacists to extend prescriptions;
- permit pharmacists to transfer prescriptions to other pharmacists;
- permit prescribers to issue verbal orders (i.e., over the phone) to extend or refill a prescription; and
- permit pharmacy employees to deliver prescriptions of controlled substances to patient's homes or other locations where they may be (i.e self isolating).

We strongly encourage all partners to work to implement these exemptions in their jurisdictions and welcome any additional suggestions you may have to maintain Canadians' access to controlled substances for medical reasons during the pandemic.

Further, Health Canada is clarifying, with the attached guidance document, activities that are currently permitted under the CDSA and its Regulations.

We strongly urge Ministries and regulators to conduct a thorough assessment of any barriers to access to medicines that could contravene public health advice for social distancing and self-isolation, when appropriate. This could include, for example, temporarily lifting restrictions on take-home doses ("carries") of opioid agonist treatments, and allowing those with chronic conditions to obtain enough medication to last through a period of self-isolation.

We also recognize that local pandemic precautions may impact the operations of Supervised Consumption Sites (SCS), and are committed to work directly with SCS Operators to assess each individual situation and develop appropriate modifications to their protocols and practices. Operators are encouraged to contact the Office of Controlled Substances' Exemptions Section at hc.exemption.sc@canada.ca.

If you have any questions, please contact Health Canada's Office of Controlled Substances, at: hc.ocs-bsc.sc@canada.ca.

Best Regards,

Michelle Boudreau
Director General
Controlled Substances Directorate
Health Canada

Canada

Health Canada Santé Canada

SUBSECTION 56(1) CLASS EXEMPTION FOR PATIENTS, PRACTITIONERS AND PHARMACISTS PRESCRIBING AND PROVIDING CONTROLLED SUBSTANCES IN CANADA DURING THE CORONAVIRUS PANDEMIC

Pursuant to subsection 56(1) of the *Controlled Drugs and Substances Act* (CDSA), and subject to the terms and conditions herein, practitioners and pharmacists, authorized within their scope of practice, are hereby exempted from the following provisions of the CDSA and its regulations when prescribing, selling, or providing a controlled substance to a patient or transferring a prescription for a controlled substance to a pharmacist in Canada:

- Section 5 of the CDSA;
- Subsection 31(1), and section 37 of the Narcotic Control Regulations (NCR);
- Sections G.03.002 and G.03.006 of Part G of the Food and Drug Regulations (FDR);
- Paragraphs 52 (c) and (d), subsection 54(1) of the Benzodiazepines and Other Targeted Substances Regulations (BOTSR).

Individuals delivering a controlled substance on behalf of a pharmacist are exempt from section 5 of the CDSA.

Patients who receive a controlled substance from a pharmacist pursuant to this exemption, are exempt from subsection 4(1) of the CDSA with respect to that controlled substance.

Except as provided below, the terms used in this exemption have the same meaning as those provided in the CDSA and its regulations:

Patient means:

a) A person who is a client of a pharmacist; and
b) A person who was prescribed a controlled substance prior to March 11, 2020;
c) A person:
  i. to whom a pharmacist may prescribe a controlled substance under this exemption ;or,
  ii. to whom a practitioner may verbally prescribe a controlled substance under this exemption.

Pharmacist means a person:

a) who is entitled under the laws of a province or territory of Canada to practise as a pharmacist;
b) who has not been named in a notice under s. 48(1) of the NCR, G.03.017.2 of the FDR or section 79 of the BOTSR unless a notice of retraction has been issued under the respective regulations; and,
c) whose scope of practice of pharmacy includes prescribing of drugs including controlled substances as authorized under this exemption and, in a manner consistent with any applicable provincial or territorial pharmacy legislation and any applicable policies of a provincial or territorial licensing authority.

Canada

Practitioner means a person who:

a) is registered and entitled under the laws of a province to practise in that province the profession of medicine, dentistry or veterinary medicine, and includes any other person or class of persons described as a practitioner;
b) has not been named in a notice under ss. 59(1) of the NCR,G.04.004.2(1) of the FDR, or 79 of the BOTSR unless a notice of retraction has been issued under the respective regulations; and,
c) whose scope of practice of medicine, dentistry, or veterinary medicine includes prescribing drugs, including controlled substances as authorized under the relevant provincial or territorial pharmacy legislation and consistent with any applicable policies of any provincial or territorial body responsible for the regulation of practitioners.

Transfer of prescription means the sending a prescription by a pharmacist to another pharmacy within the same province or territory, for the purpose of having that prescription filled and picked up by the patient at that pharmacy.

This exemption provides practitioners with the authority to issue a verbal prescription for controlled substances.

This exemption provides pharmacists with the authority to transfer a prescription for a controlled substance, and to prescribe, sell or provide a controlled substance to patients subject to the terms and conditions of this exemption.

The exemption is only applicable if the following conditions are met.

(A) Pharmacists acting under the authority of this exemption must:

1. Only prescribe, sell, provide or transfer the controlled substance to a patient while that patient is under their professional treatment at a pharmacy;
2. Only prescribe, sell, provide or transfer a controlled substance to a patient in order to extend or renew an existing prescription;
3. Only prescribe a controlled substance to a patient in accordance with any policies and/or guidelines established by the provincial or territorial government and by any relevant provincial or territorial licensing authorities;
4. Comply with a record keeping obligations established by the provincial or territorial government and any relevant provincial or territorial licensing authority regarding all transactions involving controlled substances;
5. If not already required pursuant to item 4, keep records of the following:
    a. the name and address of any patient who is prescribed, sold, or provided a controlled substance under this exemption;
    b. the name, quantity and form of the controlled substance prescribed;
    c. the name or initials of the pharmacist who prescribed, sold or provided the controlled substance;
    d. the date on which the controlled substance was prescribed, sold or provided; and
    e. the number assigned to the prescription.

6. With respect to the transfer of a prescription, keep records of the following:
    a. a copy of the prescription written by the practitioner or the record made in accordance with the practitioner's verbal prescription;
    b. the name and business address of the transferring pharmacist;
    c. the name and business address of the pharmacist receiving the prescription transfer;
    d. the number of authorized refills remaining and, if applicable, the specified interval between refills; and
    e. the date of the last refill.

7. All records should be kept in the pharmacy for a period of two years from the date that each record is made.

(B) Practitioners must:

1. Only prescribe (including verbally prescribe), sell, or provide the controlled substance to a patient while that patient is under their professional treatment;
2. Only prescribe (including verbally prescribe), a controlled substance to a patient in accordance with any policies or guidelines established by the provincial or territorial government or any relevant provincial or territorial licensing authority;
3. Comply with record keeping obligations established by the provincial or territorial government and relevant provincial or territorial licensing authorities regarding all transactions involving controlled substances;

(C) Any individual who delivers a controlled substance on behalf of a pharmacist must

1. Deliver the controlled substance to the individual identified in the prescription (or to a person responsible for that individual's care);
2. 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,
3. Have the above note as well as a copy of this exemption while effecting the delivery.

(D) Any controlled substance prescribed, sold, provided or transferred under the authority of this exemption must be for the purpose of facilitating continuation of treatment that the patient was already receiving.

This exemption expires on the earliest of the following dates:

- September 30, 2020;
- The date that it is replaced by another exemption; or
- The date on which it is revoked.

Failure to comply with the terms and conditions of this exemption may, among other things, result in immediate suspension of this exemption, and ultimately, in its revocation.

Health Canada Santé Canada

This exemption may be suspended without prior notice if the Minister deems that such suspension is necessary to protect public health, safety or security. If necessary, the Minister may change the terms and conditions of this exemption. Should this be the case, you will be informed in writing and reasons for the changes will be provided.

Notwithstanding the conditions above on the ability to suspend, the Minister may suspend or revoke the exemption if she believes that it is no longer necessary.

Signed for and on the behalf of the Minister of Health,

Michelle Boudreau
Director General
Controlled Substances Directorate
Controlled Substances and Cannabis Branch

Effective Date: March 19, 2020

Canada

Prescription management by pharmacists with controlled substances under the *Controlled Drugs and Substances Act* and its regulations

CONTEXT

Pharmacists are medication experts and play a significant role in monitoring patients and medication to ensure safe and optimal use while contributing to outcome-focussed patient care. With the goal of supporting better medication management and protecting the health and safety of Canadians, Health Canada has developed the following related to prescribing activities with substances regulated under the *Narcotic Control Regulations* (NCR*)*, the *Benzodiazepines and Other Targeted Substances Regulations* (BOTSR) and the *Food and Drug Regulations – Part G* (FDR - Part G).

SCOPE[1]

Information in this document applies to pharmacists who are registered and entitled to practice pharmacy under the laws of their province or territory and are entitled to conduct activities with controlled substances.

While this document does not constitute legal advice as to the scope of the *Controlled Drugs and Substances Act* (CDSA) and its regulations, it is Health Canada's interpretation of the legislation and regulations through which guidance is provided to pharmacists and provincial regulators.

ACTIVITIES PERMITTED

Regulations under the CDSA state that a pharmacist is authorized to sell or provide a controlled substance to a person if they have received a prescription or a written order from a practitioner.

While these regulations do not permit pharmacists to prescribe, other related activities that are included in the meaning of *sell or provide* are permitted as long as the quantity dispensed does not exceed the amount originally authorized. These activities include, but are not limited to:

- **Adjusting the formulation**: adjusting the dosage form in which the drug is prescribed;
    - e.g., change from pill to liquid formulations;

-

[1] This policy does not include substances regulated under the *Cannabis Act* and its regulations.

- **Adjusting the dose and regimen**: a structured plan that specifies the frequency in which a dose of medication should be ingested;
    - e.g., change from 20mg per day for 5 weeks to 10mg per day for 10 weeks
- **De-prescribing**: the planned and supervised process of reducing or stopping a medication;
- **Part-filling:** dispensing a quantity of a medication which is less than the total amount of the drug specified by a practitioner;
    - For greater clarity, this includes part-fills requested by a patient, when a pharmacy is dealing with an inventory shortage or other situations where the nature of the part fill is a matter of discussion between the pharmacist and patient.

This information is intended to clarify prescribing-related activities pharmacists are permitted to conduct under the CDSA and its regulations.

Pharmacists conducting any of these activities must ensure that their actions do not restrict patients' access to their needed prescriptions and that they continue to work closely with the prescribing practitioner with a view to optimizing patients' health care.

ADDITIONAL REQUIREMENTS

Please note that there may be additional federal, provincial/territorial and municipal laws, regulations, and scope of practice considerations that must be complied with in addition to those under the CDSA and its regulations.

For any questions, please do not hesitate to contact hc.ocs_regulatorypolicy-bsc_politiquereglementaire.sc@canada.ca.

Appendix 4

Early Guidance for Pharmacists in Managing Opioid Agonist Treatment during the COVID-19 Pandemic

Prepared by pharmacists from the Centre for Addiction and Mental Health

Scope

This document specifically refers to pharmacists' practice as it relates to buprenorphine and methadone as opioid agonist treatments (OAT). Unless otherwise mentioned in this document or the COVID-19 – Opioid Agonist Treatment Guidance document, pharmacists should practice as per existing OAT standards and guidelines.

General principles

- Actions taken during the COVID-19 pandemic balance the risks of community transmission with patient and community safety as it relates to OAT (e.g., risk of opioid overdose, risk of treatment interruptions). More than ever, this balance is a shared responsibility among the patient, the prescriber and the pharmacist.
- None of the guidance requires a pharmacist to provide OAT in a manner that they believe is unsafe for the patient, the pharmacy staff or the public.
- Practice may need to be modified beyond the scope of this guidance document on a case-by-case basis, applying clinical judgment to weigh risks and benefits to patient and public in each case.
- Patients who may not have been suitable for carries as defined by existing guidelines (i.e., 2011 CPSO Methadone Maintenance Treatment Standards and Guidelines) should be reassessed as per the COVID-19 – Opioid Agonist Treatment Guidance document during the COVID-19 pandemic.
- Ongoing and close communication with prescribers is critical. Pharmacists' assessments are valuable, particularly for decisions related to suitability for progressive carry doses.
- When determining the number of carries to be dispensed at one time, pharmacists and prescribers should consider a patient's ability to store carries safely and appropriately.
- Pharmacists should not make any changes to the dosage of existing therapy except in collaboration with the prescriber.
- If pharmacists are not able to meet the needs of the patient due to reduced hours, pharmacy closure or other reasons, the pharmacy must transfer the care of the patient to another pharmacy.

- Given buprenorphine's safety profile, its contingencies can be considered differently than with methadone.
- Pharmacists should ensure all patients on OAT have a take-home naloxone kit and are trained on its use along with other harm reduction strategies.
- For patients in self-isolation or quarantine, a pharmacist may release OAT doses to an authorized agent for pick up at the pharmacy or have the doses delivered. If releasing to an agent, pharmacists must take steps to confirm:
  - the patient authorizes the individual to act as an agent
  - the identity of the individual before releasing the medication
  - the receipt of the medication by the patient.
- Pharmacists should document all activities associated with using this guidance and the COVID-19 – Opioid Agonist Treatment Guidance document.

Observed doses

- For patients who are presenting to the pharmacy, pharmacists should consider extra precautions around managing observed doses, in addition to other general personal protective measures in the pharmacy. These include care in the handling and disposal of dosing cups and reduced contact by not requiring signatures for dosing.
- For patients who are self-isolating or under quarantine, pharmacists should explore alternative measures to support witnessed dosing, including virtual communication and observation methods.
- For observed dosing of buprenorphine in the pharmacy, pharmacists should consider a brief observation period and minimize close contact with the patient.

Take-home doses or "carries"

- Refer to the COVID-19 – Opioid Agonist Treatment Guidance document for recommended maximum take-home doses for methadone and buprenorphine.
- For methadone carries:
  - While an increase in carries may be recommended to limit the number of required pharmacy visits, pharmacists might consider delivering a smaller number of methadone carries at one time to enhance patient safety. For example, a patient may be authorized to receive 13 carries. A pharmacist may decide to deliver six or seven doses weekly so that there is less methadone in the residence at any given time.
  - If patients were previously instructed to return carry bottles, pharmacists should advise patients that the return of used carry bottles is not recommended at this time. Pharmacists must provide direction to these patients to ensure the used carry bottles are rinsed prior to disposal.

NOTE: This guidance may evolve over time.
March 27, 2020

camh
mental health is health

Opioid Agonist Maintenance Treatment (OAMT) Services During the COVID–19 Pandemic (March 2020)

The provision of OAMT presents unique challenges than those associated with dispensing other medications, particularly now in the midst of the current COVID-19 Pandemic. Solutions to these challenges are a shared responsibility between the patient, their primary prescriber, and pharmacists and need to be made in consideration of the fine balance of the public health risk due to COVID-19 and the public/patient risk of diversion and overdose. To support pharmacists in their efforts to continue to provide this critical service and to enable pharmacists to use their knowledge and skills to solve these challenges, the following provisions related to the *Standards of Practice: Opioid Agonist Maintenance Treatment* have been made.

For clarity, none of the provisions below require a pharmacist to provide OAMT in a manner that they believe is unsafe for the patient, the pharmacy staff, or the public.

Signatures

In instances where a signature is required, pharmacists may decide the method to be used to confirm and document the identity of the patient or their agent and confirm the receipt of the medication by the patient or their agent.

Witnessed Dosing (at the pharmacy or by delivery)

Pharmacists may decide who can provide witnessed dosing.

Pharmacists ensure that the person doing the witnessing has been given instruction on how to witness, how to recognize when it may be unsafe to provide the dose to the patient (e.g., patient impairment by drugs or alcohol), and how they should proceed in these situations, particularly if the witnessing is occurring outside of the pharmacy environment.

Pharmacists ensure documentation is completed for witnessed ingestion including documenting who witnessed the dose, and any other relevant patient care notes. (e.g., instances in which the patient did not consume the dose or did not consume the entire dose).

The need for social distancing and infection control measures may outweigh the requirement for patient privacy during this time. (e.g., the use of a private consultation room may not be appropriate)

Take-Home Doses

Prescribers are considering relaxing restrictions on take-home doses for certain patients. They have indicated that pharmacists' expertise in patient assessments is highly valued and is an important contribution to making the following decisions:

- Whether patients receiving daily witnessed doses can be provided carries.
- Whether patients receiving carries can have the number of carries provided at one time increased.

Pharmacists may provide the quantity of take-home doses as prescribed (written or verbal) if they are satisfied it is appropriate to do so.

Appendix 5

Provision of Doses for Patients Under Isolation

Should a patient be unable to come to the pharmacy to receive their dose because they are under isolation, the pharmacist may decide if delivery or alternative arrangements for pick-up at the pharmacy is a reasonable solution.

Delivery of Doses

Pharmacists may decide who can deliver to patients, however, in deciding whether delivery is a reasonable option, consideration needs to be given to:

- the ability of the person delivering the doses to identify the patient and to be safe while doing so.
- the security of the medications and the consequences resulting from their loss or diversion.
- the stability of the patient and their circumstances (e.g., housing, their ability to safely store doses, etc.), the extent to which it is critical for the patient's safety that they be assessed prior to being provided their dose, and the ability for the person doing the delivery to do this assessment.

In situations where the pharmacy is delivering to the patient, effective witnessing may not be possible. Every effort should be made to collaborate with the physician to reserve the requirement for witnessing to only those where it is imperative. If consultation with the physician is not possible and a decision is made by the pharmacist that witnessing will not take place, this decision must be communicated to the physician at the earliest opportunity.

If witnessed dosing on delivery is imperative, pharmacists will decide how this will be accomplished. If feasible, efforts should be made to conduct a patient assessment remotely (e.g., telephone, virtual communication)

For all deliveries, the pharmacist will establish a process that ensures that:

- the delivery process is explained to the patient prior to the delivery.
- the person making the delivery knows who they are authorized to release it to (the patient or an individual authorized by the patient).
- the person making the delivery understands that they do not need to put themselves in a position that threatens their health or safety. (e.g., delivery drivers do not have to enter homes - witnessing can take place from outside of a door, via virtual communication, etc.).
- the dose is returned to the pharmacy if release to the patient or authorized person was not possible. For clarity, doses cannot be left at the door.
- the delivery is appropriately documented.
- the requirements below from Health Canada are met.

Health Canada has made provisions for prescriptions to be delivered to the patient or to someone authorized by the patient as long as the person doing the delivery:

1. Has authorization to deliver the medications in writing from the pharmacist that includes the names of people to whom they are delivering and the pharmacy contact information: and
2. Has a copy of the *Health Canada Section 56 Class Exemption* in their possession while making the delivery.

In situations where the pharmacy cannot deliver the medication and the patient must have a witnessed dose, solutions could include:

- Having someone authorized by the patient, pick up, deliver, and witness the dosing.
- Having a member of the patient's recovery team pick up, deliver and witness the dosing.
- Facilitating the transfer of care to a pharmacy that can accommodate the patient.

Compounding Methadone

In the event that commercially available methadone becomes unavailable, the *Standards of Practice: Opioid Agonist Maintenance Treatment* do not preclude the compounding of methadone solution.

Inevitably, there will be numerous situations that are not specifically addressed by these provisions. You will need to decide what is best to do, guided by the *Standard of Care During a Crisis* and balancing the patient's need to be supported in their recovery and the public's safety in the context of the ongoing opioid crisis and the COVID-19 pandemic.

Appendix 6

POLICY CATEGORY: **PROFESSIONAL PRACTICE POLICY-71**
POLICY FOCUS: **Delivery of Opioid Agonist Treatment**

This policy provides guidance to pharmacists and pharmacy managers working in community pharmacy settings on the delivery of opioid agonist treatment (OAT) drugs by pharmacists directly to patients.[1] This policy does not apply to injectable opioid agonist treatment.

The *Pharmacy Operations and Drug Scheduling Act* Bylaws sections 18(2)(b-e), (l), (m) and (t), 19(4), 19(6)(a-b), 23(1)(a-b), 23.1(1), and 36, and the *Health Professions Act* Bylaws Schedule F, Part 1 - *Community Pharmacy Standards of Practice* supplement this policy. This policy must be read in conjunction with *Professional Practice Policy – 66 Opioid Agonist Treatment* and its associated Policy Guides.

COVID-19 UPDATE

Effective immediately and while permitted by a section 56 exemption to the *Controlled Drugs and Substances Act*, a pharmacist, using their professional judgement, may authorize:

1. A regulated health professional to deliver OAT to a patient, ensuring that they have the appropriate scope and competence to assess a patient and witness the ingestion of OAT; or
2. A pharmacy employee to deliver OAT to a patient on the pharmacist's behalf. Note: The authorization of a pharmacy employee should be reserved for exceptional circumstances where it is not possible for a pharmacist or regulated health professional to deliver the OAT drug.

The pharmacist must ensure that the pharmacy employee authorized to deliver the OAT drug has the appropriate knowledge and competence to provide witnessed ingestion (where applicable), and to recognize when it may be unsafe to provide the dose to the patient (e.g. the patient is intoxicated) and how they should proceed in these situations. Where possible, the pharmacist should assess the patient by phone or other virtual means before the pharmacy employee releases the dose.

The pharmacist must ensure the required documentation for each OAT delivery is completed and retained in the patient record, including the signature and name of the person authorized to deliver the OAT drug for each delivery. Unconsumed or partially consumed doses must be documented and returned to the pharmacy as soon as possible.

All other requirements outlined within this policy, and the section 56 exemption to the *Controlled Drugs and Substances Act* must be met.

For the health and safety of the public and those delivering OAT, a pharmacist should confirm if their patient is experiencing symptoms of COVID-19 or are self-isolating prior to delivering OAT. In addition, consideration should be given on how to maintain social distancing while delivering medications to a patient.

POLICY STATEMENTS:

1. Determination to Deliver OAT

a. A pharmacist may deliver OAT to a patient from whom they have received a valid OAT prescription, if using their professional judgement, the pharmacist determines that providing delivery is safe, appropriate and in the best interest of the patient.
b. The pharmacist must document in the patient's record the decision to deliver or to not deliver, including the rationale for the decision. This documentation must be easily retrievable.

[1] Transportation of Controlled Substances in Canada: https://www.canada.ca/en/health-canada/services/health-concerns/controlled-substances-precursor-chemicals/policy-regulations/policy-documents/transportation-of-controlled-substances-in-canada.html

c. The pharmacist must notify the prescriber of the decision to initiate or stop delivery as soon as reasonably possible, and this must be recorded in the patient's record.
d. A pharmacist may refuse to deliver OAT if there is concern for the safety of the patient, pharmacist or public. Where appropriate, the pharmacist should discuss any concerns with the prescriber to resolve issues in the best interest of the patient.
e. A pharmacist must not deliver OAT to a patient if the prescriber indicates that delivery is not permitted.
f. If delivery is not feasible within the services and resources the pharmacy provides, the patient should be referred to a pharmacy that can provide the delivery.

2. Delivery of OAT

If a pharmacist has made the determination to deliver OAT to a patient as noted in section 1, the pharmacist must meet the following delivery requirements:

a. The pharmacist must work with the patient to make arrangements for delivery that are in the best interest of the patient. Arrangements must include:
    i. A delivery location that is private, maintains the confidentiality of the patient, is safe for both the patient and the pharmacist, and has a verifiable address.
    ii. Time(s) and date(s) for delivery.
    iii. Procedure if the patient is not available at the location to receive the OAT delivery including communication of appropriate alternate arrangements for the patient to obtain their OAT drug.
b. The OAT drug must be packaged in the pharmacy and dispensed with the appropriate labelling.
c. A pharmacist must release an OAT drug to a patient in accordance with *Professional Practice Policy-66 Opioid Agonist Treatment* and its associated Policy Guides.
d. Due to the requirement for a pharmacist to assess a patient prior to releasing an OAT drug,
    i. only a pharmacist may deliver OAT to a patient,
    ii. the OAT drug must only be delivered directly to the patient, and
    iii. the OAT drug must not be left with any other person.
e. In addition to meeting the requirements for documentation set out in *Professional Practice Policy-66 Opioid Agonist Treatment* and its associated Policy Guides, pharmacists must record the delivery date, time and address for each delivery on the patient record, which includes the patient specific accountability log.

3. Safety and Security

a. The pharmacy manager must ensure that written policies and procedures are in place to ensure the safety of the patient and the pharmacist and the security of the drug during the delivery.
b. The dispensing pharmacist is responsible for securely transporting and appropriately storing the OAT drug.
c. OAT drugs may not be stored outside of the pharmacy under any circumstances, nor be left unattended if the delivery is unsuccessful.

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[1] Transportation of Controlled Substances in Canada: https://www.canada.ca/en/health-canada/services/health-concerns/controlled-substances-precursor-chemicals/policy-regulations/policy-documents/transportation-of-controlled-substances-in-canada.html

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