College of Pharmacists
of British Columbia

Professional Practice Policy #66

Policy Guide

Buprenorphine/Naloxone Maintenance Treatment (2018)

Buprenorphine/Naloxone Maintenance Treatment Policy Guide

Opioid use disorder is a health concern with implications for the individual patient as well as the public. The choice of opioid agonist treatment (OAT) for opioid use disorder (OUD) is an individually tailored process whereby clinicians discuss the risks and benefits of all three oral OAT options (i.e. methadone, buprenorphine/naloxone and slow-release oral morphine) with patients and taking a patient-centred approach, collaboratively select a medication that aligns with the patient's goals, treatment history and other individual circumstances. Opioid use disorder is recognized as a chronic relapsing condition. Opioid agonist treatment is recommended as the standard of care for people with OUD.

Buprenorphine is a partial opioid agonist that is available as a combined formulation with naloxone. The naloxone component is added to prevent injection use or insufflation. Compared to placebo, a 2014 meta-analysis has shown that buprenorphine at doses higher than 2 mg/day has significantly higher rates of treatment retention and at doses higher than 16 mg/day, significantly more effective suppression of unregulated opioid use.

The College of Pharmacists of British Columbia (CPBC) *Professional Practice Policy (PPP-66) – Opioid Agonist Treatment (*see Appendix 3 for a link to this *document)* requires 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 British Columbia (CPBC) *Buprenorphine/Naloxone Maintenance Treatment Policy Guide (BMT Policy Guide 2018)* and all subsequent revisions.
The responsibility of pharmacy technicians in the dispensing of BMT is consistent with their scope of practice outlined in the *Health Professions Act* (HPA) Bylaws Schedule F Part 1 section 4.

How to Use This Guide

The BMT Policy Guide is to be read in conjunction with *PPP-66 – Opioid Agonist Treatment.* The intention of the BMT 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 buprenorphine/naloxone maintenance treatment services. In addition to PPP-66 and the BMT Policy Guide, evidence-based recommendations and clinical guidance can be found in the British Columbia Centre on Substance Use (BCCSU) *A Guideline for the Clinical Management of Opioid Use Disorder*.

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

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

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 a Controlled Prescription Program (CPP) 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. The pharmacist must ensure that the patient signs the bottom of the form in the space indicated. See Principle 4.1.3 for signing procedures when releasing a buprenorphine/naloxone prescription.

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. A CPP form can only be accepted by facsimile during a public health emergency declared by the Provincial Health Officer. This includes the ongoing Overdose Crisis declared under the *Public Health Act*.

Buprenorphine/naloxone prescriptions may only be accepted **verbally** 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*. The pharmacy must receive either the original or a faxed copy of the CPP form from the prescriber as soon as reasonably possible.

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.

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 performed by a pharmacy technician or any other pharmacy support staff, unless permitted by a section 56 exemption to the *Controlled Drugs and Substances Act*. Pharmacists are responsible for confirming whether such a section 56 exemption exists at the time of release.

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. 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* (see 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 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 10-15 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 10-15 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 packaging 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 help patients manage their medication and reduce confusion about dosing. 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 dose that has been processed and prepared but is not consumed or picked up by the patient on the prescribed day is considered missed and must be reversed in 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 Missed doses can contribute to a loss of tolerance to buprenorphine and dose adjustment and re-stabilization by the prescriber may be required.

If a patient misses 6 or more consecutive days, without return to full opioid agonist use, the prescription must be cancelled, and the prescriber notified. If there are 5 or fewer consecutive once-daily missed doses, without return to full opioid agonist use, do not cancel. The patient can resume the previous dose of buprenorphine/naloxone.

If a patient misses 4 or more consecutive days, with return to full opioid agonist use, the prescription must be cancelled, and the prescriber notified. If there are 3 or fewer consecutive once-daily missed doses, with return to full opioid agonist use, do not cancel the prescription. The patient can resume the previous dose of buprenorphine/naloxone.

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

Guideline: As referenced in Section 4.0, Releasing Buprenorphine/ Naloxone Prescriptions, prior to releasing a buprenorphine/naloxone prescription, the pharmacist should assess the patient to determine if they are in any acute clinical condition that would put them at risk of an adverse event. The pharmacist should discuss the risks of precipitated withdrawal with the patient, if appropriate and necessary. If the pharmacist believes it is not safe for the patient to receive their prescription they must consult with the prescriber.

For further information about buprenorphine/naloxone missed doses, see the most recent version of the BCCSU *A Guideline for the Clinical Management of Opioid Use Disorder* - Appendix 3: Titration 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 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

Appendix 3

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 4

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