SOS OP-EX HANDBOOK

MySafeSupply®

Bucks County, Pa

Harm Reduction on Your Terms

OPEX – Contents

Section 1: Introduction

1.1 Purpose of an OP-EX

This Operational-Explanation (OP-EX) is intended to lay out a general understanding of the operation for our SOS Program. The SOS Program is one of our many wellness, and recovery pathways.This handbook will be updated as necessary to reflect any changes in practices or programmatic adjustments. The overview covers the main operational aspects of the SOS Program, including participant enrollment, assessments, dosage determination, drug dispensation, monitoring, and support resources.

1.2 Program Overview

The Safe Opioid Supply (SOS) Program is a comprehensive initiative designed to address the ongoing overdose death crisis by reducing the risks associated with illicit opioid use. The provision of a safer, regulated supply of plant-based pharmaceutical opiates serves as a first line of defense. The program aims to prevent as many deaths as possible and reduce dependence on the illicit market, thereby lowering the likelihood of overdose events caused by the lack of regulation, quality control, dosing information, and accountability in the illicit market.

The program incorporates the use of constant messaging on packaging to initiate pro-recovery thinking, promote recovery-positive mindsets, safe habits, use reduction, and healthy choices. We present actionable strategies for stakeholders to support and adopt this program, which is poised to

significantly improve public health outcomes and reduce opioid mortality rates among enrollees and their communities.The SOS program was developed with the SOS Smart program as a secondary safety net to further reduce the risk of accidental overdose. By providing participants with pharmaceutical-grade, plant-based opiates, this program aims to reduce fatalities and health complications associated with unregulated opioid consumption. It ensures access to controlled, known dosage, regulated, and comparatively safe opioids. In addition to harm reduction, the program is committed to supporting participants through recovery-oriented services, providing a clear pathway to recovery.

Section 2: Program Organizational Structure

2.1 Staff Structure

➢ Executive Program Director
➢ Medical Director
➢ Program Manager
➢ Support Staff
➢ HRDX Counselors
➢

2.2 Oversight Mechanism

➢ Advisory Board: The Advisory Board, offer strategic insights, and ensure the program remains aligned with the latest in harm reduction practices.

2.3 General Staff Responsibilities

➢ **Executive Program Director:** Ensures the program's strategic alignment with harm reduction principles and operational efficiency. Manages senior staff, secures funding, and represents the program in public and professional settings. They report to the Advisory Board.

➢ **Medical Director:** The medical director is a key leadership position within a healthcare setting, responsible for overseeing the medical program's operations. This role can be executed in one of two primary ways, depending on the organization's structure and needs. In some cases, the medical director personally writes prescriptions for most of the program's enrollees, directly managing their medical care. Alternatively, the medical director may oversee a team of physicians, delegating the responsibility of writing prescriptions to these qualified professionals. In both scenarios, the medical director ensures that the medical care provided aligns with the program's standards and objectives

➢ **Program Manager**: Manages daily operations, supervises staff, and maintains program integrity. They are crucial for ensuring that the program's day-to-day activities align with established policies and objectives. The Program Manager reports directly to the Executive Director.

➢ **Support Staff:** Provide direct services to participants, maintain participant records, They report to the Program Manager and are essential for the operational success of the program

➢ **HRDX counselors:** HRDX Counselors are critical to the program, as they have lived experience, therefore they are able to communicate, and understand the participants on a deeper level, allowing participants to be more open and communicative of their true needs. They serve as the primary contact between participants and the medical aspects of the program. They perform initial assessments, set treatment plans, and guide the medical staff indosage and treatment adjustments. HRDX counselors also conduct regular health evaluations, provide immediate assessments for any changes, and recommend dosage adjustments. They utilize a specialized app for real-time monitoring and data-driven decision-making. Additionally, they educate participants about drug safety and empower them in their recovery process.

Section 3: Program Enrollment

3.1 Eligibility Criteria

To be eligible for the SOS Program, participants must:

➢ Be at least 18 years old.
➢ Participants must be current users of illicit opioids.
➢ Consent to participate in the program and acknowledge that they are doing so at their own risk, and sign the consent, and waiver.

3.2 Participant Enrollment Process

The screening process includes several steps to ensure participants are appropriately selected:

➢ **Virtual Assessment**: In order to stay in alignment with HRDX(harm reduction) Framework, the assessment will be virtual to increase accessibility
➢ **Consent Process:** Participants are provided with detailed information about the program's objectives, benefits, and potential risks. Before beginning the program, they must sign all required documents, including waivers of liability, risk acceptance forms, acknowledgments of potential dangers, and declarations forfeiting the right to take any legal action against the program.

3.3 Registration and Documentation

Upon acceptance into the program, participants are registered in a secure, confidential database. Essential documents collected include:

➢ Signed consent forms.
➢ An agreement outlining the participant's responsibilities and the program's commitments.
➢ Any forms/history/documents/information that the participant was willing to share.

Section 4: Medical Assessment and Dosage Determination

4.1 Initial Assessment Procedures

Initial medical assessments are critical for ensuring participant safety and appropriateness of the SOS program's intervention. This process includes:

➢ Comprehensive Evaluation: Conducted in person, or on video call by one of our Approved HRDX Counselors to understand the usage patterns, and provide the medical staff with the best course of action to provide the participant with the path that will help keep them alive.
➢

4.2 Evaluations

Participants undergo regular health evaluations more frequently at the beginning of the program to monitor their wellbeing as well as if they experience any changes in their physical or mental health:

➢ Scheduled Reviews: Conducted at regular intervals (weekly for the first 4 weeks then bi-monthly for the next 6 months, and every 6 months until recovery) these reviews assess the effectiveness of the current dosage and make adjustments as necessary, but also act as a method to engage in a health checkup.
➢ Ad Hoc Assessments: Triggered by any reported or observed changes in health status, these assessments allow for timely modifications to treatment plans.

4.3 Dosage Calculation Guidelines

Dosage is initially determined based on participant tolerance levels, how likely a participant is to supplement illicit substances in addition to the program provisions, the HRDX Counselors experienced judgment, the medical staff, and their overall health assessment:

➢ Standard Dosage Protocols: Utilizes evidence-based guidelines to set initial doses for various types of opiates.
➢ Individual Adjustments: Dosages are personalized based on individual response to treatment, side effects, and progress towards recovery goals.

4.4 Dosage Adjustment Protocols

Regular adjustments to the dosage are an integral part of the program, ensuring optimal treatment efficacy and minimizing risks:

➢ **App Integration for Real-Time Monitoring and Adjustments**: Utilize the specially designed app to allow participants to report their symptoms and any side effects in real-time. This tool supports immediate adjustments and more dynamic participant management.
   ○ **Feedback Mechanism**: Participants use the app to log daily symptoms, effectiveness of the dose, and any side effects. This data is crucial for assessing the need for dosage adjustments.
   ○ **Prompt Response**: The app's real-time data collection enables healthcare providers to quickly identify trends that may necessitate dosage changes, enhancing responsiveness and personalization of treatment.
➢ **Increase or Decrease in Dosage**: is much less frequent, with data from the app we are able to provide the right dosing quickly, which allows us to achieve the best balance between efficacy and safety.
   ○ **Participant-Driven Data**: We Consider the participant's reported app data during scheduled and ad hoc medical reviews to determine if the current dosage effectively manages withdrawal symptoms without causing significant side effects.
➢ **Medical Oversight**: All dosage adjustments are rigorously overseen by the medical director and administered by qualified healthcare professionals.

- App Data Utilization: Healthcare providers review app-reported data alongside medical evaluations to make informed decisions regarding dosage changes.
- Safety Checks: Use app data to perform safety checks for signs of overmedication or adverse reactions, ensuring rapid intervention when necessary.

Section 5: Medication Dispensation

5.1 Types and Formulations Provided

The program provides selected pharmaceutical-grade plant-based opiates/opioids, chosen for their efficacy and safety profiles to cater to different phases of treatment and consumption methods. These include but are not limited to:

Long-acting opioids

➢ **Usage**: Used for ongoing maintenance to provide stable levels of opioid in the system and manage dependency more consistently.
➢ **Method of Consumption**:
  ○ **Oral**:

Short-acting opioids

➢ **Examples**: Oxycodone Immediate Release, Hydromorphone.
➢ **Usage**: Employed to manage acute withdrawal symptoms or for breakthrough pain that may occur between doses of long-acting medication.
➢ **Methods of Consumption**:
  ○ **Oxycodone**: Available as oral tablets or capsules, providing quick relief of symptoms when taken.
  ○ **Hydromorphone**: Available in oral tablets, liquid forms, and injectable solutions, suitable for various immediate needs.
  ○

5.2 Packaging and Labeling Requirements

All are packaged securely and labeled clearly to ensure safety and correct usage:

➢ Tamper-proof Packaging
➢ Clear dosage information.
➢ Health warnings.
➢ Messages that encourage reduction in use and provide contact information for addiction treatment services.
➢ Clear Labeling

5.3 Distribution Channels and Dispensing Points

Medications are distributed through controlled and secure environments:

➢ Dispensing Locations: Medications are distributed at licensed facilities staffed by trained healthcare professionals or pharmacists.

➢ Direct Delivery: (One of the goals is to create a 1 hour delivery service in order to meet the needs of underserved communities, and prevent the participants from looking to illicit markets) If possible, medications may be delivered directly to a participant's location under strict protocols.

5.4 Handling and Storage of Pharmaceuticals

Proper handling and storage are vital to ensure the safety and efficacy of medications:

➢ Secure Storage: Medications are stored in secure facilities with restricted access.
➢ Inventory Management: Regular audits are conducted to ensure accurate tracking of medication stock and prevent diversion.

Section 6: Participant Monitoring and Support

6.1 Monitoring Protocols

Continuous monitoring of participants is crucial for tracking the efficacy of treatment and early detection of potential issues:

➢ Usage Tracking: Monitoring systems are in place to record and analyze patterns of medication use and adherence to prescribed regimens.
➢ Health Monitoring: Regular health check-ups and ongoing assessment of psychological well-being.

The program provides a comprehensive range of support services to assist participants in their recovery journey:

➢ Counseling Services: Individual and group counseling focusing on addiction recovery, life skills, and mental health.
➢ Social Support Services: Assistance with housing, employment, and access to educational resources.

6.2 Use of Technology in Monitoring and Support

Technology enhances the effectiveness of monitoring and support:

➢ **Electronic Program Records (EPR):** Are Used to maintain detailed and up-to-date program information for each participant, but for security purposes the records are linked to numbers, which the patients choose themselves. This way there is no link between a person's name and the data.
➢ **Telehealth Services**: such as remote support and counseling, along with access to necessary services.

Section 7: Safety Mechanisms, and Emergency Procedures

7.1 Emergency Response Protocols

To ensure the safety of all participants and staff, our program has developed a comprehensive set of emergency response protocols:

Action Steps for *Overdose* Response:

1. Check the participant for responsiveness and breathing.
2. **Dial emergency services**
3. Administer naloxone if an *overdose* is suspected.
4. Perform rescue breathing and, if trained, CPR, while waiting for emergency responders.

7.2 Handling Overdoses

Overdoses require swift and effective management to prevent fatalities and serious health consequences:

- ➢ Staff Responsibilities:
  - All staff members working directly with participants will receive training in identifying and responding to *overdose* symptoms.
  - Keep an overdose response kit accessible at all times in all areas where participants are present.r
- ➢ Monitoring Post-*Overdose*:
  - After an *overdose* incident, closely monitor the participant
  - Schedule a follow-up evaluation within 48 hours

7.3 Reporting and Managing Adverse Events

A robust system is in place for reporting and managing adverse events to mitigate risks and improve program safety:

- ➢ Procedure for Reporting Adverse Events:
  - All staff must report any adverse events immediately to the medical director using the Adverse Event Report Form.
  - Details to include in the report: participant details, description of the event, date and time, witnesses, and immediate actions taken.
  - Store all reports in the participant's records and the program's incident database for review and analysis.

7.4 SOS Smart Safety Mechanism

➢ The SOS Smart System is designed to enhance emergency responsiveness and participant safety. Activation is triggered by abnormal health parameters. Upon activation, emergency alerts are dispatched to emergency services, and predefined contacts, sharing the participant's location and vital data. The system ensures continuous monitoring of the participant's vitals until help arrives. Post-incident, a detailed health report is generated for review. Regular training for participants and staff on system use, alongside strict maintenance routines, ensures operational reliability and data security.

Section 8: Compliance

8.1 Audit Procedures

Audits are critical for ensuring adherence to operational standards and regulatory compliance:

➢ Internal Audit Schedule:
  ○ Internal audits are conducted bi-annually, reviewing a range of operational areas including patient records, medication management, and staff compliance with safety protocols.
  ○ Any Findings are addressed by developing an action plan to correct issues, whilst improving program operations/outcomes.

Section 9: Training and Development

9.1 Staff Orientation and Training

Training programs are essential for preparing staff to meet the demands of their roles effectively:

➢ **Initial Orientation:**
  ○ Two-week orientation for all new hires, which covers the program's mission, policies, emergency procedures, and confidentiality requirements.
  ○ Hands-on sessions with experienced staff to demonstrate daily tasks and responsibilities.

9.2 Ongoing Professional Development

We are committed to the continuous professional development of our staff:

➢ **Continuous Learning Opportunities:**
  ○ Access to online courses and in-person workshops related to harm reduction.
  ○ Encourage staff to attend at least two professional development events per year.

9.3 Performance Evaluation Methods

Regular performance evaluations help ensure that staff are meeting the program's standards of care:

- ➢ **Annual Review Process:**
  - ○ Yearly summary and reflections held annually for each staff member, focusing on achievements, areas we can improve from the perspective of the participants, and the happiness level of the staff, both professionally and personally.

Section 10: Stakeholder Engagement and Communication

10.1 Communication Strategy

To ensure effective communication with stakeholders and the public, the SOS Program employs a multi-channel communication strategy:

- ➢ **Newsletters:** The newsletter includes updates on program results, upcoming events, and stories highlighting participant progress.
- ➢ **Stakeholder Meetings:** We have dedicated meetings with stakeholders to review achievements and challenges, discuss the program's strategic direction, and gather input for future planning. These meetings are crucial for maintaining transparency.
- ➢ **Public Information Sessions:** We Conduct public sessions in community centers to inform the public about the program's purpose, benefits, and ways to get involved. These sessions are open to questions and will help to demystify the program's operations and reduce community concerns.

10.2 Community and Stakeholder Engagement

Engagement activities are designed to build and maintain strong relationships with both key stakeholders and the broader community:

- ➢ **Partnership Development:** We identify and engage new community partners through outreach activities. Establish collaborative projects that benefit both the community and program participants, such as community clean-ups or public health workshops.
- ➢ **Volunteer Programs:** We have a volunteer program that allows community members to get involved in supporting SOS participants, whether through mentoring, tutoring, or supporting day-to-day program operations.

10.3 Managing External Communications

The program's communication team manages all external communications to ensure consistency and accuracy:

- ➢ **Media Relations:** Our Community Engagement Director Takes care of our media relationships by Establishing and maintaining proactive relationships with media outlets, Handling all media inquiries and interviews.`

This opex provides a detailed description of our SOS Program. The goal of the program is to prevent accidental death from overdose, prevent the spread of disease,prevent suicide due to untreated or undertreated chronic pain patients. and help participants establish a pro recovery mindset.