College of Pharmacists of British Columbia

Board Teleconference
March 23, 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
Laura Briard, Policy and Legislation Analyst
Kimberly Hilchie, Pharmacy Policy Consultant
Stephanie Kwok, Executive Assistant

Guest:
Susan Precious, College Legal Counsel, Precious Gaerdes LLP

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1. **WELCOME & CALL TO ORDER**
   Chair Antler called the meeting to order at 5:03pm on March 23, 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.

College of Pharmacists of British Columbia

2. CHAIR'S UPDATES

Chair Antler provided an update on meeting procedures and how she will be chairing the teleconference meetings. She confirmed that the March 24, 2020 Board teleconference will be cancelled as there are no items requiring Board approval.

3. REGISTRAR'S UPDATES

Registrar Nakagawa provided the Board an update on the meetings he has had since the last Board teleconference on March 20, 2020. He attended the BC Health Regulator's meeting today and touch based with the Registrar of the College of Physicians and Surgeons regarding the prescribing of Hydroxycholoroquine. He has been in ongoing exchange with NAPRA and the Ministry of Health. He had sent an email today to Dr. Bonnie Henry, Provincial Health officer regarding his concerns about the lack of COVID-19 testing and personal protective equipment for pharmacy professionals.

4. LEGISLATIVE UPDATES

Anu Sharma, Acting Director of Policy and Legislation provided an update on the legislative changes that the College will bring to the Board for approval at the Wednesday, March 25, 2020 Board teleconference.

5. HPA AND PODSA BYLAW AMENDMENTS TO PERMIT HEALTH CANADA'S EXEMPTIONS UNDER THE CONTROLLED DRUGS AND SUBSTANCES ACT (APPENDIX 1)

Anu Sharma, Acting Director of Policy and Legislation provided to the Board an overview of the exemptions announced by Health Canada on March 14, 2020.

It was moved and seconded that the Board:

1. *Approve the following resolution to amend the Health Professions Act (HPA) Bylaws relating to standards of practice on faxing of a Controlled Prescription form and transferring of a prescription for a controlled drug substance to align to Health Canada exemptions issued under the Controlled Drugs and Substances Act and to request a shortened filing period from the Minister of Health to bring the amendments into force as soon as possible.*

   "RESOLVED THAT, in accordance with the authority established in section 19(1)(k) of the Health Professions Act, and subject to filing with the Minister as required by section 19(3) of the Health Professions Act, the Board of the College of Pharmacists of British Columbia amend the bylaws of the College of Pharmacists of British Columbia, as set out in the schedule attached to this resolution, and file such bylaws with the Minister of Health."

2. *Approve the following resolution to amend the Pharmacy Operations and Drug Scheduling Act Bylaws (PODSA) relating to verbal prescriptions from a practitioner to align to Health Canada exemptions issued under the Controlled Drugs and Substances Act and to request a shortened public posting period from the Minister of Health to bring the amendments into force as soon as possible.*

College of Pharmacists of British Columbia

"RESOLVED THAT, in accordance with the authority established in section 21(1) of the Pharmacy Operations and Drug Scheduling Act and subject to the requirements in section 21(8) of Pharmacy Operations and Drug Scheduling Act, the Board of the College of Pharmacists of British Columbia approves the proposed draft bylaws, as circulated."

CARRIED

6. PDAP EXEMPTIONS FOR CE SUBMISSIONS DURING COVID-19 (APPENDIX 2)

Ashifa Keshavji, Director of Practice Reviews and Quality Assurance provided to the Board an overview of the requirement of continuing education for all registered pharmacy professionals in order to renew their license.

It was moved and seconded that the Board:
In response to the State of Emergency due to the COVID-19 pandemic, that the Board of the College of Pharmacists of BC grant PDAP Exemptions for the remainder of 2020 registration renewal deadlines (March 2020 to December 2020).

CARRIED

It was moved and seconded that the Board:
In response to the State of Emergency due to the COVID-19 pandemic, that the Board of the College of Pharmacists of BC grant PDAP Exemptions to all registrants in the non-practising category for less than 90 days and former registrants whose Full registration has expired for less than 90 days (late registration renewal) for the purposes of reinstatement.

CARRIED

ADJOURNMENT

Chair Antler adjourned the meeting at 6:40pm on March 23, 2020.

College of Pharmacists of British Columbia

BOARD MEETING
March 23, 2020

5. HPA and PODSA Bylaw Amendments to Permit Health Canada's Exemptions under the *Controlled Drugs and Substances Act*

DECISION REQUIRED

Recommended Board Motions:

1. Approve the following resolution to amend the *Health Professions Act* (HPA) Bylaws relating to standards of practice on faxing of a Controlled Prescription form and transferring of a prescription for a controlled drug substance to align to Health Canada exemptions issued under the *Controlled Drugs and Substances Act* and to request a shortened filing period from the Minister of Health to bring the amendments into force as soon as possible.

   "RESOLVED THAT, in accordance with the authority established in section 19(1)(k) of the Health Professions Act, and subject to filing with the Minister as required by section 19(3) of the Health Professions Act, the Board of the College of Pharmacists of British Columbia amend the bylaws of the College of Pharmacists of British Columbia, as set out in the schedule attached to this resolution, and file such bylaws with the Minister of Health."

2. Approve the following resolution to amend the *Pharmacy Operations and Drug Scheduling Act Bylaws* (PODSA) relating to verbal prescriptions from a practitioner to align to Health Canada exemptions issued under the *Controlled Drugs and Substances Act* and to request a shortened public posting period from the Minister of Health to bring the amendments into force as soon as possible.

   "RESOLVED THAT, in accordance with the authority established in section 21(1) of the Pharmacy Operations and Drug Scheduling Act and subject to the requirements in section 21(8) of Pharmacy Operations and Drug Scheduling Act, the Board of the College of Pharmacists of British Columbia approves the proposed draft bylaws, as circulated."

Purpose

To propose amendments to the Community Pharmacy Standards of Practice and the *Pharmacy Operations and Drug Scheduling Act* Bylaws to comply with the Health Canada *Subsection 56(1)*

Class Exemption for Patients, Practitioners and Pharmacists Prescribing and Providing Controlled Substances in Canada During the Coronavirus Pandemic.

Background

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. To support access, Health Canada announced on March 14, 2020 that preparations were underway to issue the following exemptions for prescriptions of controlled substances under the *Controlled Drugs and Substances Act* ("CDSA") and its Regulations to support access. If permitted within provincial scopes of practice, the planned exemptions will:

- permit pharmacists to extend prescriptions;
- permit pharmacists to transfer prescriptions to other pharmacists; and
- permit prescribers to issue verbal orders (i.e., over the phone) to extend or refill a prescription.

All partners were strongly encouraged to work to implement these exemptions in their jurisdictions. Health Canada's notice dated March 14, 2020 is attached as Appendix 1.

On March 19, 2020 the College received official notice from Health Canada of the above exemptions as well as a fourth exemption to:

- permit pharmacy employees to deliver prescriptions of controlled substances to patient's homes or other locations where they may be (i.e. self isolating)

No amendments related to the above fourth exemption are included in this package as the College is currently in discussion with the Ministry of Health in British Columbia to determine how best to implement this exemption. Health Canada's notice dated March 19, 2020 is attached as Appendix 2.

Controlled Drugs and Substances Act Section 56(1) Exemption by Minister

The exemptions announced by Health Canada have been made by the federal Minister of Health ("the Minister") under section 56(1) of the *Controlled Drugs and Substances Act* ("CDSA"). In accordance with section 56(1) of the CDSA, the Minister may exempt any person or class of persons from the application of all or any of the provisions of the Act or the regulations if, in the opinion of the Minister, the exemption is necessary for a medical or scientific purpose or is otherwise in the public interest.

Discussion

Upon receiving notice of Health Canada's exemptions on March 14, 2020, College staff immediately conducted a review of current legislation, bylaws and policies to determine any barriers to their implementation. Amendments are proposed to the College's Community Pharmacy Standards of Practice as well as the bylaws under the *Pharmacy Operations and Drug Scheduling Act* in order to enable the three exemptions originally announced by Health Canada. College staff have also identified an additional consideration regarding faxing controlled prescription program forms, and have proposed additional amendments to the College's Community Pharmacy Standards of Practice. The original three exemptions announced by Health Canada as well as the additional consideration are each outlined below.

Exemption #1: Extend Prescriptions

A Health Canada exemption permitting pharmacists to extend prescriptions of controlled substances is in place. College staff found no barriers to implementation, as this can already be done via the following existing provisions.

In accordance with section 25.92(2)(c) of the *Health Professions Act*, a pharmacist may renew a prescription, or dispense a drug or device contrary to the terms of a prescription, if the renewal or contrary dispensing is permitted for professional reasons described in the bylaws.

Section 19(7) of the *Pharmacy Operations and Drug Scheduling Act* Bylaws states that a new prescription from a practitioner is required each time a drug is dispensed, except for an emergency supply for continuity of care. *Professional Practice Policy-31 Emergency Supply for Continuity of Care* (PPP-31) provides guidance to pharmacists in exceptional circumstances.

As a result of the above, **a pharmacist may extend a prescription and dispense a controlled drug substance in exceptional circumstances in accordance with PPP-31**.

Note that changes to *Professional Practice Policy-58 Medication Management (Adapting a Prescription)* were considered. In accordance to PPP-58, a pharmacist may dispense a drug contrary to the terms of the prescription if the action is intended to optimize the therapeutic outcome of a treatment with the prescribed drug and meets all of the elements of a protocol to adapt a prescription. However, PPP-58 does not apply to controlled drug substances or cancer chemotherapy agents. This is outlined further in the PPP-58 Medication Management (Adapting a Prescription) Orientation Guide at principle 2.1.3, which stipulates that a pharmacist must have an original prescription and it must be current (i.e., not expired), authentic, and otherwise appropriate for the patient. As a result, PPP-58 does not provide the necessary provisions to permit a pharmacist to extend prescriptions of controlled substances.

Exemption #2: Transfer Prescriptions to other Pharmacists

Currently, the transfer of a prescription for a controlled drug substance to a pharmacy licenced in Canada is prohibited by section 8(3)(a) of the Community Standards of Practice. This provision states that a registrant can only transfer a prescription for a drug to a pharmacy licenced in Canada if the drug does not contain a controlled drug substance. As a result of this current provision, the following amendment to the Community Standards of Practice is proposed:

Prescription Copy and Transfer

8. (3) Upon request, a registrant must transfer to a pharmacy licenced in Canada a prescription for a drug if
   (a) the drug does not contain a controlled drug substance, and
   (b) the transfer occurs between a registrant and another registrant or an equivalent of a registrant in another Canadian jurisdiction.

(3.1) Despite section 3(a), a registrant may transfer a prescription for a controlled drug substance if the transfer is permitted under a section 56 exemption to the *Controlled Drugs and Substances Act*.

The proposed amendment would allow for the transfer of a prescription for a controlled drug substance to occur from a pharmacist to another pharmacist under a section 56(1) exemption to the CDSA.

Exemption #3: Permit Verbal Orders for a Prescription

As further clarified in the Frequently Asked Questions document from Health Canada released on March 23, 2020, it has been clarified that a practitioner can provide a new prescription for controlled substances to a pharmacist verbally under this exemption. Once the prescription has been "ordered" a pharmacist can extend, renew and transfer this prescription.

Currently, in accordance with section 19(6) of the PODSA Bylaws, drugs included in the controlled prescription program must not be sold or dispensed unless the registrant has received the prescription on the Controlled Prescription Program form and the prescription form is signed by the patient or the patient's representative upon receipt of the drug. As a result of this current provision, verbal orders for a subset of controlled drugs (drugs listed as Schedule IA under the *Drug Schedules Regulation)* are not permitted. The following amendment to the PODSA Bylaws is proposed:

Sale and Disposal of Drugs

19 (6) Drugs included in the controlled prescription program must not be sold or dispensed unless

(a) the registrant has received the prescription on the prescription form approved by both the board and the College of Physicians and Surgeons of British Columbia, and

(b) the prescription form is signed by the patient or the patient's representative upon receipt of the dispensed drug.

(6.1) Despite subsection (6), a registrant may dispense drugs included in the controlled prescription program upon receipt of a verbal prescription from a practitioner if doing so as permitted under a section 56 exemption to the *Controlled Drugs and Substances Act*. The pharmacy must receive the original form by mail as soon as reasonably possible.

It is important to note that when taking verbal prescriptions in community practice, a registrant must make a written record of the verbal authorization and include his or her signature or initial in accordance with section 6(7) of the Community Pharmacy Standards of Practice. Federal legislation requires that a pharmacist taking a verbal prescription must make a written record that includes additional information such as the name of the practitioner. As a result, it is recommended that best-practice principles for creating a written record of a verbal prescription are communicated to pharmacists during the implementation of the proposed amendment.

In addition to the proposed PODSA Bylaw amendment, consequential amendments are proposed to the Policy Guides for *Professional Practice Policy-66 Opioid Agonist Treatment* as well as the Policy Guide for *Professional Practice Policy-67 Injectable Hydromorphone Maintenance Treatment*. Proposed amendments to these Policy Guides are attached as appendices 5 through 8.

Additional Consideration: Faxing of Controlled Prescription Program Form

When reviewing current legislation, bylaws and policies to determine any barriers to implementing Health Canada's proposed exemptions, staff identified an additional area of consideration regarding the faxing of controlled prescription program forms. This topic was also previously identified by the Ministry of Health in British Columbia as a barrier to patient access.

Currently, in accordance with section 7(3) of the Community Pharmacy Standards of Practice, a registrant is prohibited from dispensing a drug included on the Controlled Prescription Drug List if the prescription authorization was received by facsimile.

The following amendment to the Community Pharmacy Standards of Practice is proposed:

Transmission by Facsimile

7. (3) A registrant must not dispense a prescription authorization received by facsimile transmission for a drug referred to on the Controlled Prescription Drug List,

except in a public health emergency declared by the provincial health officer. In a public health emergency, the pharmacy must receive

(a) a completed copy of the Controlled Prescription Program form transmitted by facsimile,

(b) the original form by mail as soon as reasonably possible.

The proposed amendment would allow a registrant to dispense a prescription authorization received by facsimile transmission for a drug referred to on the Controlled Prescription Drug List in exceptional circumstances.

Proposed amendments to the Community Pharmacy Standards of Practice is attached as Appendix 3. Proposed amendments to the PODSA Bylaws is attached as Appendix 4.

Next Steps

- If approved by the Board, submit proposed HPA amendments to the Community Standards of Practice to the Ministry of Health for filing (with a request to shorten the filing period);
- If approved by the Board, await response from Ministry of Health on request to shorten the public posting period of the PODSA Bylaw amendments;
- Publicly post the PODSA bylaw amendments (for time period approved by the Minister of Health); and
- Develop and implement communications on the amendments.

Guiding Questions

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

- Do the proposed amendments address the three original exemptions issued by Health Canada?
- Is there anything unclear, ambiguous, or unnecessary in the draft proposed amendments?
- Is there anything missing from the draft proposed amendments?

Recommendation

That the Board approve the proposed amendments to the Community Pharmacy Standards of Practice (Appendices 3A and 3B) and the *Pharmacy Operations and Drug Scheduling Act* Bylaws (Appendix 4) to comply with three exemptions provided by Health Canada in the *Subsection 56(1) Class Exemption for Patients, Practitioners and Pharmacists Prescribing and Providing Controlled Substances in Canada During the Coronavirus Pandemic* and related amendments to the Policy Guides (Appendix 5 to 8) under *Professional Practice Policy 66 Opioid Agonist Treatment* and *Professional Practice Policy 67 – Injectable Opioid Agonist Treatment.*

Appendix	
1	Letter from Eric Costen, Associate Assistant Deputy Minister, Controlled Substances and Cannabis Branch, Health Canada dated March 14, 2020
2	Letter and attachments from Michelle Boudreau, Director General, Controlled Substances Directorate, Health Canada dated March 19, 2020
3A	Proposed amendments to Community Pharmacy Standards of Practice (track changes)
3B	Schedule of amendments to Community Pharmacy Standards of Practice
4	Proposed amendments to the *Pharmacy Operations and Drug Scheduling Act* Bylaws (track changes)
5	Proposed amendments to *PPP-66 Policy Guide: Buprenorphine/Naloxone Maintenance Treatment* (track changes)
6	Proposed amendments to *PPP-66 Policy Guide: Methadone Maintenance Treatment* (track changes)
7	Proposed amendments to *PPP-66 Policy Guide: Slow Release Oral Morphine Maintenance (SROM) Treatment* (track changes)
8	Proposed amendments to *PPP-67 Policy Guide: Injectable Hydromorphone Maintenance Treatment* (track changes)

Health Canada | Santé Canada

March 14, 2020

Dear Colleagues,

In the context of the evolving COVID-19 outbreak and implementation of prevention and control measures across the country, it will be important to maintain Canadians' access to controlled substances when needed for medical treatments (e.g., treatment of substance use disorders and chronic pain). This is critical in order to enable individuals who are currently undergoing medical treatment, including for chronic conditions, and need to self-isolate, or adhere to social distancing guidance from public health officials.

To support access, Health Canada is preparing to issue the following 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 planned exemptions will:

- permit pharmacists to extend prescriptions;
- permit pharmacists to transfer prescriptions to other pharmacists; and
- permit prescribers to issue verbal orders (i.e., over the phone) to extend or refill a prescription.

We expect to issue these class exemptions during the week of March 16, 2020. 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.

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, or wish to discuss any other potential barriers to treatment and harm reduction services related to the COVID-19 pandemic, please contact Health Canada's Office of Controlled Substances, at: hc.ocs-bsc.sc@canada.ca.

Best Regards,

Eric Costen
Associate Assistant Deputy Minister
Controlled Substances and Cannabis Branch
Health Canada

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

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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;
b) A person who was prescribed a controlled substance; and
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.

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

Health Canada Santé 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.

Health Professions Act – BYLAWS

SCHEDULE F

PART 1 - Community Pharmacy Standards of Practice

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Application

1. This Part applies to all registrants providing pharmacy services in a community pharmacy.

Definitions

2. In this Part:

"community pharmacy" has the same meaning as in section 1 of the bylaws of the college under the *Pharmacy Operations and Drug Scheduling Act*;

"drug therapy problem" means a potential or actual adverse consequence of drug therapy that interferes with achieving the goals of the drug therapy;

"final check" means ensuring that:

(a) the prescription product and the prescription product label match the prescription information and the information on the manufacturer's label with respect to:

(i) drug,

(ii) dosage form,

(iii) strength,

(iv) quantity, and

(v) drug identification number;

(b) the prescription product label matches the prescription information with respect to the matters set out in section 6(2)(a) to (g);

(c) the drug has not expired and will not expire within the duration of use; and

(d) a pharmacist has completed a clinical assessment of the prescription after reviewing the patient profile.

"**incentive**" means money, gifts, discounts, rebates, refunds, customer loyalty schemes, coupons, goods or rewards;

"patient representative" means a person who is authorized to act on a patient's behalf;

"personal health number" means a unique numerical lifetime identifier used in the specific identification of an individual patient who has any interaction with the BC health system;

"prescription copy" means a copy of a prescription given to a patient by a registrant for information purposes only;

"prescription transfer" means the transfer via direct communication from a registrant to another registrant of all remaining refill authorizations for a particular prescription to a requesting community pharmacy;

"refill" means verbal or written approval from a practitioner authorizing a registrant to dispense additional quantities of drug(s) pursuant to a prescription;

"renewal" means authorization by a full pharmacist to dispense additional quantities of drug(s) pursuant to a previously dispensed prescription, in accordance with section 25.92 of the *Act*;

"*Residential Care Facilities and Homes Standards of Practice*" means the standards, limits and conditions for practice established in Part 3 of this Schedule.

Patient Choice

3. Registrants, owners and directors must not enter into agreements with patients, patient's representatives, practitioners, corporations, partnerships, or any other person or entity, that limit a patient's choice of pharmacy, except as required or permitted under the bylaws.

Community Pharmacy Technicians

4. (1) Pharmacy technicians in a community pharmacy may prepare, process and compound prescriptions, including

(a) receiving and transcribing verbal prescriptions from practitioners,

(b) ensuring that a prescription is complete and authentic,

(c) transferring prescriptions to and receiving prescriptions from other pharmacies,

(d) ensuring the accuracy of a prepared prescription,

(e) performing the final check of a prepared prescription, and

(f) ensuring the accuracy of drug and personal health information in the PharmaNet patient record.

(2) Despite subsection (1), a pharmacy technician in a community pharmacy may dispense a drug but must not

(a) perform the task of ensuring the pharmaceutical and therapeutic suitability of a drug for its intended use, or

(b) do anything described in

(i) sections 6(5), 6(10), 10(2), 11(3), 11(4), 12, 13(2), 13(3) or 13(4) of this Part, or

(ii) Part 4 of this Schedule

(c) dispense a drug pursuant to HPA Bylaws Schedule F, Part 5

(3) A pharmacy technician must identify his or her registrant class in any interaction with a patient or a practitioner.

Pharmacy Assistants

5. A registrant may delegate technical functions relating to the operation of the community pharmacy to a pharmacy assistant if the registrant directly supervises the pharmacy assistant and implements procedures, checks and controls to ensure the accurate and safe delivery of community pharmacy services.

Prescription

6. (1) A registrant must ensure that a prescription is authentic.

(2) Upon receipt from the practitioner, a prescription must include the following information:

(a) the date the prescription was written;

(b) the name of the patient;

(c) the name of the drug or ingredients and strength if applicable;

(d) the quantity of the drug;

(e) the dosage instructions including the frequency, interval or maximum daily dose;

(f) refill authorization if applicable, including number of refills and interval between refills;

(g) the name and signature of the practitioner for written prescriptions;

(3) For the purpose of subsection (4), “prescription” includes a new prescription, a refill, a renewal or a balance owing.

(4) At the time of dispensing, a prescription must include the following additional information:

(a) the address of the patient;

(b) the identification number from the practitioner’s regulatory college;

(c) the prescription number;

(d) the date on which the prescription was dispensed;

(e) the manufacturer’s drug identification number or the brand name of the product dispensed;

(f) the quantity dispensed;

(g) written confirmation of the registrant who

(i) verified the patient identification

(ii) verified the patient allergy information,

(iii) reviewed the personal health information stored in the PharmaNet database in accordance with section 11.4;

(iv) performed the consultation,

(v) performed the final check including when dispensing a balance owing, and

(vi) identified and addressed a drug therapy problem, if any.

(5) A full pharmacist must

(a) review prescriptions for completeness and appropriateness with respect to the drug, dosage, route and frequency of administration,

(b) review patient personal health information for drug therapy problems, therapeutic duplications and any other potential problems,

(c) consult with patients concerning the patient's drug history and other personal health information,

(d) consult with practitioners with respect to a patient's drug therapy unless s.25.92(2) of the *Act* applies, and

(e) take appropriate action respecting a drug therapy problem.

(6) A registrant may receive verbal prescription authorizations directly from a practitioner or from a practitioner's recorded voice message.

(7) A registrant must make a written record of a verbal authorization, and include his or her signature or initial.

(8) A registrant must not dispense a prescription issued for more than one patient.

(9) For refill authorizations, a registrant

(a) may accept a refill authorization for Schedule I drugs from a practitioner's agent if confident the agent consulted the practitioner and accurately conveyed the practitioner's direction, and

(b) must

(i) cancel any unused refill authorizations remaining on any previous prescription if a patient presents a new prescription for a previously dispensed drug,

(ii) advise the other pharmacy of the new prescription if unused refills are at another pharmacy, and

(iii) create a new prescription number.

(10) If a full pharmacist authorizes a prescription renewal, he or she must

(a) create a written record,

(b) assign a new prescription number, and

(c) use his or her college identification number in the practitioner field on PharmaNet.

Transmission by Facsimile

7. (1) Prescription authorizations may be received by facsimile from a practitioner to a pharmacy, if

(a) the prescription is sent only to a pharmacy of the patient's choice,

(b) the facsimile equipment is located within a secure area to protect the confidentiality of the prescription information, and

(c) in addition to the requirements of section 6(2), the prescription includes

(i) the practitioner's telephone number, facsimile number and unique identifier if applicable,

(ii) the time and date of transmission, and

(iii) the name and fax number of the pharmacy intended to receive the transmission.

(2) Prescription refill authorization requests may be transmitted by facsimile from a pharmacy to a practitioner, if the pharmacy submits refill requests on a form that includes space for

(a) the information set out in section 6(2),

(b) the name, address and 10 digit telephone number of the pharmacy, and

(c) the practitioner's name, date and time of transmission from the practitioner to the pharmacy.

(3) A registrant must not dispense a prescription authorization received by facsimile transmission for a drug referred to on the Controlled Prescription Drug List, except in a public health emergency declared by the provincial health officer. In a public health emergency, the pharmacy must receive

(a) a completed copy of the Controlled Prescription Program form transmitted by facsimile prior to dispensing the medication; and

(b) the original form by mail as soon as reasonably possible.

(4) Prescription transfers may be completed by facsimile transmission if

(a) the transferring registrant includes his or her name and the address of the pharmacy with the information required in section 8(4), and

(b) the name of the registrant receiving the transfer is known and recorded on the document to be faxed.

Prescription Copy and Transfer

8. (1) If requested to do so, a registrant must provide a copy of the prescription to the patient or the patient's representative, or to another registrant.

(2) A prescription copy must contain

(a) the name and address of the patient,

(b) the name of the practitioner,

(c) the name, strength, quantity and directions for use of the drug,

(d) the dates of the first and last dispensing of the prescription,

(e) the name and address of the community pharmacy,

(f) the number of authorized refills remaining,

(g) the signature of the registrant supplying it, and

(h) an indication that it is a copy.

(3) Upon request, a registrant must transfer to a pharmacy licenced in Canada a prescription for a drug if

(a) the drug does not contain a controlled drug substance, and

(b) the transfer occurs between a registrant and another registrant or an equivalent of a registrant in another Canadian jurisdiction.

(3.1) Despite section 3(a), a registrant may transfer a prescription for a controlled drug substance if the transfer is permitted under a section 56 exemption to the *Controlled Drugs and Substances Act*.

(4) A registrant who transfers a prescription to another registrant under subsection (3) must

(a) enter on the patient record

(i) the date of the transfer,

(ii) the registrant's identification,

(iii) identification of the community pharmacy to which the prescription was transferred, and

(iv) identification of the person to whom the prescription was transferred, and

(b) transfer all prescription information listed in subsection (2) (a) to (f).

(5) A registrant must make prescriptions available for review and copying by authorized inspectors of Health Canada.

Prescription Label

9. (1) All drugs dispensed pursuant to a prescription or a full pharmacist-initiated adaptation must be labeled.

(2) The label for all prescription drugs must include

(a) the name, address and telephone number of the pharmacy,

(b) the prescription number and dispensing date,

(c) the full name of the patient,

(d) the name of the practitioner,

(e) the quantity and strength of the drug,

(f) the practitioner's directions for use, and

(g) any other information required by good pharmacy practice.

(3) For a single-entity product, the label must include

(a) the generic name, and

(b) at least one of

(i) the brand name,

(ii) the manufacturer's name, or

(iii) the drug identification number.

(4) For a multiple-entity product, the label must include

(a) the brand name, or

(b) all active ingredients, and at least one of

(i) the manufacturer's name, or

(ii) the drug identification number.

(5) For a compounded preparation, the label must include all active ingredients.

(6) If a drug container is too small to accommodate a full label in accordance with subsection (2),

(a) a trimmed prescription label must be attached to the small container,

(b) the label must include

(i) the prescription number,

(ii) the dispensing date,

(iii) the full name of the patient, and

(iv) the name of the drug, and

(c) the complete prescription label must be attached to a larger container and the patient must be advised to keep the small container inside the large container.

(7) All required label information must be in English, but may contain directions for use in the patient's language following the English directions.

Preparation of Prescription Product

9.1 (1) A registrant who prepares a prescription product must ensure that:

(a) the prescription product label matches the prescription information and the information on the manufacturer's label with respect to:

(i) drug,
(ii) dosage form,
(iii) strength,
(iv) quantity,
(v) drug identification number;

(b) the prescription product label matches the prescription information with respect to the matters set out in section 6(2)(a) to (g);

(c) the drug is not expired and will not expire within the duration of use; and

(d) his or her identity is documented in writing.

(2) A pharmacy manager must ensure that the record in paragraph (1)(d) is readily available and is retained for at least three years from the date on which the prescription product was last dispensed.

Dispensing

10. (1) A registrant may adjust the quantity of drug to be dispensed if

(a) a patient requests a smaller amount,

(b) a manufacturer's unit-of-use standard of package size does not match the prescribed quantity,

(c) the quantity prescribed exceeds the amount covered by the patient's drug plan, or

(d) a trial prescription quantity is authorized by the patient.

(2) A full pharmacist may adjust the quantity of drug to be dispensed, if

(a) he or she consults with a practitioner and documents the result of the consultation, and

(b) if

(i) a poor compliance history is evident on the patient record,

(ii) drug misuse is suspected, or

(iii) the safety of the patient is in question due to the potential for overdose.

(3) If a registrant doubts the authenticity of a prescription, the registrant may refuse to dispense the drug.

(4) All drugs must be dispensed in a container that is certified as child-resistant unless

(a) the practitioner, the patient or the patient's representative directs otherwise,

(b) in the registrant's judgment, it is not advisable to use a child-resistant container,

(c) a child-resistant package is not suitable because of the physical form of the drug or the manufacturer's packaging is designed to improve patient compliance, or

(d) child-resistant packaging is unavailable, or

(e) the drugs are prescribed for medical assistance in dying.

(5) A registrant must not dispense a prescription more than one year from the prescribing date, except for oral contraceptives which may be dispensed for up to two years.

(6) Before dispensing a prescription product, a registrant must perform a final check and record his or her identity in writing.

(7) A pharmacy manager must ensure the record in paragraph (6) is readily available and retained for at least three years after the last date on which that prescription product was last dispensed.

Patient Record

11. (1) A patient record must be established and maintained for each patient for whom a Schedule I drug is dispensed.

(2) For purposes of subsection (1), the patient record must include

(a) the patient's full name,

(b) the patient's personal health number,

(c) the patient's address,

(d) the patient's telephone number if available,

(e) the patient's date of birth,

(f) the patient's gender,

(g) the patient's clinical condition, allergies, adverse drug reactions and intolerances if available including the source and date the information was collected,

(h) the date the drug is dispensed,

(i) the prescription number,

(j) the generic name, strength and dosage form of the drug,

(k) the drug identification number,

(l) the quantity of drug dispensed,

(m) the intended duration of therapy, specified in days,

(n) the date and reason for discontinuation of therapy,

(o) the directions to the patient,

(p) the identification of the prescribing practitioner,

(q) special instructions from the practitioner to the registrant, if appropriate,

(r) past and present prescribed drug therapy including the drug name, strength, dosage, frequency, duration and effectiveness of therapy,

(s) the identification of any drug therapy problem and the description of any action taken,

(t) the description of compliance with the prescribed drug regimen, and

(u) Schedule II and III drug use if appropriate.

(3) If a full pharmacist obtains a drug history from a patient, he or she must request and if appropriate record the following information on the patient record:

(a) medical conditions and physical limitations,

(b) past and current prescribed drug therapy including the drug name, strength, dosage, frequency, duration and effectiveness of therapy,

(c) compliance with the prescribed drug regimen,

(d) Schedule II and III drug use.

(4) A full pharmacist must review the patient's personal health information stored on the PharmaNet database before dispensing a drug and take appropriate action if necessary with respect to any concern regarding the appropriateness of the drug or any drug therapy problem.

Pharmacist/Patient Consultation

12. (1) Subject to subsection (2), a full pharmacist must consult with the patient or patient's representative at the time of dispensing a new or refill prescription in person or, where not practical to do so, by telephone.

(2) Where a patient declines the consultation, the full pharmacist must document that the consultation was offered and declined.

(3) The full pharmacist must conduct the consultation in a manner that respects the patient's right to privacy.

(4) The pharmacist/patient consultation for a new prescription must include:

(a) confirmation of the identity of the patient,

(b) name and strength of drug,

(c) purpose of the drug,

(d) directions for use of the drug including the frequency, duration and route of therapy,

(e) potential drug therapy problems, including any avoidance measures, and action recommended if they occur,

(f) storage requirements,

(g) prescription refill information,

(h) information regarding

(i) how to monitor the response to therapy,

(ii) expected therapeutic outcomes,

(iii) action to be taken in the event of a missed dose, and

(iv) when to seek medical attention.

(i) issues the pharmacist considers relevant to the specific drug or patient.

(5) The pharmacist/patient consultation for a refill prescription must include:

(a) confirmation of the identity of the patient,

(b) name and strength of drug,

(c) purpose of the drug,

(d) directions for use of the drug including frequency and duration,

(e) whether the patient has experienced a drug therapy problem.

(6) If a drug therapy problem is identified during patient consultation for a new or refill prescription, the full pharmacist must take appropriate action to resolve the problem.

(7) If an adverse drug reaction as defined by Health Canada is identified, the full pharmacist must notify the patient's practitioner, make an appropriate entry on

the PharmaNet record and report the reaction to the appropriate department of Health Canada.

Schedule II and III Drugs

13. (1) A registrant must not attribute a new prescription or refill for a Schedule II or Schedule III drug to a practitioner without the authorization of the practitioner.

(2) A pharmacist must offer to consult with the patient or the patient's representative regarding the selection and use of a Schedule II drug at the time of purchase.

(3) The pharmacist/patient consultation for a Schedule II drug must include potential drug therapy problems, including any avoidance measures, and action recommended if they occur.

(4) A pharmacist must be available for consultation with a patient or patient's representative respecting the selection and use of a Schedule III drug.

Sole Pharmacy Services Provider

14. The manager of a pharmacy may enter into an agreement with another person to be the sole provider of pharmacy services in a premise or part of a premise, if

(a) pharmacy services are provided in a manner that is consistent with the *Residential Care Facilities and Homes Standards of Practice,*

(b) patient therapeutic outcomes are monitored to enhance patient safety, and

(c) appropriate provision has been made for safe and effective distribution, administration and control of drugs.

Prohibition on the Provision of Incentives

15. (1) A registrant must not provide or distribute, or be a party to the provision or distribution of, an incentive to a patient or patient's representative for the purpose of inducing the patient or patient's representative to

(a) deliver a prescription to a particular registrant or pharmacy for dispensing of a drug or device specified in the prescription, or

(b) obtain any other pharmacy service from a particular registrant or pharmacy.

(2) Subsection (1) does not prevent a registrant from

(a) providing free or discounted parking to patients or patient's representatives,

(b) providing free or discounted delivery services to patients or patient's representatives, or

(c) accepting payment for a drug or device by a credit or debit card that is linked to an incentive.

(3) Subsection (1) does not apply in respect of a Schedule III drug or an unscheduled drug, unless the drug has been prescribed by a practitioner.

SCHEDULE OF AMENDMENTS

Schedule F – Part 1 – Community Pharmacy Standards of Practice of bylaws of the College of Pharmacists of British Columbia made under the authority of the Health Professions Act are amended to comply with the Health Canada Subsection 56(1) Class Exemption for Patients, Practitioners and Pharmacists Prescribing and Providing Controlled Substances in Canada During the Coronavirus Pandemic, as follows:

1. Section 7.(3) is repealed and replaced by the following:

    7. (3) A registrant must not dispense a prescription authorization received by facsimile transmission for a drug referred to on the Controlled Prescription Drug List, except in a public health emergency declared by the provincial health officer. In a public health emergency, the pharmacy must receive

        (a) a completed copy of the Controlled Prescription Program form transmitted by facsimile prior to dispensing the medication; and

        (b) the original form by mail as soon as reasonably possible.

2. The following new section has been added after section 8.(3):

    8. (3.1) Despite section 3(a), a registrant may transfer a prescription for a controlled drug substance if the transfer is permitted under a section 56 exemption to the *Controlled Drugs and Substances Act*.

Pharmacy Operations and Drug Scheduling Act - BYLAWS

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Definitions

1 In these bylaws:

"*Act*" means the *Pharmacy Operations and Drug Scheduling Act*;

"attestation" means the attestation referred to in section 2(2)(d)(ii) of the *Act*;

"BC Annual Report" means an annual report filed with the BC Registry Services;

"British Columbia Company Summary" means a summary issued by the BC Registry Services;

"central pharmacy" means a community pharmacy that holds one or more telepharmacy licences;

"Central Securities Register" means the register maintained under section 111(1) of the *Business Corporations Act* [SBC 2002] C.57 as amended;

"community pharmacy" means a pharmacy licensed to sell or dispense drugs to the public, but does not include a telepharmacy;

"*Community Pharmacy Standards of Practice*" means the standards, limits and conditions for practice established under section 19(1)(k) of the *Health Professions Act* respecting community pharmacies;

"controlled drug substances" means a drug which includes a substance listed in the Schedules in the regulations made pursuant to the *Controlled Drugs and Substances Act* (Canada), and Part G of the *Food and Drug Regulations* (Canada);

"controlled prescription program" means a program approved by the board, to prevent prescription forgery and reduce inappropriate prescribing of drugs;

"criminal record history" means the results of a criminal record search of Royal Canadian Mounted Police and local police databases, in the form approved by the board;

"direct owner" has the same meaning as in section 1 of the *Act*;

"direct supervision" means real time audio and visual observation by a full pharmacist of pharmacy services performed at a telepharmacy consistent with a pharmacy manager's responsibilities as set out in section 18(2);

"dispensary" means the area of a community pharmacy or a telepharmacy that contains Schedule I and II drugs;

"drug" has the same meaning as in section 1 of the *Act*;

"electronic signature" means

(a) information in electronic form that a person has created or adopted in order to sign a record, other than with respect to a prescription signed by a full

pharmacist for the purpose of prescribing, that is in, attached to or associated with a record, is secure and is only reproducible and used by that person, and,

(b) with respect to a prescription signed by a full pharmacist for the purpose of prescribing, the electronic signature must meet the requirements of paragraph (a) and must be a unique mark personally applied by that pharmacist;

"full pharmacist" means a member of the College who is registered in the class of registrants established in section 41(a) of the bylaws under the *Health Professions Act*;

"health authority" includes

(a) a regional health board designated under the *Health Authorities Act*,
(b) the Provincial Health Services Authority,
(c) First Nations Health Authority, and
(d) Providence Health Care Society;

"hospital" has the same meaning as in section 1 of the *Hospital Act*;

"hospital pharmacy" means a pharmacy licensed to operate in or for a hospital;

"hospital pharmacy satellite" means a physically separate area on or outside the hospital premises used for the provision of pharmacy services which is dependent upon support and administrative services from the hospital pharmacy;

"*Hospital Pharmacy Standards of Practice*" means the standards, limits and conditions for practice established under section 19(1)(k) of the *Health Professions Act* respecting hospital pharmacies;

"incentive" has the same meaning as in Part 1 of Schedule "F" of the bylaws of the College under the *Health Professions Act;*

"indirect owner" has the same meaning as in section 1 of the *Act*;

"manager" has the same meaning as in section 1 of the *Act*;

"outsource prescription processing" means to request another community pharmacy to prepare or process a prescription drug order;

"patient's representative" means a person who is authorized to act on a patient's behalf;

"personal health information" has the same meaning as in section 25.8 of the *Health Professions Act*;

"pharmacy" has the same meaning as in section 1 of the *Act*;

"pharmacy education site" means a pharmacy

(a) that has Schedule I, II and III drugs, but no controlled drug substances,
(b) that is licensed solely for the purpose of pharmacy education, and
(c) from which pharmacy services are not provided to any person;

“pharmacy security” means

(a) measures to prevent unauthorized access and loss of Schedule I, IA, II and III drugs, and controlled drug substances,
(b) measures providing for periodic and post-incident review of pharmacy security,
(c) measures to protect against unauthorized access, collection, use, disclosure or disposal of personal health information;

“pharmacy services” has the same meaning as in section 1 of the bylaws of the College under the *Health Professions Act*;

“pharmacy technician” has the same meaning as in section 1 of the bylaws of the College under the *Health Professions Act*;

“prescription drug” means a drug referred to in a prescription;

“professional products area” means the area of a community pharmacy that contains Schedule III drugs;

“professional service area” means the area of a community pharmacy that contains Schedule II drugs;

“record” has the same meaning as the definition of record in Schedule 1 of the *Freedom of Information and Protection of Privacy Act*;

“*Residential Care Facilities and Homes Standards of Practice*” means the standards, limits and conditions for practice established under section 19(1)(k) of the *Health Professions Act* respecting residential care facilities and homes;

“rural and remote community” means a community set out in Schedule “H”;

“Schedule I, Schedule IA, Schedule II, or Schedule III”, as the case may be, refers to the drugs listed in Schedule I, IA, II or III of the *Drug Schedules Regulation*;

“signature” on a record means either a handwritten signature in ink or an electronic signature;

“support person” has the same meaning as in the *Act* except that it does not include a pharmacy technician;

“telepharmacy” means a pharmacy located in a rural and remote community that is licensed to provide pharmacy services;

“*Telepharmacy Standards of Practice*” means the standards, limits and conditions for practice established under section 19(1)(k) of the *Health Professions Act* respecting the operation of telepharmacies.

PART I – Pharmacy Licences

Licence Types

2 (1) The registrar may issue a licence for any of the following:

(a) a community pharmacy;

(b) a hospital pharmacy;

(c) a pharmacy education site; or

(d) a telepharmacy.

New Community Pharmacy Licence

3 (1) Applicants for a new community pharmacy licence must submit an application consistent with the type of ownership under section 5(2) of the *Act*.

(2) A direct owner may apply for a new community pharmacy licence by submitting:

(a) an application in Form 1A;

(b) the fee(s) specified in Schedule "A";

(c) a diagram professionally drawn to scale, including the measurements and entrances of the pharmacy, demonstrating compliance with the physical requirements in the bylaws and applicable policies;

(d) Form 10A;

(e) photographs or video demonstrating compliance with the physical requirements in the bylaws and applicable policies; and

(f) a copy of the pharmacy's valid business licence issued by the jurisdiction to the direct owner, if applicable.

(3) In addition to the requirements in subsection (2), a direct owner described in section 5(2)(b) or (c) of the *Act* must submit:

(a) an email contact of each indirect owner;

(b) a copy of the power(s) of attorney, if applicable;

(c) a copy of the current British Columbia Company Summary; and

(d) a certified true copy of the Central Securities Register if a direct owner is or includes a corporation that is not traded publicly.

(4) If an indirect owner is a company incorporated under the *Company Act* or the *Business Corporations Act* that is not traded publicly, the following must be submitted for that company:

(a) an email contact of each indirect owner;

(b) a copy of the power(s) of attorney, if applicable;

(c) a copy of the current British Columbia Company Summary; and

(d) a certified true copy of the Central Securities Register.

(5) Proof of eligibility in Form 5 and a criminal record history in accordance with section 14 must be submitted by the following:

(a) any pharmacist who is a direct owner described in section 5(2)(a) of the *Act*;

(b) indirect owner(s); and

(c) the manager.

Community Pharmacy Licence Renewal

4 (1) A direct owner may apply to renew a community pharmacy licence no later than 30 days prior to the expiry of the existing pharmacy licence by submitting:

(a) an application in Form 2A;

(b) the fee(s) specified in Schedule "A";

(c) a copy of the pharmacy's valid business licence issued by the jurisdiction to the direct owner, if applicable; and

(d) a copy of the current British Columbia Company Summary or the most recently filed BC Annual Report, if a direct owner is or includes a corporation.

(2) At the time of the renewal application, an attestation in Form 5 must be submitted by:

(a) any pharmacist who is a direct owner described in section 5(2)(a) of the *Act*;

(b) indirect owner(s); and

(c) the manager.

(3) An application submitted later than 30 days prior to the expiry of the pharmacy licence is subject to the fee(s) specified in Schedule "A".

Community Pharmacy Licence Reinstatement

5 (1) A direct owner may apply to reinstate a community pharmacy licence that has been expired for 90 days or less by submitting:

(a) an application in Form 3A;

(b) the fee(s) specified in Schedule "A";

(c) a copy of the pharmacy's valid business licence issued by the jurisdiction to the direct owner, if applicable; and

(d) a copy of the current British Columbia Company Summary, if the direct owner is or includes a corporation.

(2) At the time of the reinstatement application, an attestation in Form 5 must be submitted by:

(a) any pharmacist who is a direct owner described in section 5(2)(a) of the *Act*;

(b) indirect owner(s); and

(c) the manager.

New Hospital Pharmacy Licence

6 (1) Applicants for a new hospital pharmacy licence must submit an application consistent with the type of ownership under section 5(2) of the *Act*.

(2) A direct owner may apply for a new hospital pharmacy licence by submitting:

(a) an application in Form 1C;

(b) the fee(s) specified in Schedule "A"; and

(c) a diagram professionally drawn to scale, including the measurements and entrances of the pharmacy, demonstrating compliance with the physical requirements in the bylaws and applicable policies.

(3) The manager must submit an attestation in Form 5 and a criminal record history in accordance with section 14.

(4) A pharmacy located in a hospital which dispenses drugs to staff, out-patients or the public and which is not owned or operated by a health authority, must be licensed as a community pharmacy or telepharmacy.

Hospital Pharmacy Licence Renewal

7 (1) A direct owner may apply to renew a hospital pharmacy licence no later than 30 days prior to the expiry of the existing pharmacy licence by submitting:

(a) an application in Form 2C; and

(b) the fee(s) specified in Schedule "A".

(2) At the time of the renewal application, the manager must submit an attestation in Form 5.

(3) An application submitted later than 30 days prior to the expiry of the pharmacy licence is subject to the fee(s) specified in Schedule "A".

Hospital Pharmacy Licence Reinstatement

8 (1) A direct owner may apply to reinstate a pharmacy licence that has been expired for 90 days or less by submitting:

(a) an application in Form 3C; and

(b) the fee(s) specified in Schedule "A".

(2) At the time of the reinstatement application, the manager must submit an attestation in Form 5.

New Pharmacy Education Site Licence

9 (1) Applicants for a new pharmacy education site licence must submit an application consistent with the type of ownership under section 5(2) of the *Act*.

(2) A direct owner may apply for a new pharmacy education site licence by submitting:

(a) an application in Form 1F; and

(b) the fee(s) specified in Schedule "A".

(3) The manager must submit an attestation in Form 5 and a criminal record history in accordance with section 14.

Pharmacy Education Site Licence Renewal

10 (1) A direct owner may apply to renew a pharmacy education licence no later than 30 days prior to the expiry of the existing pharmacy licence by submitting:

(a) an application in Form 2F; and

(b) the fee(s) specified in Schedule "A".

(2) At the time of the renewal application, the manager must submit an attestation in Form 5.

(3) An application submitted later than 30 days prior to the expiry of the pharmacy licence is subject to the fee(s) specified in Schedule "A".

Pharmacy Education Site Licence Reinstatement

11 (1) A direct owner may apply to reinstate a pharmacy education site licence that has been expired for 90 days or less by submitting:

(a) an application in Form 3F; and

(b) the fee(s) specified in Schedule "A".

(2) At the time of the reinstatement application, the manager must submit an attestation in Form 5.

New Telepharmacy Licence

12 A direct owner of a community pharmacy may apply for a new telepharmacy licence by submitting:

(a) an application in Form 1B;

(b) the fee(s) specified in Schedule "A";

(c) a diagram professionally drawn to scale, including the measurements and entrances of the telepharmacy, demonstrating compliance with the physical requirements in the bylaws and applicable policies;

(d) Form 10B;

(e) photographs or video demonstrating compliance with the physical requirements in the bylaws and applicable policies; and

(f) if applicable, a copy of the telepharmacy's valid business licence issued to the direct owner by the jurisdiction in which the telepharmacy is located.

Conditions for Telepharmacy Licence

12.1 (1) The registrar must not issue a telepharmacy licence to a central pharmacy unless

(a) the proposed telepharmacy will be the only telepharmacy or community pharmacy located in the rural and remote community,

(b) the proposed telepharmacy is located at least 25 kilometers away from any other telepharmacy or community pharmacy,

(c) the proposed name on the external signage of the telepharmacy described in section 18(2)(r) includes the word "telepharmacy",

(d) except for a pharmacy located at an address listed in Schedule "F", the proposed telepharmacy does not have a licence as a community pharmacy,

(e) the central pharmacy applicant and the telepharmacy will have the same direct owner, and

(f) the central pharmacy is in compliance, and the telepharmacy will be in compliance, with the *Telepharmacy Standards of Practice*.

(2) A telepharmacy licence issued under subsection (1) is valid only for the location stated on the telepharmacy licence.

Telepharmacy Licence Renewal

13 (1) A direct owner may apply to renew a telepharmacy licence no later than 30 days prior to the expiry of the existing telepharmacy licence by submitting:

(a) an application in Form 2B;

(b) the fee(s) specified in Schedule “A”; and

(c) if applicable, a copy of the telepharmacy’s business licence issued by the jurisdiction in which the telepharmacy is located.

(2) An application submitted later than 30 days prior to the expiry of the telepharmacy licence is subject to the fee(s) specified in Schedule “A”.

Telepharmacy Licence Reinstatement

13.1 A direct owner may apply to reinstate a telepharmacy licence that has been expired for 90 days or less by submitting:

(a) an application in Form 3B;

(b) the fee(s) specified in Schedule “A”; and

(c) if applicable, a copy of the telepharmacy’s valid business licence issued to the direct owner by the jurisdiction in which the telepharmacy is located.

Criminal Record History of Direct Owner, Indirect Owner(s) and Manager

14 A direct owner, indirect owner(s) and a manager must submit a criminal record history pursuant to section 5.1 of the *Act*, in the form approved by the board.

Unlawful Operation

15 (1) Pursuant to section 7(1) of the *Act*, persons listed in Schedule “B” are authorized under this bylaw to store, dispense or sell drugs or devices to the public.

(2) Pursuant to section 7(3) of the *Act*, the registrar may authorize the direct owner, indirect owner(s) or manager of an unlicensed pharmacy, or a full pharmacist to continue the operation of the pharmacy for a period not exceeding 90 days, for the limited purpose of transferring drugs and personal health information on the premises to another licensed pharmacy.

(3) On receiving a referral under section 16(6), the application committee may consider whether to authorize the operation of the pharmacy pursuant to section 7(3) of the *Act* pending a determination under section 4(4)(b) of the *Act* as to relevance or risk to the public.

PART II - All Pharmacies

Change in Direct Owner, Indirect Owner(s) or Manager

16 (1) If a direct owner changes, the registrar may issue a new pharmacy licence upon receipt of the following from the new direct owner:

(a) Form 8A;

(b) the fee(s) specified in Schedule “A”;

(c) a copy of the pharmacy’s valid business licence issued by the jurisdiction to the new direct owner, if applicable; and

(d) the documents listed in sections 3(3), 3(4) and 3(5) as applicable.

(2) If there is a change of indirect owner(s) the following must be submitted by the direct owner:

(a) Form 8B;

(b) the fee(s) specified in Schedule "A";

(c) a Notice of Change of Directors, if applicable;

(d) a certified true copy of the Central Securities Register, if there is a change of shareholder(s) of a non-publicly traded corporation; and

(e) the documents listed in sections 3(3), 3(4) and 3(5), as applicable.

(3) If the change in subsection (2) includes a new indirect owner(s), proof of eligibility in Form 5 and a criminal record history in accordance with section 14 must be submitted by the new indirect owner(s).

(4) If there is a change of manager, the registrar may issue a new pharmacy licence and telepharmacy licence if applicable, upon receipt of:

(a) Form 8C submitted by the direct owner;

(b) the fee(s) specified in Schedule "A"; and

(c) proof of eligibility in Form 5 and a criminal record history in accordance with section 14 submitted by the new manager.

(5) In the event that a direct owner, indirect owner(s) or manager is no longer eligible under section 3 of the *Act*, the direct owner, indirect owner(s) or manager must submit a notice in Form 6.

(6) On receipt of a Form 6 under subsection (5), the registrar must refer the matter to the application committee who may act under sections 4(3), 4(4), and 4(5) of the *Act*.

Changes to the Pharmacy Premises and Name

17 (1) If there is a change in the name of a corporation that is a direct owner, the registrar may amend the pharmacy licence, and telepharmacy licence if applicable, upon receipt of the following from the direct owner:

(a) Form 8D;

(b) the fee(s) specified in Schedule "A";

(c) a copy of the pharmacy's valid business licence issued by the jurisdiction to the direct owner with the new corporation name, if applicable; and

(d) a copy of the Alteration to the Notice of Articles.

(2) If there is a change in the name of a corporation that is an indirect owner, the following must be submitted by the direct owner:

(a) Form 8D;

(b) the fee(s) specified in Schedule “A”; and

(c) a copy of the Alteration to the Notice of Articles.

(3) If there is a change in the name on the external signage described in section 18(2)(q) or section 18(2)(r), or in the operating name of the pharmacy, the registrar may amend the pharmacy or telepharmacy licence upon receipt of the following from the direct owner:

(a) Form 8E;

(b) the fee(s) specified in Schedule “A”;

(c) for a change of operating name, a copy of the pharmacy’s valid business licence with the new operating name issued by the jurisdiction to the direct owner, if applicable; and

(d) for a change of the name on the external signage, photographs or video demonstrating compliance with section 18(2)(q) or 18(2)(r).

(4) If there is a change in location of the pharmacy, the registrar may issue a new pharmacy licence upon receipt of the following from the direct owner:

(a) Form 8F;

(b) the fee(s) specified in Schedule “A”;

(c) the requirements in sections 3(2)(c), (d) and (e) for a community pharmacy, or

(d) the requirements in section 6(2)(c) for a hospital pharmacy;

(e) a copy of the pharmacy’s valid business licence with the address of the new location issued by the jurisdiction to the direct owner, if applicable; and

(f) photographs or video demonstrating compliance with section 18(2)(ee)(v).

(5) If there is a change in layout of the pharmacy, the direct owner must submit the following:

(a) Form 8G;

(b) the fee(s) specified in Schedule “A”; and

(c) a diagram, photographs or video to demonstrate the changes in layout in accordance with sections 3(2)(c), (d) and (e) for a community pharmacy;

(d) a diagram to demonstrate the changes in layout in accordance with section 6(2)(c) for a hospital pharmacy; or

(e) a diagram, photographs or video to demonstrate the changes in layout in accordance with sections 12(c), (d) and (e) for a telepharmacy.

17.1 (1) A direct owner of a pharmacy that is permanently closing must notify the registrar by submitting the following at least 30 days before closure:

(a) an application in Form 4A;

(b) the fee(s) specified in Schedule "A";

(c) documents demonstrating compliance with sections 18(2)(ee)(i), (ii), (iii) and (iv); and

(d) photographs or video demonstrating compliance with section 18(2)(ee)(v).

(2) The manager of the pharmacy receiving drugs, medical devices, and/or patient and prescription records from the closing pharmacy must submit Part 2 of Form 4A within 14 days of receiving date the drugs, medical devices, and/or patient and prescription records.

Responsibilities of Manager, Direct Owners, Directors, Officers and Shareholders

18 (1) A full pharmacist may not act as manager of more than one pharmacy location, unless the pharmacy of which the full pharmacist is manager includes

(a) a telepharmacy,

(b) a hospital pharmacy,

(c) a hospital pharmacy satellite, or

(d) a pharmacy education site.

(2) A manager must do all of the following:

(a) personally manage and be responsible for the daily operation of the pharmacy;

(b) ensure compliance with all legislation, bylaws, policies and procedures applicable to the operation of a pharmacy;

(c) establish policies and procedures

(i) to specify the duties to be performed by registrants and support persons,

(ii) for inventory management, product selection, and proper destruction of non-usable drugs and devices,

(iii) for pharmacy security,

(iv) for emergency preparedness, and

(v) for drug recall of pharmacy inventory;

(d) ensure all policies and procedures are in writing and regularly maintained;

(e) ensure that pharmacy staff are trained in policies and procedures;

(f) ensure that all steps in the drug recall procedure are documented, if the procedure is initiated;

(g) ensure that all individuals working in the pharmacy who present themselves as registrants have been granted and maintain registration with the College, in accordance with the policies approved by the board;

(h) notify the registrar of any appointments, resignations or terminations of registrants employed at the pharmacy as those changes occur;

(i) cooperate with inspectors acting under section 17 of the *Act* or section 28 or 29 of the *Health Professions Act*;

(j) ensure that

(i) registrant and support persons staff levels are commensurate with workload volumes and patient care requirements are met at all times in accordance with the bylaws, Code of Ethics and standards of practice, and

(ii) meeting quotas, targets or similar measures do not compromise patient safety or compliance with the bylaws, Code of Ethics or standards of practice;

(k) ensure that all records related to the purchase and receipt of controlled drug substances are signed by a full pharmacist;

(l) ensure safe and secure storage of all Schedule I, II, and III drugs and controlled drug substances for all aspects of pharmacy practice, in accordance with the policies approved by the board;

(m) ensure that pharmacy records containing personal information about patients are secure from unauthorized access, use, disclosure, modification and destruction;

(n) ensure that each individual working in the pharmacy presents themselves to the public in a manner that clearly identifies their registration class;

(o) ensure that registrants identify themselves in a manner that clearly differentiates them from other individuals working in the pharmacy who are not registrants;

(p) immediately notify the registrar in writing of ceasing to be the pharmacy's manager;

(q) ensure that at a minimum, the name on the external signage of a community pharmacy must be correctly and consistently used on labels and directory listings;

(r) if the pharmacy is a central pharmacy, ensure that at a minimum, the name on the external signage of a telepharmacy must be correctly and consistently used on labels and directory listings;

(s) ensure that narcotic reconciliation is performed in accordance with the policies approved by the board;

(t) notify the registrar of any incident of loss of narcotic and controlled drug substances within 24 hours;

(u) advise the registrar if the pharmacy is providing pharmacy services over the internet, and provide to the registrar the internet address of every website operated or used by the pharmacy;

(v) ensure the pharmacy contains the reference material and equipment in accordance with the policies approved by the board;

(w) require anyone who will access the in-pharmacy computer system to sign an undertaking in a form approved by the registrar to maintain the confidentiality of patient personal health information;

(x) retain the undertakings referred to in subsection (w) in the pharmacy for 3 years after employment or any contract for services has ended;

(y) provide the registrar with access to the pharmacy and premises as defined in section 20(1) in cases where a pharmacy licence has been cancelled or suspended due to loss of eligibility under section 3 of the *Act*;

(z) ensure that no incentive is provided to a patient or patient's representative for the purpose of inducing the patient or patient's representative to

(i) deliver a prescription to a particular registrant or pharmacy for dispensing of a drug or device specified in the prescription, or

(ii) obtain any other pharmacy service from a particular registrant or pharmacy;

(aa) notify the registrar of persistent non-compliance by a direct owner and indirect owner(s) with their obligations under the bylaws to the *Act*;

(bb) notify the registrar of any change of telephone number, fax number, electronic mail address or any other information previously provided to the registrar;

(cc) in the event of an anticipated temporary closure, which is permitted for no more than 14 consecutive days,

(i) notify patients and the public of the anticipated temporary closure at least 30 days prior to the start of the closure in accordance with the policies approved by the board,

(ii) document steps taken to comply with the bylaws and applicable policies on anticipated temporary closures,

(iii) contact all patients whose prepared prescriptions are ready for pick-up to advise of the closure and provide them with the opportunity to obtain their prepared prescriptions prior to the closure start date,

(iv) make alternate arrangements with local prescribers, as appropriate, and

(v) return any prepared prescriptions in the pharmacy to inventory and reverse those prescriptions in PharmaNet;

(dd) in the event of an unanticipated temporary closure due to unforeseen circumstances, which is permitted for no more than 90 days,

(i) notify the registrar of closures of 15 to 90 days in accordance with the policies approved by the board,

(ii) where possible, contact all patients whose prescriptions are ready for pick-up to advise of the closure and provide them with the opportunity to obtain their prepared prescriptions,

(iii) where possible, notify patients, the public, and local prescribers of the closure and alternate means of obtaining essential pharmacy services during the closure in accordance with the policies approved by the board,

(iv) apply for a new pharmacy licence if the closure will exceed 90 days, and

(v) return any prepared prescriptions in the pharmacy to inventory and reverse those prescriptions in PharmaNet;

(ee) in the event of a permanent pharmacy closure, cancellation, or expiry of the pharmacy licence

(i) provide for the safe and secure transfer and appropriate storage of all Schedule I, II, and III drugs and controlled drug substances,

(ii) advise the registrar in writing of the disposition of all drugs and prescription records at the time of a closure, in accordance with policies approved by the board,

(iii) provide the registrar with a copy of the return invoice and any other documentation sent to Health Canada in respect of the destruction of all controlled drug substances,

(iv) arrange for the secure transfer and continuing availability of the prescription records at another pharmacy, or at storage facility that is monitored and secured from unauthorized access, and

(v) remove all signs and advertisements from the closed pharmacy premises;

(3) In the event of a suspension of the pharmacy licence for a period of more than 14 days,

(a) the manager and the direct owner must complete and submit Form 4C, and

(b) the registrar may direct a manager to do any of sections 18(2)(ee)(i), (iii) or (iv).

(4) Subsection (2)(z) does not prevent a manager, direct owner or indirect owner(s) from

(a) providing free or discounted parking to patients or patient's representatives,

(b) providing free or discounted delivery services to patients or patient's representatives, or

(c) accepting payment for a drug or device by a credit or debit card that is linked to an incentive.

(5) Subsection (2)(z) does not apply in respect of a Schedule III drug or an unscheduled drug, unless the drug has been prescribed by a practitioner.

(6) A pharmacy education site's manager must ensure that only registrants and instructors are present in the pharmacy education site and must also comply with subsections (2)(a), (b), (c)(ii), (d), (e), (i), (p), (ee)(i) and (ee)(ii).

(7) A direct owner, directors and officers must do all of the following:

(a) ensure compliance with subsections (2)(c)(i), (c)(iii), (c)(iv), (c)(v), (i), (j), (l), (q), (r), (y) and (z);

(b) ensure that the requirements to hold a pharmacy licence under the *Act* are met at all times; and

(c) notify the registrar of any change of name, address, telephone number, electronic mail address or any other information previously provided to the registrar;

(8) Shareholders must comply with subsections (2)(i) and (7)(c).

Sale and Disposal of Drugs

19 (1) Schedule I, II, and III drugs and controlled drug substances must only be sold or dispensed from a pharmacy.

(2) A registrant must not sell or dispense a quantity of drug that will not be used completely prior to the manufacturer's expiry date, if used according to the directions on the label.

(3) If the manufacturer's expiry date states the month and year but not the date, the expiry date is the last day of the month indicated.

(4) Every registrant practising in a pharmacy is responsible for the protection from loss, theft or unlawful sale or dispensing of all Schedule I, II, and III drugs and controlled drug substances in or from the pharmacy.

(5) A registrant must not sell, dispense, dispose of or transfer a Schedule I drug except

(a) on the prescription or order of a practitioner,

(b) for an inventory transfer to a pharmacy by order of a registrant in accordance with the policies approved by the board,

(c) by return to the manufacturer or wholesaler of the drug, or

(d) by destruction, in accordance with the policies approved by the board.

(6) Drugs included in the controlled prescription program must not be sold or dispensed unless

(a) the registrant has received the prescription on the prescription form approved by both the board and the College of Physicians and Surgeons of British Columbia, and

(b) the prescription form is signed by the patient or the patient's representative upon receipt of the dispensed drug.

(6.1) Despite subsection (6), a registrant may dispense drugs included in the controlled prescription program upon receipt of a verbal prescription from a practitioner if doing so as permitted under a section 56 exemption to the *Controlled Drugs and Substances Act*. The pharmacy must receive the original form by mail as soon as reasonably possible.

(7) A new prescription from a practitioner is required each time a drug is dispensed, except for

(a) a part-fill,

(b) a prescription authorizing repeats,

(c) a full pharmacist-initiated renewal or adaptation, or

(d) an emergency supply for continuity of care.

(8) Subsection (6) does not apply to prescriptions written for

(a) residents of a facility or home subject to the requirements of the *Residential Care Facilities and Homes Standards of Practice*, or

(b) patients admitted to a hospital.

Drug Procurement/Inventory Management

20 (1) In this section:

"premises" means:

(a) a hospital as defined in the *Hospital Act*, or
(b) the building or part of the building, within which the pharmacy is located, and includes loading spaces and excludes other businesses in the building.

(2) A full pharmacist may authorize the purchase of Schedule I, II, or III drugs or controlled drug substances only from

(a) a wholesaler or manufacturer licensed to operate in Canada, or

(b) another pharmacy in accordance with the policies approved by the board.

(3) A registrant must record a transfer of drugs that occurs for any reason other than for the purpose of dispensing in accordance with a practitioner's prescription.

(4) All drug shipments must be delivered unopened to

(a) the pharmacy, or

(b) an area of the premises other than the pharmacy if the storage of the drug shipment is temporary, safe and secure.

(5) Non-usable and expired drugs must be stored in the pharmacy in an area separate from other pharmacy stock or drug products until final disposal.

(6) A full pharmacist must not purchase Schedule I, II and III drugs and controlled drug substances unless they are for sale or dispensing in or from a pharmacy.

Interchangeable Drugs

21 When acting under section 25.91 of the *Health Professions Act,* a full pharmacist must determine interchangeability of drugs by reference to Health Canada's Declaration of Equivalence, indicated by the identification of a Canadian Reference Product in a Notice of Compliance for a generic drug.

Returned Drugs

22 No registrant may accept for return to stock or reuse any drug previously dispensed except in accordance with section 11(3) of the *Residential Care Facilities and Homes*

Standards of Practice or section 5(2) of the *Hospital Pharmacy Standards of Practice.*

Records

23 (1) All prescriptions, patient records, invoices and documentation in respect of the purchase, receipt or transfer of Schedule I, II and III drugs and controlled drug substances must be retained for a period of not less than three years from the date

(a) a drug referred to in a prescription was last dispensed, or

(b) an invoice was received for pharmacy stock.

(2) Despite subsection (1), a registrant must not destroy prescriptions, patient records, invoices and documentation as described in subsection (1) until the completion of any audit or investigation for which the registrant has received notice.

(3) Registrants, support persons, managers, direct owners, and indirect owners must not, for commercial purposes, disclose or permit the disclosure of information or an abstract of information obtained from a prescription or patient record which would permit the identity of the patient or practitioner to be determined.

23.1 (1) All records required to be kept under bylaws of the College or other legislation that regulates the practice of pharmacy shall be readable, complete, filed systematically and maintained in a manner that is secure, auditable and allows for easy retrieval.

(2) Notwithstanding subsection (1), a prescription record that is valid must be retrievable immediately.

(3) For purposes of subsection (2):

(a) prescriptions for oral contraceptives are valid for a period of up to two years from the prescribing date; and

(b) prescriptions other than for oral contraceptives are valid for a period of up to one year from the prescribing date.

(4) With respect to prescriptions for drugs included in the controlled prescription program, the original prescription form must be retained, regardless of whether or not such prescription form has also been stored electronically.

(5) Prescriptions stored electronically must accurately reflect the original prescription, including the original colour composition of that prescription.

23.2 (1) A pharmacy manager must ensure that a policy is in place that:

(a) describes the pharmacy's records filing system, the records format and the method and system for storing records;

(b) is compliant with the sections 23.1, 23.2 and 23.3 requirements; and

(c) is readily accessible to and understood by pharmacy staff.

(2) With respect to electronic records, the policy must include a description of the process for the preservation, storage and backing up of records that is compliant with section 23.3 requirements.

23.3 (1) A pharmacy may maintain electronic records containing personal health information if the pharmacy has the equipment, software and systems necessary for the input, storage, use, protection and retrieval of records that are required to be kept under bylaws of the College or other legislation that regulates the practice of pharmacy.

(2) For purposes of subsection (1), the equipment, software and systems must:

(a) be capable of storing the electronic records for the periods required by applicable law;

(b) keep the records secure from unauthorized access, use, disclosure, modification and destruction;

(c) for audit purposes, be capable of uniquely identifying each time an electronic record is accessed and modified;

(d) be capable of restricting the functions that may be used by an authorized person;

(e) be capable of tracing alterations to records by identifying the original entry, the identity of the individual who made the alteration and the date of the alteration;

(f) be capable of searching and sorting electronic prescription records chronologically, and by drug name, drug strength, patient, prescriber, prescription number and transaction number;

(g) ensure that electronic records can be stored, backed up and recovered in accordance with subsection (3); and

(h) provide for a deliberate and auditable procedure to be carried out by the pharmacy manager or by an authorized person prior to the destruction of any electronic record that includes information identifying the pharmacy manager or authorized person who destroyed the record and the date, time and reason for its destruction.

(3) A pharmacy manager must ensure that electronic records are preserved and backed up at least once daily and that such electronically preserved and backed up records are stored:

(a) in a location resistant to environment perils including but not limited to fires and floods;

(b) so that they are secure from unauthorized access, use, modification, destruction and disclosure; and

(c) in a manner that would enable the backed up records, once restored, to be compliant with section 23.1(1) requirements.

(4) Notwithstanding subsections (1), (2) and (3), a pharmacy that presently stores electronic records has six months from the date this section comes into effect to bring itself into full compliance with the requirements of subsections (1), (2) and (3).

PART III – Community Pharmacies

Community Pharmacy's Manager – Quality Management

24 (1) A community pharmacy's manager must establish and maintain written quality management policies and procedures that

(a) ensure pharmacy staff, equipment, and facilities comply with all legislation, bylaws and policies applicable to the operation of a community pharmacy,

(b) include a process to monitor compliance with the quality management policies and procedures, and

(c) include a process for reporting, documenting and following up on known, alleged and suspected errors, incidents and discrepancies.

(2) If a community pharmacy is a central pharmacy, the quality management policies and procedures in subsection (1) must include all telepharmacies associated with the central pharmacy and must comply with the *Telepharmacy Standards of Practice.*

Community Pharmacy and Telepharmacy Premises

25 (1) In locations where a community pharmacy or telepharmacy does not comprise 100 per cent of the total area of the premises, the community pharmacy manager or the central pharmacy manager in the case of a telepharmacy, must ensure that

(a) the professional products area extends not more than 25 feet from the perimeter of the dispensary and is visually distinctive from the remaining areas of the premises by signage, and

(b) a sign reading "Medication Information" is clearly displayed to identify a consultation area or counter at which a member of the public can obtain a full pharmacist's advice.

(2) Subject to subsection (3), the dispensary area of a community pharmacy or a telepharmacy must

(a) be at least 160 square feet,

(b) be inaccessible to the public by means of gates or doors across all entrances,

(c) include a dispensing counter with at least 30 square feet of clear working space, in addition to service counters,

(d) contain adequate shelf and storage space that is clean and organized,

(e) contain a double stainless steel sink with hot and cold running water,

(f) contain an adequate stock of drugs to provide full dispensing services, and

(g) contain a refrigerator.

(3) A telepharmacy that was authorized by the registrar to provide pharmacy services as a telepharmacy remote site as of January 1, 2017 is exempt from the requirements in subsections (2)(a) and (c) until such time as it commences a renovation of all or part of the premises.

(4) In all new and renovated community pharmacies or telepharmacies, an appropriate area must be provided for patient consultation that

(a) ensures privacy and is conducive to confidential communication, and

(b) includes, but is not limited to, one of the following:

(i) a private consultation room, or

(ii) a semiprivate area with suitable barriers.

Community Pharmacy and Telepharmacy Security

26 (1) A community pharmacy or telepharmacy must:

(a) keep Schedule IA drugs in a locked metal safe inside the dispensary that is secured in place and equipped with a time delay lock set at a minimum of five minutes;

(b) install and maintain a security camera system that:

(i) has date/time stamp images that are archived and available for no less than 30 days; and

(ii) is checked daily for proper operation; and

(c) install and maintain motion sensors in the dispensary.

(2) When no full pharmacist is present and the premises in which the pharmacy is located are accessible to non-registrants, the pharmacy must be secured as follows:

(a) if the premises in which the pharmacy is located are closed and accessible to non-registrant staff:

(i) the dispensary area must be secured by a monitored alarm; and

(ii) subject to subsection (2.1), Schedule I and II drugs, controlled drug substances and personal health information, are secured by physical barriers; or

(b) if the pharmacy is closed but other areas of the premises in which the pharmacy is located are open:

(i) the dispensary area must be secured by a monitored alarm;

(ii) subject to subsection (2.1), Schedule I, and II drugs, controlled drug substances and personal health information, are secured by physical barriers; and

(iii) Schedule III drugs are inaccessible to anyone other than full pharmacists, temporary pharmacists and pharmacy technicians.

(2.1) A community pharmacy or telepharmacy that exists on the date this provision comes into force and is not renovated during the period must comply with sections 26(2)(a)(ii) and (b)(ii) no later than three years after the date that provision comes into force.

(2.2) For the purposes of subsection (2), a full pharmacist is deemed to be present at a telepharmacy when he or she is engaged in direct supervision of the telepharmacy.

(3) Subject to subsection (5), a community pharmacy or a telepharmacy must clearly display at all external entrances that identify the premises as a pharmacy, and at the dispensary counter signage provided by the College.

(4) The manager, direct owner or indirect owner(s) of a community pharmacy or telepharmacy that does not stock IA drugs must complete a declaration attesting that Schedule IA drugs are never stocked on the premises.

(5) A pharmacy that is never open to the public and has no external signage identifying it as a pharmacy is exempt from the requirements in subsection (3).

Permitted Activities of a Community Pharmacy without a Full Pharmacist Present

27 (1) Except as provided in subsection (2), a community pharmacy must not operate unless a full pharmacist is present.

(2) A community pharmacy may carry on the activities set out in subsection (3) without a full pharmacist present only if:

(a) the registrar is notified of the hours during which a full pharmacist is not present;

(b) the pharmacy is secured in accordance with section 26(2); and

(c) the hours when a full pharmacist is on duty are posted.

(3) Subject to subsection (2) if a full pharmacist is not present, only the following activities may be carried out:

(a) pharmacy technicians may access the dispensary to perform activities outlined in section 4 of the *Community Pharmacy Standards of Practice*, that do not require pharmacist supervision, except if any such activity involves patient interaction; and

(b) receive drug shipments under section 20(4).

(3) Nothing contained in this section relieves a pharmacy manager of their responsibilities under section 18(2)(a).

Outsource Prescription Processing

28 (1) A community pharmacy may outsource prescription processing if

(a) all locations involved in the outsourcing are community pharmacies,

(b) all prescriptions dispensed are labeled and include an identifiable code that provides a complete audit trail for the dispensed drug, and

(c) a notice is posted informing patients that the preparation of their prescriptions may be outsourced to another pharmacy.

(2) The manager of an outsourcing community pharmacy must ensure that all applicable standards of practice are met in processing prescriptions at all locations involved in the outsourcing.

(3) In this section, “community pharmacy” includes a hospital pharmacy.

PART IV – Hospital Pharmacies

Hospital Pharmacy’s Manager – Quality Management

29 (1) A hospital pharmacy’s manager must establish and maintain written quality management policies and procedures that

(a) ensure pharmacy staff, equipment, and facilities comply with all legislation, bylaws and policies applicable to the operation of a hospital pharmacy,

(b) include a process to monitor compliance with the quality management policies and procedures,

(c) include a process for reporting, documenting and following up on known, alleged and suspected errors, incidents and discrepancies,

(d) document periodic audits of the drug distribution process,

(e) include a process to review patient-oriented recommendations,

(f) include a process that reviews a full pharmacist's documentation notes in the hospital's medical records,

(g) include a process to evaluate drug use, and

(h) regularly update policies and procedures for drug use control and patient-oriented pharmacy services in collaboration with the medical and nursing staff and appropriate committees.

(2) If sample drugs are used within a hospital, the hospital pharmacy's manager must ensure that the pharmacy oversees the procurement, storage and distribution of all sample drugs.

After Hours Service

30 (1) If continuous pharmacy services are not provided in a hospital, the hospital pharmacy's manager must ensure that urgently needed drugs and patient-oriented pharmacy services are available at all times by

(a) providing a cabinet which must

(i) be a locked cabinet or other secure enclosure located outside of the hospital pharmacy, to which only authorized persons may obtain access,

(ii) be stocked with a minimum supply of drugs most commonly required for urgent use,

(iii) not contain controlled drug substances unless they are provided by an automated dispensing system,

(iv) contain drugs that are packaged to ensure integrity of the drug and labeled with the drug name, strength, quantity, expiry date and lot number, and

(v) include a log in which drug withdrawals are documented, and

(b) arranging for a full pharmacist to be available for consultation on an on-call basis.

(2) When a hospital pharmacy or hospital pharmacy satellite is closed, the premises must be equipped with a security system that will detect unauthorized entry.

PART V – Telepharmacies

Telepharmacy Operation

31 (1) A telepharmacy must not remain open and prescriptions must not be dispensed

without a full pharmacist physically present on duty at the telepharmacy, unless

(a) a full pharmacist at the central pharmacy is engaged in direct supervision of the telepharmacy in accordance with the *Telepharmacy Standards of Practice*, and

(b) subject to subsection (2), a pharmacy technician is physically present on duty at the telepharmacy.

(2) A telepharmacy located at an address listed in Schedule "G" is exempt from the requirements in subsection (1)(b).

(3) A telepharmacy must have a security system that prevents the public and non-pharmacy staff from accessing the professional services area and the dispensary area, including any area where personal health information is stored.

(4) Prescriptions and labels relating to prescriptions dispensed at a telepharmacy must identify the prescription as having been dispensed at that telepharmacy.

(4.1) Prescriptions and labels relating to prescriptions dispensed at a pharmacy listed in Schedule "F" must distinguish between those dispensed when it is operating as a telepharmacy from when it is operating as a community pharmacy.

(5) The manager of a central pharmacy, or a full pharmacist designated by the manager, must

(a) inspect and audit its telepharmacy at least 4 times each year, at intervals of not less than 2 months,

(b) record each inspection and audit in the prescribed form, and

(c) provide the inspection and audit records to the registrar immediately upon request.

(6) A telepharmacy located at an address listed in Schedule "G" must perform a monthly count of narcotics at the telepharmacy and retain a record of each monthly count signed by the supervising pharmacist for three years at both the central pharmacy and the telepharmacy location, and provide the signed record to the registrar immediately upon request.

(7) A telepharmacy must not continue to provide pharmacy services for more than 30 days after

(a) its location ceases to be a rural and remote community,

(b) a community pharmacy is established within the community, or

(c) a community pharmacy is established within 25 kilometers of the location of the telepharmacy.

(8) In accordance with sections 18(2)(c) and (d), a telepharmacy must have policies and procedures on site that outline the methods for ensuring the safe and

effective distribution of pharmacy products and delivery of pharmaceutical care by the telepharmacy.

(9) All transactions in PharmaNet must be distinguishable between the central pharmacy and telepharmacy.

PART VI – PharmaNet

Application of Part

32 This Part applies to every pharmacy that connects to PharmaNet.

Definitions

33 In this Part:

"patient record" means the patient record described in section 11(2) of the *Community Pharmacy Standards of Practice* and in the *British Columbia Professional and Software Conformance Standards, Electronic Health Information Exchange* as the "patient record (pharmacy)".

"**PharmaNet**" means "PharmaNet" as defined in section 1 of the *Information Management Regulation*, B.C. Reg. 74/2015;

Operation of PharmaNet

34 A pharmacy must connect to PharmaNet.

Data Collection, Transmission of and Access to PharmaNet Data

35 (1) A registrant must enter the prescription information and record it in PharmaNet at the time of dispensing and keep the patient record current.

(2) A registrant may collect and record patient information in PharmaNet, or access, use and disclose a patient's PharmaNet record only for the purposes of:

(a) dispensing a drug;

(b) providing patient consultation;

(c) evaluating a patient's drug usage;

(d) claims adjudication and payment by an insurer; or

(e) providing pharmacy services to, or facilitating the care of, the individual whose personal information is being collected, accessed, used or disclosed.

(3) A registrant must revise information in PharmaNet pertaining to corrected billings for prescriptions billed to the patient or a payment agency other than PharmaCare and record the reason for the revision within 120 days of the original entry in PharmaNet.

(4) A registrant must reverse information in PharmaNet, for any drug that is not released to the patient or the patient's representative, and record the reason for

the reversal no later than 30 days from the date of the original entry of the prescription information in PharmaNet.

(5) If a registrant is unable to comply with the deadlines in subsection (3) or (4), he or she must provide the information required to make the correction to the Ministry of Health as soon as possible thereafter.

PART VII – Confidentiality

Confidentiality

36 A registrant must take reasonable steps to confirm the identity of a patient, patient's representative, registrant or practitioner before providing any pharmacy service that requires accessing, using or disclosing of patient personal health information.

PART VIII – College

Forms

37 The registrar may establish forms for the purposes of the *Act*.

Use, Disclosure and Retention of Criminal Record History Information

38 (1) The College may disclose criminal record history information only for the purpose of licensing pharmacies or for the purpose of regulating registrants (including for the discipline of registrants).

(2) The College must retain criminal record history information only for so long as is permitted by the applicable College records retention and disposal provisions established by the College.

College of Pharmacists
of British Columbia

Professional Practice Policy #66

Policy Guide

Buprenorphine/Naloxone Maintenance Treatment (2018)

Buprenorphine/Naloxone Maintenance Treatment Policy Guide

All pharmacy managers, staff pharmacists, relief pharmacists and pharmacy technicians employed in a community pharmacy that provides pharmacy services related to buprenorphine/naloxone maintenance treatment (BMT) must know and apply the principles and guidelines outlined here in the College of Pharmacists of BC (CPBC) *Buprenorphine/Naloxone Maintenance Treatment Policy Guide (2018)* and all subsequent revisions.

1.0 Administration

1.1 Pharmacy Operating Hours

Principle 1.1.1 The pharmacy hours of service must be consistent with the dosing requirements of your patient.

Guideline: When a pharmacy accepts a patient who requires daily dispense (i.e., 7 days per week) the pharmacy hours of service need to accommodate this dosing requirement. A pharmacist does not have the independent authority to adapt a prescription for buprenorphine/naloxone maintenance treatment from 'daily dispense' to a 'take-home' dose.

1.2 General Guidance for Pharmacy Professionals

Principle 1.2.1 Provide patient education on how to properly take buprenorphine/naloxone tablets.

Guideline: For example you may instruct the patient to place and hold the tablet(s) under their tongue until it fully dissolves, this may take up to 10 minutes. Avoid swallowing, talking, eating, drinking, and smoking.

Principle 1.2.2 Advise patients to talk to their prescriber and pharmacist about any continuing withdrawal symptoms, cravings, and/or non-medical opioid use. Educate on risks of precipitated withdrawal during buprenorphine/naloxone induction. Educate patients on the inclusion of naloxone in buprenorphine/naloxone formulations and its purpose to deter use in a manner not intended as prescribed.

Principle 1.2.3 Refer colleagues, prescribers, and clinical staff who are unfamiliar with the most recent version of the British Columbia Centre on Substance Use (BCCSU) *A Guideline for the Clinical Management of Opioid Use Disorder*. Recommend completion of online training through the University of British Columbia, Faculty of Medicine Continuing Professional Development's *Provincial Opioid Addiction Treatment Support Program*.

2.0 Receiving Buprenorphine/Naloxone Prescriptions

2.1 Controlled Prescription Program Forms - Overview

Principle 2.1.1 Buprenorphine/naloxone prescriptions can only be accepted when written using an original Controlled Prescription Program form. When accepting buprenorphine/naloxone prescriptions, the pharmacist must ensure that the Controlled Prescription Program form is completed by the prescriber as outlined in the Controlled Prescription Program.

Principle 2.1.2 Buprenorphine/naloxone prescriptions may only be received by facsimile in accordance with section 7(3) of the *Health Professions Act* Bylaws Schedule F, Part 1 - *Community Pharmacy Standards of Practice*. Verbal prescriptions for buprenorphine/naloxone maintenance treatment may be accepted where permitted under a section 56 exemption to the *Controlled Drugs and Substances Act* in accordance with section 19(6.1) of the bylaws to the *Pharmacy Operations and Drug Scheduling Act*.

3.0 Processing (Dispensing) Buprenorphine/Naloxone Prescriptions

3.1 Accepting a Prescription

Principle 3.1.1 Buprenorphine/naloxone for maintenance must be dispensed to patients as an approved, commercially available formulation.

Guideline: Buprenorphine/naloxone is currently available in multiple strengths of sublingual formulations. Tablets can be halved and/or combined to achieve target doses.

Principle 3.1.2 Pharmacists and pharmacy technicians (working within their scope) must review the prescription to ensure that the specific needs of the patient can be accommodated by the pharmacy.

Guideline: Each prescription should be reviewed in detail in consultation with the patient to ensure that the patient's specific needs can be accommodated. For example:

- Evaluate the end date of the prescription to ensure that the authorization for dispensing does not end on a day when the patient will not be able to see a prescriber for a new prescription (e.g., weekends and holidays).
- Review the prescription directions to determine the dosing schedule (daily dispense, take-home doses), including the specific days of the week for each dose or take-home doses, to confirm that the pharmacy operating hours match the dosing schedule.

3.2 Assessment of a Prescription

Principle 3.2.1 Should a patient present a prescription for a mood altering drug, including benzodiazepines and opioids, or if the pharmacist discovers that a mood altering drug is also being prescribed to the patient in their review of the PharmaNet patient record, they must contact both the prescriber of buprenorphine/naloxone and, if different, the prescriber of the mood altering drug, prior to dispensing the medication. The pharmacist must document the outcome of the consultation(s) with the prescriber(s) and include it with the original prescription. The purpose of the consultation is to ensure the prescriber(s) are aware that the patient is currently on the buprenorphine/naloxone maintenance program.

Guideline: Mood altering drugs, including benzodiazepines and opioids, should not be prescribed to patients on the buprenorphine/naloxone maintenance program. Co-ingestion of buprenorphine/naloxone with alcohol or benzodiazepines is contraindicated, as combined effects can potentially result in fatal respiratory depression.

4.0 Releasing Buprenorphine/Naloxone Prescriptions

4.1 Releasing a Prescription

Principle 4.1.1 A pharmacist must be present to release the buprenorphine/naloxone prescription to a patient. This function cannot be delegated to a pharmacy technician or any other pharmacy support staff.

Principle 4.1.2 Prior to releasing a buprenorphine/naloxone prescription the pharmacist must assess the patient to ensure that the patient is not intoxicated, including by centrally-acting sedatives and/or stimulants or in any other acute clinical condition that would increase the risk of an adverse event. If the pharmacist believes that it is not safe for the patient to receive their prescription they must consult with the prescriber and document the outcome of the dialogue and include it with the original prescription.

Guideline: Assess patients for symptoms such as slurred speech, ataxia, drowsiness, alcohol smell or unusual behaviour. It is important for the pharmacist to be familiar with each patient's usual behaviour in order to be able to detect significant deviations.

Principle 4.1.3 Prior to releasing a buprenorphine/naloxone prescription, the patient and pharmacist must acknowledge receipt by signing a patient/prescription-specific log. Every part-fill dispensed must be accounted for. The patient/prescription specific log must be included with the original Controlled Prescription Program form. Once complete, it must be filed sequentially by the first prescription or transaction number assigned to the prescription. The pharmacist must be able to review every part-fill dispensed as a complete history on one document.

Guideline: The sample *Buprenorphine/Naloxone Part-Fill Accountability Log* (Appendix 1) can be used for this purpose.

Neither the pharmacist nor the patient is permitted to pre-sign for future doses or backdate signing.

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Principle 4.1.4 If a prescriber orders the buprenorphine/naloxone for daily dispense, the pharmacist is not required to observe the patient ingesting the dose. If the prescriber's intentions regarding witnessing are unclear, the pharmacist must consult with the prescriber to clarify, and the outcome of this consultation must be documented and included with the original prescription.

Guideline: If the prescription states daily dispense, the patient may ingest the dose without pharmacist observation.

Patients should be given instructions on how to take the dose. For example you may instruct the patient to place and hold the tablet(s) under their tongue until it fully dissolves, this may take up to 10 minutes. The patient should avoid swallowing, talking, eating, drinking, and smoking.

Principle 4.1.5 If a prescriber orders the buprenorphine/naloxone to be dispensed as a 'Daily Witnessed Ingestion' or 'DWI', the pharmacist must directly observe the patient placing the medication under the tongue. If the prescriber's intentions regarding witnessing are unclear, the pharmacist must consult with the prescriber to clarify, and the outcome of this consultation must be documented and included with the original prescription.

Guideline: Patients should be given instructions on how to take the dose. For example you may instruct the patient to place and hold the tablet(s) under their tongue until it fully dissolves - this may take up to 10 minutes. The patient should avoid swallowing, talking, eating, drinking, and smoking.

The patient is not required to remain in the pharmacy once the pharmacist has directly observed the patient placing the medication under the tongue.

Principle 4.1.6 If take home doses (carries) are prescribed, the first dose does not need to be witnessed, unless ordered by the prescriber. The subsequent take-home doses must be dispensed in child-resistant containers with an explicit warning label indicating that the amount of drug in the container could cause serious harm or toxicity if taken by someone other than the patient. If a pharmacist determines that due to a specific patient circumstance a non-child-resistant container will be used for take-home doses, it must be documented on the patient record.

Guideline: The decision to authorize take-home doses can only be made by the prescriber. However, should a pharmacist believe that a patient is or is not ready to manage take-home doses they should discuss their recommendations or concerns with the prescriber.

Compliance packaging (e.g., blister packaging, pouch packs) may be ordered by the prescriber to discourage diversion and allow for better monitoring during medication call-backs. In these cases, the pharmacy must still ensure that the medications are provided in child-resistant packaging.

Patients should be reminded that buprenorphine/naloxone should be stored out of the reach of children, preferably in a locked cupboard or small lock box.

5.0 Responding to Buprenorphine/Naloxone Dosing Issues

5.1 Missed Doses

Principle 5.1.1 Any buprenorphine/naloxone prescription that has been processed and prepared but is not consumed or picked up by the patient on the prescribed day is considered cancelled and must be reversed on PharmaNet **before the end of the business day**.

Guideline: It is imperative that the PharmaNet patient record reflects accurate and current information in terms of consumed and picked-up buprenorphine/naloxone doses as other healthcare practitioners rely on this information in making treatment decisions.

Principle 5.1.2 If a patient misses a dose, they cannot receive the missed dose at a later date.

Principle 5.1.3 The pharmacist must notify the prescriber of any missed doses before the next scheduled release of medication. The notification document must be retained and filed with the prescription consistent with filing retention requirements.

Guideline: The *Pharmacist-Prescriber Communication* form (Appendix 2) can be used for this purpose.

Principle 5.1.4 If a patient misses 6 or more consecutive days, the prescription must be cancelled.

Guideline: The pharmacist should advise the patient to see the prescriber for a new prescription, as dose adjustment and re-stabilization may be required.

For more information, refer to the BCCSU *A Guideline for the Clinical Management of Opioid Use Disorder* - Appendix 2: Induction and Dosing Guidelines for Buprenorphine/Naloxone.

5.2 Partial Consumption of Doses

Principle 5.2.1 If a patient declines or is unable to consume their full dose, the pharmacist must respect the patient's choice. The unconsumed portion cannot be given as a take-home dose. The patient's partial consumption of a dose and their reason(s) for it must be documented and reported to the prescriber. All patient documentation including the patient-prescription specific log and PharmaNet record must accurately reflect the actual dose consumed by the patient.

Guideline: The *Pharmacist-Prescriber Communication* form (Appendix 2) can be used for the documentation and communication.

The *Buprenorphine/Naloxone Part-Fill Accountability Log* (Appendix 1) can be used for the Part-Fill Accountability Log.

5.3 Lost or Stolen Doses

Principle 5.3.1 If a patient reports that their take-home dose(s) have been lost, stolen or misplaced, a replacement dose(s) cannot be provided. The pharmacist must notify and consult with the prescriber. If the prescriber chooses to authorize a replacement dose, a new original Controlled Prescription Program form must be received by the pharmacy.

5.4 Tapering

Principle 5.4.1 If a patient has decided to initiate a self-tapering regimen by decreasing their daily dose consumption, the pharmacist must record the dose consumed on the patient/prescription specific log (refer to Principle 4.1.3), record the actual dose consumed on the patient's PharmaNet record and notify the prescriber.

Guideline: The *Pharmacist-Prescriber Communication* form (Appendix 2) can be used for the purpose of notifying the prescriber.

Appendix 1

Buprenorphine/Naloxone Part-Fill Accountability Log

Patient Name: _____

Date Dispensed	Prescription or Transaction Number	Quantity			Delivery Information (if applicable)		Pharmacist's Initials	Patient's signature
		Witnessed	Take Home	Total	Address	Time		

✂ ----------

Patient Name: _____

Date Dispensed	Prescription or Transaction Number	Quantity			Delivery Information (if applicable)		Pharmacist's Initials	Patient's signature
		Witnessed	Take Home	Total	Address	Time		

Appendix 2

Pharmacist – Prescriber Communication

Date:_____ Patient Name:_____

To (Prescriber):_____ Patient PHN:_____

Fax: _____ Prescription Form Folio Number:_____

From (Pharmacy):_____ Pharmacy Fax:_____

Pharmacist:_____ Pharmacy Telephone:_____

For Prescriber's Information and Patient Records

- ❑ This patient missed their buprenorphine/naloxone dose on _____(date).
- ❑ This patient did not take their full daily dose today _____ (date) and consumed only ____ mg of the ____ mg prescribed dose.
- ❑ This patient's dose has been held due to _____ (reason and date).
- ❑ This patient lost or had their dose(s) stolen _____(dates).
- ❑ This patient's prescription has been cancelled due to _____(number of missed doses).

Additional Information

You May Attach Controlled Prescription Program Form.

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Professional Practice Policy #66

Policy Guide

Methadone Maintenance Treatment (2013)

Forward

Opioid dependence is a health concern with implications for the individual patient as well as the public. Methadone maintenance treatment is recognized internationally as among the most effective treatments for opioid use disorder (OUD). Addiction treatment experts recommend that methadone treatment for OUD be delivered with a maintenance-oriented, rather than abstinence-oriented, philosophy. This approach acknowledges OUD as a chronic disease.

Many studies, conducted over several decades in different countries, have clearly demonstrated that the effective delivery of methadone maintenance treatment reduces non-medical opioid use, other problematic substance use, criminal activity, mortality, injection-related risks and transmission of blood-borne disease. Additional positive results are improvement in physical and mental health, social functioning, quality of living and pregnancy outcomes.

Methadone, a long-acting, orally effective opioid, is used as a substitute for heroin or other narcotics when treating opioid dependence. Methadone eliminates withdrawal from and reduces cravings for, opioids. Methadone does not produce euphoria, and it blocks the euphoric effects of other opioids. When used in the treatment of opioid dependence, a single oral dose of methadone is effective for at least 24 hours. Eventual withdrawal from methadone is not necessarily the goal of the program, although some individuals may work with their physician and pharmacist to decrease their dose and eventually stop using methadone.

Methadone prescribing is controlled by both federal and provincial legislation, as well as administrative procedures and guidelines.

Registered pharmacists are permitted to purchase and dispense methadone without federal exemption. However, the College of Pharmacists of BC (CPBC) *Professional Practice Policy (PPP-66) – Opioid Agonist Treatment* requires that the pharmacy manager and all staff pharmacists employed in a community pharmacy that provides services related to methadone maintenance treatment complete the *CPBC Methadone Maintenance* Treatment (MMT) or the British Columbia Pharmacy Association's (BCPhA) *Opioid Agonist Treatment Compliance and Management Program for Pharmacy* (OAT-CAMPP) training program, and any subsequent updates. You must log into eServices to complete the "*Declaration of Completion and Understanding*" prior to providing methadone maintenance treatment services.

How to Use This Guide

This Policy Guide (the Guide) is a companion to *Professional Practice Policy (PPP-66) –Opioid Agonist Treatment* (Appendix 1). The intention of the *Guide* is to provide pharmacists with further detail and clarity (including practical examples) to assist in the implementation of the policy into practice to ensure consistency in the safe and effective delivery of methadone maintenance treatment services.

As always the expectation is that pharmacists will practice in compliance with their legislative requirements, including the principles outlined in this *Guide*. It is understood however that pharmacy practice is not always 'black and white' and when navigating the 'grey' pharmacists must use sound professional judgment, ensuring that their decisions are made in the best interest of the patient and with appropriate collaboration, notification and most importantly, documentation.

The *Guide* is to be read in conjunction with completion of the mandatory training session. Information regarding the mandatory sessions can be found on the CPBC website at **www. bcpharmacists.org.**

Note:
This document is not intended to cover all possible practice scenarios.

Declaration

After completing the mandatory training program, and subsequently reading this *Guide*, pharmacists must log into eServices to complete the '*Declaration of Completion and Understanding*'.

Acknowledgement

The development of this *Guide* involved a collaborative and consultative process with input and feedback gathered from a volunteer group of dedicated community pharmacists currently engaged, in varying capacities, in the delivery of methadone maintenance treatment services.

The group was comprised of both frontline pharmacists and pharmacy managers and represented a cross-section of practice types (independent to large chain retailers) and practice settings including pharmacies located in Vancouver's Downtown Eastside whose primary focus is on the provision of methadone maintenance treatment.

Feedback was also solicited from other stakeholder groups including; the Ministry of Health Services, the College of Physicians and Surgeons of BC, the BCPhA, the City of Vancouver, patient advocacy groups Vancouver Area Network of Drug Users (VANDU), and the BC Association for People on Methadone (BCAPOM).

The College of Pharmacists of BC would like to sincerely thank each of these individuals and organizations for their invaluable feedback in the creation of this significant resource for pharmacists.

Feedback

Questions and comments about this *Guide* are welcome and can be sent to:
College of Pharmacists of British Columbia Telephone: 604-733-2440 or 800-663-1940

200 – 1765 West 8th Avenue Facsimile: 604-733-2493 or 800-377-8129
Vancouver, BC V6J 5C6 E-mail: practicesupport@bcpharmacists.org
Web site: www.bcpharmacists.org

Methadone Maintenance Treatment Policy Guide

In accordance with *Professional Practice Policy (PPP-66) – Opioid Agonist Treatment* (Appendix 1), all pharmacy managers, staff pharmacists, relief pharmacists and pharmacy technicians employed in a community pharmacy that provides pharmacy services related to methadone maintenance treatment must know and apply the principles and guidelines outlined here in the CPBC *Methadone Maintenance Treatment Policy Guide (2013)* and all subsequent revisions. The responsibility of pharmacy technicians in the dispensing of MMT is consistent with their scope of practice outlined in the *Health Professions Act* (HPA) Bylaws Schedule F Part 1 section 4.

1.0 Administration

1.1 Pharmacy Operating Hours

Principle 1.1.1 The pharmacy hours of service must be consistent with the supervised dosing requirements of your patient.

Guideline: When a pharmacy accepts a patient who requires daily witness ingestion (i.e., 7 days per week) the pharmacy hours of service must accommodate this dosing requirement. A pharmacist does not have the independent authority to adapt a prescription for methadone maintenance treatment from 'daily witness' to a 'take-home' dose.

1.2 Privacy and Confidentiality – Premise

Principle 1.2.1 All pharmacies offering methadone maintenance treatment must be in compliance with all relevant legislation pertaining to the structure of the licensed premise with particular attention given to ensuring there is sufficient space to accommodate patients waiting for witnessed ingestion and/or take home methadone doses while simultaneously maintaining privacy for pharmacist-patient consultation.

Guideline: It may be appropriate to establish a staggered schedule for regular patients requiring witnessed ingestion to ensure that there is adequate space within the pharmacy to accommodate patients who are waiting and ensure privacy of pharmacist-patient consultation.

1.3 Security – Premise

Principle 1.3.1 All pharmacies offering methadone maintenance treatment must ensure that their pharmacy is in compliance with all relevant legislation pertaining to pharmacy security requirements including those outlined in *Professional Practice Policy (PPP-74) – Community Pharmacy and Telepharmacy Security*.

2.0 Receiving Methadone Prescriptions

2.1 Controlled Prescription Program Forms – Overview

Principle 2.1.1 Methadone maintenance prescriptions can only be accepted when written using an original approved Controlled Prescription Program form. Verbal prescriptions for methadone maintenance treatment may be accepted where permitted under a section 56 exemption to the *Controlled Drugs and Substances Act* in accordance with section 19(6.1) of the bylaws to the *Pharmacy Operations and Drug Scheduling Act*.

Guideline: When accepting a methadone maintenance prescription written on the Methadone Maintenance Controlled Prescription form, a pharmacist must ensure that the form is completed by the prescriber as outlined in the *Methadone Maintenance Controlled Prescription Form Guidelines* (Appendix 3).

Principle 2.1.2 The pharmacist must ensure that the patient, as well as themselves, sign the form, in the space indicated on the bottom of the form.

Principle 2.1.3 Faxed Controlled Prescription Program forms are not acceptable unless under extenuating circumstances where the prescriber has determined, following consultation with the pharmacist, that the urgency of the situation warrants it, or in accordance with section 7(3) of the *Health Professions Act* Bylaws Schedule F, Part 1 - *Community Pharmacy Standards of Practice*.

Guideline: In such cases the pharmacy, prior to dispensing the medication, must receive, in addition to a fax of an approved Controlled Prescription

Program form, written confirmation (fax acceptable) signed by the prescriber that briefly describes the emergency situation and guarantees the delivery of the original approved Controlled Prescription Program form to the pharmacy the next business day or as soon as possible when the prescriber is not available.

The faxed approved Controlled Prescription Program form and related documentation, as described in Appendix 4, must be attached to the original Controlled Prescription Program form once received.

Note: The *Emergency Fax Controlled Prescription Program Form Documentation* (Appendix 4) can be used for this purpose.

Principle 2.1.4 In an effort to maximize the effectiveness of the methadone maintenance treatment program, the pharmacist may find it beneficial to engage in a specific dialogue with the patient, either when they initiate treatment or at various times throughout treatment, that clearly outlines the expectations of both the patient and the pharmacist.

Guideline: The *Methadone Maintenance Treatment Expectation Form* (Appendix 5) can be used for this purpose.

Principle 2.1.5 In the rare circumstance (disruptive or threatening behavior or verbal or physical abuse) where a pharmacist finds that they must terminate the pharmacist-patient relationship, reasonable notice must be provided to the patient to ensure their continuity of care.

Guideline: It is important to remember that the decision to terminate a pharmacist-patient relationship is a serious one and must be made with due consideration and based on appropriate rationale. It is unethical for a pharmacist to terminate the pharmacist-patient relationship or refuse to treat a patient on morally irrelevant grounds. The pharmacist's decision should be documented and retained in the patient record.

2.2 Controlled Prescription Program Forms – Alterations

Principle 2.2.1 Alterations to the approved Controlled Prescription Program form are the exception to the rule and should not be normal practice as they increase the likelihood of errors and drug diversion and put the public at risk. In the rare circumstance when an alteration is necessary to ensure the continuity of care pharmacists must always use due diligence to ensure authenticity and accuracy of the prescription.

Guideline:
Alterations completed at the prescriber's office: Alterations are only permitted on the sections of the form that the prescriber completes provided that the prescriber has initialed the alteration. Alterations are not permitted to the pre-printed sections of the form.

Alterations completed at the pharmacy: Pharmacists do not have independent authority to make any alterations or changes to the approved Controlled Prescription Program form. Any required or requested change(s) must be patient-specific and authorized by the patient's prescriber through direct consultation with the pharmacist. Any prescriber-authorized changes must be confirmed in writing, signed by the prescriber, received by the pharmacy (fax is acceptable) prior to dispensing the medication whenever possible and attached and filed with the original prescription.

Note: The *Pharmacist-Prescriber Communication Form* (Appendix 4) can be used for this purpose.

2.3 Out-of-Province Prescriptions

Principle 2.3.1 Pharmacists are permitted to dispense methadone prescriptions from prescribers in provinces other than BC.

Guideline: If there are any doubts regarding the authenticity of the out-of-province prescription, the pharmacist must contact the out-of-province prescriber to confirm the legitimacy of the prescription. When satisfied that the prescription is authentic, the pharmacist can dispense and process the prescription in the same manner as other prescriptions from out-of-province prescribers.

Note: It's important to realize that not all provinces are required to use Controlled Prescription Program forms.

3.0 Processing (Dispensing) Methadone Prescriptions

3.1 Accepting a Prescription

Principle 3.1.1 Methadone for maintenance must be dispensed to patients in a concentration of 10 mg/ ml.

Guideline: Only commercially available 10 mg/ml oral preparations are permitted for use.

Principle 3.1.2 Positive identification is required for all patients presenting a prescription for the first time, and reasonable steps to positively identify the patient must be taken prior to dispensing any subsequent prescriptions.

Guideline: The CPBC *Professional Practice Policy (PPP-54) – Identifying Patients and Patient Representatives in Community Pharmacy and Telepharmacy Settings* provides guidance for registrants on taking reasonable steps to confirm the identity of patient. The prescriber may be contacted to assist with verifying the patient's identity, if necessary.

Principle 3.1.3 Pharmacists and pharmacy technicians must review the prescription to ensure that it is completed by the prescriber as outlined in the Controlled Prescription Program, and that the directions for use appropriately meet the specific needs of the patient and can be accommodated by the pharmacy. If the prescription is written using the Methadone Maintenance Controlled Prescription Form, it should be completed by the prescriber as outlined in the *Methadone Maintenance Controlled Prescription Form Guidelines* (Appendix 3).

Guideline: Each prescription must be reviewed in detail in consultation with, and consideration given to the specific needs of, the patient. The following list is a sample only:

- Evaluate the end date of the prescription to ensure that the authorization for dispensing does not end on a weekend when the patient will not be able to see a prescriber for a new prescription.
- Review the prescription directions to determine the dosing schedule (daily witnessed ingestion, divided dose, take-home doses), including the specific days of the week for each witnessed dose or take-home doses, to confirm that the pharmacy operating hours match the dosing schedule.
- Confirm that stamped or preprinted sticker directions do not conflict with written directions.

Any ambiguous or conflicting information identified must be clarified with the prescriber. Should an alteration or change to the prescription be required, it must be done in compliance with the Principles and Guidelines outlined in section 2.2.

3.2 Assessment of a Prescription

Principle 3.2.1 Pharmacists and pharmacy technicians must correctly identify the product as prescribed 'for pain' or 'for opioid use disorder' by using the appropriate Drug Identification Number (DIN) or Product Identification Number (PIN) to ensure patient safety and accurate PharmaNet patient records.

Principle 3.2.2 As with all medications a pharmacist **must** review each individual PharmaNet patient record, as stated in *HPA Bylaws* (Schedule F Part 1), and resolve any drug-related problems prior to dispensing any methadone prescription. This step is particularly critical for methadone prescriptions as the automated drug usage evaluation (DUE) built into the PharmaNet system does not include methadone. Pharmacists providing methadone maintenance treatment must therefore ensure they maintain their knowledge with respect to potential drug interactions related to methadone. General information in this regard can be found in Appendix 7.

Guideline: A PharmaNet patient record review must be completed for all prescriptions, including those patients obtaining their prescription on a daily basis or those long-term patients whom the pharmacist may know well.

Principle 3.2.3 Mood altering drugs, including benzodiazepines and narcotics, are not generally prescribed to patients on the methadone maintenance program. Should a patient present a prescription for a mood altering drug or if the pharmacist discovers that a mood altering drug is also being prescribed to the patient in their review of the PharmaNet patient record, they must contact both the prescriber of methadone and, if different, the prescriber of the mood altering drug, prior to dispensing the medication. The purpose of the consultation is to ensure the prescriber(s) are aware that the patient is currently on the methadone maintenance program.

Guideline: The pharmacist should document the outcome of the consultation(s) with the prescriber(s) and attach it to the original prescription.

Principle 3.2.4 The 'sig field' on the prescription label must include the start and end dates of the original current prescription.

Principle 3.2.5 As required by *HPA Bylaws* Schedule F Part 1 the 'dispensing date' on the prescription label must accurately reflect the actual date dispensed on the PharmaNet system.

3.3 Preparing Methadone Prescriptions

Principle 3.3.1 Methadone doses must be accurately measured in a calibrated device that minimizes the error rate to no greater than 0.1 ml.

Guideline: All devices used to measure the methadone 10 mg/ml solutions should be distinctive and recognizable and must be used only to measure methadone solutions. Devices must be labeled with a 'methadone only' label and a 'poison' auxiliary label with the international symbol of the skull and cross bones.

Principle 3.3.2 Reconciliation procedures must be conducted in accordance with *Professional Practice Policy (PPP-65) – Narcotic Counts and Reconciliations*.

Guideline: Reconciliation means the quantity of methadone on hand must equal the quantity received minus the quantity dispensed over a specific period of time.

3.4 Loss or Theft and Disposal of Methadone

Principle 3.4.1 The *Narcotic Control Regulations* require that pharmacists report the loss or theft of controlled drugs and substances to the Office of Controlled Substances, Health Canada within 10 days of the discovery of the loss or theft. In the event of a loss or theft the pharmacy should also notify the CPBC within 24 hours.

Guideline: The form for reporting loss or theft of narcotics can be found on the CPBC website www.bcpharmcists.org under *Resources.*

Principle 3.4.2 Methadone, like any other narcotic or controlled drug, can only be disposed of with authorization from Health Canada and after being rendered unusable.

Guideline: To receive authorization to dispose of methadone the pharmacist must submit a written *Authorization to Destroy for Expired Narcotic and Controlled Drugs* to the Office of Controlled Substances, Health Canada.

An acceptable method of rendering methadone unusable is to place the product in a leak-proof container or plastic bag and add kitty litter until the mixture is almost solid.

Once the required authorization is received from Health Canada the pharmacist must record the amount of product to be disposed of, having a second healthcare professional sign for the disposal, and place the now rendered unusable product in the pharmacy's medication return container.

3.5 Methadone in Tablet Form for Air Travel

Principle 3.5.1 Hand luggage restrictions governing the transportation of fluids in air travel may be problematic for patients and in certain circumstances may necessitate the prescription of methadone in tablet form. Only commercially available methadone in tablet form may be dispensed. Pharmacists need to be aware that the prescription of methadone in tablet form may result in increased risk for both patients and the public. **Note**: Dispensing of methadone powder by way of sachet, capsule, or other format is never acceptable due to the increased potential for diversion and misuse.

Guideline: Long-term methadone maintenance treatment clearly limits patients' ability to travel because of the need for regular follow-up as well as the restrictions associated with the dispensing of methadone. If patients receiving MMT wish to travel for a period of time that exceeds their regular carry period, the usual standard of care should not be compromised, particularly if the patient is not stable and still requires daily supervised ingestion.

Patients are significantly limited in their ability to transport methadone across international borders but it is possible to arrange for methadone dispensing in some jurisdictions. The CPSBC advises physicians to research each case to ensure decisions do not compromise patient safety. In some cases, patients may require documentation for the purpose of crossing international borders or to assist in accessing temporary care from a methadone program at their destination. The physician is responsible to provide the required travel documentation.

4.0 Releasing Methadone Prescriptions

4.1 Releasing a Prescription

Principle 4.1.1 A pharmacist must be present and witness the release of a methadone prescription to a patient. This function cannot be delegated to a pharmacy technician or any other pharmacy support staff.

Principle 4.1.2 Prior to releasing a methadone prescription the pharmacist must assess the competence of the patient (i.e. ensure that the patient is not currently intoxicated or otherwise mentally impaired) to ensure that it is safe to release the medication to them.

Guideline: Pharmacists must assess patients for symptoms such as slurred speech, ataxia, drowsiness, alcohol smell or unusual behaviour. It is important for the pharmacist to be familiar with each patient's 'normal' behaviour in order to be able to detect significant deviations from normal.

If the pharmacist believes that it is not safe for the patient to receive their prescription they must consult with the prescriber and document the outcome of the dialogue and attach it to the original prescription.

Principle 4.1.3 Prior to releasing a methadone prescription the patient and pharmacist must acknowledge receipt by signing a patient/prescription-specific log (the sample *Methadone Part-Fill Accountability Log* (Appendix 9) can be used for this purpose).

Guideline: Every part-fill dispensed must be accounted for. The pharmacist must be able to review every part-fill dispensed as a complete history on one document.

The pharmacist releasing and the patient receiving the part-fill of the prescription must sign for each witnessed ingestion dose and each take-home dose. **Neither the pharmacist nor the patient is permitted to pre-sign for future doses or backdate signing.**

The patient/prescription specific log (the sample *Methadone Part-Fill Accountability Log* (Appendix 9) can be used for this purpose) must be attached to the original Controlled Prescription Program form and once complete filed sequentially by the first prescription or transaction number assigned to the prescription.

Principle 4.1.4 As with all prescriptions, prior to releasing a methadone prescription, the pharmacist must counsel the patient on the risks (including common side effects) and benefits of taking their medication as per *HPA Bylaws* Schedule F Part 1 section 12.

Guideline: The most common adverse reactions with methadone include; sweating, constipation, sexual dysfunction, change in menstruation, drowsiness, sleep disturbances, muscle and bone aches, weight changes (usually gain), skin rash, gastrointestinal upset, headaches and edema. Patients will benefit from information about the non-drug approaches, non-prescription products and prescription items that can provide relief from these side effects.

Principle 4.1.5 With respect to witnessed ingestion doses, the pharmacist must directly observe the patient ingesting the medication and be assured that the entire dose has been swallowed.

Guideline: Given the concentrated solution of 10mg/ml, it may be helpful to provide a glass of water to the patient to enable rinsing out of the dispensing container to ensure full dose administration.

Immediately following observing the patient's ingestion of the medication the pharmacist should engage the patient in a short conversation to ensure that the entire dose has been swallowed.

Principle 4.1.6 With respect to take-home doses the first dose (whether it is stated on the prescription or not) must be a witnessed ingestion with all subsequent take-home doses dispensed in child-resistant containers with an explicit warning label indicating that the amount of drug in the container could cause serious harm or toxicity if taken by someone other than the patient.

Guideline: Each dose must be dispensed in an individual, appropriately sized, child-resistant container.

Each container must be individually labeled.

If a pharmacist determines that due to a specific patient circumstance a non-child-resistant container will be used for take-home doses it must be documented on the patient record.

Patients should be reminded that methadone should be stored out of the reach of children, preferably in a locked cupboard or small lock box if stored in the refrigerator.

Note: The decision to authorize take-home doses can only be made by the prescriber. However, should a pharmacist believe that a patient is or is not

ready to manage take-home doses they should discuss their recommendations or concerns with the prescriber.

Principle 4.1.7 In extraordinary situations, when a patient cannot attend the pharmacy, the patient's representative may pick up and sign for their authorized take-home dose(s) if confirmed in writing by the prescriber.

Guideline: This authorization must be date specific, and the representative and circumstances must be clearly defined. The written and signed authorization from the prescriber (fax acceptable) must be attached to the original approved Controlled Prescription Program form.

Note: Patient representative is defined in *HPA Bylaws*.

5.0 Responding to Methadone Dosing Issues

5.1 Divided (Split) Doses

Principle 5.1.1 Only the prescriber, by stating this on the original approved Controlled Prescription Program form, can authorize a divided (split) dose of a prescription. Unless otherwise specified by the prescriber, the first portion of the daily dose must be by witnessed ingestion.

Guideline: The decision to authorize a divided dose can only be made by the prescriber, however, should a pharmacist believe that a patient would benefit from this they should discuss this option with the prescriber.

5.2 Missed Doses

Principle 5.2.1 Any methadone prescription that has been processed and prepared but is not consumed or picked up by the patient on the prescribed day is considered cancelled and must be reversed on PharmaNet before the end of the business day.

Guideline: It is imperative that the PharmaNet patient record reflects accurate and current information in terms of consumed and picked-up

methadone doses as other healthcare practitioners rely on this information in making treatment decisions.

Principle 5.2.2 If a patient misses a dose, they cannot receive the missed dose at a later date.

Principle 5.2.3 The pharmacist must notify the prescriber of any missed doses (unless a specified number of missed doses has been indicated by the prescriber) before the next scheduled release of medication.

Guideline: The notification document must be retained and filed with the prescription consistent with filing retention requirements. The *Pharmacist-Prescriber Communication Form* (Appendix 6) can be used for this purpose.

5.3 Partial Consumption of Doses

Principle 5.3.1 If a patient refuses to consume their full dose, the pharmacist must not insist that they ingest the total amount. The unconsumed portion however cannot be given as a take-home dose.

Guideline: The patient's partial consumption of a dose and their reason(s) for it must be documented and reported to the prescriber. *The Pharmacist-Prescriber Communication Form* (Appendix 6) can be used for this purpose.

All patient documentation including the *Methadone Part-Fill Accountability Log* (Appendix 9) and PharmaNet record must accurately reflect the actual dose consumed by the patient.

5.4 Vomited Doses

Principle 5.4.1 If a patient reports that they vomited their dose, a replacement dose cannot be provided without authorization from the patient's prescriber.

Guideline: The pharmacist must contact the prescriber and provide them with information about the incident (time the dose was taken, time of vomiting, and other relevant points). Should the prescriber authorize a replacement dose, it must be confirmed in writing, signed by the prescriber,

received by the pharmacy (fax is acceptable) prior to dispensing the medication and attached and filed with the original prescription.

5.5 Lost or Stolen Doses

Principle 5.5.1 If a patient reports that their take-home dose(s) have been lost, stolen or misplaced, a replacement dose(s) cannot be provided without authorization from the patient's prescriber.

Guideline: The pharmacist must contact the prescriber and discuss the situation with them. Should the prescriber determine that the situation warrants it they may authorize the acceptance of a new approved Controlled Prescription Program form by fax (refer to Principle 2.1.3) or the prescriber may advise the pharmacy that they must wait until the patient presents a new original approved Controlled Prescription Program form.

5.6 Tapering

Principle 5.6.1 If a patient has decided to initiate a self-tapering regimen by decreasing their daily dose consumption, the pharmacist must record the dose consumed on the patient/ prescription specific log (refer to Principle 4.1.3), record the actual dose consumed on the patient's PharmaNet record and notify the prescriber.

Guideline: The *Pharmacist-Prescriber Communication Form* (Appendix 6) can be used for the purpose of notifying the prescriber.

5.7 Emergency Dosing

Principle 5.7.1 Emergency dosing is not recommended. If however a pharmacist feels in their professional judgement that an emergency dose is required to ensure continuity of patient treatment the pharmacist may provide an emergency dose. The pharmacist must counsel the patient to obtain a new prescription as soon as possible. This practice is the exception to the rule and not the normal practice, refer to *Professional Practice Policy (PPP-31) – Emergency Supply for Continuity of Care*.

Guideline: Pharmacists need to document, as per *PPP-31*, the attempt to reach the prescriber with information about the situation. The prolonged half-life of methadone ensures that a patient maintains a single dose for at

least 36 hours. Although the patient may feel uncomfortable an emergency dose may not be necessary. Emergency doses may hinder treatment success and health outcomes. It is a patient's responsibility to make sure they have a valid prescription.

6.0 Continuity of Care

6.1 Transfer of Pharmacy

Principle 6.1.1 When a patient chooses to move from one pharmacy to another to receive their methadone prescription it is the responsibility of the new pharmacy to contact the previous pharmacy and prescriber (if applicable) to discuss the exact transfer date and any other pertinent concerns. The previous pharmacy must cooperate fully with the request from the new pharmacy.

Guideline: Communication between the previous and new pharmacy is critical to ensure the patient's continuity of care and to avoid duplicate or missed methadone doses. A review of the patient's PharmaNet patient record can be of assistance in determining the previous pharmacy and prescriber.

6.2 Hospitalization or Incarceration

Principle 6.2.1 When a patient is discharged or released to the community from a hospital or correctional facility it is the responsibility of the community pharmacist receiving the patient to verify the date and amount of the last dose administered.

Guideline: Effective communication sharing among those who provide the patient's methadone maintenance treatment (hospital or correctional facility and pharmacy) is essential to ensure the patient's continuity of care and to avoid duplicate or missed methadone doses.

6.3 Compounding in Exceptional Circumstances

Principle 6.3.1 The only situation that would constitute consideration of exceptional circumstances is when a commercially available 10 mg/ml oral preparation is not available.

Principle 6.3.2 Methadone for maintenance must be at the strength of 10 mg/ml to ensure minimization of errors.

Principle 6.3.3 A compounding log must be established to record when methadone solutions are prepared, how much was prepared, and who prepared the product. The *Compounding Log* (Appendix 8) can be used for this purpose.

Guideline: The compounding log must incorporate the following elements:

- Preparation date,
- Methadone powder and/or liquid concentrate manufacturer's lot number and expiry date,
- Methadone powder and/or liquid concentrate quantity used and quantity prepared,
- Batch number and use-by date assigned by the pharmacy, and
- Preparer's and pharmacist's identification.

A separate compounding log must be maintained for each strength of stock solution

Principle 6.3.4 All concentrated solution containers must be clearly labeled with the drug name, strength, use-by date and appropriate warning labels.

Guideline: If different concentrations are prepared for pain management, they must be easily identifiable with clear labeling. A best practice would be to use different styles of storage container for each concentration or use food grade dyes to differentiate between the different concentrations prepared.

In order to help ensure liquid methadone preparations remain stable for up to 30 days from the date of pharmacy dispensing and to minimize the growth of bacteria, mold and fungus the *American Association for the Treatment of Opioid Dependence* recommends that pharmacists should:

- Use distilled water for the dilution of methadone products,
- Use new, clean, light-resistant containers for dispensing,
- Refrigerate take-home containers as soon as possible and keep refrigerated until used.

Principle 6.3.5 Methadone for maintenance solutions must be made with full-strength Tang™ or similar full-strength beverage crystals with daily doses (witnessed ingestion or take-home). Plain water is never an acceptable vehicle for dispensing to patients in the methadone maintenance treatment program.

Guideline: The beverage crystals are full-strength when made according to the manufacturer's directions found on the product's packaging.

Dispensing as a standard volume (e.g., all doses dispensed as a volume of 100 mL) is not acceptable.

Appendix 1

CPBC Professional Practice Policy PPP-66 – Opioid Agonist Treatment

See the most up-to-date *Professional Practice Policy – 66 Opioid Agonist Treatment* on the CPBC website: http://library.bcpharmacists.org/6_Resources/6-2_PPP/5003-PGP-PPP66.pdf

Appendix 2

CPBC Professional Practice Policy PPP-71 – Delivery of Opioid Agonist Treatment

See the most up-to-date *Professional Practice Policy – 71 Delivery of Opioid Agonist Treatment* on the CPBC website: http://library.bcpharmacists.org/6_Resources/6-2_PPP/5003-PGP-PPP71.pdf

Appendix 3

Methadone for Maintenance Controlled Prescription Form Guidelines

When accepting a Methadone Maintenance Controlled Prescription form a pharmacist must ensure that the form is completed by the prescriber as outlined in these guidelines.

Methadone Maintenance Controlled Prescription Form (Example; Figure 1):

These duplicate copy prescriptions are pre-printed with the following information; drug name and strength, prescriber's name, address (optional), College ID number and prescription folio number. These prescription forms are used only for prescribing methadone for maintenance.

Top Section of Form:

The prescriber must complete in full, the patient information including; personal health number (PHN), name, address and date of birth. The 'prescribing date' indicates the date that the prescriber saw the patient. The 'Drug Name and Strength' section is preprinted and the prescriber must complete the 'Quantity' section by stating the total quantity of the prescription in numeric and alpha forms.

Note: If no 'start day' is indicated in the 'Directions for Use' section of the form the 'prescribing date' becomes the 'start day'.

Middle Section of Form:

The prescriber must complete the 'Directions for Use' section as follows:

- State the daily dose:
    - the daily dose multiplied by the number of days must equal the total quantity indicated on the prescription, if there is a discrepancy the pharmacist should seek clarification from the prescriber
- Indicate the 'start day' and 'last day':
    - if no 'start day' is indicated, the 'prescribing date' becomes the 'start day'
    - should the 'start day' overlap with, or leave gaps from, an existing prescription the pharmacist should seek clarification from the prescriber
- Indicate any special instructions:

    - may be used to provide special instructions to the pharmacist for example split doses, or special situations for carries.
- Indicate either DWI or CARRIES, if carries are indicated the prescriber must indicate both in numeric and alpha the required number of days per week of witnessed ingestion:
    - if neither of these options are circled the pharmacist is to assume that all doses are DWI
    - if CARRIES has been circled but the specific witnessed ingestion days (ex; Monday and Thursday) have not been noted by the prescriber the pharmacist can determine the days in consultation with the patient. However, the first dose of the prescription and the dose before any carries must be witnessed ingestion. Additionally, the witnessed ingestion doses must be spread evenly throughout the week
    - if CARRIES has been circled but the number of days per week of witnessed ingestion has been left blank the pharmacist must seek clarification from the prescriber

Note: "DWI except when pharmacy closed" is not an acceptable prescription instruction.

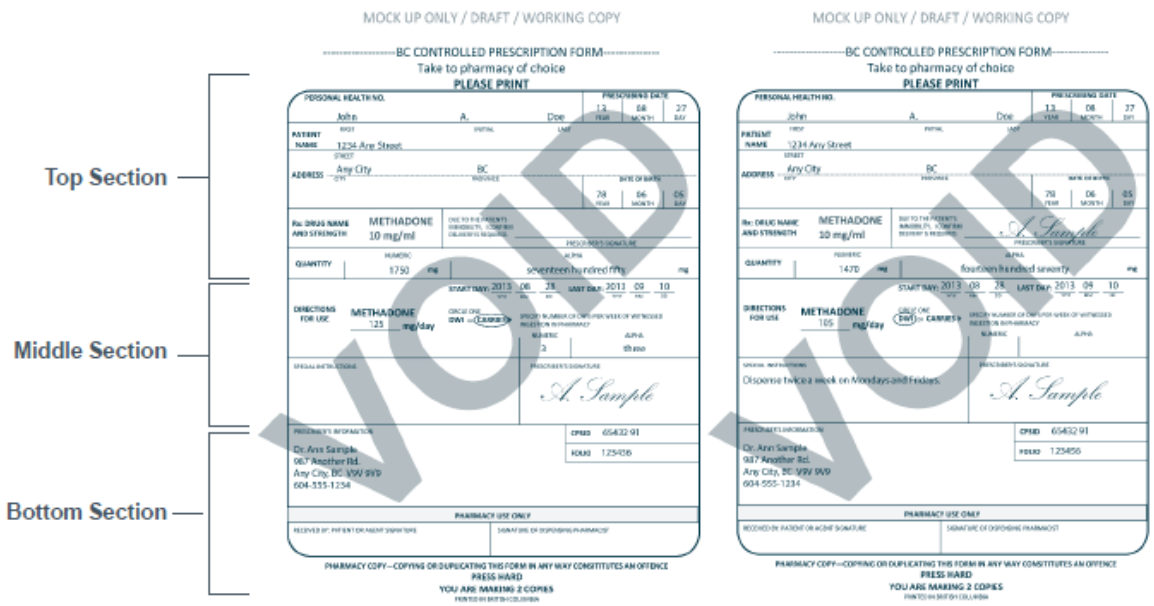
- Authorize the prescription by signing their name in the 'prescriber's signature' box

Bottom Section of Form:

As a minimum the prescriber's name, College ID number and prescription folio number will be pre-printed on the form. If the prescribers address is not pre-printed it must be completed by the pharmacist prior to dispensing the prescription. Both the patient and the pharmacist must sign the prescription in the appropriate box.

Note: A patient's representative signature is only acceptable with prior written authorization from the prescriber.

Figure 1: Methadone Maintenance Controlled Prescription Form



Appendix 4

Emergency Fax Controlled Prescription Program Form Documentation

This form is for the use only in the event of an emergency that requires a faxed Controlled Prescription Program form which has been initiated following direct consultation between the patient's pharmacist and prescriber.

It is understood that the pharmacist must obtain written documentation from the prescriber prior to dispensing any medication and as such is requesting that the prescriber complete this form and fax back to the pharmacy along with a fax of the Controlled Prescription Program form as soon as possible.

Prescriber: _____ Patient Name: _____

Pharmacy: _____ Fax Number: _____

Pharmacist: _____ Date: _____

As the prescriber, I request that the above-named pharmacy accept a faxed transmission of the Controlled Prescription Program form for the above-named patient. I understand that the Controlled Prescription Program form must be faxed to and received by the pharmacy prior to the pharmacy dispensing methadone. I guarantee that the original Controlled Prescription Program form will be sent to the pharmacy by the next business day.

Brief description of the emergency situation:

_____

_____

_____

_____

Prescriber's Name: _____

Prescriber ID: _____

Prescriber's Signature: _____

Signature Date: _____

Affix Controlled Prescription Program form here

Appendix 5

Methadone Maintenance Treatment Expectation Form

As your pharmacists, we believe in the principles of the methadone maintenance treatment program, and the valuable role it can play in improving people's lives and their health. We are committed to being an active member of your healthcare team and understand that the success of the program is dependent on ongoing collaboration and communication between yourself, ourselves and your prescriber.

To help you succeed in the program it is important that we both clearly understand the commitment and expectations of each other.

As your pharmacists, you can expect that we will:

- Treat you professionally and respectfully at all times.
- Make ourselves available to discuss any questions or concerns that you may have regarding the program.
- Provide methadone to you exactly as your prescriber has prescribed it and will ensure that they are made aware of any of the following:
    - Missed dose(s) for any reason (ie; failure to pick up, vomited, lost or stolen)
    - Less than full dose consumed (ie; tolerance, self-initiated tapering)
    - Presenting at the pharmacy while intoxicated
    - Prescribing of contraindicated medications (ie; mood-altering drugs)
- Not dispense your methadone (unless directed by your prescriber) to anyone other than you.
- Respect your choice (unless directed by your prescriber) of the pharmacy you wish to have dispense your medication.

As our patient, we can expect that you will:

- Treat all pharmacy staff and other patients respectfully at all times.
- Do your utmost to adhere to the methadone maintenance treatment program as prescribed to you.
- Discuss any concerns you may have regarding your methadone maintenance treatment with us or your prescriber prior to making any adjustments to treatment independently.
- Ensure that any take-home doses of methadone are stored safely and securely.
- Respect the pharmacy's greater community by refraining from loitering or littering.

Appendix 6

Pharmacist – Prescriber Communication

Date: _____ Patient Name: _____
To (Prescriber): _____ Patient PHN: _____
Fax: _____ Prescription Form Folio Number: _____
From (Pharmacy): _____ Pharmacy Fax: _____
Pharmacist: _____ Pharmacy Telephone: _____

For Prescriber's Information and Patient Records

❑ This patient missed their methadone dose _____ (dates).

❑ This patient did not take their full daily dose _____ (date) and consumed only ____mg of the ____ mg prescribed dose.

For Prescriber's Signature and Return of Form to Pharmacy

❑ We require clarity regarding the 'prescribing date' and/or 'start day' for the attached Controlled Prescription Program form. Please indicate the actual 'prescribing date' (actual date the prescription was written) and dispensing 'start date' or range.

Prescribing Date: _____

Dispensing Start Date or Range: _____

❑ We require clarification and/or a change to the 'Directions for Use' section of the attached Controlled Prescription Program form.

Description of authorized changes:

_____

_____

_____

_____

Prescriber's Name: _____

Prescriber ID: _____

Prescriber's Signature: _____

Signature Date: _____

Affix Controlled Prescription Program form here

Appendix 7

Drug Interactions – General Information

Methadone is extensively metabolized by cytochrome CYP3A4 in liver microsomes. Most drug interactions with methadone are associated with drugs that either induce or inhibit these enzymes.

The sequence of administration of the drugs is the key to evaluating the significance of the interaction. When a patient is stabilized on a drug that affects liver metabolism and methadone is introduced, the interaction may not be observed unless the first drug is discontinued. It is only if a patient is stabilized on methadone and an interacting drug is initiated or discontinued that an interaction may occur.

Drugs that may lower plasma levels (ie; increase the metabolism) of methadone include rifampin, barbiturates, phenytoin and carbamazepine. Drugs that may increase plasma levels (ie; decrease the metabolism) of methadone include ciprofloxacin and fluvoxamine.

Medications that might precipitate a withdrawal syndrome for patients on methadone must be avoided. These are mainly opioid antagonists such as pentazocine, butorphanol, nalbuphine, and naltrexone.

Pharmacists should not rely on PharmaNet to warn of a drug interactions for methadone. The use of PharmaNet is not intended as a substitute for professional judgment. Information on PharmaNet is not exhaustive and cannot be relied upon as complete. The absence of a warning about a drug or drug combination is not an indication that the drug or drug combination is safe, appropriate or effective in any given patient. Health care professionals should confirm information obtained from PharmaNet, and ensure no additional relevant information exists, before making patient care decisions.

Appendix 8

Compounding Log

g/ml Stock Solution

Preparation Date	Manufac-turer's Lot Number (Powder)	Manufac-turer's Expiry Date (Powder)	Quantity Used (Powder)	Quantity Prepared (Solution)	Use-By Date (Solution)	Batch Number (Assigned by pharmacy)	Preparer's ID (Initials)	Pharmacist's ID (Initials)

Appendix 9

Methadone Part-Fill Accountability Log

Patient Name: _____

Date Dispensed	Prescription or Transaction Number	Quantity			Delivery Information (if applicable)		Pharmacist's Initials	Patient's signature
		Witnessed	Take Home	Total	Address	Time		

✂ ----------

Patient Name: _____

Date Dispensed	Prescription or Transaction Number	Quantity			Delivery Information (if applicable)		Pharmacist's Initials	Patient's signature
		Witnessed	Take Home	Total	Address	Time		

Appendix 10

Methadone Information for Patients

What is methadone?

Methadone is a long-acting narcotic medication. Since the mid-1960s methadone has been used as an effective and legal substitute for heroin and other opiates. Methadone maintenance programs help opiate-dependent individuals stabilize their lives and reduce the harm associated with drug use.

How is methadone taken?

Methadone is prepared in a liquid. Doses are usually taken once a day as the effects of a single dose last for about one day. Your physician will write a prescription specifying your dose and how often you need to come to the pharmacy. Initially methadone is prescribed as a daily witnessed dose. As your treatment progresses you may be eligible for take-home doses.

How does methadone work?

Methadone is part of a long-term maintenance program for opiate or heroin dependent people. Drug cravings are reduced without producing a "high." The goal is to find the dose that will prevent physical withdrawal. The right dose will decrease your drug cravings, and help you to reduce or eliminate heroin use.

How long do I have to stay on methadone?

You should stay on methadone for as long as you experience benefits. Everyone responds differently and methadone can safely be taken for years. If you decide you want to stop taking methadone, you should discuss this with your physician.

Does methadone have side effects?

Methadone is usually tolerated well once the dose is stabilized. Most people experience few, if any, side effects. Please let your pharmacist or physician know if any of these symptoms are bothering you:

- Sweating – This can be due to the methadone itself, or a dose that is too high or too low.
- Constipation – Increasing exercise, fluids and fiber in your diet may decrease this problem.

- Sexual difficulties – This can be either a reduction or an increase in desire.
- Sleepiness or drowsiness – This may be caused by too much methadone. If this occurs consult your doctor to have your dose adjusted. Do not drive a car or participate in activities that require you to be alert when you are drowsy.
- Weight change – An increase in body weight may be due to better health and an improved appetite.

Can methadone interact with other drugs?

Yes. Alcohol and drugs, including prescription, nonprescription, herbal and street drugs, may interfere with the action of methadone in your body. Discuss all medications you are taking with your pharmacist or physician.

Is methadone dangerous?

Methadone is safe to use when it is prescribed and monitored by a physician. It can be very dangerous if used inappropriately. Methadone should never be taken by anybody except the person for whom it is prescribed as overdose and death can occur if the person is not dependent on opiates. Children are especially at risk for overdose and death if they swallow methadone accidentally.

What is my responsibility?

Your responsibility is to drink your methadone dose every day. If you have carries, you must make sure that they are stored safely to prevent possible ingestion by anyone else. If you store your carries in the fridge ensure that they are not accessible. Methadone can be very dangerous if used inappropriately so you must not give or sell your dose to anyone.

Will methadone cure me?

The methadone maintenance program can help you to make positive lifestyle changes. The goal of treatment is to stabilize your body physically and to provide an environment that supports you.

College of Pharmacists
of British Columbia

Professional Practice Policy #66

Policy Guide

Slow Release Oral Morphine (SROM) Maintenance Treatment (2018)

Slow Release Oral Morphine (SROM) Maintenance Treatment Policy Guide

All pharmacy managers, staff pharmacists, relief pharmacists and pharmacy technicians employed in a community pharmacy that provides pharmacy services related to SROM maintenance treatment must know and apply the principles and guidelines outlined here in the College of Pharmacists of BC (CPBC) *Slow Release Oral Morphine (SROM) Maintenance Treatment Policy Guide (2018)* and all subsequent revisions.

1.0 Administration

1.1 Pharmacy Operating Hours

Principle 1.1.1 The pharmacy hours of service must be consistent with the dosing requirements of your patient.

Guideline: When a pharmacy accepts a patient who requires daily witness ingestion or daily dispense (i.e., 7 days per week) the pharmacy hours of service need to accommodate this dosing requirement. A pharmacist does not have the independent authority to adapt a prescription for SROM maintenance treatment from 'daily witness' to a 'take-home' dose.

1.2 General Guidance for Pharmacy Professionals

Principle 1.2.1 Provide patient education on how to properly take SROM.

Note: See Principle 4.1.4 for detailed administration requirements.

Principle 1.2.2 Advise patients to talk to their prescriber and pharmacist about any continuing withdrawal symptoms, craving, and/or non-medical opioid use.

Principle 1.2.3 Refer colleagues, prescribers, and clinical staff who are unfamiliar with the most recent version of the British Columbia Centre on Substance Use (BCCSU) *A Guideline for the Clinical Management of Opioid Use Disorder*. Recommend completion of online training through the University of British Columbia Faculty of Medicine Continuing Professional Development's Provincial Opioid Addiction Treatment Support Program.

2.0 Receiving SROM Prescriptions

2.1 Controlled Prescription Program Forms – Overview

Principle 2.1.1 SROM prescriptions can only be accepted when written using an original Controlled Prescription Program form. When accepting SROM prescriptions, the pharmacist must ensure that the Controlled Prescription Program Form is completed by the prescriber as outlined in the Controlled Prescription Program.

Principle 2.1.2 SROM prescriptions may only be received by facsimile in accordance with section 7(3) of the *Health Professions Act* Bylaws Schedule F, Part 1 - *Community Pharmacy Standards of Practice*. Verbal prescriptions for SROM maintenance treatment may be accepted where permitted under a section 56 exemption to the *Controlled Drugs and Substances Act* in accordance with section 19(6.1) of the bylaws to the *Pharmacy Operations and Drug Scheduling Act*.

3.0 Processing (Dispensing) SROM Prescriptions

3.1 Accepting a Prescription

Principle 3.1.1 SROM for maintenance must be dispensed in approved, commercially available strengths and formulations. Capsule contents cannot be split.

Principle 3.1.2 **Guideline:** Only the once-daily, 24-hour formulation of SROM has been studied in clinical trials for the treatment of opioid use disorder. Other formulations of oral morphine, such as twice-daily, 12-hour sustained- or extended-release formulations, have not been empirically studied in this context and are not recommended. Pharmacists and pharmacy technicians (working within their scope) must review the prescription to ensure that the specific needs of the patient can be accommodated by the pharmacy.

Guideline: Each prescription should be reviewed in detail in consultation with the patient, to ensure that the patient's specific needs can be accommodated. For example:

- Evaluate the end date of the prescription to ensure that the authorization for dispensing does not end on a day when the patient will not be able to see a prescriber for a new prescription (e.g., weekends and holidays).
- Review the prescription directions to determine the dosing schedule (daily witnessed ingestion, take-home doses), including the specific days of the week for each witnessed dose or take-home doses, to confirm that the pharmacy operating hours match the dosing schedule.

3.2 Assessment of a Prescription

Principle 3.2.1 Pharmacists and pharmacy technicians must correctly identify the product as prescribed 'for pain' or 'Opioid Agonist Treatment (OAT)' by using the appropriate Drug Identification Number (DIN) or Product Identification Number (PIN) to ensure patient safety and accurate PharmaNet patient records.

Guideline: Effective June 5, 2017, PharmaCare established PINs for the use of Kadian® SROM as OAT. These PINs are to be used when submitting claims for the various dosing strengths through PharmaNet. Similar to methadone, DINs will be used by pharmacists exclusively for claims for analgesia, and the PINs will be used for claims for OAT.

Prescriptions for Kadian® should specify whether it is designated for analgesia or OAT (i.e., "for OAT" or "for opioid agonist treatment" is to be indicated on the prescription). If there is a question as to whether the prescription is for OAT (i.e., indicated by the dose strength, directions to "open and sprinkle" capsules for daily witnessed ingestion, or other elements of the prescription), but the prescription lacks the explicit indication "for OAT", the pharmacist should contact the prescriber to confirm the intended use prior to dispensing the medication and properly document any alteration of the prescription.

The claim entered into PharmaNet should match the prescription written by the prescriber. If a claim marked "for OAT" has been entered under the DIN rather than under the PIN for Kadian® for OAT, it must be reversed, following the full standard procedure for reversing a claim entered under the wrong DIN or PIN. Only after a claim has been reversed can it then be re-entered with the correct PIN.

Principle 3.2.2 As with all medications a pharmacist must review each individual PharmaNet patient record, as stated in *HPA Bylaws* (Schedule F Part 1), and resolve any drug-related problems prior to dispensing any SROM prescription. This step is particularly critical for SROM for OAT prescriptions as the automated drug usage evaluation (DUE) built into the PharmaNet system **does not include SROM for OAT**.

Pharmacists providing SROM for OAT maintenance treatment must therefore ensure they maintain their knowledge with respect to potential drug interactions related to SROM.

Guideline: A PharmaNet patient record review should be completed for all prescriptions, including those patients obtaining their prescription on a daily basis or those long-term patients whom the pharmacist may know well.

Principle 3.2.3 Should a patient present a prescription for a mood altering drug, including benzodiazepines and opioids, or if the pharmacist discovers that a mood altering drug is also being prescribed to the patient in their review of the PharmaNet patient record, they must contact both the prescriber of SROM and, if different, the prescriber of the mood altering drug, prior to dispensing the medication. The pharmacist must document the outcome of the consultation(s) with the prescriber(s) and include it with the original prescription. The purpose of the consultation is to ensure the prescriber(s) are aware that the patient is currently on the SROM maintenance program.

Guideline: Mood altering drugs, including benzodiazepines and opioids, should not be prescribed to patients on the SROM maintenance program. Co-ingestion of SROM with alcohol or benzodiazepines is contraindicated, as combined effects can potentially result in fatal respiratory depression.

4.0 Releasing SROM for OAT Prescriptions

4.1 Releasing a Prescription

Principle 4.1.1 A pharmacist must be present to release the SROM prescription to a patient. This function cannot be delegated to a pharmacy technician or any other pharmacy support staff.

Principle 4.1.2 Prior to releasing a SROM prescription the pharmacist must assess the patient to ensure that the patient is not intoxicated, including by centrally-acting sedatives and/or stimulants or in any other acute clinical condition that would increase the risk of an adverse event. If the pharmacist believes that it is not safe for the patient to receive their prescription they must consult with the prescriber and document the outcome of the dialogue and include it with the original prescription.

Guideline: Assess patients for symptoms such as slurred speech, ataxia, drowsiness, alcohol smell or unusual behaviour. It is important for the pharmacist to be familiar with each patient's usual behaviour in order to be able to detect significant deviations.

Principle 4.1.3 Prior to releasing a SROM prescription, the patient and pharmacist must acknowledge receipt by signing a patient/prescription-specific log. Every part-fill dispensed must be accounted for. The patient/prescription specific log must be included with the original Controlled Prescription Program form. Once complete, it must be filed sequentially by the first prescription or transaction number assigned to the prescription. The pharmacist must be able to review every part-fill dispensed as a complete history on one document.

Guideline: The sample *SROM Part-Fill Accountability Log* (Appendix 1) can be used for this purpose.

Neither the pharmacist nor the patient is permitted to pre-sign for future doses or backdate signing.

Principle 4.1.4 With respect to witnessed ingestion doses, the pharmacist must directly observe the patient ingesting the medication and be assured that the entire dose has been swallowed.

Guideline: SROM has a high risk of diversion, even when administered as witnessed doses (e.g., intact capsules can be 'cheeked' or 'palmed').

To reduce the risk of diversion, daily witnessed ingestion doses should be prepared by opening the capsule(s) and sprinkling the enclosed pellets for immediate ingestion. The patient should be instructed that pellets must not be chewed or crushed.

Pellets may be sprinkled into a 30 mL medicine cup or small cup followed by at least 30 mL of water to ensure that all pellets have been swallowed.

Immediately following observing the patient's ingestion of the medication, the pharmacist should ensure that the entire dose has been swallowed. This may include: engaging the patient in short conversation, asking the patient if there are pellets remaining in their teeth or gums, offering additional water for rinsing, or inspecting the inside of the patient's mouth.

Important Safety Notice: SROM pellets must be swallowed whole. Crushing, chewing, or dissolving slow-release oral morphine capsules or pellets can cause rapid release and absorption of a potentially fatal dose of morphine sulphate.

Principle 4.1.5 If take home doses (carries) are prescribed, the first dose must be a witnessed ingestion. The subsequent take-home doses must be dispensed in child-resistant containers with an explicit warning label indicating that the amount of drug in the container could cause serious harm or toxicity if taken by someone other than the patient. If a pharmacist determines that due to a specific patient circumstance a non-child-resistant container will be used for take-home doses, it must be documented on the patient record.

Guideline: The decision to authorize take-home doses can only be made by the prescriber. However, should a pharmacist believe that a patient is or is not ready to manage take-home doses they should discuss their recommendations or concerns with the prescriber.

Note that the majority of prescriptions for SROM will be for daily witnessed ingestion (DWI). In exceptional cases, patients may be transitioned to take-home dosing schedules. If a patient's prescription indicates transition to a take-home dosing schedule for SROM, it is best practice to call and confirm with the prescriber.

Compliance packaging (e.g., blister packaging, pouch packs) may be ordered by the prescriber to discourage diversion and allow for better monitoring during medication call-backs. In these cases, the pharmacy still needs to ensure that the medications are provided in child-resistant packaging.

Patients should be reminded that SROM should be stored out of the reach of children, preferably in a locked cupboard or small lock box.

5.0 Responding to SROM Dosing Issues

5.1 Missed Doses

Principle 5.1.1 Any SROM prescription that has been processed and prepared but is not consumed or picked up by the patient on the prescribed day is considered cancelled and must be reversed on PharmaNet **before the end of the business day**.

Guideline: It is imperative that the PharmaNet patient record reflects accurate and current information in terms of consumed and picked-up SROM doses as other healthcare practitioners rely on this information in making treatment decisions.

Principle 5.1.2 If a patient misses a dose, they cannot receive the missed dose at a later date.

Principle 5.1.3 The pharmacist must notify the prescriber of any missed doses before the next scheduled release of medication. The notification document must be retained and filed with the prescription consistent with filing retention requirements.

Guideline: The *Pharmacist-Prescriber Communication* form (Appendix 2) can be used for this purpose.

Principle 5.1.4 If a patient misses 2 or more consecutive doses, the prescription must be cancelled.

Guideline: The pharmacist should advise the patient to see the prescriber for a new prescription, as dose adjustment and re-stabilization may be required.

For more information, refer to the BCCSU *A Guideline for the Clinical Management of Opioid Use Disorder* - Appendix 3: Induction and Dosing Guidelines for Slow Release Oral Morphine.

5.2 Partial Consumption of Doses

Principle 5.2.1 If a patient declines or is unable to consume their full dose, the pharmacist must respect the patient's choice. The unconsumed portion cannot be given as a take-home dose. The patient's partial consumption of a dose and their reason(s) for it must be documented and reported to the prescriber. All patient documentation including the patient-prescription specific log and PharmaNet record must accurately reflect the actual dose consumed by the patient.

Guideline: The *Pharmacist-Prescriber Communication* form (Appendix 2) can be used for the documentation and communication.

The *SROM Part-Fill Accountability Log* (Appendix 1) can be used for the Part-Fill Accountability Log.

5.3 Vomited Doses

Principle 5.3.1 If a patient reports that they vomited their dose, a replacement dose cannot be provided. The pharmacist must notify the prescriber and provide them with information about the incident (time the dose was taken, time of vomiting, and other relevant points). If the prescriber chooses to authorize a replacement dose, a new original Controlled Prescription Program form must be received by the pharmacy.

5.4 Lost or Stolen Doses

Principle 5.4.1 If a patient reports that their take-home dose(s) have been lost, stolen or misplaced, a replacement dose(s) cannot be provided. The pharmacist must notify and consult with the prescriber. If the prescriber chooses to authorize a replacement dose, a new original Controlled Prescription Program form must be received by the pharmacy.

5.5 Tapering

Principle 5.5.1 If a patient has decided to initiate a self-tapering regimen by decreasing their daily dose consumption, the pharmacist must record the dose consumed on the patient/prescription specific log (refer to Principle 4.1.3), record the actual dose consumed on the patient's PharmaNet record and notify the prescriber.

Guideline: The *Pharmacist-Prescriber Communication* form (Appendix 2) can be used for the purpose of notifying the prescriber.

Appendix 1

SROM Part-Fill Accountability Log

Patient Name: _____

Date Dispensed	Prescription or Transaction Number	Quantity			Delivery Information (if applicable)		Pharmacist's Initials	Patient's signature
		Witnessed	Take Home	Total	Address	Time		

✂ ----------

Patient Name: _____

Date Dispensed	Prescription or Transaction Number	Quantity			Delivery Information (if applicable)		Pharmacist's Initials	Patient's signature
		Witnessed	Take Home	Total	Address	Time		

Appendix 2

Pharmacist – Prescriber Communication

Date:_____ Patient Name:_____

To (Prescriber):_____ Patient PHN:_____

Fax: _____ Prescription Form Folio Number:_____

From (Pharmacy):_____ Pharmacy Fax:_____

Pharmacist:_____ Pharmacy Telephone:_____

For Prescriber's Information and Patient Records

- ❑ This patient missed their slow release oral morphine dose on _____(date).
- ❑ This patient did not take their full daily dose today _____ (date) and consumed only ____ mg of the ____ mg prescribed dose.
- ❑ This patient's dose has been held due to _____ (reason and date).
- ❑ This patient lost or had their dose(s) stolen _____(dates).
- ❑ This patient's prescription has been cancelled due to _____(number of missed doses).

Additional Information

You May Attach Controlled Prescription Program Form.

College of Pharmacists
of British Columbia

Professional Practice Policy #67

Policy Guide

Injectable Hydromorphone Maintenance Treatment (2018)

Injectable Hydromorphone Maintenance Treatment Policy Guide

All pharmacy managers, staff pharmacists, relief pharmacists and pharmacy technicians employed in a community pharmacy that provides pharmacist supervision of injectable hydromorphone maintenance treatment must know and apply the principles and guidelines outlined here in the College of Pharmacists of BC (CPBC) *Injectable Hydromorphone Maintenance Treatment Policy Guide (2018)* and all subsequent revisions.

1.0 Administration

1.1 Pharmacy Operating Hours

Principle 1.1.1 The pharmacy hours of service must be consistent with the dosing requirements of your patient.

Guideline: When a pharmacy accepts a patient who requires supervised injection (i.e., 7 days per week, multiple doses per day) the pharmacy hours of service need to accommodate this dosing requirement. Patients may need to have access to injectable hydromorphone up to three times per day with a minimum of three hours between doses.

1.2 General Guidance for Pharmacy Professionals

Principle 1.2.1 Only full pharmacists who successfully fulfill the following requirements may be considered 'iOAT trained pharmacists':
- Authorized by the CPBC under the Certification of Practicing Pharmacists for Drug Administration (injection and intranasal route);
- Trained to administer emergency use naloxone as per Principle 1.2.4;
- Holds current certification in cardiopulmonary resuscitation and first aid;
- Is familiar with the information included in the most recent version of British Columbia Centre on Substance Use (BCCSU) *Guidance for Injectable Opioid Agonist Treatment for Opioid Use Disorder*;
- Completed online training through the University of British Columbia Faculty of Medicine, Continuing Professional Development's Provincial Opioid Addiction Treatment Support Program;
- Trained in the use of all equipment required under Principle 1.3.3;
- Knows and applies the principles and guidelines outlined in the CPBC *Injectable Hydromorphone Maintenance Treatment Policy Guide (2018)* and all subsequent revisions; and,
- Records self-declaration of knowledge and training completion in eServices prior to dispensing injectable hydromorphone.

Guideline: Refer to *HPA Bylaws*, Schedule F, Part 4 – Certified Practice – Drug Administration by Injection and Intranasal Standards, Limits and Conditions for more information.

Principle 1.2.2 With respect to pharmacist supervised injectable hydromorphone maintenance treatment, only iOAT trained pharmacists can: accept a prescription for injectable hydromorphone; release a dose of injectable hydromorphone to a patient; conduct a pre- or post-injection patient assessment; or, supervise patients self-administering injectable hydromorphone. These functions cannot be delegated to a pharmacy technician or any other pharmacy support staff.

Principle 1.2.3 Patients must be advised to talk to their prescriber and pharmacist about any continuing withdrawal symptoms, cravings, and/or non-medical opioid use.

Principle 1.2.4 All registrants must be trained to administer emergency use naloxone and hold current certification in cardiopulmonary resuscitation and first aid.

Guideline: It is recommended that all pharmacy staff be trained to administer emergency use naloxone, cardiopulmonary resuscitation and first aid.

Naloxone education and training resources are available through the BC Centre for Disease Control's Towards the Heart Program.

Principle 1.2.5 Registrants must always practice within the scope of their education, training and competence. Where needed, they must obtain appropriate education and training as necessary.

Guideline: Refer to *HPA Bylaws*, Schedule A - Code of Ethics.

1.3 Facility and Equipment

Principle 1.3.1 The pharmacy must have a separate injection room within which the drug is to be self-administered by the patient that is clean, safe, comfortable and appropriately private and furnished for the patient. This room must be equipped with the following at a minimum: stainless steel table, chair, secure container for sharps that is not easily removable, sink, soap, hand sanitizer, antiseptic cleaning wipes and paper-towel in a dispenser.

Principle 1.3.2 The injection room must have the following clean and sterile injection supplies for patient use, including but not limited to: needles for patient self-injection (intravenous, intramuscular and subcutaneous), tourniquets, alcohol swabs, bandages and cotton swabs.

Principle 1.3.3 The injection room must have the following equipment for assessment and overdose management: adequate naloxone and related supplies (e.g., needles, etc.), breathalyzer, pulse oximeter, blood pressure monitor, oxygen, and bag valve mask.

Principle 1.3.4 The injection room surfaces and equipment must be cleaned with appropriate disinfectant at the beginning and end of each day, and between each patient use to prevent the spread of infection.

2.0 Receiving Injectable Hydromorphone Prescriptions

2.1 Controlled Prescription Program Forms – Overview

Principle 2.1.1 Injectable hydromorphone for maintenance prescriptions can only be accepted when written using an original Controlled Prescription Program form. When accepting prescriptions for injectable hydromorphone maintenance treatment, the iOAT trained pharmacist must ensure that the Controlled Prescription Program form is completed by the prescriber as outlined in the Controlled Prescription Program.

Note: A pharmacist does not have the independent authority to adapt a prescription for injectable hydromorphone maintenance treatment.

Principle 2.1.2 Injectable hydromorphone for maintenance prescriptions may only be received by facsimile in accordance with section 7(3) of the *Health Professions Act* Bylaws Schedule F, Part 1 - *Community Pharmacy Standards of Practice*. Verbal prescriptions for injectable hydromorphone maintenance treatment may be accepted where permitted under a section 56 exemption to the *Controlled Drugs and Substances Act* in accordance with section 19(6.1) of the bylaws to the *Pharmacy Operations and Drug Scheduling Act*.

3.0 Processing Injectable Hydromorphone Prescriptions

3.1 Assessment of a Prescription

Principle 3.1.1 Should a patient present a prescription for a mood altering drug, including benzodiazepines and opioids, or if the pharmacist discovers that a mood altering drug is also being prescribed to the patient in their review of the PharmaNet patient record, they must contact both the prescriber of injectable hydromorphone and, if different, the prescriber of the mood altering drug, prior to dispensing the medication. The pharmacist must document the outcome of the consultation(s) with the prescriber(s) and include it with the original prescription.

Guideline: Concurrent use of injectable hydromorphone with other depressants such as benzodiazepines is contraindicated, as combined effects can potentially result in fatal respiratory depression.

Note: Patients on injectable hydromorphone maintenance treatment are routinely co-prescribed other oral opioid agonist drugs. Consulting with prescribers ensures that they are aware that the patient is currently receiving injectable hydromorphone maintenance treatment.

3.2 PharmaNet Records

Principle 3.2.1 The prescribed injectable hydromorphone dose (in both mg and mL) and dose frequency must be entered in the 'sig' field for each patient on PharmaNet. Any injectable hydromorphone dose that has been processed but is not self-administered by the patient on the prescribed day is considered cancelled and must be reflected accurately on PharmaNet **before the end of the business day**.

Guideline: It is imperative that the PharmaNet patient record reflects accurate and current information in terms of self-administered injectable hydromorphone doses as other health professionals rely on this information in making treatment decisions.

Example: Patient presents a valid prescription for injectable hydromorphone for supervised injection, stating 125 mg three times daily. Using commercially prepared single use vials of 50mg/mL hydromorphone, each dose corresponds to 2.5mL. Each vial is 1mL. Therefore, 3 X 1mL vials are needed to prepare each dose.

In this example, the sig field should contain something similar to: '125mg (2.5mL) three times daily supervised injection'.

The patient is injecting a total of 7.5mL per day. However, three vials are needed to prepare each dose. So, the total amount dispensed would be 9mL.

At the end of the day, it is expected that the total quantity posted on PharmaNet accurately reflects what was dispensed. If this patient attended and received two doses but missed one, the total amount on PharmaNet at the end of the day should be 6mL.

When viewing patient profiles on PharmaNet, care must be taken to distinguish between dose prescribed and quantity dispensed, as there may be discrepancies between the two due to vial size and wastage from dose preparation.

4.0 Releasing Injectable Hydromorphone Prescriptions

4.1 Releasing a Prescription

Principle 4.1.1 An iOAT trained pharmacist must release the injectable hydromorphone dose to a patient. This function cannot be delegated to a pharmacy technician or any other pharmacy support staff.

4.2 Pre-Injection Assessment

Principle 4.2.1 Prior to releasing an injectable hydromorphone dose, an iOAT trained pharmacist must complete a pre-injection assessment of the patient to assess for signs of intoxication, including severe agitation, dyskinesia, sedation, slurred speech, or smelling of alcohol. The iOAT trained pharmacist who conducts this assessment must document this by signing a patient/prescription specific log. If the patient is intoxicated, the dose must be postponed or withheld and this must be documented and included with the original prescription. The prescriber must be notified.

Guideline: The sample *Pre-Injection Assessment Checklist* (Appendix 1) can be used for the pre-injection assessment. The sample *Injectable Hydromorphone Part-Fill Accountability Log* (Appendix 2) can be used for the patient/prescription specific log.

If the initial assessment results in suspicion of recent use of psychoactive substances, the iOAT trained pharmacist should discuss with the patient if they have consumed illegal or non-medical drugs (including any non-prescribed pharmaceutical drug) or alcohol. Where observation warrants further assessment for alcohol intoxication (e.g., slurred speech, unsteady gait, or smelling of alcohol), the iOAT trained pharmacist may administer breathalyzer testing to check that the patient's blood alcohol level does not exceed 0.05%.

Note: The BCCSU *Guidance for Injectable Opioid Agonist Treatment for Opioid Use Disorder* requires a minimum of three hours between doses.

4.3 Dose Preparation

Principle 4.3.1 If after the pre-injection assessment, the iOAT trained pharmacist deems the patient fit, the injectable hydromorphone dose may be prepared.

Principle 4.3.2 Best practices and established standards for preparing and handling injections must be followed.

Principle 4.3.3 Injectable hydromorphone for maintenance must be dispensed to patients as an approved, commercially available single-use vial formulation.

Principle 4.3.4 Single-use vial formulation allows only one needle puncture per vial. Any unused injectable hydromorphone remaining in the vial must be rendered unusable at the time of dose preparation according to Principle 4.3.6. This principle must be followed unless the preparation is done according to Principle 4.3.5.

Principle 4.3.5 Vials can be used for a maximum of two needle punctures when preparing syringes for the same patient (e.g., patient specific dose), only if the most recent version of NAPRA *Model Standards for Pharmacy Compounding of Non-hazardous Sterile Preparations* is followed. Any unused injectable hydromorphone remaining in the vial must be rendered unusable by the end of beyond-use date (BUD) according to Principle 4.3.6.

Note: NAPRA "Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations" requires that preparation be done in a primary engineering control (PEC) (e.g., laminar airflow workbench or

compounding aseptic isolator) that maintains ISO Class 5 air quality. Once the single-use vial is punctured in the PEC, the BUD of the drug remaining in the vial is ***6 hours***.

In addition to equipment, facility and BUD requirements noted above, it is important to note that there are numerous requirements outlined in the NAPRA "Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations" (i.e., labelling, personnel, policy and procedure requirements, etc.) which must be met to prepare the dose under Principle 4.3.5 to ensure patient safety. Otherwise, Principle 4.3.4 must be followed.

Principle 4.3.6 Prior to being rendered unusable as per Principles 4.3.4 or 4.3.5, any unused drug in vials from dose preparation must be documented in the patient/prescription specific log. A pharmacist and one other health professional must sign off on this drug destruction. This documentation must be kept in accordance with CPBC filing retention requirements. Empty vials must be disposed of in a secure container for sharps.

Guideline: The goal is to alter or denature the drug to such an extent that consumption has been rendered impossible or improbable. It should be readily apparent that the resulting product has been safely rendered unusable.

The sample *Injectable Hydromorphone Part-Fill Accountability Log* (Appendix 2) can be used for the patient/prescription specific log.

4.4 Prior to Releasing the Dose

Principle 4.4.1 Prior to releasing the injectable hydromorphone dose, the iOAT trained pharmacist must confirm the patient's identity against the original prescription and verify that the correct quantity of the dose has been prepared in the syringe.

Principle 4.4.2 The patient and iOAT trained pharmacist must acknowledge receipt by signing a patient/prescription specific log. Every part-fill dispensed must be accounted for. The patient/prescription specific log must be included with the original Controlled Prescription Program form. Once complete, it must be filed sequentially by the first prescription or transaction number assigned to the prescription. Every part-fill dispensed must be reviewable as a complete history on one document.

Guideline: The sample *Injectable Hydromorphone Part-Fill Accountability Log* (Appendix 2) can be used for this purpose. Neither the pharmacist nor the patient is permitted to pre-sign for future doses or backdate signing.

4.5 Supervised Injection

Principle 4.5.1 An iOAT trained pharmacist must supervise the patient self-administering the prepared dose of injectable hydromorphone, to address patient safety and potential drug diversion issues. An iOAT trained pharmacist must be physically present in the injection room and directly monitor the patient for the full duration of the self-administered injection. The patient must never be left unattended in the injection room.

Guideline: Patients may inject intravenously, intramuscularly, or subcutaneously. For safety reasons, it is recommended that intravenous injection only be allowed in the upper extremities (hands or arms, no jugular use is permitted), while intramuscular injections can be allowed in the deltoid, thighs, and gluteal muscles.

Under no circumstances may a registrant administer the dose of injectable hydromorphone to a patient.

Assisting a patient to self-administer an injection (for example, by steadying a patient's hand) may place a health professional at high risk of a needle-stick injury. Part of the ongoing assessment of the patient is ensuring their continued ability to safely self-administer an injection, and notifying the prescriber if the patient can no longer do so.

Principle 4.5.2 If for any reason the patient does not self-administer a full dose, the remaining drug in the syringe must be rendered unusable. A pharmacist and one other health professional must sign off on this drug destruction. This documentation must be kept in accordance with CPBC filing retention requirements. The iOAT trained pharmacist must estimate the amount of drug injected and note this on the patient/prescription specific log. The prescriber must also be notified.

Guideline: The goal is to alter or denature the drug to such an extent that consumption has been rendered impossible or improbable. It should be readily apparent that the resulting product has been safely rendered unusable.

The sample *Injectable Hydromorphone Part-Fill Accountability Log* (Appendix 2) can be used to document the amount of drug injected in the patient/prescription specific log.

Principle 4.5.3 An iOAT trained pharmacist must only supervise one patient self-administering a dose of hydromorphone at a time (i.e., a 1:1 pharmacist to patient) ratio. The 1:1 ratio is needed to better ensure effective overdose response and emergency management.

Guideline: Staffing needs of the pharmacy should be considered when providing injectable hydromorphone treatment. While an iOAT trained pharmacist is required to monitor patients self-administering the dose of hydromorphone, appropriate supervision of the pharmacy premise is also needed, in compliance with legislative requirements.

Principle 4.5.4 Any empty used syringes and needles must be immediately disposed of in a secure container for sharps in the injection room.

4.6 Post-Injection Assessment

Principle 4.6.1 Post-injection, the patient must stay in the pharmacy for a minimum of 15 minutes, and within view of an iOAT trained pharmacist. Any refusal must be documented and the prescriber must be notified. After 15 minutes has elapsed, the iOAT trained pharmacist must conduct a post-injection assessment, observing any signs of intoxication including dyskinesia, sedation, slurred speech, agitation, or decreased respiration rate. If adverse events are observed, the pharmacist must notify the prescriber. The iOAT trained pharmacist who conducts this assessment must document this by signing a patient/prescription specific log.

Guideline: The sample *Post-Injection Assessment Checklist* (Appendix 3) can be used for the post-injection assessment. The sample *Injectable Hydromorphone Part-Fill Accountability Log* (Appendix 2) can be used for the patient/prescription specific log.

While awaiting the post-injection period to elapse, the patient must remain within the view of an iOAT trained pharmacist. This may be in the separate injection room, a reception area or elsewhere within 25 feet from the perimeter of the dispensary.

If the patient seems to be intoxicated, a pulse oximeter and/or a vital sign assessment should be completed and documented. If at any time during the post-injection assessment the iOAT trained pharmacist determines that the patient requires medical attention, they should immediately call 911.

Principle 4.6.2 If after the post-injection assessment, the iOAT trained pharmacist deems the patient fit to leave the premises, then the patient may do so.

5.0 Security and Reconciliation

Principle 5.1.1 At the end of each day the secure container(s) for sharps must be kept in a locked area, such as a locked cage or cabinet that only registrants have access to.

Principle 5.1.2 At the end of each day, a count and reconciliation for injectable hydromorphone must be conducted and signed off on by a pharmacist and one other regulated health professional. This documentation must be kept in accordance with CPBC filing retention requirements.

Principle 5.1.3 The pharmacy must have a security camera in the injection room.

Guideline: Patients must be informed of the security camera, see *Professional Practice Policy 74 – Community Pharmacy Security* for more guidance.

6.0 Responding to Dosing Issues

6.1 Missed Doses

Principle 6.1.1 If a patient misses a dose, they cannot receive the missed dose at a later date.

Principle 6.1.2 The prescriber must be notified of any missed doses before the next supervised injection. The notification document must be retained and filed with the prescription consistent with filing retention requirements.

Guideline: The *Pharmacist-Prescriber Communication* form (Appendix 4) can be used for this purpose.

Principle 6.1.3 If a patient misses 9 consecutive sessions or 3 days (whichever is first), the prescription must be cancelled, and the prescriber notified of the cancellation. A new prescription is required for the next dose.

Appendix 1

Pre-Injection Assessment Checklist

Patient Name:	Assessment Date and Time:

Yes	No	Unknown	
☐	☐	☐	Severely anxious or agitated
☐	☐	☐	Dyskinetic
☐	☐	☐	Overly sedated
☐	☐	☐	Slurred speech
☐	☐	☐	Smells of alcohol

Baseline respiration rate: _____ breaths/minute

Pasero Opioid-induced Sedation Scale (POSS) level: _____

Breathalyzer required: ☐ Yes ☐ No

If yes, breathalyzer reading: _____

Notes:

Appendix 2

Injectable Hydromorphone Part-Fill Accountability Log

Patient Name:_____

Prescription Number:_____

Date	Time	Transaction Number	Prescribed Dose (mg and mL)	Total Volume Used to Prepare Dose (mL)	Wastage after Dose Preparation (mL)	Drug Destruction (Health Professional's Signatures)	Pre-Injection Assessment (Pharmacist's Initials)	Patient's Signature	Supervision (Pharmacist's Initials)	Post-Injection Assessment (Pharmacist's Initials)	Notes

Appendix 3

Post-Injection Assessment Checklist

Name:	Assessment Date and Time:

Yes	No	Unknown	
☐	☐	☐	Severely anxious or agitated
☐	☐	☐	Dyskinetic
☐	☐	☐	Overly sedated
☐	☐	☐	Slurred speech
☐	☐	☐	Smells of alcohol
☐	☐	☐	Decreased respiration rate

Respiration rate: _____

Pasero Opioid-induced Sedation Scale (POSS) level: _____

Notes:

Appendix 4

Pharmacist-Prescriber Communication

Date:_____ Patient Name:_____

To (Prescriber):_____ Patient PHN:_____

Fax: _____ Prescription Form Folio Number:_____

From (Pharmacy):_____ Pharmacy Fax:_____

Pharmacist:_____ Pharmacy Telephone:_____

For Prescriber's Information and Patient Records

❑ This patient missed their injectable hydromorphone dose(s) _____ (dates).

❑ This patient did not take their full AM dose(s) today _____ (date) and consumed only ____ mg/mL of the ____ mg/mL prescribed dose.

❑ This patient did not take their full PM dose(s) today _____ (date) and consumed only ____ mg/mL of the ____ mg/mL prescribed dose.

Additional Information/Other

You May Attach Controlled Prescription Form.

Notes:

College of Pharmacists of British Columbia

BOARD MEETING
March 23, 2020

6. PDAP Exemptions for CE Submissions During COVID-19

DECISIONS REQUIRED

Recommended Board Motions:

Motion 1:

In response to the State of Emergency due to the COVID-19 pandemic, that the Board of the College of Pharmacists of BC grant PDAP Exemptions for the remainder of 2020 registration renewal deadlines (March 2020 to December 2020).

Motion 2:

In response to the State of Emergency due to the COVID-19 pandemic, that the Board of the College of Pharmacists of BC grant PDAP Exemptions to all registrants in the non-practising category for less than 90 days and former registrants whose Full registration has expired for less than 90 days (late registration renewal) for the purposes of reinstatement.

Purpose

To seek direction from the Board regarding COVID-19 and Professional Development and Assessment Program (PDAP) exemptions for registration renewal, and reinstatement for all registrants in the non-practising category for less than 90 days and former registrants whose Full registration has expired for less than 90 days (late registration renewal) for the purposes of reinstatement.

Background

As part of the Quality Assurance Program, set out in the College's Health Professions Act Bylaws, continuing education is mandatory for all registered pharmacy professionals in order to renew their registration.

The College ensures pharmacy professionals meet the continuing education (CE) requirements through the Professional Development and Assessment Program (PDAP) which requires that each pharmacy professional must complete a minimum of 15 hours of continuing education each year, including a minimum of 5 hours of accredited learning.

Pharmacy professionals who wish to reinstate from the non-practising category for less than 90 days and former registrants whose Full registration has expired for less than 90 days (late registration renewal) for the purposes of reinstatement, are required to complete their yearly CE requirements prior to applying for full registration.

Discussion

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 situation regarding COVID-19 continues to evolve here in BC, Canada and other jurisdictions in the world and as health care professionals, pharmacists and pharmacy technicians are playing a big role in meeting patient needs.

During the last few days, the College has received PDAP Exemption requests from renewing pharmacy professionals and former registrants whose Full registration has expired for less than 90 days (late registration renewal) who wish to re-instate. Currently, PDAP Exemptions are only granted if the pharmacy professional is excluded from practice due to medical, maternity/parental or compassionate care leave during their registration renewal deadline or for at least 6 months during their renewal year.

Below are some factors for the Board to consider:

Availability of CE

- In response to COVID-19, in-person CE courses and programs are being cancelled
- There are CE courses and programs available online however they may not meet the learning needs of pharmacy professionals

COVID-19 and the Impact on Pharmacy Professionals Practice

- Pharmacy professionals remain essential to the health care system and are required for more assistance during this pandemic. Pharmacy professionals have an important role to play in helping patients avoid non-essential visits, this includes providing deliveries, ensuring appropriate supply of medications and encouraging social distancing
    - The College has received many requests on how a non-practising registrant or a former registrant less than 90 days in the former category can be expedited to be registered to assist pharmacies.

- Practice changes are occurring daily adding strain to already stretched resources at pharmacies
    - On March 16, 2020, in a joint statement on B.C.'s COVID-19 response, Minister of Health, Adrian Dix and B.C. Provincial Health Officer, Dr. Bonnie Henry announced that patients will be able to obtain refills of their regular prescriptions at pharmacies in an effort to avoid non-essential physician visits and free doctors to treat COVID-19 cases.
    - On March 17, 2020, the new delivery requirements for Opioid Agonist Treatment were in effect, allowing pharmacists to use their professional judgement to deliver the drugs to a patient if they feel it is safe, appropriate and in the best interest of the patient to do so.

PDAP Exemption Impact for Registration Renewal

- Pharmacy professionals who receive PDAP Exemptions are required to complete PDAP requirements prior to their next yearly registration renewal deadline
- The below table summarizes the number of pharmacy professionals that still need to complete PDAP requirements for the 2020 calendar year as of March 19, 2020

Renewal Deadline	PDAP Requirements Met	PDAP Requirements Not Met	Total Number of Registrants
March	96	147	243
April	53	327	380
May	60	757	817
June	70	1647	1717
July	34	1318	1352
August	4	312	316
September	7	247	254
October	2	257	259
November	4	634	638
December	1	655	656

PDAP Exemption Impact for registrants in the non-practising category for less than 90 days and former registrants whose Full registration has expired for less than 90 days (late registration renewal) for the purposes of reinstatement

- Pharmacy professionals who receive PDAP Exemptions are required to complete PDAP requirements prior to their next yearly registration renewal deadline

- Currently there are 9 pharmacy professionals in the non-practising category for less than 90 days and 63 pharmacy professionals whose Full registration has expired for less than 90 days (late registration renewal)

Options for Registration Renewal

It is proposed that the Board direct which of three approaches to COVID-19 and PDAP Exemptions to implement for registration renewal:

Option 1
In response to COVID-19, grant PDAP Exemptions for the remainder of 2020 registration renewal deadlines (March 2020 to December 2020).

Option 2
In response to COVID-19, grant PDAP Exemptions for March 2020, April 2020 and May 2020 registration renewal deadlines.

Option 3
No change to PDAP Exemptions. PDAP Exemptions are only granted if the pharmacy professional is excluded from practice due to medical, maternity/parental or compassionate care leave during their registration renewal deadline or for at least 6 months during their renewal year.

Options for Reinstating

It is proposed that the Board determine which of two approaches to COVID-19 and PDAP Exemptions to implement for return to practice (non-practising registrants and registrants in the former category for less than 90 days):

Option 1
In response to COVID-19, grant PDAP Exemptions to all registrants in the non-practising category for less than 90 days and former registrants whose Full registration has expired for less than 90 days (late registration renewal) for the purposes of reinstatement.

Option 2
No change to PDAP Exemptions. PDAP Exemptions are only granted if the pharmacy professional is excluded from practice due to medical, maternity/parental or compassionate care leave during their registration renewal deadline or for at least 6 months during their renewal year.
(this means all registrants in the non-practising category for less than 90 days and former registrants whose Full registration has expired for less than 90 days (late registration renewal) for the purposes of reinstatement must complete the current CE requirements for the PDAP pursuant to the HPA bylaws).

Recommendation

The College recommends that the Board choose Option 1 for registration renewal and Option 1 for all registrants in the non-practising category for less than 90 days and former registrants whose Full registration has expired for less than 90 days (late registration renewal) for the purposes of reinstatement because:

- The situation regarding COVID-19 continues to evolve here in BC, Canada and other jurisdictions in the world and pharmacists and pharmacy technicians are playing a big role in meeting patient needs
- Pharmacy professionals practices are being impacted daily – they need to focus on their practices and patient care
- In-person CE courses and programs are being cancelled
- Those who receive the exemption will be required to complete PDAP requirements prior to their next yearly registration renewal deadline