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 if 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.

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		

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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.