SAFER SUPPLY PROTOCOLS

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Contents

Acknowledgements

We would like to acknowledge the critical feedback, insights and guidance of our partners and participants with lived/living experience of criminalized drug use.

We would also like to thank Dr. Christy Sutherland for sharing her early clinical guidance on fentanyl prescribing.

Note: This is a working document. Updates may have been made to these protocols since you received them. Please check back with the Victoria SAFER Initiative (vicsaferproject@gmail.com) at AVI Health & Community Services should updated versions be required.

Community Safe Supply: Flexible Models

At this time in Canada and BC, safe supply largely operates under medical models providing pharmaceutical alternatives to the toxic illegal drug supply. In order to mitigate some of the barriers associated with highly clinical models, new 'flexible' models of safe supply are being implemented to better address accessibility challenges many at risk of overdose experience. Flexible models are not treatment, but rather they are framed within the context of harm reduction and person-centered approaches to care.

Flexible Safe Supply Models

Flexible models of safe supply include "community-based initiatives that seek to provide pharmaceutical alternatives to the illegal drug supply, with as few barriers as possible and without expectation of transition to treatment" (SUAP, p. 7). Key characteristics of flexible safe supply include:

- nimble, responsive, and less treatment-intensive and less medicalized approach to providing safer supply programs;
- often offer daily-dispensed drugs;
- requirement for prescription by a doctor or nurse practitioner;
- may involve a mix of observed and unobserved titration and dosing, according to the needs of participants.

SAFER Community-Based Prescriber Workflows

The Victoria SAFER Initiative is a flexible, community-based, safer supply program with health care provider oversight. Its goal is to affirm the lives of people who use drugs by providing safer, pharmaceutical alternatives to the currently toxic supply created by criminalization.

This workflow is specifically designed for existing community-based participants. At this time, SAFER is not able to accommodate any new community-based intakes.

Guiding Principles of the Victoria SAFER Initiative

1. Harm Reduction Practice
2. Centering People Who Use Drugs
3. Expanding on Evidence for Action

Guiding Principle for SAFER Prescribing: Ask the patient/participant. We want to center their expertise and knowledge of what works best for them, and work with them to find the best possible options available to us to reduce their reliance on an unregulated and toxic supply of substances. SAFER is patient/participant-driven.

Assessment Requirements

1. SAFER Nurse assessment using SAFER intake form.

2. Assessment for evidence of opioid use (nurse witnessed use or overdose; history of OAT; history of overdose). If signs are present, urine drug screen (UDS) is not required but offered.

3. Post-start confirmatory UDS:
    a. Confirmatory UDS required within 21 days of initial start.
    b. Following this, once monthly is the target for routine confirmatory UDS.
    c. Re-initiation of community-based prescribing requires a point of care UDS
    d. Refer to **Potential or Likely Diversion** for overdue and/or negative UDS results.

Pharmacotherapy Options

› starts are 21-day prescriptions with follow-up from SAFER team one week after script

Contraindications
Do not prescribe if the patient has unstable angina or uncontrolled hypertension. The cut off consistently for uncontrolled hypertension is 160/100. Educate on potential side effects. Patients w/ concurrent psychotic or bipolar disorder should be warned of worsening symptoms w/ prescribed stimulant. See BCCSU guideline for details.

Opioids

Hydromorphone IR (Dilaudid) 8 mg tablets

- daily dispense
- maximum starting doses up to 14 tablets.
- maximum maintenance dose up to 30 tablets.

Oxycodone IR 20mg tablets

- daily dispense
- maximum starting doses up to 14 tablets.

M-Eslon 80–260 mg BID

- daily dispense
- if used as OAT, increase dose more rapidly to avoid under-dosing

Other Opioid Options

- Other opioid options, including HDM Controlled Release, should be considered if the participant is requesting and has had previous experience with that medication. Medication coverage should be considered when making this decision. If a SAFER MD decides to choose a different opioid option, a physician to physician with another SAFER MD should occur first and be documented.

Offer Opioid Agonist Therapy (OAT): Kadian, Methadone, Suboxone

- If already on OAT, consider increasing the dose and providing carries and delivery as needed.
- If using M-Eslon as OAT and MEDD >1000mg then consult a second SAFER MD
- For all OAT and PPRM prescriptions, script length is 21 days but follow up should be planned within 7 days of induction.
- There is no max dose for Kadian, provided kidney function is not compromised. Kadian inductions should be coupled with a lab requisition for renal function.
- There is no max dose for methadone, symptom-dependent, and inductions that reach 100mg/day require an ECG prior to further dose increases. Annual ECGs should be prioritized for all methadone patients.
- OAT is offered to all eligible participants, but not required. Participants are educated on the benefits of OAT, but agency of choice is honoured.

Doses should be started at the lower end of range unless there is known tolerance and up-titrated based on patient comfort, withdrawal symptoms, and cravings. Witnessed ingestion is not required for pharmaceutical alternatives but is for OAT. It is helpful to prescribe a long-acting opioid in conjunction with short acting for those not on OAT.

Episodic and Non-OUD Diagnosed Participants

Participants who report episodic opioid use qualify for pharmaceutical alternatives, but not for opioid agonist therapy (OAT).

Stimulants

Dexedrine (Dextroamphetamine) SR 10–20 mg BID; daily dispense (max dose of 40 mg) **and/or**
Dexedrine IR 10–20 mg PO BID-TID; daily dispensed with a maximum dose of 80 mg Dexedrine per day

OR

Methylphenidate SR 20–40 mg once daily; daily dispensed (max dose 100 mg/24 hours) **and/or**
Methylphenidate IR 10—20 mg BID; daily dispensed (max dose of 100 mg methylphenidate per day)

Make the initial prescription 21 days in length.

Alcohol
Includes those using non-beverage alcohol

Managed alcohol program or daily dispensed alcohol. Island Health has an IMAP program for participants who are housed either independently or via temporary shelter sites. Referrals can be made for participants left unsheltered but they must be prioritized for housing alongside the referral.

If your patient is living in supportive housing, please connect with their housing support to determine if they can help obtain and provide alcohol.

Dosing is dependent on individual use, to be evaluated on a case-by-case basis. If the individual is drinking 6-10 beers per day, provide an average dose.

Tobacco

Nicotine replacement therapy (patch, gum, lozenges, inhaler)

- Offer prescription based therapies for tobacco cessation (i.e., varenicline, bupropion).
- If NRT and prescription therapies declined: offer a pack of cigarettes.

Primary Care Workflow
SAFER Victoria will take on primary care for participants who are unattached to an existing provider. When possible, shared care with an existing provider will allow SAFER to take on more participants for their safe supply needs. Fentanyl programming is a specialized service that other PCPs can refer patients to. In those instances, the original PCP would continue providing primary care.

OSCAR EMR

SAFER MDs and nursing should follow OSCAR EMR templates and diagnostic codes for ease of reporting and evaluation.

Potential or Likely Diversion:

*Use clinical discretion specific to the scenario in determining the likelihood of diversion.

- Negative UDS: A UDS that is negative for the prescribed pharmaceutical alternative does not necessarily equate to diversion. Factors such as the frequency the participant is picking up their medications and their use patterns (eg. episodic and harm reduction-focused) need to be considered.
- Delayed UDS: Clinical discretion is exercised in these instances; however, in situations where a UDS is requested and not provided seven days after the request, the prescriber may initiate a dose reduction of 2 tabs/week.
- Any dose reductions or medication discontinuations should occur only after the participant has been informed. This may not be possible if the participant is lost to contact and multiple attempts to reach the participant have been unsuccessful.

Process:

A SAFER nurse will connect with the person and explain risks associated with diversion, including changes to the participant's prescription as ordered by the SAFER MD.

Either a 50% reduction (for an unexpected negative UDS) or a dose reduction of 2 tabs/week (for a delayed UDS) will occur and the participant will be required to provide a new UDS within 14 days of the dose reduction. If the participant provides a positive UDS, the prescription will return to original dosing. A point of care test (POCT) is sufficient.

If a persistent pattern of dose reductions due to negative or delayed UDS occurs, the MRP will request that SAFER staff connect with the participant as soon as possible for a substance use assessment and to consider if other options such as OAT, fentanyl prescribing options, or other harm reduction/safer supply supports should be pursued. This may include a discussion about discharging from the program should there be consistent challenges with matching the needs of the individual with the options available through SAFER.

Switching Oral Safe Supply Options

Please see Appendix 10 for nursing assessment and participant eligibility to change their oral safe supply medications.

Fentanyl Products and Safe Supply Through a 'Flexible' Model

SAFER currently operates according to a flexible model for safe supply of some opioids. Expansion to include fentanyl products will also follow a flexible model however this service is currently being offered as observed dosing at the SAFER consumption site. Guidelines will be regularly updated according to changes in the parameters of legislation and regulations, guidance from staff and people with lived expertise with SAFER, feedback from participants utilizing the service, the SAFER evaluation, and prescribing practices.

Available fentanyl-based safe supply programs at this time include:

- Fentanyl Tablet Program (Fentora): SL use
- Sufentanil: IV or SL use (Closed – no new intakes)
- Transdermal fentanyl patch program: Transdermal use

SAFER Fentanyl Patch Program

Eligibility:

- The Fentanyl patch program is intended to meet the needs of people who use illegal opioids daily (IV, smoke, or insufflation/nasal), who have a high tolerance to opioids, and chronic pain.
- The fentanyl patch program may also be considered for people whose dosing needs are not met by injectable hydromorphone or tablet Dilaudid treatment (i.e. continued access to illegal opioid supply regularly with high overdose risk) and opioid use disorder refractory to other typical opioid agonist therapy options.

The fentanyl patch is applied by the SAFER nurse according to a three times weekly schedule (every 48 - 72 hours), with additional protocol guidance for missed doses.

Evidence

There is currently no peer-reviewed evidence to support using fentanyl patches as a harm reduction approach and treatment for opioid use disorder. However, there is extensive evidence and provincial guidelines that support the use of long acting opioids such as methadone, buprenorphine, and slow release oral morphine to treat opioid use disorder.

While the scientific literature in this area is minimal, physicians in BC are already successfully prescribing fentanyl as a harm reduction approach and treatment for people with opioid use disorder and chronic pain.

FENTANYL PATCH PHARMACOLOGY:

The product monograph can be found here:
https://www.sandoz.ca/sites/www.sandoz.ca/files/Sandoz%20Fentanyl%20Patch%20Product%20Monograph_0.pdf

Contraindications:

- Intentional heavy use of sedative drugs such as alcohol, benzodiazepines, GHB etc.. If a person has benzodiazepine positive urine, they will have another urine test in one week. As the current illegal drug supply is heavily poisoned with benzodiazepines and/or etizolam, decision making around indications for the fentanyl patch program will occur on a case-by-case basis in collaboration with the participant, SAFER team, and physician.
- New or evolving physical health conditions that exclude the use of high dose opioid treatment or could be worsened by high-dose opioid treatment (e.g., severe respiratory disease requiring long-term oxygen, renal failure, hepatic failure).
- Pregnancy- This caution should be balanced against the potential harms of denying access to a pregnant woman who otherwise meets eligibility criteria. Decision making around indications for the fentanyl patch program will occur on a case-by-case basis with the participant, SAFER team, and physician.
- Caution should be exercised for participants who have a history of recent head injury.

If any of these newly arise during care, the SAFER nurse will notify the physician immediately.

Cautions:
Clinicians should consider the following when dosing patch strength. Discussion with the pharmacist is encouraged when considering these clinical factors:

- participant body composition. Those with low body fat may require more frequent patch changes, although our program has baseline 48 hour changes, so this may never be required.
- Hepatic and renal function
- Drug-Drug interactions, including CYP inhibitors and inducers (commonly prescribed - ritonavir, fluoxetine, paroxetine, trimethoprim/sulfamethoxazole, ciprofloxacin, fluconazole, cimetidine)
- High heat can affect metabolism of drug from patch, such as having a fever or hot bath, or performing intense physical activity can increase absorption

SPECIAL CAUTION – Interactions with ARVs

There is a severe interaction between fentanyl patches and Ritonivir and Stribild, Genvoya, and Prezcobix. These ARVs slow the metabolism of fentanyl quite significantly.

- If the person is participating in a stable ARV regimen, start fentanyl dosing slowly and be cautious with monitoring for sedation.
- If the person is on and off ARVs, they cannot start the fentanyl patch program until they have a stable ARV regimen, due to the changes in fentanyl metabolism.

Starting ARVs on the Fentanyl Patch Program:
Someone who is on the fentanyl patch is at risk of overdose if they are started on ARVs (such as if they require post exposure prophylaxis). Before starting ARVs, call and discuss with the HIV pharmacist. They may require a fentanyl adjustment, or a specific ARV regimen to account for the fentanyl patch dose.

- St. Paul's Hospital Pharmacy (Mon-Fri, 8am-5pm PST, available on-call after hours) - **1-888-511-6222**

OVERVIEW: FENTANYL PATCH PRESCRIBING, DOSING, INITIATION AND MAINTENANCE

- Fentanyl patches can be prescribed for people who use IV, inhalation/smoke, or insufflation/nasal. This OFF LABEL use of this medication.
- The fentanyl product is the Fentanyl Patch. SAFER will use strengths of 25 mcg/h, 50 mcg/h, and 100 mcg/h
- At this time, all prescriptions include the requirement for on-site SAFER nurse administration

Physician Workflow: Starting the Fentanyl Patch

- A SAFER physician will assess the person for opioid use patterns and opioid use disorder, other substance use, experiences with previous treatments and outcomes (e.g. such as iOAT) and pain history.

- Each person will have two physicians review and sign off on their chart before starting the fentanyl patch program. This needs to be documented in the ongoing concerns section of the chart: "Has 2 physician approval for fentanyl patch program".

- Each person will have a POC UDS that is confirmed positive for an opioid before starting the program. Each person will have baseline liver and renal function tests.

- If another physician in the community follows the person, that physician will be consulted before starting the fentanyl patch program.

Physician Checklist before starting the patch

1) Special Authority approval received

2) Baseline liver and renal blood work done within the last 3 months and reviewed

3) Approval from two physicians completed

4) Flovent or equivalent ordered to mist on skin prior to patch application

5) Dr. Joshi messaged to track new patient starts

Medication Coverage

Medication coverage will be arranged through a Special Authority application by the SAFER physician.

The Special Authority process must be completed before starting a person on the medication, including a confirmation fax of approval from Pharmacare.

- Confirmation of fax of approval from Pharmacare will be received by the MOA, faxed directly to Cridge Pharmacy and uploaded to the participant's chart.

- The Special Authority form is filled out by the physician who does the first approval.
    - *Example: Pain management for severe chronic pain unresponsive or intolerant to conventional, titrated, opioids such as methadone, morphine and hydromorphone.*

Fentanyl Patch Prescribing Protocols: Initiation and Maintenance

Titration schedule

All dose changes are done by a physician and require a chart note for documentation

The two options to initiate the fentanyl patch: (1) SROM to Fentanyl transition, or (2) OAT maintenance with addition of fentanyl. Note that fentanyl patch dose and oral OAT dose cannot be titrated at the same time. Participants can first titrate on SROM and convert to the fentanyl patch or they can titrate the fentanyl patch alone.

1. SROM to Fentanyl Protocol

Participants can undergo a SROM titration. When they have reached a SROM dose where they are comfortable, the physician can convert the dose over to the fentanyl patch.

Converting SROM to Fentanyl
For Fentanyl patches, a 25% dose reduction is not required when converting to transdermal fentanyl patches, as incomplete cross tolerance is already taken into account in the product monograph conversion charts when converting from oral morphine equivalent to fentanyl patch. Fentanyl patches are the only opioid where this is already accounted for; all others require dose reduction when rotating to a new opioid.

While some physicians feel more comfortable dose reducing, a 25% dose reduction from stable SROM dose may result in significant under-dosing upon rotation to the patch, unless the reason for 25% dose reduction is not related to the issue of cross-tolerance.

Dose Reductions from SROM to Fentanyl
If a SAFER physician would like to proceed with a dose decrease during SROM to fentanyl transition, it is recommended to proceed with less than the traditional 25% dose reduction when converting between opioids. This would be for patients where the clinician is very concerned about tolerance.

PRN Support: During this transition, most participants will require some prn short-acting medications. It is reasonable to bridge with some hydromorphone tablets daily dispensed. A reasonable dose is:

hydromorphone 8 mg 2-14 tabs, per day at 1-2 tabs q1 hour prn.

This can be adjusted, depending on the fentanyl patch dose, and known opioid tolerance.

Prescribing and Administration of First Patch after SROM:

Once a maintenance SROM dose has been reached and the person is ready to transition to fentanyl patch, they will receive a new prescription. See **Appendix 8** Fentanyl Dose Equivalencies for SROM Conversion.

Please specify on the prescription and in the chart to "**apply fentanyl patch 12 hours after the last SROM oral dose".** The fentanyl patch (or patches) is ideally administered **12 hours** after the last SROM oral dose, as it takes 12 hours for the patch to start to take effect, and 24 hours for the patch to reach the expected serum concentration. SROM remains at steady state for 24 hours, then serum concentration drops quickly.

This schedule provides a smooth cross titration over 24 hours. 12 hours post SROM dose may be challenging due to SAFER nursing hours. Less or more time is appropriate for this change, as the clinician is able to accommodate clinic hours.

2. OAT maintenance with addition of Fentanyl patch

Some people on OAT will want to continue on their current OAT, but find that they are still using illegal drugs, having ongoing pain, and would like to have a fentanyl patch in addition to their OAT. Typically, most participants will have a goal of being on the patch alone, without OAT. In some exceptional, well documented circumstances, the person may remain on both the patch and oral OAT. Participants have the option to initiate a fentanyl patch in addition to their regular OAT dose.

- Once they have started a fentanyl patch titration, do not further adjust their OAT dose until they have been on a stable fentanyl patch dose for 1 week.

For those on a stable dose of OAT, their fentanyl dose can be adjusted weekly according to the below chart. Key Practices include:

- Depending on baseline tolerance, the fentanyl patch can be titrated 50- 100mcg every patch change. Past the schedule below, the person can still increase by 50-100 mcg weekly if they are still feeling withdrawal or cravings.

- There is no maximum dose in this program. Each dose increase is done by a physician and includes patient evaluation, history, discussion of goals, physical exam, and mental status exam. **Above 1000mcg is a watchful dose** where the physician can be more cautious and consider asking a second physician to review the chart.

- If the person is re-titrating, or has a known high tolerance, severe pain, or uses high doses of illegal opioids, they can increase their weekly dose by 10-20% or 100 mcg (whichever is higher) when titrating.

Table: Fentanyl Patch Dose Titration

	Moderate tolerance (mcg/hr)	High tolerance (mcg/hr)
Dose 1	100	100
Dose 2	150	200
Dose 3	200	300
Dose 4	250	400
Dose 5	300	500

Writing Fentanyl Patch Prescriptions

Prescriptions will be 7 days to a maximum of 28 days in length for titrating patients and 28 to 56 days (12-24 doses) in length for maintenance patients. Ensure the end date is not on a weekend or stat holiday. The fentanyl patch will commence at 100mcg/hr and can be increased every patch change up to a maximum of 500mcg/hr. At that point, the SAFER MD will reassess and change frequency of dose increases to every two or three patch changes. When the participant reaches 1000mcg/hr, no further dose increases will occur until a physician-to-physician consultation has taken place.

The SAFER physician will write the prescription on a duplicate pad, and enter the details into the OSCAR medication function.

The prescriptions are written as “daily dispense”, and “by nurse q48-72 hours”.

Sample Prescription

Quantity= total number of patches changes

Directions for use: Fentanyl patch 100mcg/hr

Increase by 50-100mcg q patch change to a max 500mcg/hour

3 x weekly with > 48 hours between changes by SAFER nurse

Daily Dispense

Date range (7 days for titration, 28 or 56 days for a maintenance)

Workflow: SAFER Care During Fentanyl Patch Maintenance

Once the person has received their maintenance dose, ongoing participation in the Fentanyl Patch program includes:

- a check in with the nurse every Monday, Wednesday, Friday for their patch changes. The nurse uses the Fentanyl Patch Change OSCAR template to document the visit.
- A monthly review by the clinical and SAFER team in collaboration with the participant. The review will focus on participant experiences participating in the program, perceived benefits and challenges, and identification of additional requested and/or necessary support from the individual and team's perspectives.
- Standard monthly clinical assessments will include:
    - Vital Signs
    - UDS
    - Weight
- Each person should be seen by a physician at least monthly

Urine Drug Testing

All participants will be required to provide monthly urine drug testing for this program, including a Fentanyl Confirmation test. Ongoing use of illegal fentanyl will not be able to be discerned by urine drug testing, unless the person is using illegal fentanyl analogues such as carfentanil or furanyl-fentanyl that are seen on fentanyl confirmation urine drug testing. Ideally, each person will be supported with the fentanyl patch program enough to reduce or stop use of illegal fentanyl.

UDT lab requisitions should be written "UDT, Confirm ___, R/O carfentanil and etizolam".

If a participant declines to provide a urine drug test for 3 months, the SAFER nurse and physician will meet with the participant to determine next steps. Ongoing positive urine drug tests are not a reason to discharge someone from the program as the person may experience other benefits such as decreased illegal drug use, housing stability, and engagement in primary care.

Missed Dose Protocol

Purpose of the Missed Dose Protocol
This missed dose protocol will help to prevent disruptions in access to the program. This protocol will help to better manage chronic pain with a view to improving the experiences of people in the program and ongoing seamless access to their medication.

Overview
- There are person specific standing orders in place to decrease Fentanyl Patch doses after missed patch changes at the SAFER Clinic.
- When entering the program, each person on the program will have a chart review by the physician.
- There may be exceptional circumstances where the physician would like the patch to be discontinued after a missed dose. This will be documented and discussed with the team and the person so they understand the reasons. If the physician indicates that a person is not eligible for the missed dose protocol, the physician also needs to include that information on the prescription, so the pharmacy is aware.
- Dose increases will always be done by a physician; this protocol does not allow for dose increases.
- This protocol only applies if the person still has their patches intact, and on their skin. This protocol cannot be applied in cases where the previous applied patch is not intact or on the person's skin as we do not know the time or amount of the most recent fentanyl dose. In this case, the patient will not receive any patches, and needs to see a physician to potentially restart the program.

This protocol does not apply to participants who don't have a prescription from a SAFER physician. For example, if a person was started or continued on the patch in the hospital, and has a prescription from an in-patient physician, and they miss their scheduled day to get their patch change at the Safer, they are not eligible for the missed dose protocol. They need to see a SAFER physician for consideration of restarting the program.

Missed Dose Protocol Scenarios

*See the SAFER Clinical, Emergency, and Nursing Policy document for detailed nursing workflow regarding missed doses.

The following missed dose protocol applies when the person has reached their maintenance dose. See the next section for guidance on missed doses during titration. Maintenance dosing refers to being at a stable dose for >14 days, prescription dosing is no longer changing, or participant reports are no longer reliant on the illicit market.

The first dose adjustment is required if the person presents 5 days after their last patch change. Each patch contains enough medication to last for 3 days (72 hours).

- **6 days or less** since the last patch change - no change to dose
- **7 to 13 days** since last patch change: re-start at 50% of previous dose. Alternatively, at physician discretion the dose may be restarted at 300 mcg/h if the patient has an established high tolerance for fentanyl patch dosing.

- **Greater than 13 days** since the last patch change: re-start titration from the beginning. Must see or speak to the SAFER physician to re-start titration. The physician can consider a re-start dose of 300mcg/hr if the client has known high tolerance.

Any missed doses should result in nursing re-assessment and documenting of participant's tolerance. Significant tolerance breaks including withdrawal management, hospitalization, and incarceration should influence dose changes.

Day of the week	Patch change	Day Counter	Dose
Monday	Gets a new patch	0	
Tuesday		1	
Wednesday	Misses patch change	2	
Thursday		3	No change
Friday		4	No change
Saturday		5	No change
Sunday		6	No change
Monday		7	50% reduction*
Tuesday		8	50% reduction*
Wednesday		9	50% reduction*
Thursday		10	50% reduction*
Friday		11	50% reduction*
Saturday		12	50% reduction*
Sunday		13	50% reduction*
Monday		14	Re-start titration. **The re-start titration starts at 100mcg/hr.** **The physician can consider a re-start/dose reduction up to 300mcg/hr if the client has known high tolerance.*

Missed Doses During Titration Phase

Day of the week	Patch change	Day Counter	Dose
Monday	Gets a new patch	0	
Tuesday		1	
Wednesday	Misses patch change	2	
Thursday		3	
Friday		4	No dose increase Apply previous dose
Saturday		5	No dose increase Apply previous dose
Sunday		6	No dose increase Apply previous dose
Monday		7	50% reduction*
Tuesday		8	50% reduction*
Wednesday		9	50% reduction*
Thursday		10	50% reduction*
Friday		11	50% reduction*
Saturday		12	50% reduction*
Sunday		13	50% reduction*
Monday		14	Re-start titration. **The re-start titration starts at 100mcg/hr.** **The physician can consider a re-start/dose reduction to 300mcg/hr if the client has known high tolerance.*

Diversion

***See Appendix 2, SAFER Person-Centered Approaches to Diversion**

Tampered, fallen off, and/or missing patches complicate nursing assessments of opioid tolerance and therefore safety of administering the next patch dose.

Unlikely Diversion:

- Patch fallen off: participants who report that the patch has fallen off and who can present the patch can proceed with their next dose, however an assessment should be completed on how long the patch has been off. Follow the Missed Dose Protocol and/or contact SAFER MD for further direction.

Potential or Likely Diversion:

Often, participants first present to the SAFER clinic experiencing varying degrees of instability and/or systemic oppression. During these times, and other instances of episodic instability, instances of potential or likely diversion may be more common. Participants should not be subjected to a permanent record of these instances, especially when there are clear indicators the participant is benefiting from the program.

*Use clinical discretion specific to the scenario in determining the likelihood of diversion. Three instances of potential or likely diversion must have occurred within the last three months for a participant to be discharged from the program. A patient discharged from the fentanyl patch program is eligible for retrial of the patch program if it has been more than 3 months since their 1st instance of potential or likely diversion. In addition, episodes of likely diversion that are more than three months in the past will not be considered when determining if an episode represents a “first,” “second,” or “third” instance of likely diversion.

- Missing patches: While a missing patch may have simply fallen off, this scenario complicates nursing assessments due to risk of a double dose if a subsequent patch was applied.

- Tampering: if there are visible signs of patch tampering (i.e clearly non-intact, an open discussion with the participant around rationales for tampering (i.e. IV use) with respect and understanding. Avoid a punitive approach. This discussion may lead to identification of needs and potential solutions, such as adjunctive IV opioid safe supply.

First instance of potential or likely diversion:

- The SAFER nurse will connect with the person and explain risks of administering another dose at this time.
- The subsequent dose will be reduced per missed dose protocol, as if the most recent patch had not been administered, as it is unknown how long that new patch was on their skin. Document in the Ongoing Concerns section of the chart.

Second instance of potential or likely diversion:

- Will result in a written warning that an additional instance of potential or likely diversion will result in cessation of the fentanyl patch program.

Third instance of potential or likely diversion:

- Will result in discharge from the program. Update the Ongoing Concerns section of the chart to say “Discharged from fentanyl patch program due to diversion x 3 (Date)”.
- A check-in with the SAFER physician will be schedule to discuss other options for safe supply/OAT.
- The maximum SROM dose when converting a participant off of the fentanyl patch is 2500mg po OD - additional options will be added in consultation with the participant including hydromorphone/oxycodone tablets, injectable sufentanil, and/or fentanyl tablets.

Nursing Workflow: Fentanyl Patch Administration

Please administer the patch changes in a clinic booth or exam room for participant confidentiality and privacy.

1. Admission Workflow: Completed by SAFER Nurse checklist

Before applying the first patch, the SAFER nurse will go through the pre-program checklist:

- Urine drug test confirmed at Life Labs, showing opioid positive
- Urine pregnancy test negative (if applicable)
- Baseline vitals and weight
- Confirm that two physicians have approved starting the patch program
- Confirm the participant has had baseline liver and renal blood work results within 3 months that have been reviewed by a physician
- Confirm with Cridge Pharmacy that the fentanyl patch is covered by Pharmacare
- Set a reminder in the chart for 11 months after approval date to reapply for Special Authority
- Confirm the participant has had overdose training and a take home naloxone kit.
- If the participant receives OAT at another pharmacy, ensure the fentanyl patch program notification card has been faxed to their pharmacy to avoid the participant being cut off their OAT.
- Confirm that the diagnostic code for SAFER is entered into the OSCAR Code list
- Add the start date and route of administration of the program inside the OUD section of Past Medical History
- Ensure Dr Joshi and CNL have been notified of the new start by the prescribing physician

1. Pre-dose Assessment: SAFER Nurse

Open the OSCAR chart template- SAFER Pre/Post Dose. Use the “SOAP” format for charting.

- Subjective:
  - How is the participant?:
  - Drug and alcohol use since last visit (weekly or if presenting as substance affected):
  - Mood:
  - Sleep:
- Objective:
  - General appearance:
  - LOC:

and location of patches:
Any signs of tampering? i.e. tegaderm not intact, participant removed patches prior to assessment, etc.
Vitals (monthly): ensure these are entered in the measurement function when taken
Weight (monthly): ensure this is entered in the measurement function when taken
UDS (monthly): i.e. due dd/mm/yy; collected-next due dd/mm/yy; overdue-declines

If a participant has not provided a UDS in 3 months, advise their next dose will be held until they can provide a urine. Discussion on how to proceed will occur in collaboration with the participant, SAFER nurse/team, and SAFER physician.

- Assessment:
  # patches removed:
  Flovent spray applied prior to patch application?
  # of patches applied and location:
  Covered with tegaderm, signed and dated
- Plan:
  Next dose due:
  Expected dose:
  Any follow up required:

Fentanyl Patch APPLICATION

Patches prescribed for one patient can never be used for a different patient

WARNING: Wear gloves to avoid the transfer of medication. If you have been exposed to the FTY patch (ex: not wearing gloves and adheres to skin) - remove the patch immediately and irrigate the exposed area under cold water. Call Poison Control (604) 682-5050. DO NOT wash the exposed area with soap or any solvent, as this will increase absorption. Notify your nurse lead ASAP.

1. Always check the chart and MAR to assess when and where the last patch was placed and how many were applied to ensure removal of all patches before new application. There is ongoing fentanyl absorption from a patch for many days after it is due to be changed.
2. A nurse, pharmacist, or physician will perform all fentanyl patch administration.
3. After completion of the Patch Visit template, the nurse will obtain the fentanyl patch from the safe for application
4. Be cautious when a combination of patches is required to obtain the correct dose.
5. Confirm the correct combination of patches before application. If the wrong patches are administered, they need to be removed, folded in half, cut and disposed of in a tamper proof sharps container that is wall mounted with a lock or in a locked cupboard, documented and MD must be notified
6. Patches should not be used if the seal is broken or damaged
7. Patches should not be cut or changed in any way.

9 Patches must only be applied to dry, intact, non-irritated skin on a flat surface such as the chest, back, flank. Due to the potential for theft of the patch and targeting of participants; arms, extremities, or other visible areas should be avoided. In cases where extremities must be used, Safer nursing is to provide education of risks and recommend keeping areas covered.
10 In persons with cognitive impairment, the patch should be put on the upper back to avoid chances that patch will be removed.
11 Hair at the application site may be clipped but NOT SHAVED prior to application.
12 Do not use soaps, oils, lotions or any other agent on the patch site that might irritate skin or alter its characteristics.
    *Note- for participants who experience skin irritation related to the Fentanyl Patch or covering dressing, you may mist Flovent on the skin prior to each patch application.
13 Apply the patch immediately upon removal from the sealed package.
14 Remove the protective backing and apply by pressing firmly with the palm of the hand for 30 seconds, making sure the edges are sealed.
15 Never write directly on a transdermal patch. Writing on the patch is generally not advised by manufacturers due to unknown risks, including risk of tear or puncture by pen/marker; interaction of ink and patch; or effect of ink on medication delivery.
16 Secure the patch using only clear occlusive dressing such as Tegaderm hydrocolloid (never cover a patch with an opaque bandage or tape, with the risk the patch may not be seen to be removed)
17 Sign and date the Tegaderm dressing and indicate the next patch change date.

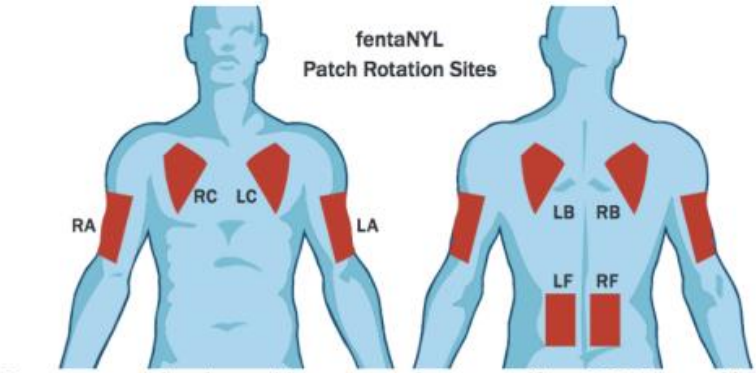
Fentanyl Patch REMOVAL

1 Removal of the previous fentanyl patch or patches requires assessment of any damage or tampering
2 If the patch is **not** intact, alert the physician before proceeding.
3 Patches should never be disposed of in the common garbage. Patches must be disposed of in a tamper proof sharps container that is wall mounted with a lock or in a locked cupboard, witnessed by two nurses.
4 Patches are to be folded in half and adhesive sides must stick together
5 Removal of the secured container from the site will be picked up by Biomed or Stericycle (depending on site) as fentanyl patches are considered hazardous waste

Patch Rotation Sites:

Patches should not be reapplied to the same site within 7 days to avoid skin irritation when rotating. Do NOT place on arms, extremities, or other visible areas due to potential for theft of the patch/targeting of the participant.

The exception is when a patch is changed in 24 hours or less. In these instances, the patch should be applied to the same site as the previous patch. This is to prevent additional fentanyl from being absorbed when a patch must be changed faster than the regular schedule.



SITES	CODE
Left Upper Arm	LA
Right Upper Arm	RA
Left Chest	LC
Right Chest	RC
Left Upper Back	LB
Right Upper Back	RB
Left Flank	LF
Right Flank	RF

Image accessed at: https://www.remedysrxsp.ca/fentaNYL_Facts.pdf

Documentation and Communication

Document in OSCAR when administering a patch change for a participant. Use the OSCAR fentanyl patch nursing template for each patch visit. Additionally:

- Document in the MAR.
- log patches administered and missed **daily** in the Fentanyl Patch Log. Fax this to the pharmacy at the end of each shift.

Clinic Supply ('Wardstock')

***See Appendix 3 for SAFER Pharmacy and Medication Policies**

Clinic supply of medications should be counted by two nurses twice daily. Baseline clinic supply is evaluated on the basis of how many participants are enrolled in the fentanyl patch program.

Clinic supply should be replenished each time the supply is used.

Clinic supply will be used for the missed dose protocol. Nurses are required to contact the pharmacist for a new order when the participant has presented, before using any medication from clinic supply.

Clinic supply will be filled under a physician, and stored in the SAFER medication safe.

SAFER Fentanyl Tablet Program (Fentora)

Eligibility:

- The Fentanyl Tablet Program is intended to meet the needs of people who use illegal opioids daily and who have a high tolerance to opioids
- The SAFER Fentanyl Tablet program is paired with OAT. Participants cannot combine this with other SAFER programs.
- Fentanyl tablets can be prescribed sublingual for people who use IV or via inhalation/smoke. This is off-label use of this medication. At this time, SAFER will not prescribe fentanyl tablets for IV use. Participants preferring the IV route can access the Sufentanil program.
- Consider facilitators and barriers to individuals attending SAFER on a twice daily basis, particularly during the higher dose stream initiation process involving successive dose titrations.

FENTORA PHARMACOLOGY:

- The product monograph can be found here:
- https://pdf.hres.ca/dpd_pm/00036628.PDF
- FENTORA is not bioequivalent with other fentanyl products. Do not convert patients on a mcg per mcg basis from other fentanyl products. (Note: This includes oral, transdermal, or parenteral formulations of fentanyl.

CONTRAINDICATIONS

- Opioid non-tolerant participants
- Participants who are hypersensitive to the active substance, fentanyl 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. Anaphylaxis and hypersensitivity have been reported in association with the use of oral transmucosal fentanyl products.
- Participants with known or suspected acute mechanical gastrointestinal obstruction (e.g., bowel obstruction or strictures) or any diseases/conditions that affect bowel transit (e.g., ileus of any type).
- Participants with suspected surgical abdomen (e.g., acute appendicitis or pancreatitis).
- Participants with acute or severe uncontrolled bronchial asthma, chronic obstructive airway, or status asthmaticus.
- Participants with acute respiratory depression, elevated carbon dioxide levels in the blood and cor pulmonale.
- Participants with acute delirium tremens, and convulsive disorders.
- Participants taking MAO inhibitors or serotonin-precursors (such as L-tryptophan, oxitriptan) and should be used with caution in combination with other serotonergic drugs (triptans, certain tricyclic antidepressants, lithium, tramadol, St. John's Wort) due to the risk of serotonergic syndrome
- Severe acute head Injury

Warnings:

1. The concomitant use of FENTORA with cytochrome P450 3A4 inhibitors may result in an increase in fentanyl plasma concentrations, and may cause potentially fatal respiratory depression.

2. Cardiovascular: Fentanyl administration may result in severe hypotension in patients whose ability to maintain adequate blood pressure is compromised by reduced blood volume, or concurrent administration of drugs such as phenothiazines and other tranquilizers, sedative/hypnotics, tricyclic antidepressants or general anesthetics. These patients should be monitored for signs of hypotension after initiating or titrating the dose of FENTORA. The use of FENTORA in patients with circulatory shock should be avoided as it may cause vasodilation that can further reduce cardiac output and blood pressure. Intravenous fentanyl may produce bradycardia. Therefore, use FENTORA with caution in patients with bradyarrhythmias.

3. CYP3A4 Inhibitors Concomitant use with inhibitors of cytochrome P450 3A4 isoform such as indinavir, nelfinavir, ritonavir, clarithromycin, itraconazole, ketoconazole, nefazodone, saquinavir, telithromycin, aprepitant, diltiazem, erythromycin, fluconazole, grapefruit juice, verapamil, or cimetidine may increase fentanyl levels, resulting in increased depressant effects

4. CYP3A4 Inducers: The concomitant use of FENTORA with CYP3A4 inducers (e.g., barbiturates, carbamazepine, efavirenz, glucocorticoids, modafinil, nevirapine, oxcarbazepine, phenobarbital, phenytoin, pioglitazone, rifabutin, rifampin, St. John's Wort, or troglitazone) may result in a decrease in fentanyl plasma concentrations, which could decrease the efficacy of FENTORA. Patients receiving FENTORA who stop therapy with, or decrease the dose of, CYP3A4 inducers should be monitored for signs of increased FENTORA activity and the dose of FENTORA should be adjusted accordingly.

5. Participants with Biliary/Pancreatic Disease: Fentanyl may cause spasm of the sphincter of Oddi and FENTORA should be used with caution in participants with biliary tract disease, including acute pancreatitis. Opioids may cause increases in serum amylase concentration.

Concurrent OAT and Fentora

- OAT and Fentora can be titrated on the same day.
- The Fentanyl tablet program can be administered concurrently with OAT. **SROM is preferred for OAT, due to drug-drug interactions with methadone.**

EKG

EKG can be considered for some participants before starting, depending on cardiac history and medications. The physician should be especially cautious for patients with bradycardia.

Benzodiazepine Considerations: Benzodiazepine contamination in the illegal supply is increasing risk for significant withdrawal complications. Prescribers are encouraged to initiate a prolonged CIWA protocol with diazepam when participants begin reporting street use has decreased by 50% or more. See Appendix 4 for protocol. At this time, the protocol can only be initiated for participants accessing the fentanyl tablet program, as daily assessment and clinical monitoring is required for safe withdrawal management.

OVERVIEW OF FENTORA PRESCRIBING, DOSING, INITIATION AND MAINTENANCE

- Sublingual Fentanyl tablets can be prescribed for people who use IV or via inhalation/smoke. This is off-label use of this medication.

- The fentanyl product is FENTORA: fentanyl citrate Buccal/Sublingual Effervescent Tablets, which come in strengths of 100 mcg, 200 mcg, 400 mcg, 600 mcg, and 800 mcg fentanyl

- FENTORA is not bioequivalent with other fentanyl products. Do not convert patients on a mcg per mcg basis from other fentanyl products. (Note: This includes oral, transdermal, or parenteral formulations of fentanyl.)

- The Fentanyl tablet program can be administered concurrently with OAT.

- **At this time, all prescriptions include the requirement for on-site or SAFER staff observed administration**

FENTANYL TABLET PROGRAM: TAILORED HIGH DOSE TITRATION vs. FIXED DOSE PRN

Participants have two options for this program: (A) a fixed dose PRN program and a (B) higher dose titration program. The higher dose titration stream requires participants to be present for specified dosing periods and includes more intensive missed dose protocols than the fixed dose PRN program.

Fentora Fixed Dose PRN Program

Overview: The fixed dose prn tablet fentanyl program is a lower barrier option than the higher dose titration stream for participants who face barriers to attending the site daily or do not want to attend the site daily for the higher dose protocol. For example, once participants have completed the initiation period, they can miss up to 60 consecutive doses without changes to their prescription.

Key Dosing and Titration Considerations:

All participants will receive a standard Fentora 400 mcg SL dose

- There is incomplete and variable cross-tolerance along with significant individual variation for tolerance
- There is no known consistent equivalent dose ratio to calculate.

PRN Program Prescription

Each individual will have an individual prescription from a physician.

Example Prescription:
Fentora 400 mcg SL BID prn for OUD
WI by nurse
Daily dispense x 28 days
Delivery
Date Range

Starting the PRN program - Initiation Workflow

The first or test dose protocol is intended to establish/confirm individual tolerance.

FIRST/ TEST DOSE:

Prescription for test dose protocol: FENTORA 400mcg sl DWI by nurse

Nursing Workflow for the test dose protocol includes:

- Post dose observation for 25 minutes.
- Completion of the POSS (Modified Posero Opioid Sedation Scale) (see Appendix 1)
- If the person experiences minimal post –dose sedation (POSS ≤score 2), the SAFER nurse will inform the physician. The physician will review and create an order and prescription for the patient to start 400mcg s/l q4 hour prn, up to 2 doses per day.
- If the person has sedation at 400mcg (POSS score >2), their tolerance is too low for the FENTORA program for today**.** The SAFER Nurse can connect with the person and assess potential reasons why they may have sedation at the first dose (e.g. additional use or other sedatives, period of non-use resulting in low tolerance?)

MAINTENANCE DOSING- PRN STREAM

Prescription:
400mcg SL BID
4 hours between doses
All witnessed by nurse at SAFER, daily dispense, delivery x 91 days

Post-Dose Observation Periods:
Post-dose observation (25 Minutes) is required for 10 **doses** (5 days) after the test dose.

Unfortunately, while this may create some barriers, the five-day dosing period for post-observation is required as it takes 5 days for Fentora to reach steady state, and the serum concentration is about 2 fold higher than that of a single dose.

- If there are missed doses during this phase, the person will have to continue with post-dose observation until they have achieved 10 consecutive doses (5 days) **with POSS ≤2.** participants do not need to remain inside SAFER in between doses.
- **After day 5, if there have been no complications, and no sedation (POSS score ≤2), no further post-dose observation periods are required.**

If this policy is creating significant barriers to an individual's participation, earlier discontinuation of the 25-minute post-observation period will occur on a case-by-case basis.

Extended Absence from the PRN Program
Changes to the dose are required if the person has missed 30 days or 60 consecutive doses or more.

Missed 30 days or 60 consecutive doses (up to less than 90 days)

If the person has not received a dose for **60 doses** (30 consecutive days), they will need to see a nurse to re-start the protocol.

The SAFER nurse will offer full assessment, including vitals, POC UDS, and updated substance use history and patterns. The nurse will connect with the person to identify reasons why they might have missed doses (e.g. structural barriers, such as transportation? Insufficient dosing?)

- If the person has not been using (i.e. detox or jail) they can be restarted at the program initiation. They are required to have post dose observation until they have had 10 doses (5 days) in a row with no sedation.
- If the person has been using opioids from another source (E.g. illegal), the SAFER nurse will document findings (self reported use, urine POC test results) The person will be restarted with a test dose, including the 25-minute observation period to restart the program.
- The duration of the observation period will be determined in consultation with the prescribing physician and team on a case-by-case basis.

After gathering the information, the SAFER nurse will call the pharmacy for direction. The pharmacy will complete a Pharmanet check, take a verbal order from the physician, and provide the medication order to the nurse.

Missed 90 days or more

If the person has not received a dose for 90 consecutive days, a SAFER physician will see them to assess if this program is beneficial for them or if another option may be a better fit.

Minimum requirements for restarting the program include an in-person nursing assessment (vitals, POC UDS, substance use patterns, review of Pharmanet and recent health changes) and discussion over phone with the prescribing physician. Some physicians may opt to assess participants directly. .

(B) Fentora Higher Dose Maintenance Program

Overview: The Higher Dose Maintenance Program is for participants who require higher doses than the PRN program and/or who are able or would like to attend the site more regularly. This stream allows participants to be titrated up from 400mcg by 100 to 200mcg/dose to a max dose of 3200mcg SL BID. Like the PRN program, the Higher Dose program includes an initiation period when post-dose observation is required for 7 - 15 consecutive days until titration is complete and the maintenance dose is achieved. However, the Higher Dose Program offers less flexibility for missed doses (i.e. re-initiation or dose change after 3.5 days of missed doses) than the PRN program (i.e. re-initiation not required until 30 days of consecutive missed doses).

Key Dosing and Titration Considerations:

- **Incremental titration is required for each participant.** FENTORA is not bioequivalent with other fentanyl products. Do not convert patients on a mcg per mcg basis from other fentanyl products. (Note: This includes oral, transdermal, or parenteral formulations of fentanyl.)
- All participants should be titrated from the 400 mcg dose. There is incomplete and variable cross-tolerance along with significant individual variation for tolerance, there is no known consistent equivalent dose ratio to calculate.

Initial Titration to Maintenance Dose

The standardized starting dose is Fentora 400 mcg for all participants, regardless of baseline opioid use. The maximum dose is 3200mcg SL q4 hours BID. Due to current hours of operation, people will be on a BID dosing as their maintenance dose. 2400mcg is a checkpoint where autotitration stops pending re-assessment with nursing and MD team, then a new Rx will be written to increase to a maximum of 3200mcg. Any decision to increase above 3200mcg requires a physician-to-physician consultation.

Titration Workflow

Each person will receive a titration prescription from the SAFER physician starting at the baseline dose (see above)

- Nurses will fax the Fentanyl Tablet Titration Record to the pharmacy each day.

Post-dose observation:

Post-dose observation (25 Minutes) is required for the entire titration period of **15 - 30 doses** (7 - 15 consecutive days) after participants have reached their maintenance dose.

Unfortunately, while this may create some barriers, the period for post-observation is required as it takes 5 days for Fentora to reach steady state, and the serum concentration is about 2 fold higher than that of a single dose.

- If there are any missed days (≥2 doses) during this phase, the person will have to repeat their previous dose and continue with post-dose observation until they have achieved 7 - 15 consecutive days **with POSS ≤2.** Participants do not need to remain inside SAFER in between doses.
- **After the titration period, if there have been no complications, and no sedation (POSS score ≤2), no further post-dose observation periods are required.**

If this policy is creating significant barriers to an individual's participation, earlier discontinuation of the 25-minute post-observation period will occur on a case-by-case basis.

Titration Schedule- Sublingual (SL)

***If any adverse events/ POSS > 2 at any dose, the SAFER Nurse connect with SAFER MD for further guidance before proceeding with next dose increase**

Day	Titration Schedule 1	Titration Schedule 2
Day 1	**Dose 1:** 400mcg SL 4 hours or more between doses **Dose 2:** 500mcg SL	**Dose 1:** 400mcg SL 4 hours or more between doses **Dose 2:** 600mcg SL
Day 2	**Dose 1**: 600mcg SL 4 hours or more between doses **Dose 2**: 700mcg SL	**Dose 1**: 800mcg SL 4 hours or more between doses **Dose 2**: 1000mcg SL
Day 3	**Dose 1:** 800mcg SL 4 hours or more between doses **Dose 2:** 900mcg SL	**Dose 1:** 1200mcg SL 4 hours or more between doses **Dose 2:** 1400mcg SL
Day 4	**Dose 1:** 1000mcg SL 4 hours or more between doses **Dose 2:** 1100 mcg SL	**Dose 1:** 1600mcg SL 4 hours or more between doses **Dose 2:** 1800 mcg SL
Day 5	**Dose 1:** 1200 mcg SL 4 hours or more between doses **Dose 2:** 1300 mcg SL	**Dose 1:** 2000mcg SL 4 hours or more between doses **Dose 2:** 2400 mcg SL
Day 6	**Dose 1:** 1400mcg SL 4 hours or more between doses **Dose 2:** 1500 mcg SL	**Dose 1:** 2600mcg SL 4 hours or more between doses **Dose 2:** 2800 mcg SL
	Dose 1: 1600 mcg SL	**Dose 1:** 3000 mcg SL

Day 7	4 hours or more between doses **Dose 2:** 1700 mcg SL	4 hours or more between doses **Dose 2:** 3200 mcg SL
Day 8	**Dose 1**: 1800 mcg SL 4 hours or more between doses **Dose 2**: 1900 mcg SL	**Titration Complete - Maintenance Rx**
Day 9	**Dose 1:** 2000 mcg SL 4 hours or more between doses **Dose 2**: 2100 mcg SL	**Titration Complete - Maintenance Rx**
Day 10	**Dose 1**: 2200mcg SL 4 hours or more between doses **Dose 2**: 2300mcg SL	**Titration Complete - Maintenance Rx**
Dose 11	**Dose 1**: 2400mcg SL 4 hours or more between doses **Dose 2**: 2500mcg SL	**Titration Complete - Maintenance Rx**
Dose 12	**Dose 1**: 2600mcg SL 4 hours or more between doses **Dose 2**: 2700mcg SL	**Titration Complete - Maintenance Rx**
Dose 13	**Dose 1**: 2800mcg SL 4 hours or more between doses **Dose 2**: 2900mcg SL	**Titration Complete - Maintenance Rx**

Dose 14	**Dose 1**: 3000mcg SL 4 hours or more between doses **Dose 2**: 3100mcg SL	**Titration Complete - Maintenance Rx**
Dose 15	**Dose 1**: 3200mcg SL 4 hours or more between doses **Dose 2**: Maintenance Rx	**Titration Complete - Maintenance Rx**

Fentora Maintenance Program - Missed Dose Protocol

A. Missed Doses during maintenance and titration

# Missed Doses	Dose Adjustment/ Observation Requirements
1 – 7 missed doses	● No dose reduction ● No post-observation requirement
8- 17 doses	● 50% dose reduction ● The physician can consider reducing dose to 800mcg if the client has known high tolerance ● **Resume post-observation until 15-30 doses (7-15 consecutive days) after maintenance dose reached**
18 or more doses (9 days)	● Re-start titration from lowest dose (400 mcg) ● The physician can consider a re-start dose of 800mcg if the client has known high tolerance. ● **Resume post-observation until 15-30 doses (7-15 consecutive days) after maintenance dose reached**
Up to 60 doses (30 days)*	● Can re-enter titration phase without seeing a physician if active prescription in place ● Re-start titration from lowest dose (400 mcg) ● The physician can consider a re-start dose of 800mcg if the client has known high tolerance. ● **Resume post-observation until 15-30 doses (7-15 consecutive days) after maintenance dose reached**
61 or more doses	● Must been seen by physician for reassessment and re-start

***Nursing Titrations for Missed Doses During Maintenance**

If a person has missed 60 doses (30 days) or less and has an active order from the physician, nurses can re-start titration as needed.

- When the person presents to SAFER with up to 60 misses, the nurse will call the pharmacist for instructions on what dose to administer.
- Pharmacists will check Pharmanet and take a verbal order from the physician for the dose.
- The nurse will wait to administer until the pharmacy has received confirmation of the dose from the physician.
- The nurse will use ward stock to fill this dose. Please see Appendix 3 and the Narcotic Control Policy.

- Nurses will fax the Fentanyl Tablet Titration Record to the pharmacy each day. The pharmacist will then send a prescription reminder to the physician, and fill the prescription on Pharmanet.

Transferring Fentanyl Options

- Participants are eligible to trial alternate short-acting fentanyl options without having to restart titrations outright. Participants who are receiving ≥ 1000mcg of fentora BID can begin the sufentanil program at the maximum dose of 250mcg following completion of a tolerance test. Conversely, participants who are at the maximum 250mcg of sufentanil can begin the fentora titration at a dose of 1000mcg.

Fentora Carries

SAFER Victoria gained experience in providing take-home (carries) doses of Fentora during the September 2021 fourth wave of COVID-19. In light of this experience, coupled with participant requests for carries, implementation of a Fentanyl Tablet Take-Home Dose Trial was conducted between December 1, 2021 to June 1, 2022 with 3 participants. The trial period produced no adverse events and as of June 1, 2022, SAFER will now offer second dose carries at the request of Fentora participants and following evaluation by the SAFER team and according to the following criteria.

Exclusion Criteria:

- Documentation of the participant intentionally seeking benzodiazepines - not to be conflated with unintentional consumption related to benzodiazepine contamination in the illegal opioid supply.
- Any long-term prescription for benzodiazepines, e.g. a patient on a long-term clonazepam prescription from their psychiatrist
- Known or suspected alcohol use disorder (AUD) or regular consumption of alcohol beyond the recommendations of the Canadian Low-Risk Alcohol Drinking Guidelines
- Documented concerns related to level of vulnerability and safety.
- Any Fentora prescription re-starts due to missed doses over the last three month timeframe.
- Documented misuse of Fentora tablets during previous access to take-home doses
- Any prior diversion of Fentora tablets any point in time

Inclusion Criteria:

- Consistent engagement with SAFER over the last three month timeframe.
- Improved clinical stability as a result of Fentora prescription.
- >90% medication adherence/prescription fill rate (specifically with regards to Fentora)
- Ability to store medications safely and consistently.
- Participant self-selecting/requesting for carries.
- Clear participant-reported functional quality of life improvement from carry doses is considered inclusion criteria to continue take-home doses.

Parameters for Carries

Fentora tablet carries could be reduced, paused, or ended immediately upon the discretion of the prescriber team. Instances of known or suspected diversion will result in the immediate cessation of this and participants will be required to resume witnessed dosing.

Participants should receive clear direction about the limitations of the take-home carries, including the potential for the carry to end at the prescribers discretion. Documentation of this education, and the participant's subsequent verbalization of understanding the education, must be in the EMR prior to initiating take-home dosing.

Fentanyl Product Nursing Considerations

FENTORA PRE-ASSESSMENT, ADMINISTRATION, AND POST-ASSESSMENT

SAFER Staff Roles- Administration, Witnessing, and Assessment:

- **The SAFER Nurse** is responsible for completing the pre-dose assessment and verifying that it is safe to proceed with administration (i.e. no hold-dose indications), preparing the dose, physically handing the dose to the person, and visually assessing the person prior to leaving the site. The nurse must be on site to respond to any identified adverse events by the post-dose observer (Systems Navigator and/or Support Worker). See "Post Dose Assessment" below.

- **SAFER System Navigators and Support Workers** can be delegated to witness the person self-administer SL by the SAFER Nurse and according to SAFER Nurse discretion. The Systems Navigator or Support Worker can also be delegated to monitor during the post-observation period for adverse events and will alert the SAFER nurse for further assessment if any indications of adverse events are identified.

- **SAFER System Navigators and Support Workers,** when delegated to complete post-dose monitoring, will alert the SAFER Nurse immediately of any of the following signs of an adverse event:
  agitation, anxiety, sedation (POSS>2), slurring/mumbling words, decreased respiratory rate (<10 breaths/minute), appearance, nausea/vomiting- do they look unwell?

Admission Workflow: Completed by SAFER Nurse

1. Note 2 physician approval for starting the program
2. Confirm urine drug test within the past 2 weeks with lab confirmation of opioid or fentanyl use
3. Complete a Pharmanet Check: Benzodiazepines; Any prescribed medication from physicians who are not with SAFER; OAT
4. Confirm renal and liver function tests within the past 3 months, that have been reviewed by the prescribing physician
5. Confirm the person has signed the intake paperwork, including the Fentanyl Tablet consent form
6. Confirm urine pregnancy test negative, when applicable
7. Confirm that the person has overdose training and a take home naloxone kit
8. If the patient receives OAT at another pharmacy, ensure the SAFER information sheet has been faxed to that pharmacy
9. Confirm that the diagnostic code for SAFER is entered into the OSCAR Code list
10. Add the start date and route of administration of the program inside the OUD section of Past Medical History

1. Pre-dose assessment: Completed by SAFER Nurse

The purpose of the pre-dose assessment is to ensure that the person is not intoxicated or experiencing any acute clinical condition that would increase the risk of an adverse event. Consider holding or delaying a dose, or contact the prescriber if any of the following assessments indicates concerns:

Indications for Holding Dose

- Assess for: decreased respiratory rate (<10 breaths/min), severe agitation, dyskinesia, slurred speech, odour of alcohol, and safety concerns. Hold the dose if necessary and contact the physician.
- Consider the person's baseline presentation in the assessment and decision-making. Holding doses is based on subjective assessment in combination with objective assessment and overdose risk (i.e. POSS ≤2 is safe to administer).
- If it is determined the participant should NOT receive their dose, the dose will be held and documented.
- If the person is too sedated or intoxicated, they can be asked to return in a few hours for a reassessment or rest at the SAFER site; this needs to be clearly explained to the person and charted.
- Emphasize that the person can return for their next dose and that they are not being "cut off. Respectfully explain the risks of combining Fentora with other sedatives
- If the person is experiencing ongoing alcohol or benzodiazepine while trying to access the program, the SAFER nurse should check in with the person and physician to make changes to the safe supply plan. If a patient has ongoing use of benzodiazepines that are from the illicit supply, they may require a different plan.

Open the OSCAR chart template- SAFER Pre/Post Dose. Use the "SOAP" format for charting.

- Subjective
  Drug and alcohol use since last visit (Weekly and if presenting as substance affected):
  Mood:
  Sleep:
- Objective
  General appearance:
  Sedation status: POSS Level (Appendix 1)
  LOC:
  O2 and HR (during titration/initiation phase only):
  Vitals (monthly):
  Weight (monthly):

2. Post Dose Assessment: Completed by SAFER Nurse and/or SAFER Staff with nursing delegation and supervision

- Assessment
  Dose:
  Route/location:
  Dose Tolerated?

- Assess and Identify ADVERSE EVENTS: agitation, anxiety, sedation (POSS>2), slurring/mumbling words, decreased respiratory rate (<10 breaths/minute), appearance, nausea/vomiting- do they look unwell?
- If any ADVERSE EVENTS identified by SAFER staff completing post-dose monitoring, the SAFER nurse will be immediately notified for further assessment.

- Plan:

  Next dose due:
  Expected dose:
  Any follow up required:

Nursing Procedure: Fentora Preparation and Administration

Preparing the Dose

Least Amount of Tablets Policy: (see Table- Fentora Least Tablet Combinations)

- **The least amount of tablets should be administered to meet the total dose for both the initiation and maintenance periods**
- There are subtle differences in absorption between single tablet administration and multiple tablet administration. For example if someone is administered four x 100mcg tablets, it will be faster absorption due to increased surface area covered by the tablets versus a single tablet of 400mcg.

Due to variations in absorption, do not use other combinations of tablets to create a dose, unless specifically instructed by the physician or pharmacy to do so.

Administering the dose

Confirm the person's identity and the medication order. Complete the 8 Rs of medication administration: right person, right medication, right dose, right route, right time, right reason, right to refuse, and right documentation.

Opening the Blister Package

1. Verify the order and check the MAR
2. Verify the person's identity
3. Put on new gloves
4. The first and second doses might be packaged together in the same pouch and may need to be separated. Separate a single blister unit from the blister card by bending and tearing apart at the perforations, on the indicated line.
5. Peel back the blister backing to expose the tablet. DO NOT attempt to push the tablet through the blister as this may cause damage to the tablet.
6. Open the blister pack and drop the tablet directly into a medication cup or cooker.

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

Tablet Administration

Sublingual

1. Once the tablet is removed from the blister unit, the person should immediately place the entire FENTORA tablet in the buccal cavity (above a rear molar, between the upper cheek and gum), or sublingually.
2. DO NOT remove the tablet from the blister pack until the person is ready for immediate administration.
3. Advise the person to not split the tablet.
4. The FENTORA tablet should not be sucked, chewed or swallowed, as this will result in lower plasma concentrations than when taken as directed.
5. The FENTORA tablet should be left between the cheek and gum until it has disintegrated, which usually takes approximately 14-25 minutes.
6. Advise the person not to split, suck, chew, or swallow FENTORA tablets. This will result in reduced absorption.
7. Use FENTORA tablets whole.
8. After 30 minutes, if remnants from the FENTORA tablet remain, they may be swallowed with a glass of water.
9. It is recommended the person alternates sides of the mouth when administering subsequent doses of FENTORA

SAFER Sufentanil PRN Program

**The Sufentanil PRN Program at SAFER is currently closed. Participants already enrolled in this program may continue but there will be no new intakes/transfers into the sufentanil program.*

Overview: Eligibility for Sufentanil sublingual PRN option includes people who use illegal opioids and are at risk of overdose from opioids, with a high tolerance to opioids, and who want to inject or take the medication sublingually. This program provides Sufentanil solution as a fixed dose PRN. There is standardized dosing for this program at 100mcg Sufentanil SL or IV prn q1 hour, up to 4 doses per day. Sufentanil is constituted in vials and drawn up into syringes by the SAFER nurse, therefore there is no requirement for the individual to draw up the medication for IV use as with Fentora and other opioid tablet safe supply.

Sufentanil Pharmacology:

The product monograph for Sufentanil can be found here:
https://www.sandoz.ca/sites/www.sandoz.ca/files/Sufentanil%20PMe%2020140702.doc.pdf

- This is OFF LABEL use of this medication. This program is only indicated for those with known high tolerance to opioids.
- Sufentanil comes in vials of 50mcg/ml. Each vial is 1ml in volume. The vials are single use.
- Sufentanil has 5-7 times the analgesic potency when compared to fentanyl.

Contraindications

- Opioid non-tolerant participants
- participants who are hypersensitive to Sufentanil or to any ingredient in the formulation or component of the container.
- participants with known hypersensitivity to fentanyl or to other morphinomimetics.
- participants who present with an acute severe head injury

Caution

Clinicians will exercise caution in the following clinical scenarios:

- Elderly participants
- participants with severe underlying conditions such as COPD or CHF
- Youth
- People who are pregnant
- Concurrent Alcohol or Benzodiazepine use
- Hepatic or renal disease
- Hypothyroidism and Alcoholism: Careful titration of dosage may be required in patients with conditions such as uncontrolled hypothyroidism

Adverse Events

- Skeletal Muscle Rigidity: Intravenous administration or inadvertent intravascular injection during epidural administration of Sufentanil may cause skeletal muscle rigidity, particularly of the truncal muscles.
- Hypotension
- Hypertension

- Bradycardia

Drug-Drug Interactions

- Sufentanil is metabolised mainly via the cytochrome CYP3A4 enzyme.
    - CYP3A4 inhibitors will slow the metabolism of sufentanil. However, no in vivo inhibition by erythromycin (a known cytochrome CYP3A4 enzyme inhibitor) has been observed. Although clinical data are lacking, other drugs such as ketoconazole, itraconazole, and ritonavir, are also known to be clinically important inhibitors of cytochrome CYP 3A4. As such they may inhibit the metabolism of sufentanil. This could increase the risk of prolonged or delayed respiratory depression. The concomitant use of such drugs requires special patient care and observation; in particular, it may be necessary to lower the dose of sufentanil.
    - CYP3A4 inducers will increase the metabolism of sufentanil

- Sufentanil is contraindicated in patients taking MAO inhibitors
- Exercise caution in a patient who is also on beta blockers due to the potential for bradycardia.
- Sufentanil can contribute to risk of serotonin syndrome.

Pharmacokinetics
- Onset of action - immediate
- Peak Plasma concentration - 10 minutes
- Elimination half life - 148 minutes
- Metabolized to a large number of inactive metabolites that are excreted in urine and feces.

Concurrent Sufentanil OAT titration
OAT can be titrated at the same time as sufentanil initiation.

EKG
EKG can be considered for some participants before starting, depending on cardiac history and medications. The physician should be especially cautious for patients with bradycardia.

OVERVIEW OF SUFENTANIL DOSING, INITIATION, AND MAINTENANCE

- **Sufentanil can be administered IV, IM, or SL**. For each route, participants go through a test-dose protocol for either method. If they go through the initiation IV, they have established tolerance for IV administration only. If an individual wants to change to SL from IV, they can change directly over to SL administration. However, if an individual wants to change to IV administration from SL, they need to re-start the test-dose protocol. For the purposes of this, IM dosing can be considered equivalent to IV dosing.

- **At this time, all prescriptions include the requirement for on-site or SAFER staff observed administration**

Sample Sufentanil PRN Prescription

Test Dose Prescription:

100mcg SL or IV x 1 doses PRN administered and witnessed by SAFER nurse

Monitor x15 minutes and assess POSS score

Maintenance Prescription:

Sufentanil 100-250mcg SL or IV q 1 hour prn, up to 4 doses per day

Begin at 100mcg SL or IV and dose can increase by an additional 50 mcg after every dose based on nurse assessment of post-dose sedation to a maximum of 250mcg.

Administered and witnessed by SAFER nurse daily dispense, delivery x 28 days

Starting Sufentanil PRN

The first or test dose protocol is intended to establish/confirm individual tolerance.

Nursing Workflow for the test dose protocol includes:

- One single test dose of 100mcg SL or IV will be witnessed by the SAFER nurse
- Post dose observation for 15 minutes.
- Completion of the POSS (Modified Pasero Opioid Sedation Scale) (see Appendix 1)
- If the person has sedation at 100mcg (POSS>2), their tolerance is too low for the Sufentanil program. The SAFER Nurse and physician should reassess their drug use history, urine drug test results, and create a new clinical plan.
- If the person is sedated (POSS >2) The SAFER Nurse should connect with the person and assess potential reasons why they may have sedation at the first dose (e.g. additional use or other sedatives, period of non-use resulting in low tolerance?)
- If the person has no or minimal sedation (POSS ≤2) and no other adverse events in the post dose assessment the physician will review and create an order and maintenance prescription for the person to start Sufentanil 100mcg s/l or IV q1 hour prn, up to 4 doses per day.
  For the first day of maintenance dosing, or any day where dosing is increased, post-dose observation will occur for 15 minutes after each dose.

Some participants may want to stay on the 100mcg, or 150mcg, or 200mcg depending on their reaction to each dose. The participant and SAFER nurse can discuss this with the physician to make a dosing plan and may choose to remain on 100mcg.

Missed Dose Protocol:

- Changes to the prescription may be required if the person has an active prescription and has not been seen in one month (30 days). The SAFER nurse will do a Pharmanet check, complete a POC UDS, assess and document vital signs, and contact the doctor of the day to determine.

# Missed Day	Dose Adjustment/ Observation Requirements
Up to 30 days	● Can proceed with previous dose with active prescription ● **Resume post-observation until 10 consecutive doses after maintenance dose reached**
30 or more days	● Must been seen by physician for reassessment and re-start

Transferring Fentanyl Options

Participants are eligible to trial alternate short-acting fentanyl options without having to restart titrations outright. Participants who are receiving ≥ 1000mcg of fentora BID can begin the sufentanil program at the maximum dose of 250mcg following completion of a tolerance test. Conversely, participants who are at the maximum 250mcg of sufentanil can begin the fentora titration at a dose of 1000mcg.

SAFER NURSING AND STAFF PROCEDURE:
SUFENTANIL PRE-ASSESSMENT, ADMINISTRATION, AND POST-ASSESSMENT

SAFER Staff Roles- Administration, Witnessing, and Assessment:

- **The SAFER Nurse** is responsible for completing the pre-dose assessment and verifying that it is safe to proceed with administration (i.e. no hold-dose indications), preparing the dose, physically handing the dose to the person, and visually assessing the person prior to leaving the site. The nurse must be on site to respond to any identified adverse events by the post-dose observer (Systems Navigator and/or Support Worker). See "Post Dose Assessment" below.

- **SAFER System Navigators and Support Workers** can be delegated to witness the person self-administer SL by the SAFER Nurse and according to SAFER Nurse discretion. The Systems Navigator or Support Worker can also be delegated to monitor during the post-observation period for adverse events and will alert the SAFER nurse for further assessment if any indications of adverse events are identified.

- **SAFER System Navigators and Support Workers,** when delegated to complete post-dose monitoring, will alert the SAFER Nurse immediately of any of the following signs of an adverse event:
  agitation, anxiety, sedation (POSS>2), slurring/mumbling words, decreased respiratory rate (<10 breaths/minute), appearance, nausea/vomiting- do they look unwell?

1. Admission Workflow: Completed by SAFER Nurse

1. Note 2 physician approval for starting the program
2. Confirm urine drug test within the past 2 weeks

3. Complete a Pharmanet Check: Benzodiazepines; Any prescribed medication from physicians who are not with SAFER; OAT
4. Confirm renal and liver function tests within the past 3 months, that have been reviewed by the prescribing physician
5. Confirm the person has signed the intake paperwork, including the Sufentanil PRN consent form
6. Confirm urine pregnancy test negative, when applicable
7. Confirm that the person has overdose training and a take home naloxone kit
8. If the patient receives OAT at another pharmacy, ensure the SAFER information sheet has been faxed to that pharmacy
9. Confirm that the diagnostic code for SAFER is entered into the OSCAR Code list
10. Add the start date and route of administration of the program inside the OUD section of Past Medical History

1. Pre-dose assessment: Completed by SAFER Nurse

The purpose of the pre-dose assessment is to ensure that the person is not intoxicated or experiencing any acute clinical condition that would increase the risk of an adverse event. Consider holding or delaying a dose, or contact the prescriber if any of the following assessments indicates concerns:

Indications for Holding Dose

- Decreased respiratory rate (<10 breaths/min), severe agitation, dyskinesia, slurred speech, odour of alcohol, and safety concerns. Hold the dose if necessary and contact the physician.
- Consider the person's baseline presentation in the assessment and decision-making. Holding doses is based on subjective assessment in combination with objective assessment and overdose risk (i.e. POSS ≤2 is safe to administer).
- If it is determined the participant should NOT receive their dose, the dose will be held and documented.
- If the person is too sedated or intoxicated, they can be asked to return in a few hours for a reassessment or rest at the SAFER site; this needs to be clearly explained to the person and charted.
- Emphasize that the person can return for their next dose and that they are not being "cut off. Respectfully explain the risks of combining Sufentanil with other sedatives
- If the person is experiencing ongoing alcohol or benzodiazepine while trying to access the program, the SAFER nurse should check in with the person and physician to make changes to the safe supply plan. If a patient has ongoing use of benzodiazepines that are from the illicit supply, they may require a different plan.

Open the OSCAR chart template- SAFER Pre/Post Dose. Use the "SOAP" format for charting.

- Subjective

  Drug and alcohol use since last visit (Weekly and if presenting as substance affected):
  Mood:
  Sleep:

- Objective

  General appearance:
  Sedation status: POSS Level (Appendix 1)
  LOC:

O2 and HR (during titration/initiation phase only):
Vitals (monthly):
Weight (monthly):

2. **<u>Post Dose Assessment: Completed by SAFER Nurse and/or SAFER Staff with nursing delegation and supervision</u>**

- <u>Assessment</u>
  Dose:
  Route/location:
  Dose Tolerated?
    - Assess and Identify ADVERSE EVENTS: agitation, anxiety, sedation (POSS>2), slurring/mumbling words, decreased respiratory rate (<10 breaths/minute), appearance, nausea/vomiting- do they look unwell?
    - If any ADVERSE EVENTS identified by SAFER staff completing post-dose monitoring, the SAFER nurse will be immediately notified for further assessment.
- <u>Plan:</u>
  Next dose due:
  Expected dose:
  Any follow up required:

<u>Nursing Procedure: Sufentanil Preparation and Administration</u>

Preparing and administering the dose
Confirm the person's identity and the medication order. Complete the 8 Rs of medication administration: right person, right medication, right dose, right route, right time, right reason, right to refuse, and right documentation

Sublingual:
1. Draw up the required dose into a syringe using a blunt filter needle tip.
2. Offer to Place the prescribed dose under the person's tongue or witness self-administration. Administer a maximum of one mL at a time.
3. Instruct the person to keep the medication under the tongue for at least 2 minutes without swallowing.
4. Food, water, and other medications should not be administered for 3-5 minutes following sublingual dose.
5. Document using the EMR OSCAR template

IV:
1. The SAFER Nurse will Draw up the required dose into a syringe using a blunt filter needle tip.
2. Ask the person which needle gauge and length they prefer for injection and apply this equipment
3. The SAFER Nurse will hand the injection supply tray and syringe to the person, who will take the injection supply tray and syringe to the injection booth
4. The person will be observed for their injection.

<u>Incomplete IV Administration</u>

1. If a participant is unable to inject their dose IV in the allotted time frame, it is considered an attempted missed dose. As the amount of drug received is unknown, the person may return in 1 hour for another attempt. The hour time frame is to account for the unknown amount of medication that may have been administered during the attempt.

2. The syringe and its contents will be disposed of and wasted per the Wasted Dose policy (Appendix 3). This should be documented as an attempted missed dose on the electronic charting system and the MAR, and as a full dose wastage on the Narcotic Administration Record.

Sufentanil Injection supply trays

There are a variety of injection supplies available to people in the program. These are pre-made for ease of use. The standard trays contain:

- Tourniquet
- Alcohol swab
- Gauze

All syringes are marked with a sticker. *See the SAFER Person-Centered Approaches to Diversion (Appendix 2)

SUFENTANIL STORAGE AND STABILITY

- Store between 15 and 30ºC.
- Protect from light.
- Discard any unused portion, as per the wasted dose policy.
- All vials are single use

Combined Fentanyl Product Protocol

SAFER Victoria operates using three subsets of interventions:

1. Community-based prescribing: this subset refers to tablet safe supply options including hydromorphone or oxycodone for opioids and dexedrine for stimulants.

2. Long acting: this subset can refer to either traditional OAT, or the fentanyl patch protocol.

3. Short acting: this subset can refer to either sufentanil or fentora fentanyl tablet protocols.

Participants may be on any combination of community-based, long acting, and short acting interventions. They cannot however, be on multiple medications within one subset. For example, a participant can be on sufentanil injectable and a fentanyl patch but participants cannot be on sufentanil and fentora fentanyl tablet at the same time.

Participants will not be titrating more than one intervention at the same time. If a new intervention is being trialed, no additional safe supply medication will be added until at least one week has passed with the current intervention.

Some participants may already be receiving their safe supply outside of these revised guidelines. In these instances, they will not be forced to change their regimen but will be encouraged to do so. If a participant is on both sufentanil and fentora, mandatory post-dose waiting times must be adhered to. That means neither sufentanil nor fentora can be administered until one hour following a sufentanil dose. Neither sufentanil nor fentora can be administered until four hours following a fentora dose. A suggested strategy would be to begin with a sufentanil dose, wait one hour, then provide fentora. The participant would return four hours later for a sufentanil dose, wait an additional hour, then receive fentora at the end of the day.

Appendix 1: Modified Pasero Opioid-Induced Sedation Scale

SAFER Sedation Scale Protocol (Modified Pasero Opioid-Induced Sedation Scale)

S - Sleeping, but easily rousable - OK to receive dose

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**.

Check O2/HR/RR q 5 minutes. Call the physician if the patient remains level 3 after 30 minutes.

4 - Unresponsive to verbal stimuli, may or may not be responsive to physical stimuli - call 911 and follow PHS Overdose Policy

Appendix 2: Person-Centered Approaches to Diversion

Instances of possible diversion of safe supply medications should be approached with empathy and understanding of the complex reasons that people may divert to have their needs met. SAFER recognizes that for many people, current safe supply initiatives are not an adequate replacement for a legal and regulated drug supply. Currently, SAFER is limited to operate within a medicalized model with regulatory restrictions that may not meet the needs of participants in regards to dosing, time, and place of use. It is important to remember that current requirements for participants to attend the site twice daily for access to safe supply is disruptive to their everyday lives.

Conversations with participants around diversion should be approached in a non-punitive and supportive way. Where possible, conversations should focus on the individual's needs, the role of diversion in fulfilling that need, and how SAFER can better meet their needs through potential changes to their safe supply plan to help avoid it.

Appendix 3: Medication and Pharmacy Policies

Medication Storage

Please see the narcotic policy. Medication storage standards are the same across all sites.

- All medications are stored in the narcotic safe, in a locked room, equipped with cameras and alarm.
- Sufentanil & Fentora: The pharmacist delivers the next day's medication each evening.Fentanyl Patches: The pharmacy will deliver the patches either weekly or 3 times per week (Sunday, Tuesday, and Thursday) based on the site-specific protocol.
- The pharmacist has a key to the building and alarm code, and uses the back door to enter the site. The bag of medications is unmarked
- The day's supply of medications are brought up to the medication cart each morning.
- Each person will have an individual medication pouch containing their day's dose, stored inside their participant specific box inside the medication cart.

Storage of Missed Patches:
If a participant misses a patch change, the SAFER nurses will keep those patches on site in the Medication Cart for one additional day (with the exception of a missed dose on Friday, when the dose is kept for 2 days). This will facilitate administering the dose the next day (or Sunday), should the patient present. There is no need for a dose reduction in these circumstances. The patches will be kept in the narcotic safe overnight.

Example 1:

- Pouya is on 500mcg/hr/h fentanyl patch and misses his patch change on Monday
- The nurse stores his patch in the safe overnight.
- He presents to the SAFER on Tuesday, and receives the same dose he would have received on Monday.
- His next patch change is on Wednesday.

Example 2:

- Pouya misses his patch change on Friday.
- The nurse stores his patches in the safe overnight.
- He presents to the SAFER on Sunday, and receives the same dose.
- His next patch change is on Monday.
- If the patient does not present within this window, the patches are returned to the pharmacy with the narcotic returns. In this case, see the missed dose protocol to determine the next dose.

Clinic Supply ('Wardstock')

The clinic supply of fentanyl patches, sufentanil, and fentora is for restarts and dose adjustments after missed doses. **Clinic supply can be used for new starts or dose increases.**

Wasted Doses
All wasted doses and attempted missed doses will be disposed of in accordance with the AVI Narcotic Control Policy and witnessed by a second nurse.
A dose will be considered wasted (1) if the tablets are spilled onto the floor or (2) the plunger of the syringe is depressed accidentally and the contents are spilled before injection has been attempted. In

both situations, the spillage must be witnessed by two staff members and documented in the MAR and electronic charting system. The nurse will then contact the pharmacy who may advise them to remove the dose from ward stock to administer, pending a verbal order from the physician.

Incomplete IV Administration

If a participant is unable to inject their dose IV in the allotted time frame, it is considered an attempted missed dose. As the amount of drug received is unknown, the person may return in 1 hour for another attempt. The hour time frame is to account for the unknown amount of medication that may have been administered during the attempt.

The syringe and its contents will be disposed of and wasted as Wasted Dose per policy. This should be documented as an attempted missed dose on the electronic charting system and the MAR, and as a full dose wastage on the Narcotic Administration Record.

If this happens during titration, the person will have to repeat the same dose as the previously wasted dose at their next dose.

Medication Returns

Please see the AVI Narcotic Policy Medication returns are the same across all the sites.

Appendix 4: CIWA Protocol for Benzodiazepine Withdrawal

Alcohol Withdrawal Assessment Scoring Guidelines (CIWA - Ar)

Nausea/Vomiting - Rate on scale 0 - 7

0 - None
1 - Mild nausea with no vomiting
2
3
4 - Intermittent nausea
5
6
7 - Constant nausea and frequent dry heaves and vomiting

Tremors - have patient extend arms & spread fingers. Rate on scale 0 - 7.
0 - No tremor
1 - Not visible, but can be felt fingertip to fingertip
2
3
4 - Moderate, with patient's arms extended
5
6
7 - severe, even w/ arms not extended

Anxiety - Rate on scale 0 - 7
0 - no anxiety, patient at ease
1 - mildly anxious
2
3
4 - moderately anxious or guarded, so anxiety is inferred
5
6
7 - equivalent to acute panic states seen in severe delirium or acute schizophrenic reactions.

Agitation - Rate on scale 0 - 7
0 - normal activity
1 - somewhat normal activity
2
3
4 - moderately fidgety and restless
5
6
7 - paces back and forth, or constantly thrashes about

Paroxysmal Sweats - Rate on Scale 0 - 7.
0 - no sweats
1- barely perceptible sweating, palms moist
2
3
4 - beads of sweat obvious on forehead
5
6
7 - drenching sweats

Orientation and clouding of sensorium - Ask, "What day is this? Where are you? Who am I?" Rate scale 0 - 4
0 - Oriented
1 – cannot do serial additions or is uncertain about date

2 - disoriented to date by no more than 2 calendar days

3 - disoriented to date by more than 2 calendar days
4 - Disoriented to place and / or person

Tactile disturbances - Ask, "Have you experienced any itching, pins & needles sensation, burning or numbness, or a feeling of bugs crawling on or under your skin?"
0 - none
1 - very mild itching, pins & needles, burning, or numbness
2 - mild itching, pins & needles, burning, or numbness
3 - moderate itching, pins & needles, burning, or numbness
4 - moderate hallucinations
5 - severe hallucinations
6 - extremely severe hallucinations
7 - continuous hallucinations

Auditory Disturbances - Ask, "Are you more aware of sounds around you? Are they harsh? Do they startle you? Do you hear anything that disturbs you or that you know isn't there?"
0 - not present
1 - Very mild harshness or ability to startle
2 - mild harshness or ability to startle
3 - moderate harshness or ability to startle
4 - moderate hallucinations
5 - severe hallucinations
6 - extremely severe hallucinations
7 - continuous hallucinations

Visual disturbances - Ask, "Does the light appear to be too bright? Is its color different than normal? Does it hurt your eyes? Are you seeing anything that disturbs you or that you know isn't there?"
0 - not present
1 - very mild sensitivity
2 - mild sensitivity
3 - moderate sensitivity
4 - moderate hallucinations
5 - severe hallucinations
6 - extremely severe hallucinations
7 - continuous hallucinations

Headache - Ask, "Does your head feel different than usual? Does it feel like there is a band around your head?" Do not rate dizziness or lightheadedness.

0 - not present
1 - very mild
2 - mild
3 - moderate
4 - moderately severe
5 - severe
6 - very severe
7 - extremely severe

Procedure:

1. Assess and rate each of the 10 criteria of the CIWA scale. Each criterion is rated on a scale from 0 to 7, except for "Orientation and clouding of sensorium" which is rated on scale 0 to 4. Add up the scores for all ten criteria. This is the total CIWA-Ar score for the patient at that time. Prophylactic medication should be started for any patient with a total CIWA-Ar score of 8 or greater (ie. start on withdrawal medication). If started on scheduled medication, additional PRN medication should be given for a total CIWA-Ar score of 15 or greater.
2. Document vitals and CIWA-Ar assessment on the Withdrawal Assessment Sheet. Document administration of PRN medications on the assessment sheet as well.
3. The CIWA-Ar scale is the most sensitive tool for assessment of the patient experiencing alcohol withdrawal. Nursing assessment is vitally important. Early intervention for CIWA-Ar score of 8 or greater provides the best means to prevent the progression of withdrawal.

Assessment Protocol a. Vitals, Assessment Now. b. If initial score ≥ 8 repeat q1h x 8 hrs, then if stable q2h x 8 hrs, then if stable q4h. c. If initial score < 8, assess q4h x 72 hrs. If score < 8 for 72 hrs, d/c assessment. If score ≥ 8 at any time, go to (b) above. d. If indicated, (see indications below) administer prn medications as ordered and record on MAR and below.	**Date**												
	Time												
	Pulse												
	RR												
	O_2 sat												
	BP												
Assess and rate each of the following (CIWA-Ar Scale):	**Refer to reverse for detailed instructions in use of the CIWA-Ar scale.**												
Nausea/vomiting (0 - 7) 0 - none; 1 - mild nausea ,no vomiting; 4 - intermittent nausea; 7 - constant nausea , frequent dry heaves & vomiting.													
Tremors (0 - 7) 0 - no tremor; 1 - not visible but can be felt; 4 - moderate w/ arms extended; 7 - severe, even w/ arms not extended.													
Anxiety (0 - 7) 0 - none, at ease; 1 - mildly anxious; 4 - moderately anxious or guarded; 7 - equivalent to acute panic state													
Agitation (0 - 7) 0 - normal activity; 1 - somewhat normal activity; 4 - moderately fidgety/restless; 7 - paces or constantly thrashes about													
Paroxysmal Sweats (0 - 7) 0 - no sweats; 1 - barely perceptible sweating, palms moist; 4 - beads of sweat obvious on forehead; 7 - drenching sweat													
Orientation (0 - 4) 0 - oriented; 1 - uncertain about date; 2 - disoriented to date by no more than 2 days; 3 - disoriented to date by > 2 days; 4 - disoriented to place and / or person													
Tactile Disturbances (0 - 7) 0 - none; 1 - very mild itch, P&N, ,numbness; 2-mild itch, P&N, burning, numbness; 3 - moderate itch, P&N, burning ,numbness; 4 - moderate hallucinations; 5 - severe hallucinations; 6 – extremely severe hallucinations; 7 - continuous hallucinations													
Auditory Disturbances (0 - 7) 0 - not present; 1 - very mild harshness/ ability to startle; 2 - mild harshness, ability to startle; 3 - moderate harshness, ability to startle; 4 - moderate hallucinations; 5 severe hallucinations; 6 - extremely severe hallucinations; 7 - continuous.hallucinations													
Visual Disturbances (0 - 7) 0 - not present; 1 - very mild sensitivity; 2 - mild sensitivity; 3 - moderate sensitivity; 4 - moderate hallucinations; 5 - severe hallucinations; 6 - extremely severe hallucinations; 7 - continuous hallucinations													
Headache (0 - 7) 0 - not present; 1 - very mild; 2 - mild; 3 - moderate; 4 - moderately severe; 5 - severe; 6 - very severe; 7 - extremely severe													
Total CIWA-Ar score:													
PRN Med: (circle one) Diazepam Lorazepam	**Dose given (mg):**												
	Route:												
Time of PRN medication administration:													
Assessment of response (CIWA-Ar score 30-60 minutes after medication administered)													
RN Initials													

Scale for Scoring:
Total Score =
0 – 9: absent or minimal withdrawal
10 – 19: mild to moderate withdrawal
more than 20: severe withdrawal

Indications for PRN medication:
a. Total CIWA-AR score 8 or higher if ordered PRN only (Symptom-triggered method).
b. Total CIWA-Ar score 15 or higher if on Scheduled medication. (Scheduled + prn method)
Consider transfer to ICU for any of the following: Total score above 35, q1h assess. x more than 8hrs required, more than 4 mg/hr lorazepam x 3hr **or** 20 mg/hr diazepam x 3hr required, or resp. distress.

Patient Identification (Addressograph)

Signature/ Title	Initials	Signature / Title	Initials

Alcohol Withdrawal Assessment Flowsheet (revised Nov 2003)

Appendix 5: COVID Mitigation Protocol

SAFER Victoria – COVID19 Mitigation Protocol

Date: _____

Reviewed by: _____

Hand Washing	● Soap and water is #1; if that's not available then sanitizer with >60% alcohol. ● Wash after handling objects or touching people; before and after eating; before and after using the washroom; before and after wearing gloves. ● Remind participants to wash hands; offer a spray of hand sanitizer as they come to the desk.
Personal Precautions	● Stay home if you are symptomatic; arrange for testing and await results before making a return-to-work plan with your employer. ● Do not bring water bottles, jewellery (rings, necklaces), watches, or any other non-essential item to work (including hats). They all act as potential reservoirs for infections. ● Fake nails are one of the top reservoirs for infection in health care; it is important to avoid having them right now. ● Bring a change of clothes with you; change into them at work. Change back into your other clothes before going home. When you get home, put the clothes in the wash (high heat is best), or into a garbage bag for you to wash all in a lump sum later. ● Lanyards should not be worn; people take them off and on throughout the day, and the lanyard touches your face when that happens. ● Stop touching your face. Remind each other to stop touching your face.
Cleaning / Disinfecting	● Every 30 minutes, do a clean of common surfaces (door handles, elevator buttons, sink handles, etc.…) ● Use either alcohol solutions with >70% alcohol or diluted household bleach. Those are the only things that will work! ● Clean between bathroom uses; if there is a line then make a quick clean. If there's nobody waiting, then do a deep clean. ● You must clean, then disinfect, let the disinfectant sit, then wipe. Applying disinfectant then immediately wiping is ineffective. ● Remove all non-essential items from our workplace(s). Books, posters, Tupperware, etc. are not our friends right now. ● The novel coronavirus can live on a surface in the form of a fomite, for 12-24 hours.
Communicating	● Communicate updates on closures to community members. ● Reassure everyone that we are doing our best to keep them safe and healthy. ● Use posters to remind staff and community members of symptom screening
Screening	● Staff stationed at the front door will screen participants for Fever, Cough (Usually Dry), Shortness of Breath. ● SAFER nurses can administer COVID19 swabs and support participants to

	self-isolate while awaiting results. ● Call 1-888-COVID19 if you suspect someone may be infected or contact your local public health authority/COVID19 outreach team. ● Self-Screen if you have symptoms at https://covi19.thrive.health/ ● If someone is in distress with these symptoms, Call 9-1-1. ● If a community member is coughing/sneezing, we should be encouraging them to wear a mask.
Mask & Eye Protection	● Masks and eye protection should be worn whenever you cannot guarantee 6' or 2 meters of social distancing. Due to the unpredictable nature of shelters/overdose prevention sites, staff should put on masks and eye protection at the start of shift. ● Change your mask and disinfect eye protection whenever they become wet or soiled.
Gloves	● Gloves are single use only; wearing the same pair of gloves for multiple interactions can transmit the virus from one person to another. ● Perform hand hygiene before and after wearing gloves. ● Do not sanitize gloves for re-use, the chemicals can degrade gloves making them ineffective.
Overdose	● At this stage, the BCCDC does not recommend the use of pocket-valve masks, high-flow oxygen (>6-10L/min) or bag-valve mask (BVM) for overdose due to increased risk of aerosolizing the virus. ● Overdose response requires gloves, mask, eye protection, and gown (if available) ● Mild Overdose – Apply low flow oxygen via simple mask at a rate of <6-10L/min. Consider the initial dose of naloxone, or half dose if agency policy permits. Monitor oxygen saturations and maintain above 90%. ● Severe Overdose (Requiring Naloxone) – Call 911 and administer a double dose of naloxone (0.8mg). ● If you must give respirations, use the THN kit face-shields. They are the safest option available.
Supplies	● Monitor stock of vital supplies (gloves, masks, gowns, soap, hand sanitizer, naloxone, disinfectant, tissues) and proactively order to prevent service disruptions. ● Inform your supervisor if supplies are running low.
Social Distancing	● Social distancing is 6' or 2 meters. ● Encourage community members to not crowd together. ● Applying tape to the floors provide visual reminders of social distancing. ● Ask participants not to hug/kiss/handhold in the building.

PPE Order of Operations

On:	**Hand Hygiene**	**Off:**	**Gloves**
	Mask		**Hand Hygiene**
	Eye Protection		**Eye Protection**
	Gloves		**Mask**
			Hand Hygiene

References

PPE RECOMMENDATIONS FOR HEALTHCARE PERSONNEL PARTICIPATING IN RESIDENT/CLIENT CARE

PPE Recommendations for Overdose Prevention Sites (OPS)				
Location	**Client COVID-19 Status**	**Activity**	**Type of PPE**	**Comments**
Waiting Room, Injection Area, and Shared Spaces	**Clients without symptoms AND low-risk of COVID-19 infection**	Providing direct care	Medical Mask Eye Protection Gloves	The same Mask and Eye Protection should be used between clients and in the Common Spaces. Use of additional PPE should be as per standard non-COVID-19 Infection Control Routine Practices/Additional Precautions. Gloves should be changed between clients and doffed when leaving the client care area.
	Clients with symptoms/high-risk of COVID-19 infection or with pending/positive COVID-19 test	Providing direct care	Medical Mask Eye Protection Gown Gloves	Droplet/Contact Precautions The same Mask and Eye Protection should be used between clients and in the Common Spaces. Gowns and gloves should be doffed between clients and upon leaving client care area.
		Aerosol-Generating Medical Procedures (AGMP)	N95 Respirator or equivalent (Re-usable or disposable) Eye Protection Gown Gloves	Airborne + Droplet/Contact Precautions The same Respirator and Eye Protection should be used between clients and Common Clinical Spaces. Gowns and gloves should be doffed between clients and upon leaving client care area.
Common Spaces (eg. Reception, waiting room, supply rooms, utility rooms)		Any activity 2 or more meters away from clients	Medical Mask Eye Protection permitted	The same Mask and Eye Protection should be used between client rooms and Shared/Common Clinical Spaces to conserve PPE. Mask should be worn in break room when not eating or drinking. Eye Protection can be removed if no further client care is anticipated before a break, meal, or end of shift. Gloves and Gowns should not be worn in these spaces.

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COVID-19

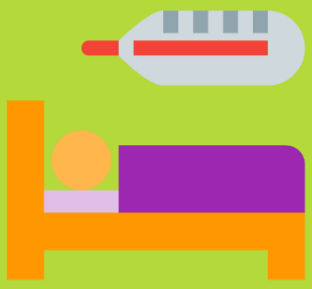
Self-Assessment & Testing

1

Travel

Have you traveled outside of Canada or been in contact with someone who has traveled outside of Canada in the past 14 days?

2



Positive Contact

Have you tested positive for COVID-19 or had close contact with a confirmed positive case of COVID-19 without wearing appropriate PPE?

3

Public Risk

Have you been in a setting in the last 14 days that has been identified by public health as a risk for acquiring COVID-19, such as on a flight, in a workplace or community with a cluster of cases, or at an event?

4

Do you have any of the following?

- Fever
- New onset cough
- Worsening chronic cough
- Shortness of breath
- Difficulty breathing
- Sore throat
- Difficulty swallowing
- Decrease or loss of sense of taste/smell
- Chills
- Headaches
- Unexplained fatigue/muscle aches
- Nausea/vomiting/diarrhea/abdominal pain
- Pink eye
- Runny nose or nasal congestion

5

Test & Self-Isolate

Complete the COVID-19 self-assessment tool online at https://bc.thrive.health/covid19/en

Arrange testing by calling 1-844-901-8442

STAY HOME until your test is negative and symptoms are gone.

Coronavirus COVID-19

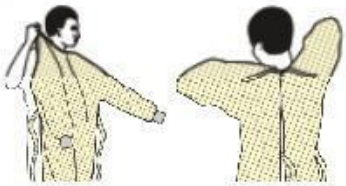
BC Centre for Disease Control | BC Ministry of Health

The 5 steps to Don (put on) Personal protective equipment (PPE)

1 Hand hygiene

Clean all surfaces of hands and wrists

2 Gown

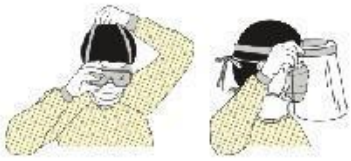


Cover torso and wrap around back, fasten in back of neck and waist

3 Surgical/procedure mask

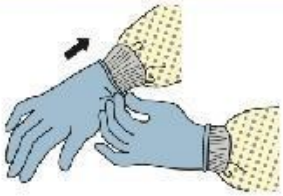
Secure ties at middle of head and neck, fit nose band to your nose and pull bottom down to completely cover chin

4 Eye protection



Place goggles or face shield over face and eyes and adjust to fit

5 Gloves



Extend to cover wrist of gown

BRITISH COLUMBIA Ministry of Health

BC Centre for Disease Control

If you have fever, a new cough, or are having difficulty breathing, call 8-1-1.

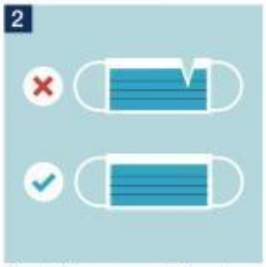
Coronavirus COVID-19

BC Centre for Disease Control | BC Ministry of Health

BRITISH COLUMBIA Ministry of Health

How to Wear a Face Mask

Wash your hands with soap and water for 20-30 seconds or perform hand hygiene with alcohol-based hand rub before touching the face mask.



Check the new mask to make sure it's not damaged.

Ensure colour side of the mask faces outwards.

Locate the metallic strip. Place it over and mold it to the nose bridge.

Place an ear loop around each ear or tie the top and bottom straps.

Cover mouth and nose fully, making sure there are no gaps. Pull the bottom of the mask to fully open and fit under your chin.

Press the metallic strip again to fit the shape of the nose. Perform hand hygiene.

Do not touch the mask while using it, if you do, perform hand hygiene.

Replace the mask if it gets wet or dirty and wash your hands again after putting it on. Do not reuse the mask.

Removing the Mask

Perform hand hygiene.

Do not touch the front of your mask. Lean forward, gently remove the mask from behind by holding both ear loops or ties.

Discard the mask in a waste container.

Perform hand hygiene.

BRITISH COLUMBIA | Ministry of Health

BC Centre for Disease Control

If you have fever, a new cough, or are having difficulty breathing, call 8-1-1.

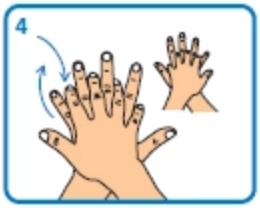
Non-medical inquiries (ex. travel, physical distancing): 1-888-COVID19 (1888-268-4319) or text 604-630-0300

Hand-washing technique with soap and water

Wet hands with water

Apply enough soap to cover all hand surfaces

Rub hands palm to palm

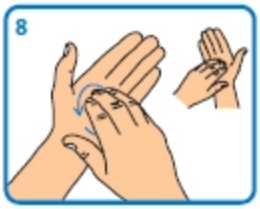


Rub back of each hand with palm of other hand with fingers interlaced

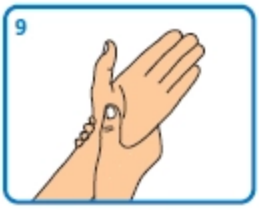
Rub palm to palm with fingers interlaced

Rub with back of fingers to opposing palms with fingers interlocked

Rub each thumb clasped in opposite hand using a rotational movement

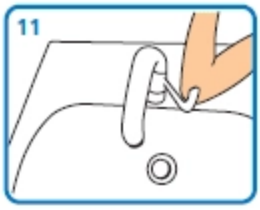


Rub tips of fingers in opposite palm in a circular motion



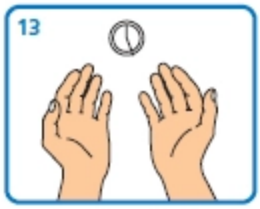
Rub each wrist with opposite hand

Rinse hands with water



Use elbow to turn off tap

Dry thoroughly with a single-use towel



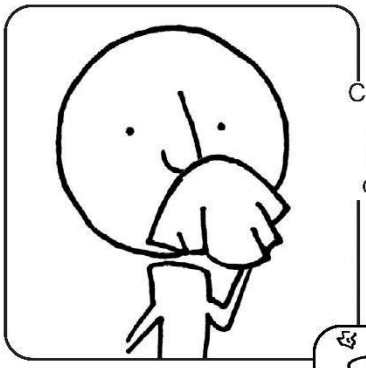
Hand washing should take 15–30 seconds

cleanyourhands campaign

NHS
National Patient Safety Agency

Stop the spread of germs that make you and others sick!

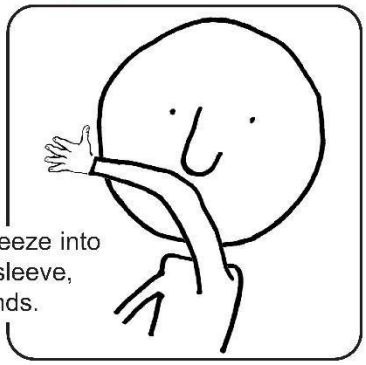
Cover your Cough



Cover your mouth and nose with a tissue when you cough or sneeze

or

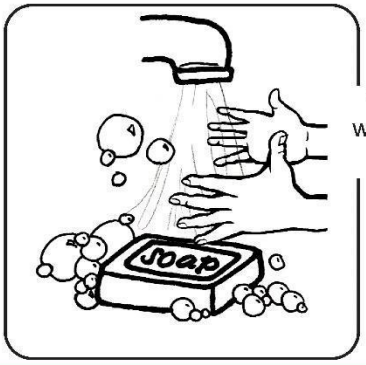
cough or sneeze into your upper sleeve, not your hands.



Put your used tissue in the waste basket.

Clean your Hands

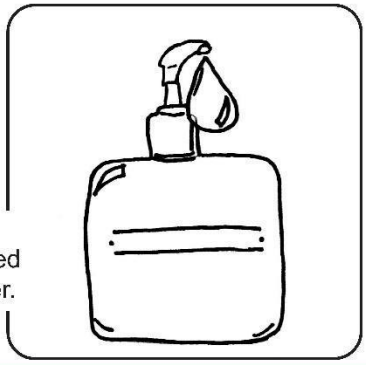
after coughing or sneezing.



Wash hands with soap and warm water

or

clean with alcohol-based hand cleaner.



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Appendix 6: 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, participants require appointment with MRP for further examination.**
	Return to Step 2 once desired results are achieved.

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

Appendix 7: Nicotine Replacement Therapy (NRT) Protocol

If the participant is agreeable, provide tobacco cessation literature.

CAUTION: If participant experiences symptoms of too much nicotine (i.e. insomnia, nausea, vomiting, sweats, tremors, lightheadedness, confusion, racing heart or weakness), hold nicotine and ask prescriber to reassess dose.

Nicotine Patch

	Nicotine Dose	**Cigarettes/Day***
□	Apply nicotine patch 7 mg daily	1 – 9
□	Apply nicotine patch 14 mg daily	10 – 15
□	Apply nicotine patch 21 mg daily	16 – 20
□	Apply nicotine patch 28 mg (14 mg + 14 mg) daily	21 - 30
□	Apply nicotine patch 35 mg (21 mg + 14 mg) daily	31 – 40
□	Apply nicotine patch 42 mg (21 mg + 21 mg) daily	Greater than 40

** Note: These are suggested equivalencies only. Prescriber may choose a nicotine dose that differs from that based on daily cigarette consumption.*

For cravings while on/not on nicotine patch

□ Nicotine polacrilex 2-4 mg gum q1h PRN **Max 20 pieces per day** **OR**
□ Nicotine bitartrate 1 mg lozenge q1h PRN **Max 20 pieces per day** **OR**
□ Nicotine inhaler PRN **Max 12 cartridges per day**

Titration for withdrawal symptoms (cravings, irritability, frustration, anger, headache, anxiety, difficulty concentrating or restlessness not accounted for by other physical or mental health conditions).

□ Increase nicotine patch by 7 mg if withdrawal symptoms are not controlled by 24-48 hours.

Any increase in dosage will be documented in OSCAR EMR. **Max daily dose via patch = 42 mg**

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

Appendix 8: Fentanyl Dose Equivalencies for SROM Conversion

Current Analgesic	Daily Dosage (mg/d)						
Oral morphine	60-134	135-179	180-224	225-269	270-314	315-359	360-404
IM/IV morphine (based on a 1:3 IM:PO ratio)	20-44	45-60	61-75	76-90	NA[2]	NA[2]	NA[2]
Oral oxycodone	30-66	67-90	91-112	113-134	135-157	158-179	180-202
Oral codeine	150-447	448-597	598-747	748-897	898-1047	1048-1197	1198-1347
Oral hydromorphone	8-16	17-22	23-28	29-33	34-39	40-45	46-51
IV Hydromorphone[3]	4-8.4	8.5-11.4	11.5-14.4	14.5-16.5	16.6-19.5	19.6-22.5	22.6-25.5
	⇓	⇓	⇓	⇓	⇓	⇓	⇓
Sandoz Fentanyl Patch Dose	**25 mcg/h**	**37 mcg/h**	**50 mcg/h**	**62 mcg/h**	**75 mcg/h**	**87 mcg/h**	**100 mcg/h**

[1]**Table 1.1 should not be used to convert from Sandoz Fentanyl Patch to other therapies because this conversion to Sandoz Fentanyl Patch is conservative. Use of Table 1.1 for conversion to other analgesic therapies can overestimate the dose of the new agent. Overdosage of the new analgesic agent is possible (see DOSAGE AND ADMINISTRATION, Safe Use of Tables 1.1 and 1.2).**

[2] **NA reflects insufficient data available for guidance. Prescribers should make these conversions very carefully and conservatively.**

[3]The conversion ratio of parenteral hydromorphone to oral hydromorphone of 1:2 is based on clinical experience in patients with chronic pain. Reference: Parenteral Drug Therapy Manual, Vancouver General Hospital, Pharmaceutical Sciences Clinical Services.

Table 1.2[#]
Recommended Initial Sandoz Fentanyl Patch Dose Based Upon Daily Oral Morphine Dose[‡]

Oral 24-hour morphine (mg/day)		Sandoz Fentanyl Patch Dose (mcg/h)
Dose Adjustment	45-59	12
Initiation Dose	60-134	25
	135-179	25+12
	180-224	50
	225-269	50+12
	270-314	75
	315-359	75+12
	360-404	100
	405-494	125
	495-584	150
	585-674	175
	675-764	200
	765-854	225
	855-944	250
	945-1034	275
	1035-1124	300

[‡] In clinical trials these ranges of chronic daily oral morphine doses were used as a basis for conversion to fentanyl transdermal system. See Recommended Dose and Dosage Adjustment and Dose Adjustment.

[#] 12 mcg/h dose is included in this table for dose adjustment. 12 mcg/h dose generally should not be used as the initiating dose, except in the case of patients for whom clinical judgment deems it appropriate to start Sandoz Fentanyl Patch at less than 25 mcg/h; Sandoz Fentanyl Patch at any dose is contraindicated in opioid-naive patients (see CONTRAINDICATIONS).

Appendix 9: Clinical Opiate Withdrawal Scale

For each item, circle the number that best describes the patient's signs or symptoms. Rate on just the apparent relationship to opiate withdrawal. For example, if heart rate is increased because the patient was jogging just prior to assessment, the increased pulse rate would not add to the score.

Patient's name: _____ Date and time: ____ / ____ / ____ : _____

Reason for this assessment: _____

Resting pulse rate: _____ beats/min *Measured after patient is sitting or lying for one minute* 0 pulse rate 80 or below 1 pulse rate 81–100 2 pulse rate 101–120 4 pulse rate greater than 120	**GI upset:** *Over last ½ hour* 0 no GI symptoms 1 stomach cramps 2 nausea or loose stool 3 vomiting or diarrhea 5 multiple episodes of diarrhea or vomiting
Sweating: *Over past ½ hour not accounted for by room temperature or patient activity* 0 no report of chills or flushing 2 flushed or observable moistness on face 3 beads of sweat on brow or face 4 sweat streaming off face	**Tremor:** *Observation of outstretched hands* 0 no tremor 1 tremor can be felt, but not observed 2 slight tremor observable 4 gross tremor or muscle twitching
Restlessness: *Observation during assessment* 0 able to sit still 1 reports difficulty sitting still, but is able to do so 3 frequent shifting or extraneous movements of legs/arms 5 unable to sit still for more than a few seconds	**Yawning:** *Observation during assessment* 0 no yawning 1 yawning once or twice during assessment 2 yawning three or more times during assessment 4 yawning several times/minute
Pupil size: 0 pupils pinned or normal size for room light 1 pupils possibly larger than normal for room light 2 pupils moderately dilated 5 pupils so dilated that only the rim of the iris is visible	**Anxiety or irritability** 0 none 1 patient reports increasing irritability or anxiousness 2 patient obviously irritable or anxious 4 patient so irritable or anxious that participation in the assessment is difficult
Bone or joint aches: *If patient was having pain previously, only the additional component attributed to opiate withdrawal is scored* 0 not present 1 mild diffuse discomfort 2 patient reports severe diffuse aching of joints/muscles 4 patient is rubbing joints or muscles and is unable to sit still because of discomfort	**Gooseflesh skin** 0 skin is smooth 3 piloerrection of skin can be felt or hairs standing up on arms 5 prominent piloerrection
Runny nose or tearing: *Not accounted for by cold symptoms or allergies* 0 not present 1 nasal stuffiness or unusually moist eyes 2 nose running or tearing 4 nose constantly running or tears streaming down cheeks	Total score: _____ The total score is the sum of 11 items. Initials of person completing assessment: _____

Score: 5–12 = mild; 13–24 = moderate; 25–36 = moderately severe; more than 36 = severe withdrawal

Appendix 10: Clinical Assessment for Changing Oral Safe Supply Options

Participants may self-select the community-based or fentanyl product that will best meet their needs--requests to change oral safe supply options should be guided first and foremost by the participant. Ultimately, the decision to change oral safe supply options rests on the prescribing physician and should be made with the following criteria in mind.

Prior to nursing contacting a SAFER MD with a request to change medications, they should assess the participant using the below prompts, and document the rationale in OSCAR prior to consulting the MD.

1. Route of consumption - Does the participant smoke their drugs? If so, oxycodone would be more reasonable given participants reporting that dilaudid cannot be smoked. Conversely, if the route of consumption is injection, both dilaudid and oxycodone could be considered.

2. Previous experience - Has the participant been on either medication previously? Have they had better reported impacts (i.e. pain control) from one medication or the other?

3. Adverse reactions - Is the participant experiencing adverse reactions and/or complications related to their current oral option that could potentially be ameliorated through a different option?

4. Inadequate dosing - Is the issue less about drug of choice and more about the current prescription not meeting the participant's tolerance? Ask how much the participant is still using on top of their current prescription. At what point in the day do they run out of medications? How many tablets constitutes a single dose for the participant?

5. Generic vs brand - There are legitimate reasons why participants do not want to have the generic tablets, and no, it's not because of diversion and resale value. If there is a dilaudid shortage, and participants are being given generic formulations, they may request a change to a different oral option.

Appendix 11: Take-Home Dose by Exception Protocol

SAFER Victoria acknowledges there may be exceptional circumstances where a take-home dose should be offered to participants on a temporary basis. The following circumstances may warrant temporary allowance of take-home doses. Wherever possible, take-home doses should be treated as an exceptional contingency measure with interventions such as medication delivery prioritized first.

Circumstances Warranting Take-Home Doses

- COVID19 Infection - All efforts should be made to support participants to shelter-in-place when recovering from COVID19 infection. That includes increasing community-based tablet prescribing, increasing OAT, and offering take-home doses of fentora. In the instance of take-home dose, the first dose of fentora should be witnessed and the second dose should be offered as a carry. This option is dependent on staffing capacity to offer medication delivery while the participant is isolating. Titration of fentora tablets can only occur with witnessed doses, not with the take-home dose. Participants who receive sufentanil from SAFER can have a dose brought to them by outreach for witnessed consumption, but take-home doses of sufentanil are not currently available.

- Extreme Weather Protocols (EWP) - In instances where inclement weather affects participants who experience mobility and accessibility challenges, a take-home dose should be considered. Considerations related to outreach/medication delivery capacity should be factored in, and take-home doses will only be made available for the duration of the weather event.

- Acute Injury or Illness - Any instance where a participant is impacted by acute injury or illness requires re-assessment by the clinical team and treatment on a case-by-case basis. In circumstances where a take-home dose would benefit the participant or assist in avoiding further harms related to the acute injury or illness, it should be offered on a temporary basis.

Considerations

- Any instance of potential or likely diversion will result in cessation of take-home doses.
- Participants are to be made aware of the timeline in which take-home doses are offered, emphasizing that this is a temporary measure offered on the basis of exceptional circumstances.
- In situations where take-home doses are offered as a result of mobility/accessibility concerns, the SAFER Systems Navigators are to prioritize solutions that enable the participant to attend clinic in-person.