Fentanyl Tablet
(Maintenance Program)

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 Fentanyl Tablet Policy.

1.2 Evidence Supporting this Intervention

Providing fentanyl tablets 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. Prescribed fentanyl tablets have been utilized in three programmatic settings in BC (i.e., PHS, InSite, and Victoria SAFER) with evaluation of this novel intervention underway in these locations.

In response to continued and accelerated toxicity of the unregulated drug supply and deaths and harms resulting from unregulated drug toxicity, this document is informed by current clinical practice and emerging evidence to provide considerations and guidance for the off-label use of fentanyl tablets to reduce unregulated fentanyl use and associated harms. This guidance is based on clinical experience and policies (which have been informed by participant experience) at PHS Community Services Society, AVI Health and Community Services' Victoria SAFER Initiative, and InSite Supervised Consumption Site.

1.3 How to Use this Document

This document offers the clinical foundations and medico-legal considerations for the provision of fentanyl tablets in a higher dose maintenance program.

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 consultations 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 fentanyl tablet 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. Fentanyl tablet 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 fentanyl tablet program.

2.1 Dosing Strategies

There are two dosing strategies for the fentanyl tablet program:

1. **Fixed dose as-needed (PRN) program** at 800 mcg every 3 hours (Q3H), which would allow twice daily (BID), three times daily (TID), or four times a day (QID) dosing depending on operational hours, after an initial test dose with post-dose observation. This approach may be desirable for participants with lower opioid needs and/or those who do not want to undergo a titration or missed dose procedures. The fixed dose PRN program may also be desirable to those who experience higher accessibility barriers and/or more episodic needs than someone who intends to consistently attend the program twice or more daily.
2. **Higher dose maintenance program** requires titration to achieve a scheduled maintenance dose. This approach may be preferred for participants who require doses above 800mcg Q3H.There is no maximum dose in this resource; dose is determined by participant comfort and sedation post-dose. See the *Fentanyl Tablet (PRN Program): Prescribed Safer Suppl Protocols* for more.

Programs may offer the PRN program, the maintenance program, or both, depending on client need and programmatic capacity. The maintenance program allows for higher doses, while the PRN program requires less capacity.

This protocol focuses on the higher dose maintenance dosing strategy.

2.2 Medication Dispensation

Depending on the resources available at the program administrating site, as well as the needs of population served, the fentanyl tablet program may involve one of the following:

A. Participant attends clinic 2–4 times daily as operational hours allow to receive medication and any other care.
B. Participant titrates at clinic. Once the participant reaches a dose for a sufficient period of time at which the prescriber deems post-dose observation is no longer required, the participant goes to the pharmacy for daily witnessed ingestion, if agreed upon by the pharmacy. Take-home dosing may be considered for subsequent daily dose(s), depending on clinical judgment, participant preference, and meeting eligibility criteria (see 5.8.viii Take-home Doses). Thereon, the participant attends clinic regularly for assessment and any other care.

> Note: Before writing a prescription that will utilize witnessed dosing at a pharmacy, the prescriber or other staff should connect with the pharmacy to ensure capacity, establish a relationship, and identify any barriers to this model.

See Appendix 11: Sample Service Delivery Models for more details of different dispensation models.

2.3 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 fentanyl tablets. 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.

2.4 Regional Adaptation

Note: This document is meant to provide a standardized protocol for the provision of fentanyl tablets. 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 participant access, public safety, and clinical judgment. See Appendix 11: Sample Service Delivery Models for program options and 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

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 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 fentanyl tablet 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:

- Active 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) and opportunities for harm reduction teaching
- Comorbid mental and physical health conditions
- Prescribed and non-prescribed medication(s) and natural health products
    - 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)
- Ability to attend pharmacy and/or clinic for daily witnessed ingestion twice or more a day
    - Note: Specific pharmacy details should be confirmed ahead of time

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

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

If the participant is receiving medications from a community pharmacy that could precipitate a drug–drug interaction with fentanyl tablets, 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 fentanyl tablet 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.
    - 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.

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[a] Teva Canada Ltd. Fentora fentanyl citrate: Product monograph. Montreal, Quebec 2016. https://pdf.hres.ca/dpd_pm/00036628.PDF
[b] Note: Clinical experience at AVI SAFER shows that, with proper safeguards and a modified titration plan/post-dose observation plan, prescribed fentanyl tablets can be effective and safe for people who also drink alcohol.

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
        - If benzodiazepine dependence is suspected (with or without a benzodiazepine use disorder) conversation should also include teaching and education on the risks of benzodiazepine withdrawal with abrupt cessation of benzodiazepine use. Consider referrals to medical withdrawal management settings when appropriate
    - 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
    - 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)

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[b] Note: Clinical experience at AVI SAFER shows that, with proper safeguards and a modified titration plan/post-dose observation plan, prescribed fentanyl tablets can be effective and safe for people who also drink alcohol.

[c] See the BCCSU's "Benzodiazepines and Opioids" for guidance on providing care to individuals who have been exposed to benzodiazepines through the use of adulterated opioids.

- 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 the fentanyl tablet.[d] The examples within each category should not be considered comprehensive; prescribers should consult the product monograph of any drug co-administered with fentanyl 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 fentanyl plasma concentrations
    - Concomitant use of CYP3A4 inhibitors is not recommended, unless participant is closely monitored
- CYP3A4 inducers
    - The concomitant use of drugs that induce CYP3A4 metabolizing enzymes (e.g., carbamazepine, phenytoin, or rifampicin) may reduce the efficacy of fentanyl requiring a dose adjustment

[d] Teva Canada Limited. Product Monograph: Fentora fentanyl citrate. Montreal, Quebec 2016. https://pdf.hres.ca/dpd_pm/00036628.PDF

    - After stopping treatment with a CYP3A4 inducer, the effects of the inducer will decline gradually, which may result in an increase in fentanyl plasma concentration
- MAO inhibitors
    - Fentanyl is contraindicated in individuals 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 fentanyl tablets, 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 fentanyl tablets
- Muscle relaxants
    - Concomitant use may lead to respiratory depression
    - Monitor participant to prevent oversedation—consider a slower titration process and/or dosage decrease of fentanyl tablets or muscle relaxant
- 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

SPECIAL CAUTION—Antiretoviral medications

There is a strong interaction between fentanyl 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 fentanyl 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 fentanyl if they meet the above eligibility criteria; however, fentanyl titration for participants on both ARV and fentanyl should be slower than for other participants, and they must be monitored closely for sedation. Switching to bictegravir-emtricitabine-tenofovir alafenamide (Biktarvy) helps to avoid drug–drug interaction between fentanyl tablets and ARV regimen. Prescribers should weigh the risks and benefits of ARV change before initiating the switch, in consultation with the HIV physician.

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

Individuals currently using fentanyl tablets 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 fentanyl tablet dose as required.

If an individual has already been stabilized on fentanyl tablets in combination with cobicistat or ritonavir, and the ARV regimen is subsequently changed to remove cobicistat/ritonavir, a fentanyl tablet 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.

4.0 Coverage

Special Authority coverage must be secured for each participant enrolled in a fentanyl tablet program. Once Special Authority is approved, coverage is available through PharmaCare, including Plan G and Plan W for those eligible.

Once approved, the approval period lasts for one year, at which point coverage must be renewed annually.

In order to avoid delays:

- Complete **all** request form fields (see the link for the e-Form below)
- Write **legibly**
- **Sign** the form
- Include the **diagnosis**
- Submit a request **once** only

The following forms, resources, and pages provide relevant information on applying for Special Authority coverage for fentanyl tablets:

Special Authority (SA) – Province of British Columbia

Limited Coverage Drugs—Fentanyl (Tablet)

Special Authority e-Forms login page

Submitting a Special Authority Request—Information for Prescribers

Prescriber Checklist

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 fentanyl tablets 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 the participant's 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. Participants should receive notifications up front of the program's policy on take-home doses and alternative options available (if there are any) should they experience unintentional absenteeism from the program.

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).
- ☐ 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 fentanyl tablets 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)
- ☐ Verify and document confirmation of Special Authority approval. Do not dispense without confirmation and documentation of coverage unless the program is able to cover costs in the interim
- ☐ Set reminder for 11 months after approval date to reapply for Special Authority

- ☐ If planning to utilize a model in which doses are witnessed at a pharmacy, connect with the pharmacy in question prior to prescribing, to ensure capacity, establish a relationship, and identify any barriers
- ☐ 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 fentanyl tablet 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 fentanyl tablets and program requirements (see box below)

Important points to discuss with participants before starting the fentanyl tablet program

- It takes 4 post-dose observation periods across 4 consecutive days to no longer require post-dose observation
- Following any dose change, participants must stay for post-dose observation for 4 post-dose observation periods across 4 consecutive days, to ensure their safety
- If there is sedation after the first dose, the participant will not be eligible to continue with this program and must be reassessed by their prescriber
- Participant may be required to come to clinic 2–4 times daily, as doses need to be witnessed by a nurse or designated provider (unless the individual is eligible for and prefers take-home dosing; see 5.8.vii Take-home Doses)
- Chewing, sucking, or swallowing the tablets is contraindicated, as the tablets are absorbed sublingually or buccally and other methods of consumption will result in the medication being destroyed, thereby significantly reducing efficacy—buccal administration is the most efficient route of ingestion
- Any program-specific constraints that may impact access to fentanyl tablets, including hours of operation and capacity limits

5.3 Initiation

The higher dose fentanyl tablet maintenance program may be preferred by participants who require doses above 800mcg Q3H. (Individuals with lower opioid needs, episodic needs, or higher accessibility barriers may consider the fixed dose as-need [PRN] program at 800mcg Q3H.)

Participants can administer the dose buccally or sublingually.

Regardless of baseline opioid use, the initial dose is 800mcg. Post-dose observation is required for 25 minutes, after which the participant can access an additional dose of 200mcg if desired, followed by another post-dose observation period.

If there is no sedation after the first dose(s), the participant may begin their titration starting at 800mcg, with a minimum of 3 hours between doses, and an increase of 100mcg each subsequent dose. Post-dose observation is required for 25 minutes after each dose during the initiation phase.

Provided there is no sedation, doses can increase by 100mcg per dose.

5.4 Titration Schedule

The higher dose fentanyl tablet maintenance program requires titration to achieve a scheduled maintenance dose. Participants will attend twice or more daily for the initial titration, followed by a period of post-dose observation once they have achieved their maintenance dose to establish tolerance and safety (i.e., 4 observed doses over 4 consecutive days with no sedation). The prescriber can make a clinical judgement on a case-by-case basis to stop post-dose observation early.

There is no maximum dose for this program. All participants should be titrated from 800mcg until an effective dose is reached (e.g., once cravings and withdrawal symptoms are managed), as long as there are no complications or issues noted with sedation.

Table 1 shows an example BID titration schedule to reach a dose of 1300mcg.

Table 1. Fentanyl Titration Schedule for Maintenance Program

Day	Procedures
1	800mcg SL (Q3H) 3 hours or more later 900mcg SL
2	1000mcg SL 3 hours or more later 1100mcg SL
3	1200mcg SL 3 hours or more later 1300mcg SL

SL=sublingual

Based on hours of operation and program capacity, BID, TID, or QID dosing may be appropriate.

There are subtle differences in absorption between single tablet administration and multiple tablet administration. If a person is administered four 100mcg tablets, absorption will be faster due to a larger total surface area from four tablets versus a single tablet of 400mcg. For consistency and cost consideration it is recommended that participants are administered the tablet combination using the fewest tablets possible, as outlined in **Table 2** below.

The maximum dose for the higher dose fentanyl tablet maintenance program is not strictly defined. Once cravings and withdrawal symptoms are managed (and/or other individual goals are achieved), that dose will be considered a person's 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 during titration, it is recognized that this may not be solely due to the fentanyl tablet dose but may be due to other contributors such as sleep deprivation or having used other substances before presentation to the program. If a participant has one-time sedation at a dose, they may continue to titrate up the next day, after the underlying cause of the sedation has been resolved.

Whenever a dose is titrated up, post-dose observation is once again required. After **4 witnessed doses over 4 consecutive days** at a new dose without sedation, the participant no longer requires

post-dose observation until further increases are made. The prescriber can make a clinical judgement on a case-by-case basis to stop post-dose observation early.

See Appendix 10: Operational Considerations for operational considerations regarding staffing and nurse-led titration.

5.5 Tablet Combining

Some doses will be a single tablet, while other doses will require a combination of different tablet strengths. **Clinicians must be vigilant about the dose and required combination of tablets, with the least number of tablets possible recommended each time** (see **Table 2**). Due to variations in absorption, clinicians may not use other combinations of tablets to create a dose, unless specifically instructed by the prescriber or pharmacy to do so.

Table 2. Fentanyl Tablet Combinations

Dose (mcg)	Tablet Combination		
	Tablet 1	Tablet 2	Tablet 3
800	1 x 800mcg		
900	1 x 800mcg	1 x 100mcg	
1000	1 x 800mcg	1 x 200mcg	
1100	1 x 800mcg	1 x 200mcg	1 x 100mcg
1200	1 x 800mcg	1 x 400mcg	
1300	1 x 800mcg	1 x 400mcg	1 x 100mcg
1400	1 x 800mcg	1 x 600mcg	
1500	1 x 800mcg	1 x 600mcg	1 x 100mcg
1600	2 x 800mcg		
1700	2 x 800mcg	1 x 100mcg	
1800	2 x 800mcg	1 x 200mcg	
1900	2 x 800mcg	1 x 200mcg	1 x 100mcg
2000	2 x 800mcg	1 x 400mcg	
2100	2 x 800mcg	1 x 400mcg	1 x 100mcg
2200	2 x 800mcg	1 x 600mcg	
2300	2 x 800mcg	1 x 600mcg	1 x 100mcg
2400	3 x 800mcg		
2500	3 x 800mcg	1 x 100mcg	
2600	3 x 800mcg	1 x 200mcg	
2700	3 x 800mcg	1 x 200mcg	1 x 100mcg
2800	3 x 800mcg	1 x 400mcg	
2900	3 x 800mcg	1 x 400mcg	1 x 100mcg
3000	3 x 800mcg	1 x 600mcg	

5.6 Missed Doses

Participants must have **4 doses over 4 consecutive days** (e.g., a participant may stay for all 4 doses in one day, 2 doses over 2 days, or 1 dose on each of 4 consecutive days) with no sedation during the 25-minute post-dose observation period, after which they no longer require post-dose observation (the prescriber can make a clinical judgement on a case-by-case basis to stop post-dose observation early).

If there are missed doses during this time, participants continue with post-dose observations until they have 4 doses in a row, with no sedation post-dose.

See Appendix 6: Fentanyl Tablet Participant Journey Map which includes procedures in brief for missed doses.

5.6.i Missed doses during titration

This applies to participants undergoing their initial titration to a maintenance dose or restarting after an extended absence.

For participants who are re-titrating after a dose decrease on maintenance follow 5.6.ii Missed doses during maintenance, below.

If a participant misses 2 consecutive doses, there is no change and they can continue with the next step in titration.

If a participant misses 3 doses or more, their titration must be started again from the beginning.

An example of missed dose scenario during titration follows:

> **Question:** Lena is on 700mcg BID and titrating to 1000mcg. She misses 15 consecutive doses. Based on the procedures for missed doses during titration, what is Lena's restart dose and titration plan?
>
> **Answer:** Lena has missed ≥3 consecutive doses during her titration, and therefore she will restart titration from the beginning at 400mcg BID. Lena can increase by 100mcg each dose and stop titration at her discretion. The titration can also be stopped if Lena becomes over-sedated with a SAFER Sedation Scale (SSS) >2. When Lena reaches 1000mcg BID, titration will pause pending prescriber assessment and participant request to increase.

Table 4. Summary of procedures for missed doses during titration

Consecutive doses missed	Action
2	No change; continue with the next step in titration
≥3	Restart titration from the beginning

5.6.ii Missed doses during maintenance

This applies to participants who have reached maintenance or 4 consecutive doses without sedation.

A participant on a maintenance dose may miss **up to and including 14 consecutive doses** with no change to the dose and no post-dose observation requirement.

If participant on a maintenance dose misses 15–16 consecutive doses, there is no dose reduction, but the person must have one 10-minute post-dose observation to confirm their tolerance.

Participants receiving a maintenance dose do not require a dose adjustment unless they miss 17–22 consecutive doses. If this occurs, a 25% dose reduction is recommended. If a participant misses **23–28 consecutive doses**, a 50% dose reduction is recommended. When calculating doses, the amount should be rounded up to the nearest 100mcg. If a participant misses **17–28** consecutive doses, the prescriber and/or the pharmacy should be notified, depending on the service delivery model (see Appendix 11: Sample Service Delivery Models). However, individual providers and pharmacists may agree that notification is required for fewer missed doses. All dose adjustments must be made by a prescriber.

After **29 or more consecutive doses misse**d, titration will restart from the beginning. Individual programs may determine their own protocols and workflows for reassessment and re-titration.

An example of missed dose scenario during maintenance follows:

> **Question:** Lena is on 1000mcg BID maintenance dose and misses 18 consecutive doses. Based on the procedures for missed doses during maintenance, what is Lena's restart dose and titration plan?
>
> **Answer:** Lena's missed doses falls under the 17–22 consecutive missed doses range, and therefore she will require a dose decrease by 25%, rounding up to the nearest

100mcg. This means Lena will restart at 800mcg (i.e., 750mcg rounded up to the nearest 100mcg). She can increase by 100mcg each dose and stop titration at her discretion. The titration can also be stopped if Lena becomes over-sedated with a SSS >2. When Lena reaches 1000mcg BID, titration will pause pending prescriber assessment and participant request to increase.

Table 5. Summary of procedure for missed doses during maintenance

Consecutive doses missed	Action
1–14	No change; no post-dose observation required.
15–16	No dose reduction; one post-dose observation required to confirm tolerance.
17–22	Decrease dose by 25%, rounding up dose amount to the nearest 100mcg. All dose adjustments must be performed by a prescriber.
23–28	Decrease dose by 50%, rounding up dose amount to the nearest 100mcg. All dose adjustments must be performed by a prescriber.
29+	Restart titration from the beginning with assessment.

Post-dose observations are always resumed when participants are titrating. If they had previously achieved 4 post-dose observation periods across 4 consecutive days without sedation at maintenance, there is 1 post-dose observation after reaching maintenance. If there are no complications, participants may continue with no post-dose observation. If they had not previously achieved 4 post-dose observation periods across 4 consecutive days without sedation, they must have 4 post-dose observation periods across 4 consecutive days at maintenance with no sedation (the prescriber can make a clinical judgement on a case-by-case basis to stop post-dose observation early).

5.6.iii Missed doses during re-titration

This applies to individuals who previously reached either maintenance or 4 post-dose observation

periods across 4 consecutive days without sedation, had a 25–50% dose decrease due to missed doses, and then missed 1 or more doses during the re-titration phase.

Table 6. Missed doses during re-titration

Consecutive doses missed	Action	Example scenario
1–6	Continue with titration	Xio is re-titrating after a decrease to 800mcg. He received the 1000mcg dose, missed the following 6 doses, then presents to clinic. He will receive 1100mcg.
7	Repeat last dose received	Sammy received 900mcg, missed 7 doses, and presents to clinic. She will receive 900mcg and continue re-titrating at the next dose.
8–17	Decrease dose by 50%	Zee was re-titrating from 800mcg. They got up to 1800mcg, then missed 14 doses. They present to clinic and receive 900mcg.

5.6. iv Missed doses after an increase

If a maintenance participant is scheduled for a dose increase the following day, they may miss up to 4 doses and still receive the increase. If they miss 5–7 doses after a scheduled increase, the nurse will contact the prescriber for a new prescription to return to their previous dose. If the participant has missed 15 doses, they require one post-dose observation, as per the missed dose procedures above (see Missed doses during maintenance).

5.7 Visit Assessment

Participants accessing the fentanyl tablet 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 fentanyl tablet program, both initially and on an ongoing basis, 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 not required for running a fentanyl tablet program.

5.7.i Initial and Ongoing Assessment

Assessment should be performed and documented prior to starting the program and continuously, approximately every 2 months, depending on clinical 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 fentanyl tablet 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 fentanyl tablet program should not disqualify participants from being offered other alternatives that may better reflect their needs and preferences or from restarting fentanyl tablets in the future.

5.7.ii Pre- and Post-dose Assessment

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

5.8 Provision of Fentanyl Tablets

A prescriber or non-prescriber regulated health professional working within their scope and competency should provide the fentanyl tablets. Institution or site-specific protocols for handling controlled substances should be followed.

5.8.i Opening the Foil Package

1. Verify the order and check the medication administration record.
2. Verify the participant's identity.
3. Put on new gloves.
4. Triple check the dose prior to opening the foil package.
5. Confirm that the participant is ready for immediate administration of the tablet.
6. Separate a single unit from the foil package by bending and tearing apart at the perforations, on the indicated line.
7. Peel back the foil backing to expose the tablet. DO NOT attempt to push the tablet through as this may cause damage to the tablet.
8. Open the foil package and drop the tablet directly into a medication cup.

Do not store the tablet once it has been removed from the foil package as the tablet integrity may be compromised and, more importantly, because this increases the risk of accidental exposure to the tablet.

5.8.ii Administration to participant

1. Encourage the participant to have a drink of water prior to administration. This is not a requirement but will help moisten the mouth to aid in the tablet dissolving.
2. DO NOT remove the tablet from the foil package until the participant is ready for immediate administration.
3. Once the tablet is removed from the foil package unit, the participant should immediately place the entire fentanyl tablet in the buccal cavity (above a rear molar, between the upper cheek and gum) or sublingually.
4. Use fentanyl tablets whole. Participants should not split the tablet.
5. Instruct the participant to not split, suck, chew, or swallow fentanyl tablets as this will affect absorption of the drug and reduce its efficacy.
6. The fentanyl tablet should be left in place until it has fully dissolved, which takes approximately 14–25 minutes.
7. After 30 minutes, if remnants from the fentanyl tablet remain, the participant may be swallowed with a glass of water.

8. It is recommended that participants alternate sides of the mouth when administering subsequent doses of fentanyl tablets (i.e., administer all tablets of a given dose on one side of the mouth and then all tablets on the other side of the mouth for the next scheduled dose).

The medication cup should be returned after each administration.

Depending on the program, doses may come from clinic (ward) stock or may be delivered by the pharmacy. Doses may be delivered daily from the pharmacy to be taken at the clinic or the participant may have witnessed ingestion at the pharmacy.

5.8.iii 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 by the end of the clinic day or shift. (See Appendix 12: 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 12: 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.
- Tablets must be accounted for in the Narcotic Count.
- Internal program policies and procedures for narcotic counts must be adhered to.

5.8.iv Titrating Participants

- If a participant is in the titration phase, complete the visit assessment and determine if they would like to increase their dose or remain at their current dose.
- During titrations, each dose requires post-dose observation.
- The case conference (e.g., prescriber/non-prescriber regulated health professional and

any other team members) must be documented.
- Fax the new prescription to the participant's pharmacy.
  - Note: The original prescription should be sent to the pharmacy as soon as possible.
- Administer the dose to the participant as per the administration procedures (see 5.8.ii Administration to Participant).
- When a participant has received the titration final dose, the nurse will check the box on the Fentanyl Tablet Titration Record (see Appendix 7: Sample Titration Record for sample) indicating the person is moving to maintenance.

5.8.v Maintenance Participants

- Workflows will vary based on program specifics.
- Write a new maintenance prescription for daily witnessed ingestion or delivery to clinic, as per protocol. Nurses must track the number of consecutive maintenance doses after reaching maintenance that require post-dose observation. This should be clear in their chart note (e.g., dose 3/4).
- Once the participant has administered 4 doses over 4 consecutive days with no sedation, post-dose observation period is no longer required and this should be indicated on the prescription. The prescriber can make a clinical judgement on a case-by-case basis to stop post-dose observation early.
- The dose administration schedule will depend on program or pharmacy hours, capacity, and individual preferences. A clearly established schedule is important.
- Use the least number of tablets required to obtain the correct dose and be cautious when a combination of tablets is required to obtain the correct dose (see 5.5 Tablet Combining).

5.8.vi Wasted Doses

- A dose will be considered wasted if the tablets are spilled onto the floor. The disposal of the wasted tablets must be witnessed by nursing or pharmacy staff. Wasting doses should be independently verified and documented by a second member of the care team. Unaccounted for spilled doses will not be replaced.
- Tablets that are broken or partially crushed during medication dispensation should be wasted, and wastied doses should be independently verified and documented by a second member of the care team.
  - Partially crushed or broken tablets should not be administered, as absorption is unpredictable.
- 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.

5.8.vii Medication Storage and Returns

- Medication storage will vary by program specifics. Please see regulations under the *Controlled Drug and Substances Act* regarding storage and return of fentanyl tablets.[e]

5.8.viii Take-home Doses

Take-home doses may be considered in the following situations:

- Participant has completed titration and are displaying psychosocial and clinical stability
  - Clinical stabilization includes (but is not limited to) lack of cravings, improved sleep quality and duration, overall well-being, reduction or cessation of unregulated opioid use, and consistent attendance at appointments
  - Psychosocial stabilization includes (but is not limited to) integrating new activities, re-connecting with family, and attaining safe housing

    AND

  - Participant preference

    AND

  - Participant is able to safely store medication (i.e., secure, locked container or cabinet)
  - Clinical judgment
- Assessment of stabilization depends on each individual's circumstances, needs, goals, and how these change over time. A review of the participant's baseline assessments (e.g., physical and mental comorbidities, social determinants of health—see 3.1 Assessment for a detailed list) and ongoing monitoring (see 7.0 Assessment, Continuing Care, and Program Evaluation) can support this assessment.
- Operational considerations may necessitate take-home dosing for one or more doses per day; however, operational considerations alone are insufficient rationale for providing take-home doses
  - Participants who are not suitable for take-home doses should continue to access all doses as witnessed doses, which may limit the programmatic models they can access in a given time

[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

- Individual and community safety should be prioritized in making decisions about take-home doses.
- The decision to prescribe take-home doses should be documented, including the rationale.

5.9 Dosing and Conversion with Other Fentanyl Products

- **Fentanyl tablets are not bioequivalent with other fentanyl products.**
- 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.

5.10 Sedation and Post-Dose Observation

5.10.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 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.

Post-Dose

A SSS 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 must 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.

5.10.ii Ending Post-Dose Observation

The post-dose observation period will be finished when the participant has administered **4 observed doses over 4 consecutive days** with no post-dose sedation or after a prescriber assessment, whichever comes first (the prescriber can make a clinical judgement on a case-by-case basis to stop post-dose observation early). For example, if an individual attends 3 days in a row on BID dosing and misses the 4th day, then attends 3 more days in a row with no signs of oversedation, the prescriber may determine that the post-dose observation period can be ended.

Once a participant no longer requires post-dose observation, this should be documented in their chart.

5.10.iii Leaving Early from Post-Dose Observation

All participants will be educated on the rationale for post-dose observation and the risk of overdose. Participants are strongly encouraged to wait on site for the full 25 minutes post-dose, although they cannot be prevented from leaving if they choose to do so.

When a participant on titration leaves before the post-dose observation is complete, they may repeat the same dose with observation at the next visit (until adherence to post-dose observation is reached), based on clinical discretion, but staff should encourage them to stay and make sure they understand the risks of leaving early.

Each time an individual leaves early, staff will reiterate the risk of overdose and encourage the participant to remain in the space. If the participant chooses to leave, the staff should document that the individual was informed of the potential risks.

If a participant frequently leaves before the post-dose observation is complete, the team will work with the individual to come up with a collaborative care plan. If it continues to be an issue, the participant will need to see the prescriber to discuss further.

If a participant leaves early from post-dose observation, this may prompt a reassessment of their eligibility for the program. Repeated departures during the post-dose observation period may indicate that this program is not meeting the client's needs. However, programs should avoid discharging participants solely because they leave early. Pausing titration when post-dose observation requirements are not adhered to, with witnessing and documentation that the tablet has dissolved by the time of departure, may be a safe and pragmatic way to address the issue.

5.11 Titration with OAT

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

Fentanyl tablet 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*.

5.12 Prescriptions

Before writing the prescription, confirm Special Authority approval by checking the chart for confirmation fax or calling pharmacy to check on approval status. Many programs have funding to start the medication and cover costs through operational funding in the short time before Special Authority is processed. This allows for same day starts on the program.

5.12.i Duration of prescription

The length of 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. Ensure that the prescription does not end on days the program is closed (e.g., weekends or statutory holidays).

5.12.ii Writing Prescriptions

An example of 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**

Fentanyl Citrate 1000mcg

QUANTITY (IN UNITS)

28,000mcg (NUMERIC) | Twenty-eight thousand mcg (ALPHA)

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 1000mcg sublingual
Twice daily as needed
Minimum three hours between doses
Daily witnessed ingestion
Rx: May 1-14

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

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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.

5.13 Holding Medication

- If it is determined the participant should NOT receive their fentanyl tablets (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

5.14 Discontinuation

Individuals may discontinue taking fentanyl tablets due to their 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.

5.14.i Voluntary Transition to Oral OAT

If an individual prefers to transition on to OAT and stop fentanyl tablets, 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, fentanyl tablets can be tapered or outright discontinued at the participant's discretion if cravings and withdrawal symptoms are adequately managed.

5.14.ii Transition Due to Repeated Diversion

Fentanyl Tablet Alone

Individuals who are on fentanyl tablets 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*.

Fentanyl Tablet and OAT

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

5.15 Community Pharmacy Involvement in Care

Programs and prescribers that plan to utilize community pharmacies for fentanyl tablet delivery, dispensation, or administration should take the following precautions:

1. Confirm the community pharmacy has a copy of the fentanyl tablet protocol available on site.
2. Connect with pharmacy to ensure capacity, establish relationship, and identify any barriers, prior to the prescription being sent.
3. Confirm that participating community pharmacies have access to and attend BCCSU education sessions on fentanyl tablet programming.
4. Ensure participating community pharmacies have access to contact information for the prescriber or an alternative in the event the prescriber is unavailable.

Additional precautions are required should the community pharmacy assume other roles including post-dose sedation assessment, and those precautions should be clearly co-developed and documented by the participating pharmacy and fentanyl prescribing program.

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.

Point-of-care urine drug tests should be performed for individuals 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. Fentanyl tablets were 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 fentanyl tablets.

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 12: 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 7. 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 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
- Vitals measured and recorded (every 2 months)
- 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 fentanyl tablet 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. Diversion of fentanyl tablets can involve an individual spitting out their dose discretely or leaving from the clinic to do so. In general, there is lower street value for a medication that has been in someone's mouth. Fentanyl tablets are effervescent and are witnessed going into the person's mouth, which makes it challenging to remove an intact tablet from the mouth. Therefore, although the person may be leaving with a portion of the tablet still undissolved, the risk of diversion is mitigated by the low demand for drugs that are partially used and the nature of the effervescent tablet.

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 fentanyl tablets without being offered transition to OAT or adjustment of concurrent OAT dose.

To assess diversion, clinicians can use urine drug testing to monitor. However, it is impossible to differentiate unregulated fentanyl from prescribed fentanyl tablets via urine drug tests. Benzodiazepine screening (specifically 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 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: «»
Review and assessment of participant's previously identified goals: «»

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.*

Fentanyl tablet programs are trialing fentanyl tablets 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:

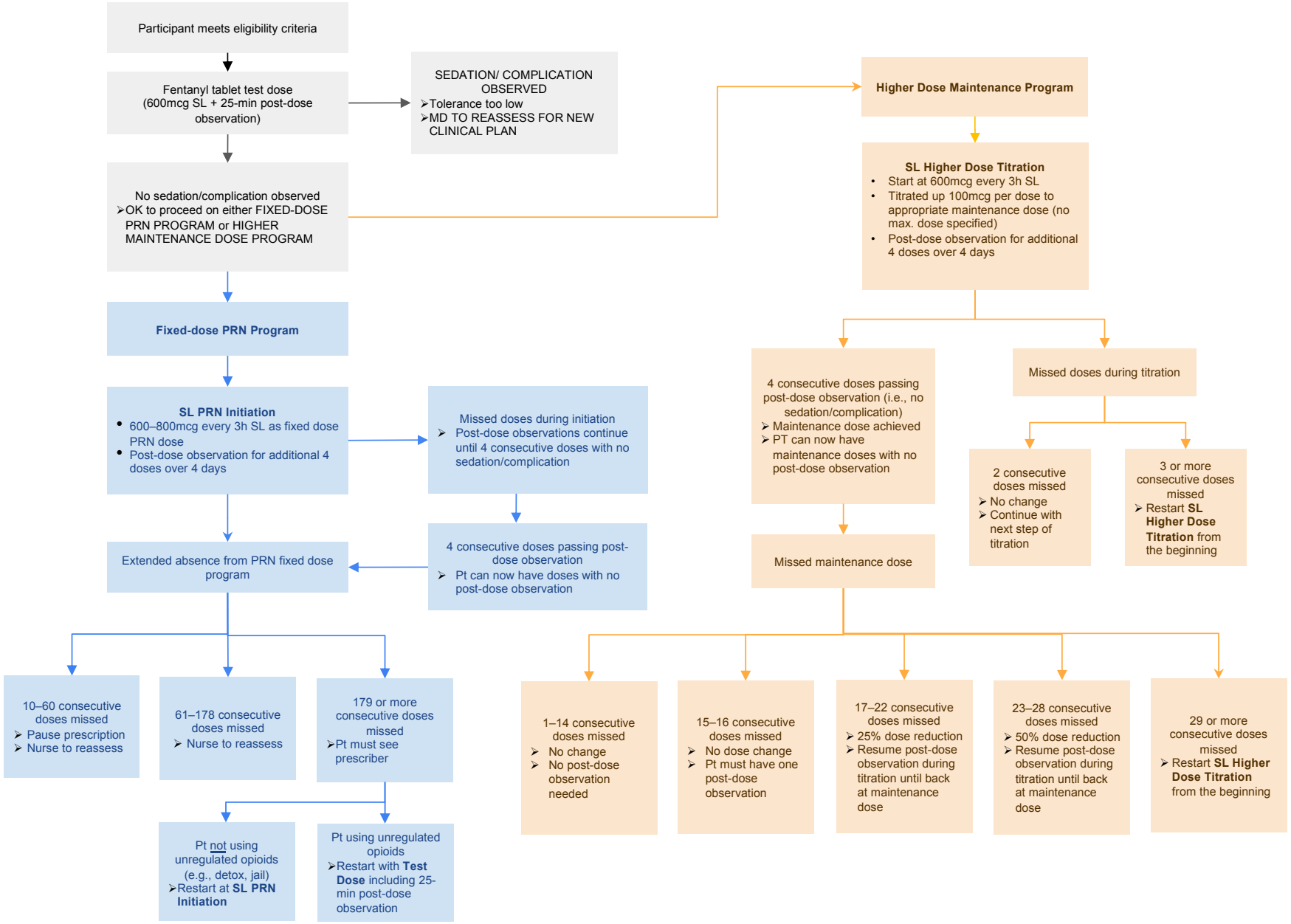
1. I am being enrolled in this program to try to decrease my overdose risk.
2. For safety reasons, the program staff will contact my current health care providers to review my enrollment in this program.
3. My prescriber will work with me to develop a clinical plan and set goals. These goals will be 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 medications.

Appendix 6: Fentanyl Tablet Participant Journey Map



Appendix 7: Sample Titration Record

Date: ______________________ Prescriber: ____

Participant Info	AM Dose Administered	Admin. Nurse	Start maintenance Rx next dose
	PM Dose Administered	Admin. Nurse	
	Daily Total		☐
Participant Info	AM Dose Administered	Admin. Nurse	Start maintenance Rx next dose
	PM Dose Administered	Admin. Nurse	
	Daily Total		☐
Participant Info	AM Dose Administered	Admin. Nurse	Start maintenance Rx next dose
	PM Dose Administered	Admin. Nurse	
	Daily Total		☐
Participant Info	AM Dose Administered	Admin. Nurse	Start maintenance Rx next dose
	PM Dose Administered	Admin. Nurse	
	Daily Total		☐

Tablet Combinations:

100mcg	200mcg	300mcg	400mcg	500mcg	600mcg	700mcg	800mcg	900mcg	1000mcg
1 x 100mcg	1 x 200mcg	1 x 100mcg + 1 x 200mcg	1 x 400mcg	1 x 100mcg + 1 x 400mcg	1 x 600mcg	1 x 100mcg + 1 x 600mcg	1 x 800mcg	1 x 100mcg + 1 x 800mcg	1 x 200mcg + 1 x 800mcg
1100mcg	**1200mcg**	**1300mcg**	**1400mcg**	**1500mcg**	**1600mcg**	**1700mcg**	**1800mcg**	**1900mcg**	**2000mcg**
1 x 800mcg + 1 x 200mcg + 1 x 100mcg	1 x 800mcg + 1 x 400mcg	1 x 800mcg + 1 x 400mcg + 1 x 100mcg	1 x 800mcg + 1 x600mcg	1 x 800mcg + 1 x 600mcg + 1 x 100mcg	2 x 800mcg	2 x 800mcg + 1 x 100mcg	2 x 800mcg + 1 x 200mcg	2 x 800mcg + 1 x 200mcg + 1 x 100mcg	2 x 800mcg + 1 x 400mcg

Appendix 8: Sample Ongoing Maintenance Record

FENTANYL TAB NEW ONGOING MAINTENANCE RX RECORD

Prescribing Date: _____ (all Rxs will be for 91 days starting TOMORROW)

All doses recorded in MICROGRAMS (mcg)

Patient Info	Dose Total Quantity:	
Prescribing MD	1st day doses administered from WS: AM ☐ | PM ☐	All doses missed: ☐
Patient Info	Dose Total Quantity:	
Prescribing MD	1st day doses administered from WS: AM ☐ | PM ☐	All doses missed: ☐
Patient Info	Dose Total Quantity:	
Prescribing MD	1st day doses administered from WS: AM ☐ | PM ☐	All doses missed: ☐
Patient Info	Dose Total Quantity:	
Prescribing MD	1st day doses administered from WS: AM ☐ | PM ☐	All doses missed: ☐

Directions to nurse: Fax this form at the end of the day for new maintenance doses that start tomorrow. The next morning, use this form as a record of authorized doses (MARs and meds will not yet be updated). Mark all administered doses on this form and fax with the packing list at the end of the day. *Dose = quantity of each dose administered; Total Quantity = total of all doses per day x 91 days*

COMMUNITY APOTHECARY

(P) 604-757-1254 (F) 604-563-7852 402-3701 Hastings St, Burnaby, BC, V5C 2H6

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 well-situated to offer fentanyl tablet programming. Low threshold primary care clinics and community pharmacies are also viable service delivery environments for fentanyl tablet 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 with verbal reminders provided regularly.
- Establishing or formalizing a partnership with pharmacies is an important step in managing the storage, handling, and tracking of fentanyl tablets or other prescribed fentanyl options. Ideally, a program will have one pharmacy partner for on-site opioid deliveries. For pharmacy-based programs, a clinic may have multiple community pharmacy partnerships.
- Determine prior to operationalizing the program 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 splitting and sharing of non-prescription drugs brought into the site by participants. 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, participants should receive clear and ongoing communications around the “latest possible first dose.” The fentanyl tablet program is offered with a minimum of 3 hours between doses. If the clinic closes at 5:00PM and a participant arrives after 2:00PM for their first dose on BID dosing, they will not be eligible for their second dose that day. Transparency around these limitations is critical in improving participant outcomes and reducing likelihood of conflict.

- 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

- Dehydration and dry mouth can significantly impact the time needed for the fentanyl tablet to dissolve. A selection of beverage options will encourage participants to hydrate prior to receiving their dose which will reduce delays in clinic wait-times.

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.

Setting

- Consider a semi-private space for participants to wait while the fentanyl tablet dissolves.
- Consider a separate "chill" or post-dose observation space that offers snacks and access to support workers—this is particularly valuable while participants are required to complete 25-minute post-dose assessments.
- Incorporate physical space design considerations for a double-lock system (and a time-release safe in a pharmacy setting) that is in accordance with safe storage standards for Schedule 1 medications.
- Whenever possible, site design should be informed by the participant and by staff with lived/living experience given they are best suited to articulate the needs of those accessing the site.

Training

- Staff should receive, at minimum, training on witnessed consumption, post-dose sedation assessment, team overdose response, and crisis prevention/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, communication, and therapeutic relationships.

Combination with other safe supply interventions

- Consider fentanyl tablets (and other prescribed fentanyl options) in conjunction with other prescribed safer supply interventions. For example, participants who receive OAT and fentanyl tablets during clinic hours may have unmet needs outside of clinic hours (i.e., in the evening or overnight). The addition of tablet hydromorphone prescribed under BCCSU's *Opioid Use Disorder Practice Update* may be considered to address those unmet needs.
- Use a person-centered approach to determine the best combination of pharmaceutical options for each individual program. This can be achieved through participant-led goal setting, a comprehensive substance use assessment, and creating accessible channels for feedback dose adjustments can occur in a timely manner.

Nurse-led program

- Assessments, titration, and maintenance doses are conducted by nurses.
- Nurses may call the prescriber for new prescriptions or changes in prescriptions.
- For nurse-led titration, a nursing decision support tool can outline the titration schedule and a titration ceiling (e.g., 1000mcg) beyond which prescriber assessment may be required (this can depend on prescriber availability based on program resources).
- To alleviate administrative burden, programs may consider charting by exception when conducting pre- and post-dose assessments with notes on the Narcotic Record.

Daily dosing

- Depending on operational capacity, BID, TID, or QID dosing may be accommodated.
- Further considerations may include developing criteria for weekend or extended take-home doses (see 5.8.viii Take-home Doses).

Pharmacy-based dosing

- See Appendix 11: Sample Service Delivery Models for examples of mixed and exclusive pharmacy-based dosing.

Appendix 11: Sample Service Delivery Models

The following information is intended to offer alternate suggestions for service delivery to acknowledge the unique capacity and resource availability of different programs and sites. Innovative approaches and considerations are needed, particularly to support scalability in rural and remote areas. An important consideration of implementing alternate service delivery models is prescriber flexibility on both witnessed dosing and post-dose observations.

This is not an exhaustive list of potential models but a prompt to tailor each program depending on resource availability, local engagement, and consultation with people who use drugs, local cultural practices, and program-specific strengths and constraints. Further considerations may include developing criteria for weekend or extended take-home doses (see 5.8.viii Take-home Doses).

In instances where alternate service delivery models are required, including take-home doses and post-dose observation requirements that differ from those set out in this document, operators and prescribers should clearly document their rationale and what safeguards are in place to reduce potential risk.

Clinic/Site-exclusive

- Clinics/sites that offer 7-day/week services and extended hours are best positioned to implement fentanyl tablet programming. Overdose prevention sites/supervised consumption services that have extended hours and weekend coverage are ideal locations where fentanyl tablet programming can be offered.

Mixed Clinic/Site and Community Pharmacy

- Weekend coverage is not feasible for many programs and services, particularly when considering rural and remote resource disparity. In situations where partial coverage is available in the clinic/site, operators are encouraged to partner with willing community pharmacies that can fill gaps in coverage.
- This model may not be appropriate for individuals who require witnessed ingestion of all doses, depending on operational constraints.
- Take-home doses may be appropriate for some participants to receive their subsequent dose(s) (see 5.8.viii Take-home Doses).
    - For example, a clinic in Kamloops offers fentanyl tablet programming but is only

open from Monday to Friday. The clinic partners with a local pharmacy that is open on weekends, which participants access outside of clinic hours. Titrations can only occur in clinic and do not begin on Thursdays or Fridays to allow for two days of stable post-dose observation prior to the weekend once a person transitions to dose administration at the pharmacy.
    - In the above example, the prescriber balances safer prescribing practice with meeting the accessibility needs of the participant and utilizes local community partnerships to address resource gaps.

Mixed Clinic and Outreach

- Some programs may have outreach capacity for medication delivery either as a means to address weekend coverage or to augment the overall accessibility of the program. Consider the sustainability and capacity limitations of the outreach team prior to implementation.
    - Additional uses of the outreach team could include episodic delivery. In cases where participant access is temporarily limited due to illness (i.e., COVID-19 infection), displacement, homelessness, or changes in mobility, medication delivery should be temporarily utilized if outreach capacity allows for it.

Outreach-exclusive

- See Mixed Clinic and Outreach model for important considerations.
- An outreach-exclusive model requires key modifications from clinic-based models. For example, it is not feasible or reasonable for outreach teams to locate participants twice daily for BID dosing of fentanyl tablets. It is neither scalable nor a good use of program resources or participant time.
- An outreach-exclusive model should consider a first-dose witness, with a subsequent dose(s) carry protocol where titration only happens during the first witnessed dose. After completion of a 25-minute post-dose assessment, participants would receive the same dose as a carry. The next day, the first dose would be an increase from the previous day.

Pharmacy-exclusive

- This option may be considered under the following circumstances:
    - The pharmacy has capacity to provide multiple witnessed doses per day.
    - Participants complete the post-dose observation requirements. The prescription is transferred to the participating pharmacy and subsequent doses occur in

pharmacy. Requests for further titrations will require a return to clinic-based dosing.
    - A community pharmacy is willing to complete any required post-dose observation
    - A community pharmacy is willing and able to follow the protocols established by the BCCSU in this document.
- Take-home doses may be appropriate for some participants to receive their subsequent dose(s) (see 5.8.viii Take-home Doses).
- This model may not be appropriate for individuals who require witnessed ingestion of all doses, depending on operational constraints (see 5.8.viii Take-home Doses).

Appendix 12: 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[h]:** 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

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