Beehive Program Protocols

- Beehive Program Description for Ward 86 Providers
- Beehive Program Provider–Patient Expectations
- Referral Procedures for HIV/AIDS Patients From SFGH OTOP to the Beehive Program
- Clinical Guidelines for Prescribing Buprenorphine in the Office-Based Treatment of Opioid Dependence at the UCSF Positive Health Program
- San Francisco BHIVES–Jail Health Services Buprenorphine Inventory and Transfer Protocol

Buprenorphine HIV Integrated Care

BeeHIVe

PROGRAM DESCRIPTION
Ward 86 Providers

Beehive Patient Identification

Beehive patients will be opioid-using and desiring treatment for opioid dependence or abuse (e.g. heroin, methadone, or prescription opioids). They will have HIV disease and currently receive or be willing to receive primary medical care at the Positive Health Program at San Francisco General Hospital. Patients must be able to comply with program rules for attendance and appointments. Patients may be identified by their primary care or other providers and may be referred for evaluation and treatment at either the Positive Health Program or the Office-based Buprenorphine Induction Clinic (OBIC). Patients also may be self-referred or be referred by any provider in the community.

Clinical Eligibility

- HIV-positive
- Opioid dependent or abusing and desiring treatment (or wishing to transfer from methadone maintenance treatment).
- Currently receiving primary care (or willing to start primary care) at the Positive Health Program at San Francisco General Hospital.
- No chaotic or unprescribed benzodiazepine use. (Low-dose benzodiazepine prescriptions are not contraindicated.)
- No alcohol dependence or binge drinking.
- Age > 18 years or emancipated minor able to consent for medical and substance abuse treatment
- If female: not pregnant or trying to become pregnant, and using adequate birth control to prevent pregnancy
- No medical or psychiatric contraindications for buprenorphine treatment, including serious hepatic dysfunction (e.g., LFTs >5x ULN)
- Patients with acute or chronic pain syndromes requiring prescription opioid analgesics should be carefully screened, as buprenorphine may not be as effective an analgesic as a full opioid agonist, i.e., methadone

Patients who are appropriate for buprenorphine treatment but do not meet eligibility criteria for the Beehive Program will be referred for treatment to the Integrated Buprenorphine Intervention Services (IBIS) at (415) 502-7223.

Patient Entry into Beehive Treatment and Optional Evaluation Study

The patient entry process begins with an initial evaluation by the Beehive Clinical Nurse Coordinator, who then consults with the Beehive physician and the patient's primary care provider to review the patient's clinical eligibility for buprenorphine treatment. Appropriate patients are offered participation in an optional evaluation study and scheduled for an enrollment appointment where they are assigned to buprenorphine induction either at the Positive Health Program or the Outpatient Buprenorphine Induction Clinic (OBIC).

Initial Patient Evaluation

Patient education and clinical eligibility for buprenorphine treatment is determined at the initial patient evaluation visit. Patients receive information on how buprenorphine works and how to prepare for the induction visit. Eligible patients review and sign consent forms, complete a medical history, physical exam, and laboratory tests. Medication support for withdrawal symptom management in the days prior to the induction visit is made available.

Buprenorphine Induction & Stabilization

Patients must be in mild opioid withdrawal in order to start buprenorphine. Patients who have recently ingested any opiate and do not appear to be in withdrawal will be asked to return at a later time. At the induction appointment, the Beehive staff will assess for opioid withdrawal, and administer an initial dose to patients ready for induction. The patient will be observed for 1-2 hours, and may receive additional stabilization dosing as determined by the physician. Follow-up appointments to stabilize the dose level will be scheduled by program staff. Patients are generally seen 2-3 times during the first week. After this period, frequency of appointments may be decreased. Most patients will reach a stable dose in less than 2 weeks, and will be moved to an observed dosing, weekly, bi-weekly, or monthly dispensing schedule as determined by the treating physician and clinical staff. Patients can receive up to once monthly prescriptions once stabilized.

Counseling & Ongoing Care

Substance use counseling is available at Beehive and OBIC during treatment. All patients will be referred to and are eligible to attend weekly groups with other patients on buprenorphine. Counselors with training in substance use issues also will be available for more focused individual counseling. Assessment and referral for comprehensive services may be provided by a PHP Social Worker, Beehive Clinical Nurse Coordinator, and/or OBIC counselor/case manager, including medical, psychiatric, psychosocial, and case management referrals. Ongoing supervision is available for all mental health and substance abuse counselors serving Beehive patients.

Program, Clinical, and Evaluation Requirements

Urine toxicology specimens will be collected and used as indicators of clinical progress. Frequency of urine toxicology specimens will be determined by clinical need. They will be sent to SFGH laboratory and results will be posted in the LCR. Once stabilized on buprenorphine, patients should have contact with the Beehive or OBIC clinic at least once a month for either a counseling visit, a physician visit, or to submit a urine sample to the counselor. Patients should meet with their Beehive physician on at least a quarterly basis. Failure to comply with UA screenings, scheduled appointments, or buprenorphine dispensing requirements may lead to termination from the program.

Beehive Clinical Nurse Coordinator (415) 206-2452

PositiveHealthProgram
HIV/AIDS Division at SFGH

BEEHIVE PROGRAM
PROVIDER-PATIENT EXPECTATIONS

Examples of expectations that the provider may want to convey to the patient who is being considering for treatment with buprenorphine

THE PROVIDER'S EXPECTATIONS:

The physician should provide the patient with a written list of his/her rules and expectations, which can include items such as:

- The general philosophical approach utilized by the physician in the treatment of opioid addiction (e.g., a chronic illness that responds best to a combination of medication and non-pharmacological services; treatment provided in a respectful way and received in a similar fashion; etc.).
- Proper storage of medication (i.e., in a safe place inaccessible to children, household members, and guests).
- Taking the medication as prescribed (i.e., the indicated dose, not adjusting medication on his or her own).
- Reporting of lost or stolen medication to the physician's office immediately. (The physician may require a police report be filed, and a copy given to the physician's office.)
- Promptly responding to requests for urine testing. (It may be helpful to describe urine and blood testing for glucose in diabetics, and how these can be used to monitor compliance and treatment success in an analogous way to urine testing for opioid addiction.)
- Promptly notifying the physician about any lapse in any drug use before this is detected by urine testing.
- Immediate reporting of prescriptions written by other physicians, and of emergency medical interventions (e.g., emergency department visits).
- Policy on cancellation of appointments.
- Policy on individual and group counseling.
- Management and consequences to continued drug and/or problematic alcohol use.

THE PATIENT'S EXPECTATIONS:

At the first office visit, the physician should also include a list of what the patient can expect, which can include items such as:

- An uninterrupted supply of medication (potentially including a small reserve of medication in case unforeseen circumstances should delay the patient's return to the office for several days).
- Routine collection of urine specimens (including when and how).
- Special arrangements when travel, illness, or work requires a change in the schedule of office visits.
- Access to the physician, or a covering doctor, in emergency situations.
- Appointments scheduled at convenient times, with minimal waiting times.
- Accommodations for patients who travel long distances or have other special needs.
- Willingness by the physician to adjust the dose as clinically indicated.
- Treatment in a professional setting with respect for confidentiality of information about the patient's identity and condition.

Referral Procedures for HIV/AIDS Patients From SFGH OTOP (Methadone) to the Beehive (Buprenorphine) Program

Beehive Program Patient Identification

Potential patients will be opiate using and desiring treatment for opioid dependence or abuse (e.g., heroin, methadone, or prescription opioids). They will have HIV disease and currently receiving primary care services (or willing to engage in primary care services) at the Positive Health Program at San Francisco General Hospital. Patients may be identified by primary care and other providers. Patients may be self-referred or be referred by any provider in the community.

Clinical eligibility evaluation is conducted by the Beehive Program. All clinically eligible patients will be invited to participate in the program evaluation. If they opt to enroll in the evaluation study, then they may be referred for buprenorphine treatment at either the Positive Health Program or the Office-based Buprenorphine Induction Clinic (OBIC).

Importantly: Study participation is not required to receive services in the clinical Beehive program. The cost of treatment for patients without MediCal (Medicaid) coverage, however, is covered for study participants. Patients without MediCal (Medicaid) prescription coverage who do not wish to participate in the evaluation study will be referred to OBIC for buprenorphine services.

Eligibility

- ❑ Age > 18 years
- ❑ Fluent in English
- ❑ Receive or willing to receive HIV primary care at the UCSF Positive Health Program at SFGH
- ❑ Meet DSM-IV-TR criteria for opioid dependence
- ❑ Clinical exclusion:
    - o Severe hepatic dysfunction, i.e., AST and/or ALT $\geq$ 5X upper limit of normal
    - o DSM-IV criteria for benzodiazepine abuse or dependence within the past 6 months
    - o DSM-IV criteria for alcohol dependence within the past 6 months
    - o Actively suicidal
    - o Psychiatric impairment that impedes ability to consent (dementia, delusional, actively psychotic)
    - o Methadone or opiate analgesic doses exceed level allowing for safe transition to buprenorphine
    - o Patients with acute or chronic pain syndrome requiring regular narcotic analgesics should be carefully screened as buprenorphine may not be as effective an analgesic as a full opiate agonist
    - o Pregnant women and women actively trying to become pregnant

Patient Referral to Beehive Program from the Opiate Treatment Outpatient Program (OTOP/Ward 93)

OTOP clients may be referred or self-referred from a number of different sources and treatment settings. The following procedures attempt to address the variety of ways in which referrals may occur.

Referral Procedures for HIV/AIDS Patients From SFGH OTOP (Methadone) to the Beehive (Buprenorphine) Program

OTOP-INITIATED REFERRAL OF METHADONE DETOXIFICATION PATIENTS

1. **Identification:** OTOP Admission Coordinator will identify interested and potentially eligible detox clients and refer for evaluation. Clients receive copies of the Beehive Program Pamphlet. OTOP Admission Coordinator arranges for Evaluation visit by one of three methods:
   a) Schedule appointment with Ward 86 front desk (206-xxxx) for "86BUP Clinic"
   b) Schedule appointment for "86BUP Clinic" directly through LCR.
   c) Page Beehive Clinical Nurse Coordinator at 443-xxxx (pager) or leave her a voicemail message with patient's phone number at 206-xxxx.

2. **Evaluation & Education**:
   a) Clinical eligibility is determined by Beehive Clinical Nurse Coordinator.
   b) The Beehive Care Team is responsible for making sure the patient is prepared and educated about induction preparation and procedures.

3. **Notification**:
   a) If the patient is clinically eligible and still interested in Beehive Program, the Beehive Clinical Nurse Coordinator will call OTOP Admission Coordinator and send a group email to the following individuals notifying them on status of evaluation and to coordinate a transfer of care date.
      - OTOP Admission Coordinator
      - OTOP Charge Nurse
      - OTOP Nurse Manager
      - OTOP Medical Director
      - Beehive Medical Director

   b) If the patient is not clinically eligible, Beehive Clinical Nurse Coordinator will contact OTOP Admission Coordinator with reasons and potential plan and timeline for re-evaluation, i.e., decrease in LFTs or titration off of prescription opiates)

4. **Approval**: The OTOP Medical Director (or designate) and Beehive Medical Director (or designate) will discuss patient case if needed and reply to all in email above to "sign off" on agreement to transfer care within one week of above notification.

5. **Transfer:**
   a) The Beehive Clinical Nurse Coordinator will notify OTOP Nurse Manager when induction appointment is scheduled.
   b) OTOP Nurse Manager will verify that patient has been titrated to appropriate dose and has no dose scheduled for the day prior to induction.
   c) On day of induction, Beehive Clinical Nurse Coordinator will:
      i) Contact OTOP dispensary (206-xxxx) to check that patient has not dosed methadone prior to induction (to avoid "double dosing" that day).
      ii) Contact OTOP Nurse Manager after induction to confirm participant enrollment in the Beehive (to facilitate immediate discharge from OTOP). OTOP charge nurse will also be notified in the event of patient "No Show".

Referral Procedures for HIV/AIDS Patients From SFGH OTOP (Methadone) to the Beehive (Buprenorphine) Program

OTOP-INITIATED REFERRAL OF METHADONE MAINTENANCE PATIENTS

1. **Identification:** OTOP staff identifies potentially eligible OTOP clients with HIV/AIDS, who desire transfer to buprenorphine maintenance therapy. Client's OTOP MMT Counselor should be involved early in discussion of potential transfer. OTOP Staff arranges for Evaluation visit by one of three methods:
   a) Schedule appointment with PHP Ward 86 Front Desk (206-xxxx) for "86BUP Clinic"
   b) Schedule appointment for "86BUP Clinic" directly through LCR.
   c) Page Beehive Clinical Nurse Coordinator at 443-xxxx (pager) or leave her a voicemail message with patient's phone number at 206-xxxx.

2. **Evaluation & Education**:
   a) Clinical eligibility is determined by the Beehive Clinical Nurse Coordinator.
   b) The Beehive Care Team is responsible for making sure the patient is prepared and educated about induction preparation and procedures.

2. **Notification**:
   a) If the patient is clinically eligible and still interested in Beehive Program, the Beehive Clinical Nurse Coordinator will phone the OTOP Nurse Manager or Charge Nurse, who will notify the patient's OTOP MMT counselor.
   b) The Beehive Clinical Nurse Coordinator also will send a group email to the following individuals notifying them on the status of the evaluation and to coordinate a transfer of care date.
      - OTOP Admission Coordinator
      - OTOP Charge Nurse
      - OTOP Nurse Manager
      - OTOP Medical Director
      - Beehive Medical Director
   c) If the patient is not clinically eligible, Beehive Clinical Nurse Coordinator will phone the OTOP Nurse Manager or Charge Nurse, who will notify the patient's OTOP MMT counselor, with reasons and potential plan and timeline for re-evaluation, i.e., decrease in LFTs or titration off of prescription opiates)

3. **Approval**: The OTOP Medical Director (or designate) and Beehive Medical Director (or designate) will discuss patient case if needed and reply to all in email above to "sign off" on agreement to transfer care within one week of above notification.

4. **Transfer:**
   a) The Beehive Clinical Nurse Coordinator will notify the OTOP Nurse Manager when induction appointment is scheduled.
   b) On day of induction, the Beehive Clinical Nurse Coordinator will:
      i) Contact OTOP dispensary (206-xxxx) to check that patient has not dosed methadone prior to induction (to avoid "double dosing" that day).
      ii) Contact OTOP Nurse Manager after induction to confirm participant enrollment in the Beehive. OTOP charge nurse will also be notified in the event of patient "No Show".
   c) Propose: To permit the patient an adequate trial of buprenorphine and to avoid loss of time in the methadone program if the patient wishes to transfer back to methadone, discharge from OTOP will not occur immediately after buprenorphine induction. State laws, however, require that this trial period be limited to no more than 14 days.

Referral Procedures for HIV/AIDS Patients From SFGH OTOP (Methadone) to the Beehive (Buprenorphine) Program

SELF REFERRAL BY OTOP CLIENTS (Detox or Maintenance)

1. **Presentation:** OTOP clients may have heard about buprenorphine from friends or media (i.e., non-medical source) and self-present to Beehive Program for evaluation.

2. **Evaluation:**
   a) The Beehive Clinical Nurse Coordinator will review the Beehive program with patient and obtain consent to contact OTOP program.
   b) Clinical eligibility is determined by the Beehive Clinical Nurse Coordinator.
   c) The Beehive Care Team is responsible for making sure the patient is prepared and educated about induction preparation and procedures.

3. **Notification:**
   a) If the patient is clinically eligible and still interested in Beehive Program, the Beehive Clinical Nurse Coordinator will:
      i) For **maintenance** patients: Phone the OTOP Nurse Manager or Charge Nurse, who will notify the patient's OTOP MMT counselor
      ii) For **detox** patients: Phone and email the OTOP Admission Coordinator
   b) The Beehive Clinical Nurse Coordinator also will send a group email to the following individuals notifying them on the status of the evaluation and to coordinate a transfer of care date.
      - OTOP Admission Coordinator
      - OTOP Charge Nurse
      - OTOP Nurse Manager
      - OTOP Medical Director
      - Beehive Medical Director
   c) If the patient is not clinically eligible, the Beehive Clinical Nurse Coordinator will phone the OTOP Nurse Manager or Charge Nurse, who will notify the patient's OTOP MMT counselor, with reasons and potential plan and timeline for re-evaluation, i.e., decrease in LFTs or titration off of prescription opiates)

4. **Approval**: The OTOP Medical Director (or designate) and Beehive Medical Director (or designate) will discuss patient case if needed and reply to all in email above to "sign off" on agreement to transfer care within one week of above notification.

5. **Transfer:**
   a) Beehive Clinical Nurse Coordinator will notify OTOP Nurse Manager when induction appointment is scheduled.
   b) On day of induction, Beehive Clinical Nurse Coordinator will:
      i) Contact OTOP dispensary (206-xxxx) to check that patient has not dosed methadone prior to induction (to avoid "double dosing" that day).
      ii) Contact OTOP Nurse Manager after induction to confirm participant enrollment in the Beehive (to facilitate immediate discharge from OTOP). OTOP charge nurse will also be notified in the event of patient "No Show".
   c) Propose: To permit the patient an adequate trial of buprenorphine and to avoid loss of time in the methadone maintenance program if the patient wishes to transfer back to methadone, discharge from OTOP will not occur immediately after buprenorphine induction. State laws, however, require that this trial period be limited to no more than 14 days.

Referral Procedures for HIV/AIDS Patients From SFGH OTOP (Methadone) to the Beehive (Buprenorphine) Program

REFERRALS FROM PHP WARD 86 PROVIDERS:

1. **Identification:** PHP Ward 86 Providers (primary care providers, social workers, etc.) may refer their patients that are OTOP clients to Beehive for evaluation.

2. **Evaluation**: Beehive Clinical Nurse Coordinator will review program and obtains consent to contact OTOP program. Clinical eligibility is determined by Beehive Clinical Nurse Coordinator.

3. **Notification**:
   a) If the patient is clinically eligible and interested in Beehive Program, the Beehive Clinical Nurse Coordinator will call patient's Ward 86 Provider & send a group email to the following individuals notifying them on status of evaluation and to coordinate a transfer of care date.
      - Ward 86 Provider
      - OTOP MMT Counselor or OTOP Admission Counselor for Detox patients
      - OTOP Charge Nurse
      - OTOP Nurse Manager
      - OTOP Medical Director
      - Beehive Medical Director

   b) If the patient is not clinically eligible, Beehive Clinical Nurse Coordinator will contact the Ward 86 Provider with reasons and potential plan and timeline for re-evaluation, i.e., decrease in LFTs or titration off of prescription opiates)

4. **Approval**: The OTOP Medical Director (or designate) and Beehive Medical Director (or designate) will discuss patient case if needed and reply to all in email above to "sign off" on agreement to transfer care within one week of above notification.

5. **Transfer:**
   a) Beehive Clinical Nurse Coordinator will notify OTOP Nurse Manager when induction appointment is scheduled.
   b) On day of induction, Beehive Clinical Nurse Coordinator will:
      i) Contact OTOP dispensary (206-xxxx) to check that patient has not dosed methadone prior to induction (to avoid "double dosing" that day).
      ii) Contact OTOP Nurse Manager after induction to confirm participant enrollment in the Beehive (to facilitate immediate discharge from OTOP). OTOP charge nurse will also be notified in the event of patient "No Show".
   c) Propose: To permit the patient an adequate trial of buprenorphine and to avoid loss of time in the methadone maintenance program if the patient wishes to transfer back to methadone, discharge from OTOP will not occur immediately after buprenorphine induction. State laws, however, require that this trial period be limited to no more than 14 days.

6. **Confirmation with Ward 86 Provider:** On day of induction, Beehive Clinical Nurse Coordinator will notify Ward 86 Provider of induction outcome.

Clinical Guidelines for Prescribing Buprenorphine in the Office-Based Treatment of Opioid Dependence at the UCSF Positive Health Program

PURPOSE

These guidelines provide recommendations for prescribing buprenorphine for the office-based treatment of opioid dependence at the UCSF Positive Health Program at San Francisco General Hospital. They were developed through a HRSA-funded grant by the UCSF Beehive Program at the PHP in collaboration with the San Francisco Department of Public Health's Office-Based Opiate Treatment (OBOT) program and the Integrated Buprenorphine Intervention Service (IBIS).

Overview

Buprenorphine, a partial opioid agonist, was approved by the FDA in 2002 for the treatment of opioid dependence. As per the Drug Addiction Treatment Act of 2000, buprenorphine can be prescribed outside the Narcotic Treatment Program (NTP) setting by physicians who have done the necessary 8-hour training and received a special waiver.

Currently, buprenorphine is available in two sublingual preparations. One is composed of buprenorphine hydrochloride (Subutex®). The other is a combination tablet composed of buprenorphine hydrochloride and naloxone hydrochloride (Suboxone®). Naloxone is not absorbed sublingually and use of the combination tablet decreases the risk of diversion, injection, and fatal overdose. Suboxone, not Subutex, is used in the SFDPH Integrated Buprenorphine Intervention Service (IBIS). The only exception would be in the case of pregnancy.

Since buprenorphine acts as a partial agonist as well as an antagonist at the opiate receptors, it may precipitate opiate withdrawal in the opioid-dependent patient who has recently used opiates. A patient should not be induced on buprenorphine, if they have used a short-acting opiate such as heroin less than 12 hours before induction, or a long-acting opiate such as methadone less than 24 hours. Therefore, patients should only be induced on buprenorphine if they are showing objective signs of opiate withdrawal (unless they have been opioid-free for at least several days).

This protocol recommends procedures for evaluating patients and inducing buprenorphine treatment. Prior to performing patient history and physical, one should confirm patient suitability for buprenorphine treatment, including diagnosis of opioid dependence and review of other inclusion/exclusion criteria. An induction phase beginning with a low dose of buprenorphine, followed by increasing doses over several days is highly recommended to minimize the likelihood of precipitating opiate withdrawal. After induction, buprenorphine may be taken once daily or every other day. Once a stable dose of buprenorphine is established, a therapeutic dose can be maintained over a stable period of time.

Eligible patients may undergo induction and stabilization at the SFDPH Office-based Buprenorphine Induction Clinic (OBIC); 552-OBIC (552-6242), then return to the PHP clinic for maintenance therapy. Most patients will receive their medication during that time from the CBHS Pharmacy. Both OBIC and the CBHS Pharmacy are located at 1380 Howard Street at 10th Street.

Clinical consultation for all patients is available from Drs. Paula Lum, Jacqueline Tulsky, and David Hersh.

PATIENT SELECTION

One should confirm patient suitability for buprenorphine treatment, including diagnosis of opioid dependence and review of other inclusion/exclusion criteria.

Inclusion Criteria

- Patient is at least 18 years old
- Patient meets DSM-IV criteria for Opioid Dependence (see Worksheet in Appendix)
- Patient, if female, is not pregnant, trying to become pregnant, or nursing. It is recommended that patients receiving buprenorphine use adequate birth control methods (pill, IUD, condom with spermicide, abstinence, etc.) as its safety in pregnancy has not been fully established. Methadone is the medication of choice for this population.
- Patient is eligible for medical care at a DPH site

Exclusion Criteria

- Patient has serious uncontrolled/untreated psychiatric problems (suicidality, active psychosis, etc.)
- Patient has serious/uncontrolled/untreated medical problems (hypertension, hepatic failure, asthma, diabetes, etc.)
- Patient currently uses more than 30 mg/day of methadone
- Patient has a chronic pain disorder for which high-dose opioid analgesic medication is required (evaluated on case-by-case basis)
- Patient uses alcohol in a chaotic manner, i.e. binge drinker
- Patient uses high doses of non-prescribed, or misuses prescribed benzodiazepines, sedatives or hypnotics
- Patient requires the structure of a higher level of care (i.e., methadone maintenance)
- Patient has a known allergy/hypersensitivity to buprenorphine or naloxone

All eligible patients should have a complete health history and recent physical exam documented in HERO prior to treatment initiation.

Health history: Obtain a substance use history; review concurrent medical/psychiatric problems, medications and labwork. For female clients of childbearing age, assess and document effective use of birth control.

1. Substance use history:
    a. **Current opioid habit**, i.e. type of opioid, method of administration, frequency of use, last use.
    b. **Other substance use:** Review alcohol, sedative, and other substance use. Chaotic alcohol and sedative (e.g. benzodiazepines) use in conjunction with the injection of pulverized buprenorphine tablets (Subutex) has been associated with opioid overdose. This clinic uses only the combined buprenorphine/naloxone formulation (Suboxone) to deter this practice.
    c. **Previous opioid treatments:** Review past treatment experiences, including patient response to treatment, side effects, and perceived effectiveness.

2. Medical problems & medications
    a. **Liver disease:** Patients with decompensated cirrhosis may require closer monitoring
    b. **Pain syndromes:** Buprenorphine has analgesic properties when dosed three times daily, but it cannot be used in patients with acute or chronic pain syndromes requiring high doses of full opioid agonist therapy (e.g. morphine, methadone, oxycodone, hydromorphone).
    c. **Medications** metabolized by cytochrome P450 3A4 system, e.g. many ARVs and psychiatric medications; may require dose adjustments. For example, patients on ritonavir-boosted regimens may require only low doses of buprenorphine.

3. Other recently obtained lab results, including the following:
    a. **ALT, AST**—results over 5 times the normal upper limit may increase the risk of buprenorphine-induced hepatitis; buprenorphine treatment should be delayed until transaminitis has resolved;
    b. **Urine drug testing**: Expect opiate/opioid-positive urine tox screens. An additional urine toxicology screen should be obtained on day of induction and be opiate free.
    c. **Pregnancy test** (serum or urine HCG) within 72 hours for female patients of childbearing age. Assess and document an effective **birth control method** for female patients of childbearing age.

Physical exam: A full recent physical exam should be documented, including:

1. Documentation of opiate **withdrawal** symptoms, including autonomic excitation (elevated BP, increased HR), mydriasis, tremors, agitation/restlessness. Also note the presence or absence of yawning, rhinorrhea, piloerection, diaphoresis, lacrimation, vomiting and muscle fasciculations. To assess opioid withdrawal severity, use the Clinical Opiate Withdrawal Scale (COWS), see Appendix.
2. Observation of possible substance **intoxication**, including but not limited to EtOH odor, nystagmus, positive Romberg test, patient disinhibition, or other altered mental status.
3. Documentation of **drug or needle use sequelae**, including presence of track marks, abscesses, cellulitis.

Patient consents and authorizations: Review and insure all consent, agreement and authorization forms have been signed and are completed. Obtain the following prior to patient induction, (see Appendices):

1. Consent to Treatment with Buprenorphine
2. OBIC Referral Form: if patient is to be induced at OBIC
3. Authorization to Exchange Health Information: to confirm methadone dosing and transfer with MMT clinic
4. Buprenorphine Take-Home Dose Agreement (optional)

INDUCTION, STABILIZATION, & MAINTENANCE

This protocol in SOAP format details the procedures for assessing for physical dependence (symptoms of withdrawal) and starting and maintaining patients on buprenorphine. Patients initiating office-based buprenorphine treatment already will have been assessed for treatment appropriateness, including confirmation of diagnosis of opioid dependence and other clinical criteria (as described above).

Clinically appropriate patients are instructed to present for induction in an **opiate-free state** to reduce the risk of precipitated withdrawal. On the day of induction, the patient should exhibit signs of at least mild withdrawal (COWS > 5) prior to receiving their first dose of Suboxone.

- Heroin withdrawal typically begins 12 to 24 hours after last use, peaks at 2 to 3 days, and lasts 5 to 7 days. Heroin use should be stopped at least 12 hours prior to buprenorphine induction.
- Methadone withdrawal typically begins 1 to 3 days after last use, peaks at 5 to 7 days, and lasts 14 to 21 days. For patients on methadone, a taper down to dose of 30mg/day is recommended prior to buprenorphine induction to reduce the risk of precipitated opiate withdrawal. Methadone intake should be stopped at least 24-48 hours prior to buprenorphine induction.

In preparation for initiating treatment and to ease discomfort, patients may be given a "kickpack" tailored to their typical withdrawal symptoms:

- Clonidine 0.1 to 0.3mg PO q4 to 6 hours PRN lacrimation, diaphoresis, rhinorrhea, piloerection;
- Lorazepam (Ativan) 0.5-1.0 mg PO/SL q 8 hours PRN anxiety or irritability
- Promethazine (Phenergan) 25mg PO q4 to 6 hours PRN nausea/vomiting;
- Loperamide (Immodium) 4mg PO x I PRN diarrhea, then 2mg PO PRN each loose stool or diarrhea thereafter, NTE 16mg/24h;
- OTC acetaminophen 500-1000 mg q 4-6 hrs, ibuprofen 600 mg q 8 hrs, or naproxen 500 mg q 12 hrs PRN myalgias or arthralgias

SUBJECTIVE DATA

Chief Complaint: Review patient's opioid withdrawal symptoms: cravings, cravings, anxiety, discomfort, pain, nausea, hot or cold flushes. Include patient subjective rating of these symptoms (mild, moderate, or severe).

OBJECTIVE DATA

Physical Exam:
- Documentation of opiate **withdrawal** symptoms, including autonomic excitation (elevated BP, increased HR), mydriasis, tremors, agitation/restlessness. Also note the presence or absence of yawning, rhinorrhea, piloerection, hot and cold flushes, diaphoresis, lacrimation, vomiting and muscle fasciculations. To assess opioid withdrawal severity, use the Clinical Opiate Withdrawal Scale (COWS), see Appendix.
- Assessment of possible substance **intoxication**, including but not limited to EtOH odor, nystagmus, positive Romberg test, patient disinhibition, or other altered mental status.

Lab Results:

- Urine will be collected on the first day of induction and sent to the SFGH Clinical Lab for routine toxicology. This test can be done more frequently if needed, e.g. weekly during stabilization period.
- For female patients, a urine pregnancy test will be done on the day of induction.

ASSESSMENT

Opioid Withdrawal: Include severity (mild, moderate, severe) based on COWS scale.

If the patient appears intoxicated or exhibits no signs of withdrawal, then she/he should not be started on buprenorphine. Patient should be rescheduled for a later date or time and counseled regarding the need to present in some withdrawal prior to being dosed.

An exception may be made for patients that have gone through non-medical detoxification (e.g. jail) and now present opiate free (by urine tox) and with drug craving. Another exception may be made for select buprenorphine-experienced patients who are capable of home induction.

PLAN

Opioid agonist therapy: Buprenorphine/naloxone induction and upward titration.

Table 1: Induction, stabilization and maintenance dosing:

	Mon mg (range)	Tue mg (range)	Wed mg (range)	Thu mg (range)	Fri mg (range)	Sat mg (range)	Sun mg (range)
INDUCTION & STABILIZATION							
Week 1	8* (2-12)	12 (4-20)	16 (8-24)	16 (8-24)	16 (8-24)	16 (8-24)	16 (8-24)
Week 2	16-20	16-20	16-20	16-20	16-20	16-20	16-20
MAINTENANCE							
Baseline	16	16	16	16	16	16	16
1st dose increase**	20	20	20	20	20	20	20
2nd dose increase**	24	24	24	24	24	24	24

*Dosage refers to the buprenorphine component of the combination buprenorphine/naloxone tablet, which is formulated in a 4:1 ratio, i.e. 8 mg tablet = 8 mg buprenorphine + 2 mg naloxone

** Dose increases above 16mgs daily should come in 4mg increments and not before the patient has been on the current dose for at least 5 days.

INITIAL VISIT

1. For patients exhibiting **mild** withdrawal, give buprenorphine 2mg SL. For patients exhibiting **moderate** to **severe** withdrawal, give buprenorphine 4mg SL. The sublingual tablet must dissolve completely under a moist tongue. A sour hard candy placed on top of the tongue is sometimes helpful.
2. Observe patient for 20 to 30 minutes in exam room or treatment room. Most patients experience relief of withdrawal symptoms or reduction in cravings within the first 5-15 minutes after tablet dissolution.
    a. If there is no change in symptoms (no worsening), or symptoms are improved, an additional dose of buprenorphine 2 to 4mg SL may be given. Observe patient for again for symptom relief. The patient may be provided with 2-4mg take-home doses should withdrawal +/or marked craving recur in the evening.
    b. A sudden exacerbation of opioid withdrawal symptoms after administering buprenorphine usually indicates the continued presence of other (full agonist) opioids and the phenomenon known as "precipitated withdrawal." Providing additional buprenorphine will probably make symptoms worse in the short term. Discuss with patient and review time of last opiate use. Give other medications at the clinic for symptom management and instructed to return the following day for re-evaluation.

    - Clonidine 0.1 to 0.3mg PO q4 to 6 hours PRN lacrimation, diaphoresis, rhinorrhea, piloerection;
    - Lorazepam (Ativan) 0.5-1.0 mg PO/SL q 8 hours PRN anxiety or irritability
    - Promethazine (Phenergan) 25mg PO q4 to 6 hours PRN nausea/vomiting;
    - Loperamide (Immodium) 4mg PO x I PRN diarrhea, then 2mg PO PRN each loose stool or diarrhea thereafter, NTE 16mg/24h;
    - OTC acetaminophen 500-1000 mg q 4-6 hrs, ibuprofen 600 mg q 8 hrs, or naproxen 500 mg q 12 hrs PRN myalgias or arthralgias

3. Have all patients return to clinic in the next 1-2 days for re-evaluation and upward dose titration. If patient is to return in 2 days, make sure to give patient adequate supply of take-home doses until their next visit.
4. Record all take-home doses in CURES Reporting Log. Current legislation within the California prescription law requires all practitioners and prescribers to report directly dispensed Schedule II and III controlled substances to the Department of Justice, on a monthly basis by using the Prescribers' Direct Dispensing Log (see Appendix). Buprenorphine tablets that are administered in the clinic do not need to be reported.

Note: Initial doses that are too high may acutely exacerbate withdrawal symptoms, while titrating up too slowly may needlessly prolong withdrawal—either of these situations may result in patient relapse or other treatment non-compliance. Typical dose for first 24 hours is between 8 and 12mgs, and should not exceed 16mg. (See Table 1 for average daily dosing and ranges in first two weeks of treatment.)

STABILIZATION VISITS

1. Assess opioid withdrawal using COWS worksheet and review patient use of any adjunct medications for symptom management. Obtain urine for toxicology.
2. Give total daily dose administered on Day 1 plus an additional 2 to 4mg as needed (up to 16mgs) based on severity of withdrawal symptoms; i.e. 2 mg for mild WD, 4 mg for mod-severe WD.
3. Observe patient for 15 to 30 minutes again to rule out exacerbation of symptoms. If symptoms are improved but not completely relieved, the patient may be given an additional dose of buprenorphine 2-4 mg and/or provided with an evening dose of 2-4 mg as a take-home.
4. Have patient return for continued monitoring and stabilization – either daily (for unstable patients) or BIW-TIW with phone monitoring (very stable patients). Use COWS at each visit. Increase buprenorphine dose daily by 2 to 6 mg until the patient no longer presents signs and symptoms of withdrawal.

   Criteria for dose increases:
   - Significant opioid craving (especially towards end of dosing cycle) assuming adequate medication adherence and/or dissolve time (5-10 minutes);
   - Significant opioid withdrawal symptoms (especially towards end of dosing cycle) assuming adequate medication adherence and/or dissolve time (5-10 minutes);
   - Urine toxicologies persistently positive for opioids

5. **Target Dose:** The dose that results in the optimal relief of objective and subjective opioid withdrawal symptoms. This expected range is **12-16mg** daily, though lower doses may be sufficient with patients on boosted atazanavir and higher doses may be required for patients on efavirenz. (See Table 1 for average daily dosing and ranges in first two weeks of treatment.) **Maximum daily dose is 32mg**.
6. Dosing and Schedule: Most patients reach their target dose within the first two weeks of treatment. Observed dosing may occur at the PHP until a stable dose is achieved, though many patients do well with BIW-TIW observed dosing visits and phone monitoring. All patients will receive take home doses on weekends. Review with patient that diversion or misuse of buprenorphine may result in treatment discontinuation. Make sure to give patient adequate supply of take-home doses until their next visit.
7. Record all take home doses in CURES Reporting Log. Record all take-home doses in CURES Reporting Log. Current legislation within the California prescription law requires all practitioners and prescribers to report directly dispensed Schedule II and III controlled substances to the Department of Justice, on a monthly basis by using the Prescribers' Direct Dispensing Log (see Appendix). Buprenorphine tablets that are administered in the clinic do not need to be reported.

MAINTENANCE VISITS

1. **Medication visits:** When a stable buprenorphine dose is achieved, patients enter into a maintenance phase of treatment. If induction and stabilization are done at OBIC, the patient will be transferred back to his/her primary care site for buprenorphine maintenance.

   Medication visits are scheduled between weekly and monthly. Patients should see the prescribing provider at least every 3 months. (See schedule below)

   Medication visit frequency:
   Week 1: 2-3 times
   Week 2: 1-2 times
   Week 3: 1-3 times or once depending upon clinical stability
   Week 4: 1-2 times or once depending upon clinical stability
   Month 2-12: weekly to monthly depending upon clinical stability

2. **Urine drug testing (UDT):** UDT in clinical practice is a consensual diagnostic test that: (1) Provides objective documentation of compliance with the mutually agreed-upon treatment plan; (2) Aids in the diagnosis and treatment of the disease of addiction or drug misuse; (3) Advocates for the patient in family and social issues. UDT provides an opportunity for patients to discuss substance use issues with their provider. Positive results should be managed in a non-punitive manner and are not used for forensics purposes.

   Opioid negative urine tests receive positive reinforcement. Positive urine tests are opportunities for counseling and brief intervention. Remember that opioid agonist therapy is not an effective treatment for stimulant use or dependence.

   UDT frequency:
   Week 1-4: Once weekly during induction and stabilization
   Month 2-12: Weekly to monthly depending upon clinical stability

   At the SFGH Clinical Lab, buprenorphine is not included in the regular assay but it sometimes has cross-reactivity with the lab's opiate screen; confirmation can be requested from the Lab Medicine Resident within a week of testing. Point-of-service drug kits offer specific buprenorphine tests and may be useful in settings where diversion is suspected.

3. **Medication dispensing**

   MediCal patients: Send prescription to pharmacy with ample time allotted for pharmacy processing of TAR application. (MOMS Pharmacy at Castro and Golden Gate are experienced with this medication.) Indicate whether medication should be dispensed in weekly or monthly amounts. We recommend weekly dispensing for at least the first month of treatment.

   Provide patient with sufficient amount of buprenorphine (no more than one week supply) to allow for TAR approval. If processing requires more than one week, have patient return to PHP clinic for additional take home doses.

   Record all take-home doses in CURES Reporting Log. Current legislation within the California prescription law requires all practitioners and prescribers to report directly dispensed

Schedule II and III controlled substances to the Department of Justice, on a monthly basis by using the Prescribers' Direct Dispensing Log (see Appendix). Buprenorphine tablets that are administered in the clinic do not need to be reported.

Uninsured patients: Buprenorphine is not listed on the ADAP formulary in California. Uninsured patients can continue to receive buprenorphine medication from the PHP clinic (through the end of BHIVES funding) or CBHS pharmacy (SFDPH agreement, contact David Hersh, MD at 255-3601).

4. **Counseling:** Best practices office-based opioid treatment consists of opioid agonist therapy combined with substance use counseling. We recommend weekly participation in group counseling for support and relapse prevention tools. Individual counseling is beneficial for many patients in addressing the underlying issues for their substance use and available on-site with trained PHP social workers or by referral to off-site agencies, e.g. Center for Special Problems. Brief counseling should be conducted by buprenorphine prescribers during medication visits.

   Individual counseling visit frequency:
   - Month 1: Once weekly
   - Months 2-3: Once weekly to every other week
   - Months 4-12: Once weekly to monthly

5. **Record keeping:**
   - Each Beehives Program patient visit will be documented in the HERO database.
   - Copies of treatment consents and authorizations are added to medical record.
   - All buprenorphine dispensed from clinic will be documented in the CURES reporting log.

NOTES ON SPECIAL POPULATIONS

Jailed Patients:
We have observed lower buprenorphine doses and slower upward titration among incarcerated patients.

Because jailed patients typically are not referred for treatment until after they have gone through detoxification, they are usually (but not always) opiate-free several days to several weeks at the time of presentation for treatment. Therefore, they present more with symptoms of psychological craving or "prolonged abstinence syndrome" rather than frank physical manifestations of opioid withdrawal. Opioid effects, i.e. feeling "high", have been consistently reported among incarcerated patients with daily doses as low as 2-4 mg.

PRIOR TO INDUCTION:

- Obtain LFT's and, if elevated, get prothrombin time (INR) to evaluate synthetic function.
- We continue to obtain urine specimens for urine drug testing (UDT), as there is widespread diversion of prescription opioids in jails.
    - Advise patient to avoid any opiate pain-medication (eg., Vicodin, Percocet, TyCo's #3 or #4's, all common in jail-formulary) 48 hours prior to scheduled day of induction.
    - Advise that a UDT will be done and that any present opiates will preclude induction that day.
- Advise patient that medication must be dissolved under tongue and that the SF Jail Health staff will crush the tablet when dispensed to reduce dissolution time and to prevent diversion.

AT THE TIME OF JAIL RELEASE:

- Psychological craving tends to increase even among patients stabilized on buprenorphine. Consider a dose increase prior to release from jail.
- Make arrangements to include buprenorphine in patient's property, especially if release is anticipated over the weekend.
- Often times, an incarcerated patient's release date is unpredictable. Make sure the patient knows where to find you for follow up care, if s/he is released unexpectedly.

Buprenorphine-experienced patients:

Patients who have previously been on buprenorphine and are familiar with the its pharmacodynamics, know their withdrawal/craving symptoms, and have demonstrated both comfort and skill at restarting the medicine without clinical observation, can "self-reinduce" at home. Such patients always have telephone and pager access to the BHIVES clinical staff for advice and/or coaching through the induction, if needed.

APPENDICES

I. DSM-IV criteria for Opioid Dependence worksheet
II. Clinical Opioid Withdrawal Scale (COWS) worksheet
III. Consent for Treatment with Buprenorphine
IV. OBIC referral form (if patient is to be induced at OBIC)
V. Authorization to Exchange Health Information
VI. Buprenorphine Take-Home Dose Agreement (optional)
VII. CURES Prescribers' Direct Dispensing Log

SAN FRANCISCO BHIVES – JAIL HEALTH SERVICES
BUPRENORPHINE INVENTORY & TRANSFER PROTOCOL

PURPOSE

The purpose of this document is to provide step-by-step procedures for the management of buprenorphine medication for prisoners participating in the BHIVES Patient Evaluation Study and in accordance with the study protocol approved by the UCSF Committee on Human Research (CHR), on 12/20/2006, after review and ratification by the HHS/OHRP. It will serve as the "go to" document for implementation of BHIVES study recruitment in the San Francisco City and County Jails, as well as procedures for ordering medications through the jail pharmacy, reimbursement of medication to the jail pharmacy, and providing participants with discharge medication upon their release from jail.

Any exceptions to the study protocol will be documented and amended to this document. Any protocol violations must be documented and reported to the UCSF Committee on Human Research.

BUPRENORPHINE CLINICAL ELIGIBILTY (Beehive Program) AND STUDY RECRUITMENT (BHIVES)

FAP or JHS staff disseminates information about buprenorphine treatment for opioid dependence to HIV+ prisoners. Interested persons are referred to the FAP Nurse (Avery) or Beehive Clinical Nurse Coordinator (Blake) to assess clinical eligibility for buprenorphine treatment. Clinically appropriate prisoners will be told about the opportunity to participate in an evaluation study at the time that clinical eligibility is determined. If the prisoner wishes to participate in the evaluation study, an enrollment appointment will be scheduled with the Evaluation Project Coordinator at the jail within one week. Buprenorphine induction and stabilization will be delivered according to Jail Health Services policies and procedures and with consultation from the Beehive clinical team.

- Buprenorphine treatment is delivered by JHS. Therefore, verbal orders for medication must come from Dr. Estes or Dr. Goldenson.
- Medication orders to the jail pharmacy must be entered with the code #BHV for inventory accounting.

JAIL HEALTH SERVICES MEDICATION INVENTORY & REPLACEMENT BY BHIVES

All medication will be provided by the Jail Health Services Pharmacy. Buprenorphine orders will be entered with the **code #BHV** in the CHART electronic medical-records system as per standard JHS protocol.

A monthly Medication Administration Record (MAR) query on the Jail Health Services CHART system will be executed by the BHIVES Project Coordinator to determine the number and dosage of buprenorphine tablets administered by JHS to BHIVES study participants. Based on this tally of medication dispensed by Jail Health Services personnel, a monthly delivery will be made by the Beehive Clinical Nurse Coordinator to the Jail Health Services Pharmacy in San Bruno County Jail. The BHIVES Clinical Coordinator will obtain a receipt from the receiving JHS pharmacist to balance against the tally of dispensed medication.

Medication will be replaced in sealed full-count (#30) bottles of the 2mg and 8mg dose formulations of buprenorphine/naloxone.

The Beehive clinical nurse coordinator will keep and regularly update (at minimum, per each monthly MAR and reimbursement) a bound inventory log of meds delivered and dispensed,

with a running balance of medication owed or replaced at Jail Health Services Pharmacy. Patients will be identified in this log by confidential BHIVES study ID and patient initials. This log will always be kept in a locked and secure location, when not in use.

RELEASE MEDICATIONS

At release, JHS or Beehive medical staff will place 1 day worth of medication, if released during the week, or 2 days worth of medication (3 days worth if a holiday weekend), if scheduled for release during the weekend, into the patients property with instructions and contact information/appointment cards for continued care at the Positive Health Program at San Francisco General Hospital ward 86. This medication will come from the stores of the Beehive program.

Procedures:

1. FAP notifies Beehive Clinical Nurse Coordinator of potential discharge date.
2. If patient is to be discharged to residential drug treatment, then Beehive will deliver discharge meds to the drug treatment facility directly.
3. If patient is discharged to the community, then discharge medications are placed in patient's property as follows:
4. Beehive places discharge medication placed in labeled bottle* with childproof cap, and bottle staple shut in brown paper bag. Bag is labeled with patient's Last Name, First Name, DOB and Jail ID #.
5. Per the instructions of the discharge planner, once discharge date is confirmed, bag of release medication is taken to C.J. #9 and placed in patient's property. A receipt to acknowledge receipt of meds will be signed by deputy in property room.
6. The Beehive Clinical Nurse Coordinator will use the electronic chart to monitor if patient is released on planned discharge date. If patient is not released, then discharge meds will be removed from the patient's property.

*Sample label for discharge medications:

Jane W. Doe, M.D.
Positive Health Program / SFGH, Ward 86
995 Potrero Ave., San Francisco, CA 94110
Tel: 415.476.XXXX, Fax: 415.476.XXXX

Name_____ Date _____
Drug/Dose **Buprenorphine 2mg/Naloxone 0.5mg**
Take _____ tablets PRN, q _____ ,
as needed for opiate withdrawal
Qty Given_____ Exp Date __/___/___

CAUTION: Federal law PROHIBITS transfer of this drug to any person Other than the person for whom it was prescribed