Sufentanil

Prescribed Safer Supply Protocols

BRITISH COLUMBIA
BRITISH COLUMBIA CENTRE ON SUBSTANCE USE
Networking researchers, educators & care providers
phs COMMUNITY SERVICES SOCIETY

Land Acknowledgement

The British Columbia Centre on Substance Use would like to respectfully acknowledge that the land on which the BCCSU is situated is the unceded homelands of the Coast Salish Peoples, including the territories of the xʷməθkwəy̓əm (Musqueam), Sḵwx̱wú7mesh (Squamish), and səlililwətaʔɬ (Tsleil-Waututh) Nations. We would also like to recognize that our work and partnerships are provincial in nature and take place across the province, including on the traditional homelands of the 198 distinct First Nations in BC. We recognize that the ongoing criminalization, institutionalization, and discrimination against people who use drugs disproportionately harm Indigenous peoples, and that continuous efforts are needed to dismantle colonial systems of oppression. We see our work connected to these efforts and hope that this protocol contributes to an addiction care system that provides safe, respectful, evidence-based care.

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About the BC Centre on Substance Use

The BC Centre on Substance Use (BCCSU) is a provincially networked organization with a mandate to develop, help implement, and evaluate evidence-based approaches to substance use and addiction. The BCCSU seeks to improve the integration of best practices and care across the continuum of substance use through the collaborative development of evidence-based policies, guidelines, and standards. With the support of the Province of BC, the BCCSU aims to transform substance use policies and care by translating research into education and care guidance, thereby serving all British Columbians. The BCCSU seeks to achieve these goals through integrated activities of its three core functions: research and evaluation, education and training, and clinical care guidance.

Research and Evaluation—Leading an innovative multidisciplinary program of research, monitoring, evaluation and quality improvement activities to guide health system improvements in the area of substance use.
Education and Training—Strengthening addiction medicine education activities across disciplines, academic institutions, and health authorities, and training the next generation of interdisciplinary leaders in addiction medicine.
Clinical Care Guidance—Developing and helping implement evidence-based clinical practice guidelines, treatment pathways, and other practice support documents.

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1.0 Introduction

1.1 Background

In July 2021, the Ministry of Mental Health and Addictions, Ministry of Health, and Office of the Provincial Health Officer released *Access to Prescribed Safer Supply in British Columbia: Policy Direction*, which enables individuals to access a range of medications through prescription to reduce the risk of drug toxicity death due to accessing the unregulated drug supply. The first phase of implementation of this policy focused on the medications included in the *Risk Mitigation in the Context of Dual Health Emergencies: Interim Clinical Guidance* to reduce harms associated with accessing the unregulated opioid and stimulant supply, through the development and publication of the BCCSU's *Opioid Use Disorder: Practice Update* and *Stimulant Use Disorder: Practice Update*, while other novel pilot programs funded by Health Canada (e.g., SAFER) trialed other medications that are being carefully evaluated, including sufentanil. Prescribed safer supply is not intended for treatment of substance use disorders; rather, it is a harm reduction approach for reducing the risks of unregulated drug toxicity events and deaths.

This document provides a standardized protocol for the provision of sufentanil as a way to reduce reliance on the unregulated drug supply and associated harms. Provision of other medications for harm reduction is outside the scope of this document. See the BCCSU's *Risk Mitigation in Dual Health Crises: Interim Clinical Guidance* for guidance on supporting individuals who use drugs to self-isolate or quarantine due to COVID-19; the BCCSU's *Opioid Use Disorder Practice Update* for information on prescribing hydromorphone, and/or sustained-release oral morphine (M-Eslon) to help reduce individuals' reliance on the unregulated drug supply and, thus, overdose risk; and the BCCSU's forthcoming Stimulant Use Disorder Practice Update for information on trialing stimulant prescribing to help reduce individuals' reliance on the unregulated drug supply and related harms.

This protocol is adapted from PHS Community Services Society's Sufentanil Policy.

1.2 Evidence Supporting this Intervention

Providing sufentanil to reduce harms associated with unregulated opioid use is not an evidence-based intervention. To date, there is no evidence available supporting this intervention, safety data, or established best practices for when and how to provide it. In response to continued and accelerated toxicity of the unregulated drug supply, this protocol is informed by current clinical practice and emerging evidence to provide standardized guidance for the off-

label use of sufentanil to help reduce unregulated fentanyl use and associated harms. This protocol is based on clinical experiences at PHS Community Services Society, InSite Supervised Consumption Site, and AVI Health and Community Services' Victoria SAFER Initiative with evaluation of this novel intervention underway in these locations.

1.3 How to Use this Document

This protocol offers the clinical foundations and medico-legal considerations for the provision of sufentanil.

It is imperative for each program and health authority to meaningfully engage with people who use drugs (PWUD), PWUD organizations, and family groups in the community via consultation and engagement in program design.

1.4 Planned Review

As this is a new and emerging practice, this protocol will be regularly reviewed and updated to align with emerging evidence and additional clinical experience. The next planned review period for this protocol begins in January 2024.

2.0 Program Models

Implementation of the Ministry of Health & Ministry of Mental Health and Addictions' *Access to Prescribed Safer Supply in British Columbia—Policy Direction* includes provision of sufentanil programs through regional health authority-operated/funded programs and federally funded programs (e.g., SAFER). This may include adding sufentanil provision to a variety of existing programs and services, including opioid agonist treatment (OAT), injectable opioid agonist treatment (iOAT), and overdose prevention/supervised consumption sites. Sufentanil programs can be administered concurrently with OAT (both methadone and slow-release oral morphine are acceptable). As with all substance use care, care plans should be individually tailored to each client's situation, needs, and goals, and may include offering OAT, psychosocial interventions and supports, harm reduction education and supplies, prescribed safer supply, or a combination of any of these. For individuals seeking prescribed safer supply, education should be offered about the benefits of a combined long-acting and short-acting approach. Access and adherence to OAT should not be made a condition of the sufentanil program.

2.1 Dosing Strategies

Sufentanil can be offered as an **as-needed (PRN) program** at 50–250mcg sublingual (SL) or intravenous/intramuscular (IV/IM) every 1 hour (Q1H), up to participant's desired dose and as hours of operation allow.

2.2. Two-prescriber Approval

Each program may determine the most appropriate evaluation and approval process, based on resources and participant needs. Some programs may use two-prescriber approval, in which one prescriber conducts the intake and a second prescriber reviews the participant's chart and signs off on the participant initiating sufentanil. Given the novel nature of this program, the two-prescriber approval system can help ensure participant safety. Although a two-prescriber approval system is highly recommended, it may not be possible in all treatment settings, and should not delay initiation of the program. Consultation with the BCCSU 24/7 Line may be useful where operational limitations exist for two-prescriber review.

2.3. Regional Adaptation

This document is meant to provide a standardized protocol for the provision of sufentanil. However,

certain contexts (e.g., rural and remote) may need to adapt the protocols to their regional contexts based on capacity, resources, and geographic realities in order to reduce barriers to access. Any such adaptations should balance individual patient access, public safety, and clinical judgment. See Appendix 10: Operational Considerations for program operation considerations.

3.0 Eligibility

The following considerations for eligibility should be assessed and documented in the participant's health record:

- Active opioid use disorder diagnosis (OUD; see note below)

AND

- Ongoing active unregulated fentanyl use
    - **For injection program only:** Ongoing injection fentanyl use

AND

- At high risk of overdose, injection-related harms, or other harms related to the use of unregulated opioids via a detailed clinical assessment including overdose history

Note: There may be some individuals who have not been diagnosed with an OUD, who use unregulated fentanyl and would benefit from accessing prescribed safer supply. The sufentanil PRN program may be appropriate for these individuals, based on clinical judgment and individual circumstances.

It is not a requirement for individuals to have trialed OAT (oral and/or injectable) to be considered for the sufentanil program; however, prescribers should explore all options with participants, including evidence-based pharmacotherapy and psychosocial treatment supports, in an ongoing manner.

For participants who are youth age <19 years, two-prescriber approval is strongly recommended.

3.1 Assessment

Assessment for eligibility should include the following:

- Substance use assessment (i.e., type of substance, quantity used, frequency of use, route of administration)
- Substance use and treatment history
    - Including previous oral OAT and iOAT trials (e.g., dosage, duration on treatment)

as well as psychosocial treatment interventions and harm reduction programming, including other types of safer supply

- History of overdose and other drug-related harms (e.g., criminalization)
- History of injection-related harms (e.g., abscess, infection, scarring)
- Comorbid mental and physical health conditions
- Prescribed and non-prescribed medication(s)
  - See drug–drug interactions below
- Urine drug test (positive for fentanyl) within the last 2 weeks
  - Urine drug test may be waived based on clinical discretion if:
    - The participant is known to the clinician/staff/program
    - There is objective evidence of fentanyl use
    - There is sufficient collateral information
    - The decision to waive urine drug test has been documented
- Baseline liver and renal function tests completed within the last 3 months and reviewed
- Precautions (see below)
- Contraindications (see below)

If another physician or nurse practitioner in the community follows the participant, that clinician should be updated prior to starting the sufentanil program, with the consent of the participant to do so.

Seek consent from the individual to complete a PharmaNet/Medinet medication profile search to verify current medication regimen, including concurrent prescribing of sedatives.

If the person is receiving medications from a community pharmacy, the pharmacy should be consulted, in addition to any other physicians or practitioners who follows the participant in community, especially to review drug–drug interactions.

Depending on the results of the eligibility assessment, a second prescriber review may be necessary. See Precautions, below.

3.2 Contraindications

The following conditions preclude an individual from being eligible for the sufentanil program:

- No history of opioid use
- Opioid non-tolerance as evidenced by a negative urine drug test, no past history of OAT confirmed through PharmaNet search, and no documentation of witnessed consumption

- Opioid use disorder without fentanyl use. Assess what the participant is using and offer OAT and psychosocial treatment interventions and/or more applicable pharmaceutical alternatives. Refer to the BCCSU's *Opioid Use Disorder Practice Update* for guidance on prescribing hydromorphone and/or sustained-release oral morphine as an alternative to the unregulated supply.
- Hypersensitivity to the active substance, sufentanil citrate, or other opioid analgesics or to any ingredient in the formulation. For a complete listing, see the DOSAGE FORMS, COMPOSITION AND PACKAGING section of the Product Monograph.[a] Anaphylaxis and hypersensitivity have been reported in association with the use of oral transmucosal fentanyl products
- Any disabling medical or mental health condition as assessed by medical history, physical exam, vital signs and/or laboratory assessment that, in the opinion of the prescriber, precludes the safe participation or the ability to provide fully informed consent, including[b]:
    - Acute respiratory depression, elevated carbon dioxide levels in the blood, and cor pulmonale
    - Acute or severe uncontrolled bronchial asthma, chronic obstructive airway, or status asthmaticus.
    - Known or suspected acute mechanical gastrointestinal obstruction (e.g., bowel obstruction, strictures) or any diseases/conditions that affect bowel transit (e.g., ileus of any type)
    - Suspected surgical abdomen (e.g., acute appendicitis, pancreatitis)
    - Acute delirium tremens and convulsive disorders
    - Severe acute head injury
    - Current or recent (<14 days) monoamine oxidase inhibitors (MAOI) or serotonin-precursors (e.g., as L-tryptophan, oxitriptan)
- Pregnancy
    - There may be exceptional circumstances in which this intervention would be appropriate for a pregnant person. Two-prescriber review is highly recommended for pregnant individuals.
    - Consultation with a perinatal addiction specialist is encouraged but not required.
    - The 24/7 Addiction Medicine Clinician Support Line provides telephone consultation to physicians, nurse practitioners, nurses, midwives, and pharmacists who are involved in addiction and substance use care and treatment in British Columbia. This service extends beyond clinicians and provides addiction medicine guidance to any addiction support staff calling from Indigenous communities within BC. Call 778-945-7619 for support.

[a] Sandoz Canada Incorporated. Product Monograph: Sufentanil citrate injection USP. Boucherville, Quebec 2018. https://www.sandoz.ca/sites/www.sandoz.ca/files/9567-Sufentanil%20Citrate%20Injection%20Product%20Monograph.pdf.

- Rapid Access to Consultative Expertise (RACE) for Addictions is available Monday to Friday 8:00am-5:00pm for additional consultation and support for physicians and nurse practitioners

If any of these contraindications newly arise during care, the prescriber should be notified immediately and the care plan reassessed.

3.3 Precautions

If any of the following precautions are identified during the assessment process, they should be documented and a second prescriber should review. The second prescriber review, discussion, and final decision should be documented.

- Youth (<19 years of age)
- Active use of benzodiazepine, alcohol, or other CNS depressant (i.e., gabapentin, dimenhydrinate, etc.). Use of alcohol or benzodiazepines should not result in an automatic disqualification from sufentanil prescribing, but rather it should prompt more in-depth assessment and implementation/documentation of safeguards in place.[b]
  - Individuals intentionally using unregulated and/or prescribed benzodiazepines should be considered separately from those who are unintentionally exposed via contaminated drug supply
    - Clinical judgment should be used, with safety prioritized, when considering this intervention for individuals who intentionally use unregulated benzodiazepines and meet criteria for a moderate to severe benzodiazepine use disorder
    - For individuals who are unintentionally exposed to benzodiazepines through the contaminated drug supply,[c] it may be reasonable to start the program, as long as the participant is not sedated
  - Consider sending UDT for confirmatory testing, as etizolam and other benzodiazepine analogues may not be detected by point-of-care testing
    - See the BCCSU's *Urine Drug Testing—Breakout Resource* for more information on urine drug testing
- Any acute or chronic medical condition that may make this intervention unsafe
  - Examples of acute conditions: hepatic/renal/cardiac failure, injection-related infections (i.e. cellulitis, sepsis, osteomyelitis, infectious endocarditis), recent head injury

[b] Note: Clinical experience at AVI SAFER shows that, with proper safeguards and a modified titration plan/post-dose observation plan, prescribed sufentanil can be effective and safe for people who also drink alcohol.
[c] See "Benzodiazepines and Opioids" for guidance on providing care to individuals who have been exposed to benzodiazepines through the use of adulterated opioids.

    - Examples of chronic conditions: heart disease, liver cirrhosis, kidney failure, cognitive impairments, dementia, severe mental illness
- Anti-retroviral (ARV) medications (due to potential drug–drug interactions [see Special Caution], below)
- Certain drug–drug interactions (see below)
- Frailty (assess using the Clinical Frailty Scale)
- Driving a vehicle or operating heavy machinery
    - For individuals whose work or other obligations require them to drive or operate machinery, document their assessment findings and offer education on why driving is contraindicated while accessing the program
    - Prescribers should be familiar with the *Canadian Council of Motor Transport Administrators Medical Standards with B.C. Specific Guidelines*, as they pertain to individuals with substance use disorders

If any of these precautions newly arise during care, the prescriber should be notified immediately and the care plan reassessed.

3.4 Drug–drug Interactions

The following list of drug–drug interactions is based on the product monograph for sufentanil.[d] The examples within each category should not be considered comprehensive; prescribers should consult the product monograph of any drug co-administered with sufentanil and other sources of information on drug–drug interactions, including a pharmacist.

- CNS depressants (refer to 3.3 Precautions, above)
    - Participants should be warned of the risk of combining multiple CNS depressants and if a new medication is initiated, a dose reduction should be considered
    - Participants should be carefully monitored during the titration phase to prevent oversedation, with considerations of a slower titration process if there are multiple potential concerns
- CYP3A4 inhibitors
    - The concomitant use of drugs that inhibit CYP3A4 metabolizing enzymes (e.g., clarithromycin, fluconazole, erythromycin, certain antiretrovirals—see below) may result in an increase in sufentanil plasma concentrations
    - Concomitant use of CYP3A4 inhibitors is not recommended, unless participant is closely monitored

[d] Sandoz Canada Incorporated. Product Monograph: Sufentanil citrate injection USP. Boucherville, Quebec 2018. https://www.sandoz.ca/sites/www.sandoz.ca/files/9567-Sufentanil%20Citrate%20Injection%20Product%20Monograph.pdf.

- CYP3A4 inducers
  - The concomitant use of drugs that induce CYP3A4 metabolizing enzymes (e.g., carbamazepine, phenytoin, rifampicin) may reduce the efficacy of sufentanil requiring a dose adjustment
  - After stopping treatment with a CYP3A4 inducer, the effects of the inducer will decline gradually, which may result in an increase in sufentanil plasma concentration
- MAO inhibitors
  - Sufentanil is contraindicated in participants taking MAOIs or within 14 days of use due to the risk of serotonin syndrome
- Serotonergic drugs
  - Concomitant use of a serotonergic agent, such as a selective serotonin re-uptake inhibitor (SSRI) or serotonin norepinephrine re-uptake inhibitor (SNRI) may increase the risk of serotonin syndrome
  - Use caution and monitor the participant closely if co-prescribed
- Opioids
  - Co-occurring opioid use can lead to CNS depression or, in some cases, serotonin syndrome
    - If co-prescribing OAT, either methadone or slow-release oral morphine is acceptable.
  - Partial agonists (e.g., buprenorphine) may induce withdrawal symptoms in individuals on sufentanil, due to their high affinity for opioid receptors and low intrinsic activity
- Opioid antagonists
  - Opioid antagonists (e.g., naltrexone, naloxone) can precipitate withdrawal in individuals on sufentanil
- Muscle relaxants
  - Concomitant use may lead to respiratory depression
  - Monitor participant to prevent oversedation, with considerations of a slower titration process and/or decrease dosage of sufentanil or muscle relaxant if there are multiple potential concerns
- Diuretics
  - Opioids can reduce the efficacy of diuretics
  - Monitor participant for signs of diminished diuresis or effects on blood pressure
- Anticholinergic drugs
  - Concomitant use may increase risk of urinary retention and/or severe constipation
  - Monitor participant for signs of urinary retention or reduced gastric motility
- Beta-blockers
  - Concomitant use may lead to bradycardia
  - Monitor participant for signs of bradycardia

SPECIAL CAUTION—Antiretoviral medications

There is a strong interaction between sufentanil and some antiretroviral (ARV) drugs used for HIV treatment. Certain ARV products, particularly those containing the "boosters" cobicistat or ritonavir, inhibit CYP3A4, which can lead to significant increases in sufentanil levels. These ARVs include combination tablets with elvitegravir-cobicistat (Stribild, Genvoya), darunavir-cobicistat (Prezcobix, Symtuza) and lopinavir-ritonavir (Kaletra), all ritonavir-boosted protease inhibitors, and unboosted atazanavir.

Individuals who are stable on a potentially-interacting ARV regimen may be started on sufentanil if they meet the above eligibility criteria; however, sufentanil titration should be slower than for other participants, and participants must be monitored closely for sedation. Switching to bictegravir-emtricitabine-tenofovir alafenamide (Biktarvy) helps to avoid drug–drug interaction between sufentanil and ARV regimen. Prescribers should weigh the risks and benefits of ARV change before initiating the switch, in consultation with the HIV physician or pharmacist.

In individuals who take potentially-interacting ARVs, and who might stop and restart ARVs without medical supervision, or who often miss ARV doses, starting sufentanil is not recommended, due to the risk of fluctuating fentanyl levels. Consider alternatives to sufentanil or reviewing for potential ARV regimen modification to avoid drug–drug interactions.

Individuals currently using sufentanil are at risk of fentanyl toxicity if they start an ARV regimen including cobicistat or ritonavir. Modify the ARV regimen to avoid drug–drug interactions or monitor closely for fentanyl toxicity and reduce the sufentanil dose as required.

If an individual has already been stabilized on sufentanil in combination with cobicistat or ritonavir, and the ARV regimen is subsequently changed to remove cobicistat/ritonavir, a fentanyl dose adjustment may be needed to manage opioid withdrawal symptoms.

A clinician who specializes in HIV care should be consulted prior to initiating or changing ARVs.

If any of these drug–drug interactions newly arise during care, notify the prescriber immediately.

3.5 Adverse Events

Sufentanil may result in the following adverse events:

- Skeletal muscle rigidity: IV administration of sufentanil may cause skeletal muscle rigidity, particularly of the truncal muscles
- Hypotension
- Hypertension
- Bradycardia

4.0 Coverage

Sufentanil does not require Special Authority coverage. This is a regular benefit drug and coverage is available through PharmaCare Plans, including Fair PharmaCare, Plan G, Plan C, and Plan W.

5.0 Procedures

The procedures outlined in this section are based on limited clinical experience to date and may be updated as clinical experience increases.

5.1 Informed Consent

The informed consent process should include a discussion and documentation of the potential risks and benefits of prescribed sufentanil as a safer supply option, a discussion of the absence of evidence supporting this approach, and a discussion of continuing care and harm reduction education. This should include a clear explanation that their access to this novel intervention will likely be impossible if they are discharged, hospitalized, incarcerated, attending withdrawal management or substance use treatment facilities, or otherwise unable to attend the clinic.

Programs are encouraged to develop pathways with other community services so that continuity of care and contingency planning can be prioritized. It is also important to develop clear guidance on what to do when participants are unable to attend the program for extended periods of time due to illness or injury.

There are currently no programs offering take-home sufentanil. As clinical experience grows, this option may be explored in the future.

The informed consent process should also include a discussion of the participant's goals, as well as which clinical and psychosocial parameters would indicate that the participant is benefitting from the intervention, and which clinical and psychosocial parameters would indicate that the participant is not benefitting from the intervention, and how the treatment plan would change if the participant is not benefitting. See Appendix 3: Ongoing Monitoring—Participant Benefit Assessment (EMR Typing Template) for more information on clinical and psychosocial parameters indicating benefit.

Prescribers should also provide education on the risk of ingesting multiple CNS depressants (e.g., opioids and benzodiazepines or alcohol).

5.2 Pre-initiation Checklist

Before administering the first dose, and following confirmation of eligibility and coverage, the

following pre-application checklist must be completed by a prescriber or non-prescriber regulated health professional working within their scope and capability:

- ☐ Discuss and document participant's goals
- ☐ Discuss and document agreed upon indicators that they are benefitting and should continue to receive this intervention (see 7.0 Assessment, Continuing Care, and Program Evaluation for a list of indicators)
- ☐ Review and signature of program consent form, including consent for PharmaNet review and contacting other health providers, if applicable
    - **Note:** Requiring a signed consent form can constitute a barrier for some individuals. In these cases, clinical judgment may determine that documentation of consent process is sufficient
- ☐ Confirmatory urine drug test positive for fentanyl and negative for benzodiazepines
    - **Note:** Given increased adulteration of the unregulated drug supply, individuals may be unintentionally exposed to benzodiazepines and benzodiazepine analogues. A urine drug test positive for benzodiazepines must be discussed with the prescriber prior to initiating this intervention (see 3.3 Precautions above for more information)
    - There may be exceptions to the urine drug test requirement for program eligibility (see 3.1 Assessment).
- ☐ Confirmation of route of use
    - Confirm injection drug use for the injectable program
    - Individuals who smoke/inhale unregulated opioids can receive sufentanil sublingually
- ☐ Negative urine pregnancy test (if applicable)—if the test result is positive, two-prescriber review, approval, and documentation prior to initiation are strongly encouraged. Consultation with perinatal addiction specialist through the RACE line is encouraged but not required.
- ☐ Baseline vital signs and weight
- ☐ PharmaNet review (check for benzodiazepines, any prescribed medication from other prescribers, OAT)
- ☐ Provide education regarding potency of sufentanil and inherent significant risk to those without opioid tolerance (including other adults, children, and pets)
- ☐ Confirm baseline liver and renal bloodwork results within past 3 months that have been reviewed by prescriber (not a requirement, but a consideration with other comorbidities)
- ☐ Before writing prescription, confirm provincial drug coverage and address any barriers to coverage prior to beginning sufentanil

- ☐ Confirm participant has had overdose training and received a take-home naloxone kit
- ☐ If participant receives OAT at another pharmacy, ensure the pharmacy has been notified that their patient is beginning the sufentanil program, to avoid discontinuation of their OAT
- ☐ If other potential drug–drug interactions have been identified and a decision has been made to proceed, then indicating that the other medication can still be dispensed on each prescription will prevent delays caused by the pharmacy contacting the primary prescriber
    - e.g., "Aware of potential drug interaction between x and y, OK to dispense."
- ☐ Provide education on sufentanil and program requirements (see box below). Education and support for injections should be offered to participants prior to giving the dose as part of the nurse's assessment.

Important points to discuss with participants before starting the sufentanil program

- Nurses may support participants through coaching, helping to landmark, and helping with injection technique.
- Standard protocols for IV/IM injection including rotating sites and matching site to volume of medication should be followed.
- Participants initially choose the route of administration and may select a different route during the course of the program.
- If there is sedation after the initial test dose, the participant will not be eligible to continue with this program and must be reassessed by their prescriber.
- Any program-specific constraints that may impact participant access to sufentanil including hours of operation and capacity limits.

5.3 Initiation

Each participant will go through an observed test dose to initiate the program. **The participant must choose the route of administration when starting (i.e., IV/IM or SL), and the prescriber will specify the route of administration on the prescription.** If a participant would like to change the route of administration after starting the program, refer to Routes of Administration.

The participant will receive an initial test dosage of 50mcg via chosen route (i.e., IV/IM or SL), followed by a 10-minute post-dose observation period.

a. If there is sedation after the first dose (i.e., SAFER Sedation Scale [SSS] score >2; see Appendix 4), the participant is not eligible for this program and must see a prescriber (see 5.2 Sedation and Post-Dose Observation). The prescriber should reassess the individual's drug use history and UDT result and create a new clinical plan. Consider recent prescribed or unregulated substance use when considering tolerance in these situations.
b. If there is no sedation (i.e., SSS score ≤2) after 10 minutes of receiving the first dose, the participant can access an additional dose of 50mcg, if desired, followed by another 10-minute post-dose observation. The participant may continue on 50mcg Q1H PRN dosing or increase to 100mcg, depending on their reaction. The prescriber can review and write an ongoing prescription.

5.3.i Titration

If the participant experiences withdrawal or cravings at 50 or 100mcg, they can continue to increase by 50mcg each subsequent dose to a **maximum of 250mcg**, as long as they have received a dose within the past 7 days.

Each dose increase requires a 10-minute post-dose observation period. If the participant's SSS score is >2 after 10 minutes, they are ineligible to increase doses further.

The doses are not required to be consecutive to continue titration.

Example scenario:

> Max receives 100mcg via IM administration and tolerates the dose well but does not return for any additional doses on the same day. They present the next day and request a 50mcg increase. The nurse can administer 150mcg followed by a 10-minute post-dose observation.

Once cravings and withdrawal symptoms are managed (or other individual goals are achieved), that dose will be considered their maintenance dose unless a decision is subsequently made to undergo further titration. Participants who have experienced sedation at any point during titration should be decreased to their last tolerated dose until assessed by a prescriber for consideration of any further dose increases.

If a person experiences sedation resulting in a SSS score >2 during titration, the titration will be stopped and the participant's dose will be set at the last dose tolerated with a SSS score ≤2.

5.4 Ending Titration

Once a participant has titrated to a dose that is comfortable for them or has achieved the maximum dose of 250mcg, the prescriber should review and write an ongoing script for the participant's set dose.

If the participant experiences sedation (i.e., SSS score >2) during titration, titration must be stopped and the participant's dose should be set at the last dose tolerated without sedation.

Once the participant has started on their set dose, they cannot increase the dose without a new order from a prescriber, even if it is below the maximum dose of 250mcg.

Note: Post-dose observation is only required when increasing dose or switching route of administration (unless switching to SL).

5.5 Dose Increases

If a participant decides to stop titration before the maximum dose is reached, or if they experience sedation and titration is stopped, they require an assessment and a new order from the prescriber to increase dose.

5.6 Routes of Administration

Participants have the option to switch routes of administration and may switch multiple times on the same day.

Participants on sublingual or IM administration who would like to switch to IV must have one post-dose observation period of 10 minutes at the same dose to ensure tolerance to IV.

If a participant is on IV and would like to try sublingual, they can switch directly without a post-dose observation. When participants are approved for additional routes, the changes in routes of administration should be documented. If participants are experiencing challenges with IV use, including multiple misses or the presence of an infection, the care team should offer education on trialing sublingual to allow for vein healing.

5.7 Missed Attempted Dose

If a participant has attempted to inject IV unsuccessfully and declines IM or SL, or if the syringe is clogged, the dose is considered a missed attempted dose. In this circumstance, the participant can return to retry their dose (there is no limit to the wait time between missed attempted dose and a second attempt, but programs may consider a range of 10 minutes to 1 hour). Nurses will document this as a missed attempt. The full dose will be wasted and indicated as a full dose waste in the participant's medical record. The participant will still be able to access all regular doses that day if the program hours of operation allow—the missed IV attempt does not count as a received dose.

The only time doses are wasted and redrawn is if it is clearly witnessed by staff that none of the medication was injected or there was a crack in the barrel or mechanical error with the participant accidentally depressing the plunger before injecting.

5.8 Missed Doses

The following procedures apply to both titration and maintenance doses.

If a participant has been away from the program for **7–29 consecutive days**, there should be an assessment and documentation of the participant's recent substance use, including unregulated opioid use, which may suggest that the participant can tolerate restarting at the maintenance dose.

Regardless of opioid use, the participant may receive the last dose given but will be asked to wait for 10 minutes post-dose. For those who have not been using opioids, reinstitute post-dose observation if they have missed 7–10 consecutive days; if the patient has missed 11–29 days, they should be reassessed.

5.8.i Extended Absence

If the participant has not received a dose for **30 or more days**, they will need to be re-assessed to re-enter the program. The assessment should include vitals, weight, a point-of-care urine drug screen, and the reason(s) for missed doses.

- If the participant has not been using unregulated fentanyl (i.e., due to withdrawal management, incarceration, or other factors/events) they must restart the PRN program at the initiation phase and require post-dose observation.

- If the participant has been using unregulated opioids, document findings (e.g., self-reported use, witnessed consumption of unregulated drugs, injection marks, recent hospitalizations due to overdose, point-of-care urine drug test results). The participant may then be provided a 50mcg test dose, including a 10-minute post-dose observation period to confirm tolerance.

After gathering the information, the pharmacy will receive an order from the prescriber to restart the prescription.

Table 6. Summary of procedures for missed doses

Consecutive Days of Doses Missed	Procedure
7–29 **with** ongoing unregulated opioid use	Assess participant for recent substance use. Administer the last dose given with 10-minute post-dose observation.
7–10 **without** ongoing unregulated opioid use	Assess participant for recent substance use. Administer the last dose given with 10-minute post-dose observation.
11-29 **without** ongoing unregulated opioid use	Re-assess participant including their treatment goals and program engagement.
30+	Conduct re-assessment (vitals, weight, point-of-care UDT, use of unregulated opioids): • If no unregulated opioid use present: restart program at initiation • If unregulated opioid use present: restart program with test dose + 10-minute post-dose observation Pharmacy receives order from prescriber to re-start prescription.

UDT=urine drug test

5.9 Visit Assessment

Participants accessing the sufentanil program may present with a number of other primary care and psychosocial needs which they may or may not seek support in addressing. During visits for the sufentanil program, both initially and ongoing, assessment of needs and person-centered goal-setting should be offered. Supports related to harm reduction, substance use treatment, contraception, and addressing psychosocial needs (i.e., birth certificate, income assistance, housing applications) should be readily available, but these resources are not required for running a sufentanil program.

5.9.i Initial and Ongoing Assessment

The initial assessment should be performed and documented prior to starting the program. Participants should have a full assessment at least every 2 months, depending on clinical and participant context and capacity. This assessment can be performed by prescribers or regulated health professionals acting within their scope and competency. If the assessment is performed by a non-prescriber regulated health professional, the prescriber should be consulted if any concerns are raised by the assessment. If performed by a non-prescriber regulated health professional outside the program site, a process must be in place to ensure the visit assessment is communicated to the prescriber and team and documented in the participant's chart (see 2.0 Program Models). See Appendix 2: Assessment for suggested assessment.

If the participant is not benefitting from the intervention, clinical judgment should guide the treatment plan. Adjustments to the treatment plan may include:

- Increasing the sufentanil dose
- Co-prescribing opioid agonist treatment or increasing OAT dose
- Increasing psychosocial supports
- Stopping the intervention

The decision to stop the intervention should be participant-directed wherever possible. If there is an increased risk of harm to the individual or others by continuing the program, providers should discuss the risks with the participant and assess whether the program is right for them. Cessation of the sufentanil program should not disqualify participants from being offered other alternatives that may better reflect their needs and preferences or from restarting sufentanil in the future.

5.9.ii Pre- and Post-dose Assessment

Pre- and post-dose assessment should be performed. See Appendix 2: Assessment for example assessment.

5.10 Provision of Sufentanil

A prescriber or non-prescriber regulated health professional working within their scope and competency should dispense or provide the sufentanil. Witnessing the injection and supporting safer injection may be roles for clinical or non-clinical staff (with appropriate training). People with lived and living experience of substance use can help clients feel more comfortable and provide education on injection. Institution or site-specific protocols for handling controlled substances should be followed.

Participants may choose to take the medication sublingually, IV, or IM and request assistance to inject. Registered Nurses (RNs) and Registered Psychiatric Nurses (RPNs) may administer the IM or IV injections with a client-specific order from an authorized health professional. Licensed Practical Nurses (LPNs) and pharmacists may administer IM injections (but not IV) with a client-specific order. Nurses can also assist with landmarking, finding a vein, and stabilizing to support self-injections.

5.10.i Sublingual Administration

1. Confirm that the participant is ready for immediate administration of sufentanil.
2. Prepare necessary equipment including marked syringe, blunt filter needle tip, and sharps container.
3. Open the ampoule(s) by cracking along the score line away from you.
4. Draw up the required dose of sufentanil into a syringe using a blunt filter needle tip.
5. Remove the blunt filter needle tip.
6. Give the sufentanil-containing syringe to the participant and have them administer it under their own tongue. Administer a maximum of 2.5mL at a time.
7. Instruct the participant to keep the medication under the tongue for at least 2 minutes without swallowing.
8. Food, water, and other medications should not be administered for 3–5 minutes following sublingual dose.
9. Ensure the participant returns the marked syringe. The marked syringe should be documented as returned and wasted.

5.10.ii Intravenous Administration

1. Confirm that the participant is ready for immediate injection of sufentanil.
2. Prepare necessary equipment including medication ampoule(s), marked syringe, blunt filter needle tip, injection needle tip(s), injection supply tray, and sharps container.
3. Open the ampoule(s) by cracking along the score line away from you.
4. Draw up the required dose of sufentanil into a marked syringe using a blunt filter needle tip.
5. Change the needle tip to the participant's preferred size.
6. Place the syringe into an injection supply tray and give to the participant.
7. The participant may not add anything to the sufentanil-containing syringe.
8. The participant has 15 minutes to inject their dose.
9. Verbally intervene after 7 minutes to provide assistance if needed.
10. The participant may inject themselves, or a physician, nurse prescriber, or nurse (RN/RPN/LPN; with client-specific order) may complete the injection for them.
11. Observe the participant during their injection.

12. If the participant is unable to complete the IV injection after 15 minutes, they may choose to inject it IM*—see IM Administration.
13. Ensure the participant returns the marked syringe after they have completed their dose. The marked syringe should be documented as returned and wasted.

*If the participant declines the dose IM after an unsuccessful IV attempt, they may return (10 minutes to 1 hour depending on program capacity/policy) for another dose. The unsuccessful dose should be marked as an attempted missed dose on the participant's medical record and disposed of as per the Institutional Narcotic Control Policy.

Participants are encouraged to use peripheral venous access at all times. However, if a participant has poor venous access and requests to inject into their jugular vein ("jugging"), this should be considered on a case-by-case basis, depending on program and site policies. Additionally, the option of IM injection should be offered. Jugular vein injection is not recommended, but if not offering the option presents a barrier to accessing the sufentanil program, then it may be appropriate. Document participant report of experience with jugular vein injection and discuss risks with the participant, including stroke, infection, and death. Participants may only self-inject into the jugular vein—they can assist or be assisted by another person.

See Appendix 8: Insite Procedure for Supporting Participants with Jugular Injection for an example procedure to support participants with jugular injection.

5.10.iii Intramuscular Administration

Intramuscular administration can be the participant's initial choice for administration or become the route of administration after an IV attempt is unsuccessful.

For IM administration by participant choice:

1. Confirm that the participant is ready for immediate injection of sufentanil.
2. Prepare necessary equipment including medication ampoule(s), marked syringe, blunt filter needle tip, injection needle tip(s), injection supply tray, and sharps container.
3. Open the ampoule by cracking along the score line away from you.
4. Draw up the required dose into a marked syringe using a blunt filter needle tip.
5. Change the needle tip to an appropriate IM needle tip for the participant's preference and body composition.
6. The participant may inject themselves, or the nurse (RN/RPN/LPN) may complete the injection for them if they have a client-specific order.
7. Depending on the dose, the participant may require multiple IM injections in different

sites. No more than 2mL of medication should be administered in the deltoid, 0.5–4.0mL in the vastus lateralis or 2–5mL in the ventrogluteal site.
8. Ensure injection sites are rotated at each injection.
9. Observe the participant during their injection (if self-injecting)
10. Ensure the participant returns the marked syringe after they have completed their dose. Marked syringe should be documented as returned and wasted.

For IM administration after unsuccessful IV attempt:

1. Have the participant switch the needle to an appropriately sized needle for IM administration.
2. The participant may inject themselves, or the nurse may assist or administer, depending on program capacity and workflow.
3. Nurses must wear gloves when administering IM after an unsuccessful IV attempt.

Changes in routes of administration should be documented.

5.10.iv Documentation

- The assessment must be documented in the participant's medical record.
- All doses and dose changes must be documented per program requirements and medication management regulatory standards, including documentation on a medication administration record if administered by a non-prescriber. Any dose changes must also be documented using the transaction medication update (TMU) function on Pharmanet.
    - Clinic health care professionals or delegates are to document any changes made to pharmacy-prepared participant-specific medication—such as increased doses, decreased doses, or missed doses—on PharmaNet using the TMU function by the end of the clinic day or shift. (See Appendix 11: Transaction Medication Update (TMU) Entry Guidance on PharmaNet)
    - In cases where a participant requires a dose and the pharmacy is unable to prepare it, the dose can be prepared by a nurse and provided through clinic (ward) stock. The nurse (or a delegate on their behalf) must document the exceptional reason and enter it in PharmaNet by using the TMU. (See Appendix 11: Transaction Medication Update (TMU) Entry Guidance on PharmaNet)
    - The TMU is to be completed by the prescriber (or delegate), not the pharmacy, and is an important part of ensuring patient safety and continuity of care.
- Sufentanil ampoules must be accounted for in the Narcotic Count.
- Internal program policies and procedures for narcotic counts must be adhered to.

5.10.v Syringe Preparation

- Prepare medication as per order and following the appropriate regulatory standards to support participants to complete their dose. Where possible, the nurse should use the participant's preferred size of syringe and needle size. Each syringe should be marked, and the participants must be asked to return the used syringe after administering their dose for appropriate disposal.

5.10.vi Wasted Doses

- A dose will be considered wasted if the sufentanil is spilled or the plunger of the syringe is accidentally depressed and all or some of the contents are expelled. In order for the participant to be eligible for a replacement dose, the spillage must be witnessed, and the wasted doses must be disposed following program or health authority processes. Wasting doses should be independently verified and documented by a second member of the care team. Unaccounted for spilled doses will not be replaced.
- Dose replacement will vary by program specifics but may include delivery from the pharmacy, clinic (ward) stock, or a new dose being provided at the pharmacy.
- Replacement doses must be documented, and wasted doses must be destroyed following program or health authority processes.

5.10.vii Medication Storage and Returns

- Sufentanil should be stored between 15–30°C, away from light.
- Medication storage will vary by program specifics. Please see regulations under the *Controlled Drug and Substances Act* regarding storage and return of sufentanil.[e]
- All ampoules are single use.

5.11 Dosing and Conversion with Other Fentanyl Products

- **Sufentanil is not bioequivalent with other fentanyl products. Sufentanil has 5–7 times the analgesic potency compared to fentanyl.**
- Do not convert participants on a mcg per mcg basis from other fentanyl products.
  - **Note:** This includes oral, transdermal, or parenteral formulations of fentanyl.
- There is incomplete and variable cross-tolerance along with significant individual variation for tolerance; there is no known consistent equivalent dose ratio to calculate.

[e] For guidance on the storage and destruction of returns containing controlled substances, see https://www.canada.ca/en/health-canada/services/health-concerns/controlled-substances-precursor-chemicals/controlled-substances/compliance-monitoring/compliance-monitoring-controlled-substances/post-consumer-returns.html

5.12 Sedation and Post-Dose Observation

5.12.i Managing Sedation: Pre-dose

Participants who have used unregulated drugs prior to arriving at the clinic may be too sedated to receive their dose.

Note: It is important for staff to receive education on distinguishing between substance use-related sedation and sleep deprivation. Fatigue related to sleep deprivation is not an indicator to withhold a dose. A participant who is sleep-deprived rather than overdosing will have a stable oxygen on pulse oximetry.

A pre-dose SSS score of 3 or 4 will result in the dose being held and documented. Participants may return later to receive their dose when they are less sedated. See Appendix 4: SAFER Sedation Scale (PSS).

5.12.i Managing Sedation: Post-dose

A SSS score of 3 or 4 post-dose indicates the dose may be too high for the individual.

If a participant experiences significant sedation post-dose, the nurse or pharmacist will contact the prescriber to adjust the dose and create a plan, including possible reassessment.

The next dose will be held until the prescriber has been contacted and a new order is received.

If a participant's post-dose SSS score is >2 during titration, they are ineligible to increase their doses further.

5.13 Titration with OAT

Note: The protocols outlined in this section are based on limited clinical experience. Additional titration methods may be developed as clinical experience increases.

Sufentanil dose and oral OAT dose can be titrated at the same time. Opioid agonist treatment dose can be titrated as per titration schedule outlined in the BCCSU *Opioid Use Disorder Practice Update*.

5.14 Prescriptions

Before writing the prescription, confirm standard provincial drug coverage and address any barriers to coverage prior to commencing the intervention.

5.14.i Duration of prescription

The length of maintenance prescriptions will depend on each program's operational needs and capacity; however, prescriptions should be written in a way that avoids the prescription ending on a day that a prescriber is not available (e.g., weekend or statutory holiday).

It is best practice to make prescriptions end on a day when the same prescriber is in clinic for continuity of care. If the program rotates prescribers, ensure clear documentation of treatment plan is included in the chart.

5.14.ii Writing Prescriptions

An example of sufentanil PRN prescription follows.

----------BC CONTROLLED PRESCRIPTION FORM----------

PERSONAL HEALTH NO. 1234 567 890

PRESCRIBING DATE 01 (DAY) 05 (MONTH) 22 (YEAR)

PATIENT NAME FIRST (GIVEN): Generic | MIDDLE / INITIAL: A | LAST (SURNAME): Name

PATIENT ADDRESS STREET: 123 Main Street | CITY: Victoria | PROVINCE: BC

DATE OF BIRTH 16 (DAY) 12 (MONTH) 76 (YEAR)

Rx: DRUG NAME AND STRENGTH — ONLY ONE DRUG PER FORM — **VOID IF ALTERED**

Sufentanil Citrate 50mcg

QUANTITY (IN UNITS)

NUMERIC: 2,800mcg | ALPHA: Twenty-eight hundred mcg

THIS AREA MUST BE COMPLETED IN FULL FOR OPIOID AGONIST TREATMENT (OAT)

START DATE: ____ (DAY) ____ (MONTH) ____ (YEAR) **END DATE:** ____ (DAY) ____ (MONTH) ____ (YEAR)

TOTAL DAILY DOSE NUMERIC | ALPHA | mg/day

NUMBER OF DAYS PER WEEK OF DAILY WITNESSED INGESTION NUMERIC | ALPHA

☐ **NOT AUTHORIZED FOR DELIVERY**

DIRECTION FOR USE, INDICATION FOR THERAPY, OR SPECIAL INSTRUCTIONS

Sufentail citrate 100mcg sublingual
As needed up to four times per day
Minimum one hour between doses
Daily witnessed ingestion at Main St Clinic
Rx: May 1-7

SA

NO REFILLS PERMITTED

VOID AFTER 5 DAYS UNLESS PRESCRIPTION IS FOR OAT

PRESCRIBER'S SIGNATURE

PRESCRIBER'S CONTACT INFORMATION
Generic Prescriber
123 Health Street
Victoria BC V8Z 4H4
Tel: 250-999-9911
Fax: 250-999-9119

91-09898 **PRESCRIBER ID**

FOLIO

PHARMACY USE ONLY

RECEIVED BY: PATIENT OR AGENT SIGNATURE | SIGNATURE OF DISPENSING PHARMACIST

PHARMACY COPY - PRESS HARD YOU ARE MAKING 2 COPIES
PRINTED IN BRITISH COLUMBIA

Prescriber and Pharmacist Procedures for Prescribed Safer Supply Prescriptions

The safety and sustainability of prescribed safer supply are predicated on ongoing fulsome monitoring and evaluation to inform program effectiveness and identify any unintended risks or harms. Accurately capturing these prescriptions in PharmaNet is essential to enable comprehensive and rigorous evaluation.

Many of the drugs prescribed as safer supply are used for additional indications; therefore, prescriptions for safer supply must be distinguished from other indications (e.g., pain). Prescribers and pharmacists are therefore being asked to assist as follows:

Instructions for Prescribers

Any prescription written for a drug to be used as prescribed safer supply should clearly include "SA" in the Directions for Use section of the form, BELOW the instructions for dispensation. This code is not part of the official instructions, but indicates to the dispensing pharmacist that the prescription is to be tagged with the on-public facing code that will allow the prescription to be identified in the PharmaNet database. An example can be found on the previous page.

Instructions for Pharmacists

When a prescription for prescribed safer supply is processed (new or refill/part-fill), it should be entered per usual prescription entry standards with the addition of an "SA" intervention code in the customary intervention code section of the software, not the Directions for Use ("sig") section. This code goes in the intervention code field and is simply a tag on the prescription that can be captured when monitoring and evaluating these harm reduction prescriptions for program evaluation. Entry of the intervention code with each prescription fill is the only action required on the pharmacist's part and has no monetary reimbursement attached.

5.15 Holding Medication

- If it is determined the participant should NOT receive their sufentanil (e.g., due to sedation), the doses will be held and documented
- If the participant is too sedated or intoxicated based on pre-dose assessment, they can be asked to return in a few hours for a reassessment:
  - This must be explained to the participant and documented
- The participant should be reminded of the risks of administering their medication in combination with other medication or street drugs
- Oral OAT doses will be adjusted or held for reassessment as per *A Guideline for the Clinical Management of Opioid Use Disorder*'s missed dose protocols

5.16 Discontinuation

Individuals may discontinue taking sufentanil due to participant choice to transition to oral OAT and/or other psychosocial treatment interventions, due to repeated diversion, or as a result of discharge from the program for other reasons, including violence or safety concerns.

5.16.i Voluntary Transition to Oral OAT

If an individual prefers to transition on to OAT only and stop sufentanil, they can do so at any time. Opioid agonist treatment titration should follow the protocols in the BCCSU's *Guideline for the Clinical Management of Opioid Use Disorder* and *Opioid Use Disorder Practice Update*. During OAT titration, sufentanil can be tapered or outright discontinued at the participant's discretion if cravings and withdrawal symptoms are adequately managed.

5.16.ii Transition Due to Repeated Diversion

Sufentanil Alone
Individuals who are on sufentanil alone who are being discharged from the program due to diversion should be offered a standard oral OAT titration following the guidance in the BCCSU's *Guideline for the Clinical Management of Opioid Use Disorder* and *Opioid Use Disorder Practice Update*.

Sufentanil and OAT
Individuals who are on both sufentanil and OAT who are being discharged from the program due to diversion should be continued on their OAT dose following discontinuation of sufentanil. The dose can be increased following a standard dose increase process (see *Guideline for the Clinical Management of Opioid Use Disorder*).

6.0 Urine Drug Testing

Ongoing urine drug tests positive for other substances are not a reason to discharge someone from the program as the participant may have experienced other benefits such as decreased unregulated drug use, titration of OAT, housing stability, and engagement in primary care.

A point-of-care urine drug test within 2 weeks of starting the program is recommended but may be waved based on clinical discretion if:

- The participant is known to the clinician/staff/program
- There is objective evidence of fentanyl use
- There is sufficient collateral information
- The decision to wave urine drug test has been documented

Ongoing use of unregulated fentanyl will not be discerned by urine drug testing, unless the person is using unregulated fentanyl analogues such as carfentanil or furanyl-fentanyl, which can only be detected through confirmatory testing. It should be noted that sufentanil cannot be detected on point-of-care urine drug tests and will not cause a false positive fentanyl test.

Point-of-care urine drug tests should be performed for participants who have been away from the program for 30 or more consecutive days, or if requested by the prescriber.

For ongoing monitoring

For ongoing monitoring, urine drug tests should be collected about every 2 months and sent to the laboratory for:

- Amphetamines
- Benzodiazepines (including confirmation)
- Cocaine
- Opioids

For consideration

Clinical judgment and individual participant circumstances may suggest including some or all of the following:

- Fentanyl
- 2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP, methadone metabolites)

- Hydromorphone
- 6-Monoacetylmorphine (6-MAM)
- Etizolam

7.0 Assessment, Continuing Care, and Program Evaluation

Following the initial assessment, a thorough assessment should be performed to determine whether the participant is benefitting from the intervention. Clinical experience at PHS has found that it takes 3–6 months on average to determine if the participant is benefitting from the intervention. Sufentanil was found to be an excellent engagement tool at the AVI SAFER program, where some participants began by attending the program sporadically but eventually attended more regularly as trust was established over time. Re-assessment was also found to be important for responding to participants' changing preferences for the fentanyl option and/or considerations for OAT in addition to sufentanil.

The results of this assessment along with expert consultation, where appropriate, and individual preference should inform the decision to continue or discontinue this intervention. Clear indication of individual benefit, supported by clinical judgment and aligned with participant goals, supports the continuation of this intervention.

Clinical and psychosocial indicators for ongoing individual participant assessment can also function as measures for overall program assessment and evaluation. It is imperative for effective monitoring and program evaluation to have the Safer Alternative (SA) intervention code included on the prescription, and for dose changes to be entered using the TMU function in PharmaNet (see Appendix 11: Transaction Medication Update (TMU) Entry Guidance on PharmaNet). Although a provincial evaluation framework has been drafted and an external evaluation is in progress, sites are encouraged to develop a consistent approach to documentation in participants' charts, to facilitate evaluation efforts. (See the Ministry of Mental Health and Addictions, Ministry of Health, and Office of the Provincial Health Officer's *Access to Prescribed Safer Supply in British Columbia: Policy Direction* for current information on the evaluation and monitoring framework for this intervention.)

Table 10. Clinical and Psychosocial Indicators of Participant Impact and Program Evaluation

	Participant is benefitting	Participant is not benefitting	Program evaluation measure
Clinical Indicators			
Concurrent substance use	Reduced	No change or increased	Amount, frequency, UDT results
Reliance on unregulated supply	Reduced	No change or increased	Amount, frequency, UDT results
Recent overdose history	Reduced	No change or increased	Number of events, presence of overdose prevention safety plan
Visits to emergency department/acute care since last visit	Reduced	No change or increased	Number of visits to emergency department/ acute care
Other harms associated with accessing unregulated supply	Reduced	No change or increased	Over-sedation, amnesia, infections, wounds
Cravings	None or reduced	Ongoing	Severity
Withdrawal symptoms	Eliminated	Ongoing	Severity
Overall wellbeing and functioning	Improved	No change	Participant self-report
Missed doses (including partial doses)	None or minimal	Frequent	Number of doses missed
Access to primary care and/ or mental health supports	Increased	No change or reduced	Participant self-report, charts
Chronic disease management	Improved	No change or reduced adherence	Participant self-report, adherence to treatments/ medications
Psychosocial Indicators[f]			
Income/employment	Reduced need to engage in high-risk and criminalized activities (e.g., sex work); seeking or gaining employment or volunteer activities	No change	Engagement in high-risk and criminalized activities; employment status; volunteering activities; income status/ source

[f] Structural barriers such as lack of affordable and accessible housing or suitable employment may make these difficult to achieve for individuals who are otherwise benefitting from the intervention. Improvements in these domains are not required, but—where possible—may be additional indications that the participant is benefitting and should continue to receive this intervention.

Housing	Attaining or maintaining safe housing	No change or loss of safe housing	Housing status
Social connection	Reconnecting with family and friends	No change	Connection to family and friends; other connections in community
New activities since program initiation	Integrating new activities	No change	Number and types of new activities
Participant-identified goals	Setting and meeting goals	No change	Progress and notes

If thorough assessment of participant-identified goals and indicators of clinical and psychosocial stability suggest that the participant is not benefitting from the intervention despite attempts at optimizing dosing and psychosocial supports, it may be appropriate to discontinue the intervention and explore alternative harm reduction, treatment, and recovery options. Alternative options may include initiating OAT, increasing existing OAT dose, trial of another opioid medication available through the pharmaceutical alternatives policy, or a combination. The assessment, treatment plan, and rationale should be documented in the participant's medical record. It may be helpful to consult the 24/7 Line for assistance in determining whether the intervention is or is not beneficial, and next steps.

An example checklist that may be included in regular assessments is available in Appendix 2: Assessment.

7.1 Ongoing Participant Assessment

The following can be performed monthly during stabilization, with frequency following stabilization determined based on individual participant needs and site capacity:

- If participant is not seen by the prescriber for each prescription refill, case conference review by the clinical team
  - During this case conference review, the team should discuss engagement, progress to recovery, and any clinical concerns for each participant
  - **Note:** Case conferences will differ by program and may include only the prescriber and non-prescriber regulated health professional, or a larger team, as appropriate
- Urine drug testing (every 2 months)
- Weight measured and recorded (every 2 months)
- Substance use assessment with prescriber

After stabilization, the case conference can continue at an interval determined by the team.

8.0 Diversion

Instances of diversion of prescribed supply medications should be approached with an understanding of the complex reasons that people may divert prescribed medications. Conversations with clients around diversion should be approached in a non-punitive and supportive way. Although there are no evidence-based methods available for addressing diversion, clinical experience shows that, where possible, conversations should focus on the individual's needs, the role of diversion in filling that need, and what may be done to better meet the needs of participants.

A single incidence of diversion is not a reason for discharging a participant from the sufentanil program. Individual circumstances can be considered (e.g., insufficient dosing to manage cravings and withdrawal symptoms and thus requiring a dosage increase; psychosis and other psychiatric conditions).

Repeated diversion indicates that a client's needs are not being met, such as inaccessibility or ineffectiveness of the intervention or other reasons (e.g., income insecurity). Repeated diversion should prompt prescribers and other members of the care team to reassess and explore alternative options (or combination of options) that better match the substance use patterns and needs of the participant. This should be done in collaboration with the participant via shared decision-making.

The following are considered to be diversion of medication:

- Missing syringes that cannot be accounted for
- A syringe that has signs of tampering (e.g., damaged, opened, or changed in any way)

Participants should be observed by clinical or to delegated non-clinical staff (with appropriate training) while injecting or administering doses sublingually. The doses should be drawn up in marked syringes that must be returned after the dose.

In some circumstances, when alternative options and current program optimization have been trialed and diversion still occurs, the participant may need to be discharged from the program. Each program may develop their own approach to diversion, prioritizing participant safety, continuity of care, and community safety. The reasons for diversion should be discussed and addressed where possible. Participants should not be abruptly discontinued from sufentanil without being offered transition to OAT or adjustment of concurrent OAT dose.

Clinicians may use urine drug testing to help identify diversion, if appropriate. However, it should be noted that sufentanil cannot be detected on point-of-care urine drug tests and will not cause a

false positive fentanyl test; confirmatory testing is required to detect sufentanil. Benzodiazepine screening (specifically confirmatory testing for etizolam) may provide an additional level of information, as etizolam and other benzodiazepines are commonly found in unregulated fentanyl samples.

Appendix 1: Intake Form (EMR Typing Template)

Substance History

Substance(s) currently using: «»

How many overdoses have you had: «»

In the last month: «» in the last 6 months: «»

Do you have a THN kit («Y/N»)

Offer THN and provide education

Are you on OAT program currently? («Y/N»)

If no, have you ever been on OAT in the past? («Y/N»)

Details about dose and duration of each medication

Have you tried any other forms of substance use treatment (e.g., counselling, recovery programs, group meetings)? («Y/N»)

If yes, details about treatment attempts and duration

Medical History

Are you receiving primary care: («Y/N»)

If yes, primary care physician: «»

Other provider: «»

Medical condition/co-morbidities: «»

Pharmacy: «»

Allergies: «»

Clinical

Signs/symptoms of substance withdrawal: «»

Signs/symptoms of sedation: «»

To do:

- Vitals: «BP_, RR_, PR_, Temp_, sO2_»
- PharmaNet review: «»
- UDS result: «»
- Pregnancy test (where appropriate)
- HIV/UDT/STI/HCV testing
- Collect pending bloodwork

Social Status

Housing status: «Apt/house, SRO, shelter, NFA, other: »

Financial income source: «Employed, PWD, social assistance, other: »

Client Priorities and Goals

What are your short-term goals: «»
What are your long-term goals: «»
Plans/strategies to achieve goals: «»

Agreement and Consent

Orientation Form: («Y/N»)
Program consent: («Y/N»)

Signs Patient is Benefitting from Program (for subsequent visits)

Current unregulated substance use (amount, frequency): «»
Recent overdose history: «»
Visits to acute care since last assessment: «»
Cravings: «»
Withdrawal symptoms: «»
Overall wellbeing: «»
Engagement in high-risk and criminalized activities (e.g., sex work) to support substance use: «»
Seeking or gaining employment or volunteer activities: «»
Integrating new activities: «»
Reconnecting with family and friends (e.g., improved social functioning): «»
Attaining or maintaining safe housing: «»
Accessing social services: «»
Missed doses: «»
Urine drug test results: «»

Appendix 2: Assessment

Initial and Ongoing Assessment (approximately every 2 months)

Subjective	• How is the participant doing • How well is the current treatment supporting the participant's goals • Any changes the participant would like to be better supported • Substance use since last visit • Specify drug, amount, and route of use • Any overdoses since last visit • How the participant is keeping themself safe (e.g., preventing overdoses) • How is their physical and mental health • What has the participant been doing to keep themselves well • Any new prescription medications since last visit • Mood • Sleep

Objective	• General appearance
	• Signs of intoxication
	  • Severe agitation
	  • Dyskinesia
	  • Sedation
	  • Slurred speech
	  • Smelling of alcohol
	• Level of consciousness
	• Pupil size
	• Vitals
	• Weight
	• UDT
	  • If a participant has not provided a UDT in 3 months, advise that their next dose will be held until they can provide a sample
	• Any other health-related assessments
	• Objective
	• SAFER Sedation Scale score
	• Injection-related harms (e.g., abscess at injection site, HIV or hepatitis C infection)

Participant Benefit Assessment	• Current substance use (amount, frequency) • Recent overdose history • Visits to emergency department/acute care since last assessment • Cravings • Withdrawal symptoms • Overall wellbeing • Income/employment • Participant-identified goals • Seeking or gaining employment or volunteer activities • Integrating new activities • Reconnecting with family and friends (e.g., improved social connection) • Attaining or maintaining safe housing • Accessing social services • Missed doses • UDT results
Plan	• Any changes to dose or new medications • Follow up or referral to other services

Pre-dose Assessment

Subjective	Last dose tolerated Any concerns?
Objective	SAFER Sedation Scale score

Post-dose Assessment

Subjective	Dose + time administered SAFER Sedation Scale score post-dose
Objective	Next dose due Follow up or referral to other services

Appendix 3: Ongoing Monitoring—Participant Benefit Assessment (EMR Typing Template)

Current unregulated substance use (amount, frequency): «»
Recent overdose history: «»
Visits to acute care since last assessment: «»
Cravings: «»
Withdrawal symptoms: «»
Overall wellbeing: «»
Engagement in high-risk and criminalized activities (e.g., sex work) to support substance use: «»
Seeking or gaining employment or volunteer activities: «»
Integrating new activities: «»
Reconnecting with family and friends (e.g., improved social functioning): «»
Attaining safe housing: «»
Accessing social services: «»
Missed doses: «»
Urine drug test results: «»

Appendix 4: SAFER Sedation Scale

The SAFER Sedation Scale (SSS) is a Modified Pasero Opioid-Induced Sedation Scale

Score	Presentation	Action
1	Awake and alert	OK to receive dose
2	Slightly drowsy but easily rousable	OK to receive dose
3*	Frequently drowsy, drifts off to sleep during conversation, rousable to verbal stimuli	Hold dose and monitor respiratory status and sedation level closely until sedation level is less than 3. Call the prescriber if the participant remains level 3 after 30 minutes.
4*	Unresponsive to verbal stimuli, responsive to physical stimuli	Check O2/RR/HR every 5 minutes. Notify prescriber. If O2 is less than 90% or RR less than 10, proceed to action for level 5.
5	Unresponsive to verbal stimuli, may or may not be responsive to physical stimuli	Call 911 and follow site overdose policy

*If participant presents as a 3 or 4, more documentation describing participant's condition/ rousablility is required

Appendix 5: Sample Consent Overview

Note: *This is a sample consent form that may be adapted to individual program needs, based on PHS's consent form. Program staff should be aware that some individuals may find the requirement to sign a form to be a significant barrier (e.g., inability to sit still, literacy barriers). Clinical judgment and thorough documentation of consent discussion may be appropriate in these circumstances.*

Sufentanil programs are trialing sufentanil to help people with opioid use disorder to separate from the unregulated drug supply and reduce their risk of overdose. Currently, this practice does not have an evidence base to support it, and it is considered an "off-label" use of the medication. This approach has been trialed in the Downtown Eastside in Vancouver, BC, and in Victoria, BC, with some positive benefits.

Potential benefits of this program may include:

- Reduced cravings and withdrawal symptoms
- Reduced unregulated opioid use
- Reduced overdose risk
- Improved overall wellbeing

In this program, I understand and agree that:

1. I am being enrolled in this program to try to decrease my overdose risk.
2. For safety reasons, the program staff will contact my current health care providers to review my enrollment in this program.
3. My prescriber will work with me to develop a clinical plan and set goals. These goals will be reviewed regularly and changed as needed.
4. In addition to the program medication, I can choose to participate in counselling, peer support groups, or other groups. My team can review these resources with me.
5. I can expect confidentiality from my medical team about my care, and my personal information will not be shared.
6. I can choose to stop this program at any time and my prescriber will help create a plan with alternative options for me.
7. During the duration of this program, I will only receive opioids or other sedative prescriptions (e.g., sleeping pills, benzodiazepines) from my prescriber here, and I will notify my prescriber if I receive these medications elsewhere.
8. If I am not benefitting from the program, I will have a discussion with my care team and make a plan for different medication options.

9. While on this program, I will not operate a motor vehicle or heavy machinery.
10. While on this program, I consent to my care team accessing relevant medical records including regular PharmaNet reviews.
11. While on this program, I will take the medication as discussed with my care team and not divert it to give/sell to others. If the medication is not meeting my needs, I will discuss this with my care team.
12. I give permission for my care team to act as my agents/participant representatives when accepting my medications from my pharmacy.

I understand that I am expected to:

1. Provide urine for testing on a regular basis.
2. Avoid using alcohol, benzodiazepines, or other drugs that, when combined with opioids, can lead to overdose or other serious harms.
3. Notify my prescriber if I become pregnant, suspect that I am pregnant, or am planning to become pregnant.
4. Notify my prescriber if my health changes or I start taking any new medication.

Appendix 6: Sample Titration Record

Sufentanil Titration Record

Date: ______________________ Prescribing physician: _________________________________

****All doses recorded in MICROGRAMS (mcg)* ***

Patient Info	Time	1st Dose	Time	Top Up Dose	Admin. Nurse
	Time	2nd Dose			Admin. Nurse
	Time	3rd Dose			Admin. Nurse
	Time	4th Dose			Admin. Nurse
	Route:		Daily Total		
Patient Info	Time	1st Dose	Time	Top Up Dose	Admin. Nurse
	Time	2nd Dose			Admin. Nurse
	Time	3rd Dose			Admin. Nurse
	Time	4th Dose			Admin. Nurse
	Route:		Daily Total		
Patient Info	Time	1st Dose	Time	Top Up Dose	Admin. Nurse
	Time	2nd Dose			Admin. Nurse
	Time	3rd Dose			Admin. Nurse
	Time	4th Dose			Admin. Nurse
	Route:		Daily Total		

Directions to Nurse:
Please note either IV/IM or SL for route
Use ampoules for all titration doses below 250mcg, use a vial for the final dose of 250mcg

COMMUNITY APOTHECARY

Appendix 7: Sample Ongoing Maintenance Record

SUFENTANIL NEW MAINTENANCE RX RECORD

Prescribing Date: _____ Prescribing physician: _____

(All Rxs will be weekly dispense for 91 days starting TOMORROW)

****All doses recorded in MICROGRAMS (mcg)****

Patient Info	Dose	Route
	Total Quantity:	
Patient Info	Dose	Route
	Total Quantity:	
Patient Info	Dose	Route
	Total Quantity:	
Patient Info	Dose	Route
	Total Quantity:	

Dose = quantity of each dose administered; Total Quantity = total of all doses per day (qid) x 91 days

Directions to nurse: Fax this form at the end of the day for new maintenance doses that start tomorrow. A new MAR and a full week supply of sufentanil will be delivered tomorrow morning. Further supply to be requested on weekly reorder form.

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Appendix 8: Example Procedure for Supporting Participants with Jugular Injection

This example procedure for supporting participants with jugular injection is adapted from InSite's procedure, with gratitude.

Procedure for Supervised Injection Education into the Jugular Vein[g]

Background

Individuals who use and inject unregulated drugs are at high risk for soft tissue infections and more serious infections such as endocarditis. These infections and other serious medical problems can occur from injection into any vein. The jugular veins pose higher risk for the following reasons:

- The anatomical location of the jugular is very close to large blood vessels (including arteries), nerves, the trachea, and the esophagus
- An abscess in close proximity to these structures can cause compression of nerves, and vessels supplying blood to the brain
- A large abscess on the jugular line can potentially cause compression or narrowing of the airway
- Jugular infection can travel easily to the brain or heart
- Air embolus can easily enter the blood stream from jugular injection and travel into the heart and coronary arteries (resulting in a heart attack), the brain (resulting in a stroke), or the lungs (resulting in a pulmonary embolism)
- Air is more likely to enter through injection into the jugular vein because of the lack of valves and because of the negative pressure in the jugular, associated with inspiration

Nursing procedure

It is the role of all staff, including nurses, to build a trusting and therapeutic relationship with program participants. Nurses and program staff are to be constantly scanning the room and IR booths for both overdose and opportunities for education, while performing daily tasks. Nurses to approach participants who are noted to be injecting into the jugular, and offer education.

[g] Kupp S, St. George K, Riley S. Appendix P: Supervised injection into a jugular vein. In Overdose Prevention Site 2022 Manual (v. 2). Vancouver Coastal Health; 2022. Available from: http://www.vch.ca/Documents/Overdose-Prevention-Site-OPS-Manual.pdf

Nurse to determine the following:

i. Participant's rationale for using the jugular, and participant's knowledge of risks of injecting into the jugular
ii. Whether the participant has any visible or palpable venous access other than the jugular
iii. Whether or not the participant is able to inject their drugs IM

Then, based on the above assessment, the nurse should do the following, in priority sequence:

1. Educate the participant to self-inject into a different vein
2. Educate the participant to self-inject IM
3. Educate the participant on the risks involved with injecting into the jugular
4. Educate the participant to safely self-inject into their jugular vein, if and only if the participant is determined to do so

Nurses are ethically obligated to provide proper and adequate education as outlined in the Canadian Nurses Association Code of Ethics (i.e., "Promoting and respecting informed decision-making") and the British Columbia College of Nurses and Midwives (BCCNM) Standards of Practice (i.e., "duty to provide care"). This ethical obligation includes:

- Providing information on the risks involved (e.g., clot or obstruction, embolus, infection, overdose, heart attack/stroke, embolus, compression of vital structures in the neck)
- Providing education on how to minimize these risks (i.e., harm reduction education), how to landmark the vein for injection, and other safe-injection education
- Documenting appropriately and accurately in the medical record

Appendix 9: Bowel Care Protocol

Note: The following medications are only covered under the First Nations Health Benefits (Plan W) of PharmaCare; programs are advised to plan accordingly.

SAFER Bowel Care Protocol

STEPS	MEDICATION
STEP 1:	No medication
STEP 2: (Last BM more than 48 hours ago)	***Recommend PEG as first choice:*** □ polyethylene glycol 3350, RANGE DOSE 8.5 g to 17 g oral, x 1 today, PRN constipation **OR** □ lactulose 30 mL, Syrup, oral, x 1 today, PRN constipation *(if patient prefers)* **If no results by next AM proceed to step 3**
Step 3: (Last BM more than 72 hours ago)	***Recommend PEG as first choice:*** □ polyethylene glycol 3350, RANGE DOSE 8.5 g to 17 g oral, BID, PRN constipation **OR** lactulose 30 mL, Syrup, oral, BID, PRN constipation *(if patient prefers)* **AND** □ sennosides A & B, 24 mg, tab, oral, x 1 today, PRN constipation **If no results after 24 hours, proceed to Step 4**
Step 4: (Last BM more than 96 hours ago)	***Recommend PEG as first choice:*** □ polyethylene glycol 3350, RANGE DOSE 8.5 g to 17 g oral, TID, PRN constipation **OR** lactulose 30 mL, Syrup, oral, BID, PRN constipation *(if patient prefers)* **AND** □ sennosides A & B, 24 mg, tab, oral, x 1 today, PRN constipation **If no results, participant requires appointment with MRP for further examination.**
	Return to Step 2 once desired results are achieved.

Signature, Designation **College License #** **Date** **Time**

Appendix 10: Operational Considerations

Program operations will depend on resources and personnel available, including prescribers and nurses. Programs are encouraged to build clinic flow and program-specific protocols based on staffing available.

Logistical Considerations

- Sites that offer supervised consumption services (SCS), overdose prevention services (OPS), injectable opioid agonist treatment (iOAT) or tablet injectable opioid agonist treatment (TiOAT) are best situated to offer sufentanil programming. Low threshold primary care clinics may also viable service delivery environments for sufentanil programming.
- Establishing baseline minimum staffing standards and procedures for service closure, as well as an emergency plan (e.g., in case of fire, flooding, power outage, or staffing shortage), are imperative in ensuring continuity of care and safety for all. Hours of operation and any potential disruption of services should be communicated clearly in writing to participants and staff as well as community partners such as the pharmacy, with verbal reminders provided regularly.
- Establishing or formalizing a partnership with pharmacies is an important step in managing the storage, handling, and tracking of sufentanil or other prescribed fentanyl options. Ideally, a program will have one pharmacy partner for on-site opioid deliveries.
- Prior to operationalizing the program, determine if your site allows use of non-prescribed substances and how your team will respond if participants want to "top up" their dose with their personal supply.
- Consider your program's policy on peer-assisted injection, splitting and sharing, and self-administered jugular injection. Have these policies clearly communicated to participants during intake and accessible in writing at your site.
- Program hours of operation and staffing capacity will influence the number of doses participants can access in a single day, and the total number of participants who can access the program.
    - For example, if the program has 20 participants accessing up to four doses/day, a maximum of 80 drug dispensations and witnessed injections can occur in that day. If the program has three injection booths, staff will have to turnover, disinfect, and prepare booths ~26 times in a day.
- Prior to commencing a participant on the program, offer orientation to the site, review the consent form (see Appendix 5: Sample Consent Form), review expectations around safety, and discuss program limitations.

Supplies and Equipment

- Offering a variety of injection-related equipment to meet the needs of participants is critical. The volume of sufentanil at the maximum dose is 5mL. Offering a variety of needle tip gauges and syringe sizes to accommodate the preferences and style of each participant is an important step in improving the experiences and outcomes of participants.
- Additional equipment related to injection, including hot/cold packs, adequate standalone lighting, and portable mirrors, should be made available based on participant preference.

Staffing

- ***Prescribers:*** Programs may consider full-day, half-day, and remote clinic options for physicians and/or nurse practitioners, including prescribers working out of another location. A combination of these options may be ideal to implement a two-prescriber approval system.
- ***Nurses:*** Programs may consider a combination of full- or part-time nurses (e.g., clinical nurse lead, outreach nurse, clinic nurse) and casuals to fulfill clinic needs.
- ***Additional staff*** include support workers, systems navigators, medical office assistants, program manager, and project director. Hiring people with lived and living experience (or "peers") as support workers and system navigators is considered a best practice and can help to build trust with participants and increase program engagement.
- ***Pharmacy*** plays an integral role in the supply, delivery, monitoring, and reporting of medications and are an invaluable resource in supporting access to medication coverage, maintaining a clinic (ward) stock, and anticipating supply chain issues.

Settings

- Consider having additional injection spaces to increase program capacity.
- Ensure environmental design considers both privacy for participants injecting and visibility for witnessed dosing and post-dose observation.
- Have protocols in place to support individuals who take more time to inject.
- Consider a separate "chill" or post-dose observation space that offers snacks and access to support workers—with sufentanil dosing occurring potentially only an hour apart, participants benefit from having space to wait between doses.
- Incorporate design considerations for medication storage in accordance with safe storage standards for Schedule 1 medications.
- Participants and staff with lived/living experience can be a resource for site design and logistics, given their expertise on the needs of those accessing the site.

Training

- Staff should receive, at minimum, training on safer injection/consumption practices, offering assistance to participants who are injecting, team overdose response, and crisis prevention and response.
- Programs should build in continuing education and competency trainings on a range of subjects including harm reduction, trauma- and violence-informed care, Indigenous cultural safety and humility, communications, and developing therapeutic relationships.

Combination with other safe supply interventions

- Consider sufentanil (and other prescribed fentanyl options) in conjunction with other safe supply interventions. For example, at Victoria SAFER, sufentanil program was well suited for individuals who were on a high maintenance OAT dose and were unwilling or unable to continue titrating up but were still actively injecting.
- Use a person-centered approach to determine the best combination of medication options for each individual participant. This can be achieved through participant-led goal setting, a comprehensive substance use assessment, and creating accessible channels for feedback.
- Dose adjustments should occur in a timely manner.

Nursing role in the program

- Assessments and ongoing clinical monitoring are conducted by the nurse.
- Titration and maintenance doses are administered by nurses.
- Nurses may call the prescribe for new prescriptions or changes in prescriptions.
- To alleviate administrative burden, programs may consider charting by exception when conducting pre- and post-dose assessments with notes on the Narcotic Record.

Appendix 11: Transaction Medication Update (TMU) Entry Guidance on PharmaNet

How to annotate participant PharmaNet records when providing addiction treatment

It is critical for continuity of care and participant safety that health professionals keep participant medication histories up to date in PharmaNet.

In the context of addiction treatment, such as oral and injectable opioid agonist treatment (OAT and iOAT) and prescribed safer supply, health professionals in emergency departments and community health facilities (clinics, programs) must update a participant's PharmaNet record when:

- Emergency department take-home doses are provided. (e.g., buprenorphine-naloxone)
- Clinic (ward) stock is dispensed
- The participant receives a higher or lower dose at the point of care than the pharmacy-dispensed prescription
- Participant misses a dose(s)

Access to PharmaNet and PRIME

Prescribers and nurses must be authorized to access PharmaNet to view and add notes to participant profiles.

Request access by enrolling in PRIME. See www.gov.bc.ca/pharmanet/PRIME

Updating PharmaNet

Some health professionals with access to PharmaNet can add a record to a participant's PharmaNet profile.

In PharmaNet these records are called transaction medication updates (TMUs). Intervention codes are used to help ensure accurate collection of data for monitoring and evaluation.

Intervention Codes are a mandatory field in TMU, please use the following:

- SA = safer alternative – prescribed safer supply every fill/dispense, OR
- UA= consulted prescriber and filled prescription as written (not safer prescribed supply)

All entries must be made by end of clinic day or end of emergency department shift during which action occurred.[h]

[h] For extended-release injectable buprenorphine, PharmaNet must be updated if a) a participant is provided a dose from clinic (ward) stock, b) receives a dose that differs from that dispensed by the pharmacy, or c) a missed dose, if the participant does not receive the pharmacy-dispensed dose within the clinic protocol or clinically appropriate treatment interval.

The following table provides guidance on when and where to record controlled substance dispenses in TMU (e.g., opioids, stimulants, benzodiazepines).

Clinic (ward) stock used (enter PIN in DIN field)		**Participant-specific pharmacy-dispensed changes** (enter PIN in DIN field)		
Clinic (ward) stock dose used to provide dose when there is no pharmacy-dispensed prescription	**BUP-NX induction doses** given on site or "to go" to an outpatient	**Participant missed all or some doses** at the clinic from the pharmacy-dispensed prescription	**Dose increased at clinic visit** and participant received a dose that was more than the pharmacy-dispensed prescription	**Dose decreased at clinic visit** and participant received a dose that was less than the pharmacy-dispensed prescription
PIN: **66128342** **Directions**[i]**:** drug, dose and directions, time **Quantity:** # of tablets/capsules/ patches, volume of injection (mL) **Days' supply:** 1 **Intervention code: UA or SA** **Prescriber name:** add if different than person entering *Please do an entry for each molecule/drug provided by clinic stock (excluding BUP/NX-next column)	**PIN: 66128346** **Directions:** standard dosing, microdosing**,** or total dose taken/provided, **Days' supply: as appropriate** **Intervention code: UA** **Prescriber name:** add if different than person entering	**PIN**: **66128343** **Directions:** drug, record which dose(s) missed, **Days' supply**: **as appropriate** **Intervention code**: UA **Prescriber name:** add if different than person entering	**PIN: 66128344** **Directions:** Drug name, total dose taken **Days' supply**: **as appropriate** **Intervention code**: UA **Prescriber name**: if different than person entering *Only use this one PIN, even if providing with clinic stock	**PIN**: **66128345** **Directions:** Drug name, total dose taken **Days' supply: as appropriate** **Intervention code**: UA **Prescriber name:** add if different than person entering
Example: **PIN:** 66123342 **Directions:** Fentanyl patches 100 mcg, apply to skin and replace every 3 days **Days' supply:** 3 **Intervention code: SA** **Prescriber name:** Dr. Bond	**Example:** **PIN** in DIN field**:** **66128346** **Directions:** Microdosing regimen, take home **Days' supply:** 5 **Intervention code: UA** **Prescriber name:** Dr. Tran	**Example 1:** Participant has pharmacy-dispensed diacetylmorphine iOAT TID **PIN**: 66128343 **Directions:** diacetylmorphine injectable, 100 mg Dose 1 and 150 mg Dose 2 **Days' supply:** 1 **Intervention code: UA** **Prescriber name**: Dr. Pate **Example 2:** **Directions:** Kadian, 700mg, daily **Days' supply:** 1 **Intervention code:** UA **Prescriber name:** Dr. Day	**Example 1:** Participant has pharmacy-dispensed Fentora 400 mcg QID **PIN** in DIN field: 66128344 **Directions:** Fentora 600 mcg, 3rd and 4th doses **Days' supply:** 1 Intervention code: UA Prescriber name: Dr. Da **Example 2:** Participant has pharmacy-dispensed Suboxone 8mg/2mg. **PIN** in DIN field: 66128344 **Directions:** Suboxone 16mg/4mg **Days' supply:** 1 **Intervention code:** UA **Prescriber name:** Dr. Fleur	**Example:** Participant has pharmacy-dispensed sufentanil 1000 mcg five times per day PRN **PIN** in DIN field: 66128345 **Directions:** sufentanil, 900 mcg 5th dose, new Rx **Days' supply:** 1 **Intervention code**: UA Prescriber name: Dr. Yu

BUP/NX=buprenorphine/naloxone; TID=three times per day; QID=four times per day; PRN=as needed; iOAT=injectable opioid agonist treatment

[i] TMU Directions field has a maximum of 80 characters.