



Implementing buprenorphine in Opioid Treatment Programs

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Webinar 1: operational and logistical steps, 9/27/2018



Background to these webinars

- The Drug Medi-Cal/Organized Delivery System requires addition of sublingual buprenorphine to the opioid agonist treatment medications offered in Opioid Treatment Programs (known in CA statute as Narcotic Treatment Programs, or NTPs)
<https://www.dhcs.ca.gov/provgovpart/Pages/Drug-Medi-Cal-Organized-Delivery-System.aspx>, IN 16-048
- Sublingual buprenorphine is different from methadone in various ways that require adjustment of clinic logistics as well as patient selection and care.
- There are seven OTPs that are part of DMC/ODS in San Francisco, and the ability to offer sublingual buprenorphine has varied from clinic to clinic. There are some common challenges, and we would like to offer a central forum for sharing questions and successes among methadone provider colleagues that might be more available than the monthly provider meetings.
- All of our SF OTPs use MethaSoft electronic record and dispensing system. Some of the slides will be specific to that technology.

Two webinars

We have prepared two webinars to address:

- ▶ - logistics and clinic structure and operations in Webinar 1
- ▶ - patient treatment considerations in Webinar 2

Each webinar has time set aside for questions and comments, which may lead to further technical assistance or training.

Educational Objectives, Webinar 1.

Webinar participants will:

- ▶ change the clinic operations manual (protocol) to include buprenorphine.
- ▶ send NDC (national drug code) for selected medication preparations to billing director
- ▶ adjust MethaSoft to include buprenorphine dosing and reconciliation
- ▶ provide DHCS-required documents as laid out in IN: 18-004
 - ▶ Estimated impact
 - ▶ Patient selection criteria
 - ▶ Patient orientation materials
 - ▶ Procedures for dosing and storing

Step one: add schedule 3 to clinic DEA license

- OTPs have usually had a DEA license for schedule 2, because methadone is schedule 2. Buprenorphine is schedule 3, and must be added.
- This change is easily done online by filling out the 'update' form on the DEA diversion control website:
- <https://apps.deadiversion.usdoj.gov/webforms/jsp/regapps/common/updateLogin.jsp>

Registration Update Request - Login Screen

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Update Request for Registrations Under Controlled Substances Act of 1970

DEA Registration/Application Update Request Login:

DEA Number (Required for CURRENT Registrants - Not Case Sensitive)

Registration Control Number (Required for NEW/Pending applicants - Not Case Sensitive)

Last Name or Business Name (Required - Not Case Sensitive)
As it appears on your registration. Example: If "Smith, John Q MD" is on your registration, then enter: **Smith** If "Smith's, Pharmacy" is on your registration, then enter: **Smith's** If "Smith's Pharmacy" (no comma) is on your registration, then enter: **Smith's Pharmacy**

SSN (Required if given on application)

Tax ID (Required if given on application)

-Month- -Day- -Year-

Current Expiration Date (Required for registrants. Listed on registration certificate.)

-State-

State (from registered address) (Required)

Zip (from registered address) (Required)

Step two: Select the medications you will order

- ▶ Your usual methadone supplier may also offer buprenorphine
- ▶ Selecting the type of medication will require a conversation with your medical and nursing staff.
- ▶ Discuss which types of tablet or film you will use
 - ▶ What dosages to stock?
 - ▶ Combination with naloxone, or plain buprenorphine?
 - ▶ For any take-home, the combination preparation is preferred. (The naloxone is not active if taken sublingually, but if injected, it may precipitate withdrawal, so it serves as a deterrent to needle use.)
 - ▶ The buprenorphine only tablet is used for pregnant patients, so you may need some.

Poll question: Which medication did your clinic select?

For **most** of your (non-pregnant) patients, will you use:

- ▶ 1. Buprenorphine only tablet
- ▶ 2. Combination tablet (buprenorphine/naloxone)
- ▶ 3. Combination film
- ▶ 4. Buprenorphine only at the window, combination for takehomes.

Select the medications, continued

- ▶ In selecting the medication, consider the dosing rates offered by DHCS. These change every year, but for year 18-19, the rate for the mono-buprenorphine is \$16.91 per dose, and for combination buprenorphine/naloxone is \$20.10 per dose:
https://www.dhcs.ca.gov/formsandpubs/Documents/MHSUDS%20Information%20Notices/MHSUDS_Information_Notices_2018/MHSUDS_Information_Note_18_036_MAT_FY_1819_Exhibit.pdf
- ▶ Also consider the type of buprenorphine covered under Medi-Cal as a pharmacy benefit when prescribed in primary care. Some clinics plan to stabilize their patients, thinking eventually to transfer – sort of ‘graduate’ - to primary care when they’ve achieved their treatment goals. Patients don’t like to change their medication once it’s working.

Buprenorphine/naloxone covered **at present** by Medi-Cal pharmacy benefit in office-based care. (non-OTP, at retail pharmacies)

BUPRENORPHINE/NALOXONE

- ▶ *Sublingual tablets **Brand name Suboxone**, company Reckitt-Benkiser, Invidior
 - ▶ 2 mg/0.5 mg, 8mg/2 mg
- ▶ *Sublingual tablets **Brand name Zubsolv**, company Orexo
 - ▶ 1.4mg/0.36 mg, 5.7mg/1.4 mg, 11.4 mg/2.9 mg
- ▶ * Sublingual Film **Brand name Suboxone**, Company Reckitt-Benkiser, Invidior
 - ▶ 2mg/0.5 mg , 4mg/1 mg, 8mg/2 mg, 12mg/3 mg

https://files.medi-cal.ca.gov/pubsdoco/manual/man_query.asp?wSearch=%28%23filename+drugscdl%2A%2Edoc+OR+%23filename+drugscdl%2A%2Ezip%29&wFLogo=Contract+Drugs+List&wFLogoH=52&wFLogoW=516&wAlt=Contract+Drugs+List&wPath=N

Jargon

- ▶ What does this mean?
- ▶ 2 mg/0.5 mg, 8mg/2 mg

This is how the combination medication buprenorphine/naloxone is expressed, with naloxone after the slash mark.

So, 2 mg/0.5 mg means the film or tablet contains two milligrams of buprenorphine and 0.5 milligrams of naloxone. In practice, when we discuss this with patients, we often leave out the naloxone, since it's not active unless injected. So this would be a two milligram tablet or film. And 8mg/2 mg would be the 8mg tablet. If the person takes both, it's a 10mg dose.

Don't confuse this naloxone in the buprenorphine tablet, added as a deterrent to needle use, to the liquid naloxone used for rescue from overdose. It's the same ingredient, but different packaging and purpose. The nasal rescue spray is 4mg – the one you hope everyone carries.

Selecting medication: finding the National Drug Code

- ▶ The FDA has a website with a look-up, if you don't know the NDC for your particular formulations.
<https://www.accessdata.fda.gov/scripts/cder/ndc/index.cfm>

<https://www.accessdata.fda.gov/scripts/cder/ndc/index.cfm>

The screenshot shows the FDA National Drug Code Directory homepage. At the top, there's a navigation bar with links for Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Tobacco Products. Below the navigation is a search bar labeled "Search FDA". The main content area is titled "National Drug Code Directory" and features a search form for "NDC finished products search". The search form includes fields for "Select Type" (with a dropdown menu) and "Enter at least three characters" (with a text input field), along with "Search" and "Clear" buttons. A note at the top of the page states: "The National Drug Code (NDC) Directory is updated daily. Current through: 9/24/2018".

Step three: get your billing codes

- Once you have selected the various film or tablets you will order, send the NDC numbers to our billing director, Maria Bartheaux, maria.j.barteaux@sfdph.org, Phone: (415) 255-3536. There are billing codes for each one. (really, there are!)
- Since there is only one claim for dosing paid per day by DHCS, you might notice that this creates a problem. For example, if someone stabilizes at a dose of 10 mg, this might be made up of 2mg plus 8mg, each with their own NDC number and billing code. Yet they are dosing once daily – with two different strengths of tablet. Which code to claim that day?
- Most clinics end up deciding to send the larger of all the tablets or film the person is taking each day.
- DHCS (the state) is still pondering how to manage this issue.



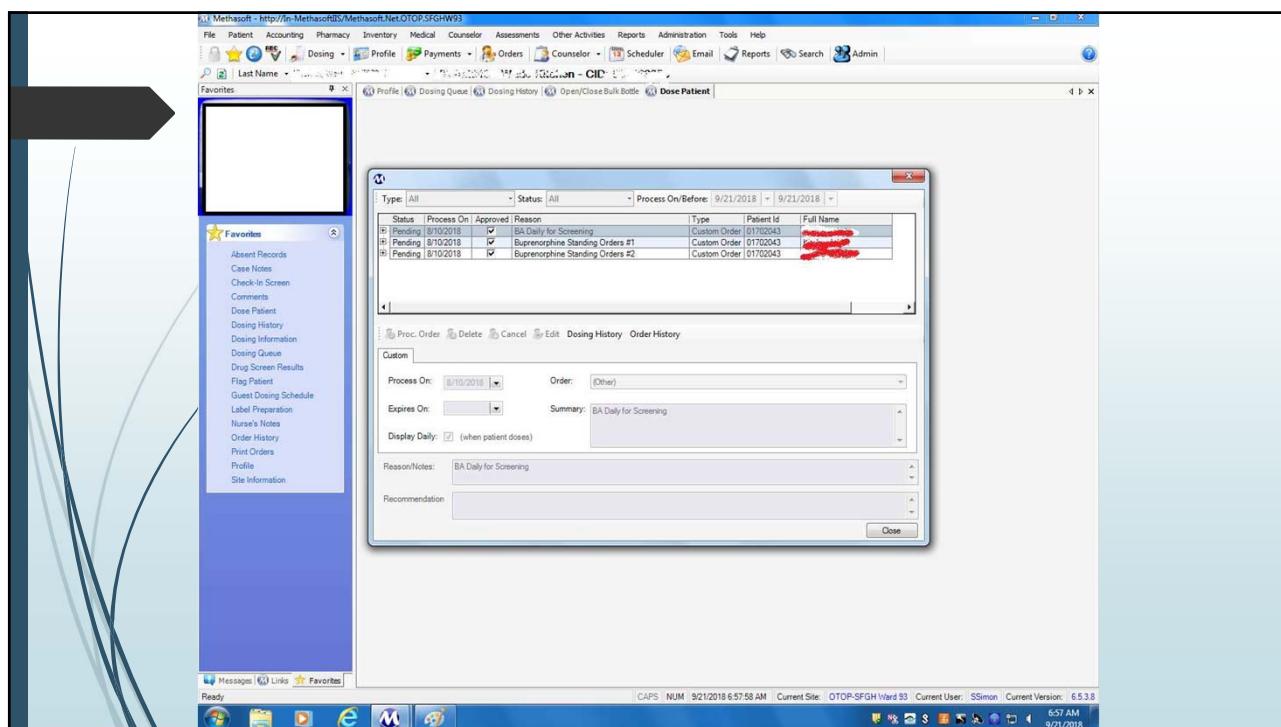
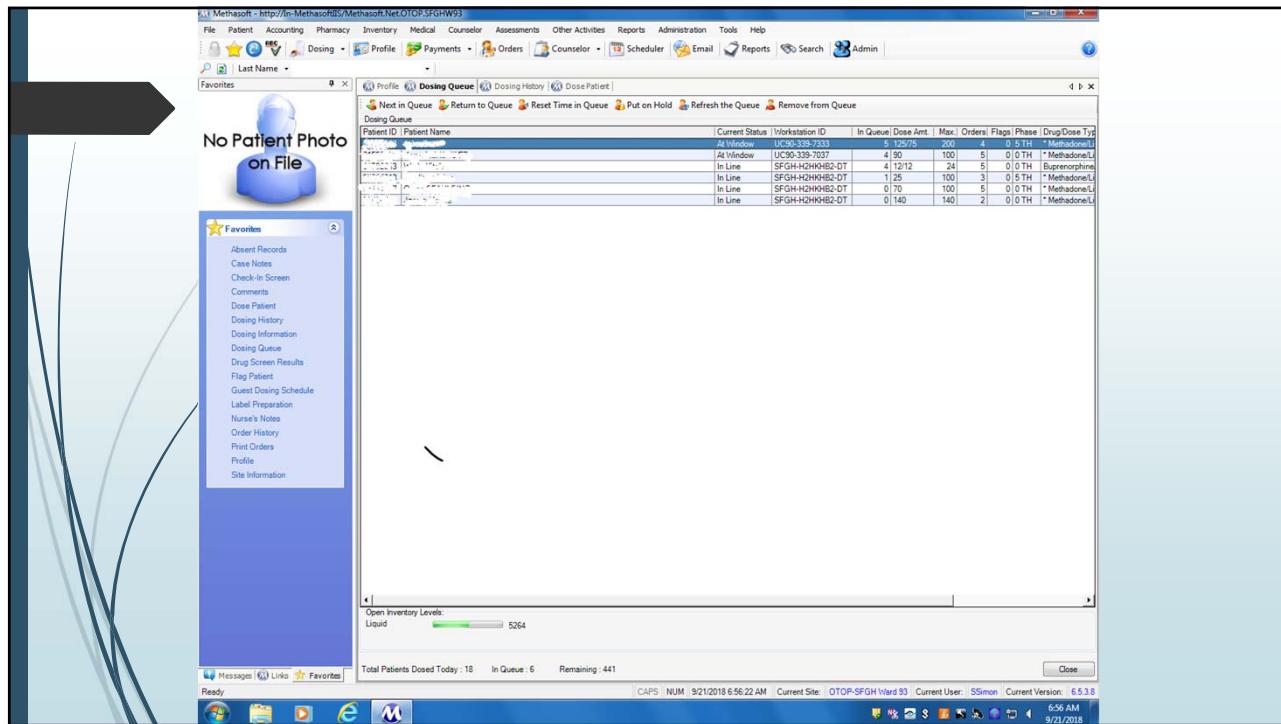
Poll question: Do you have the billing codes you need for buprenorphine?

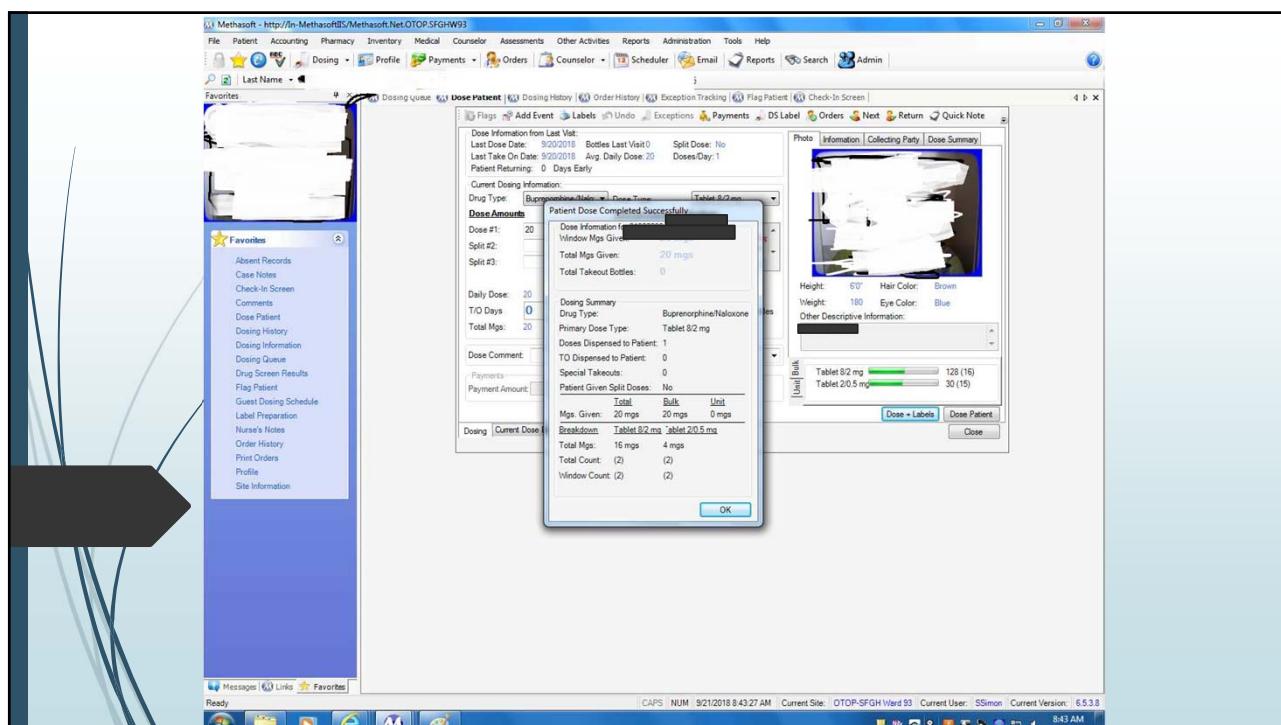
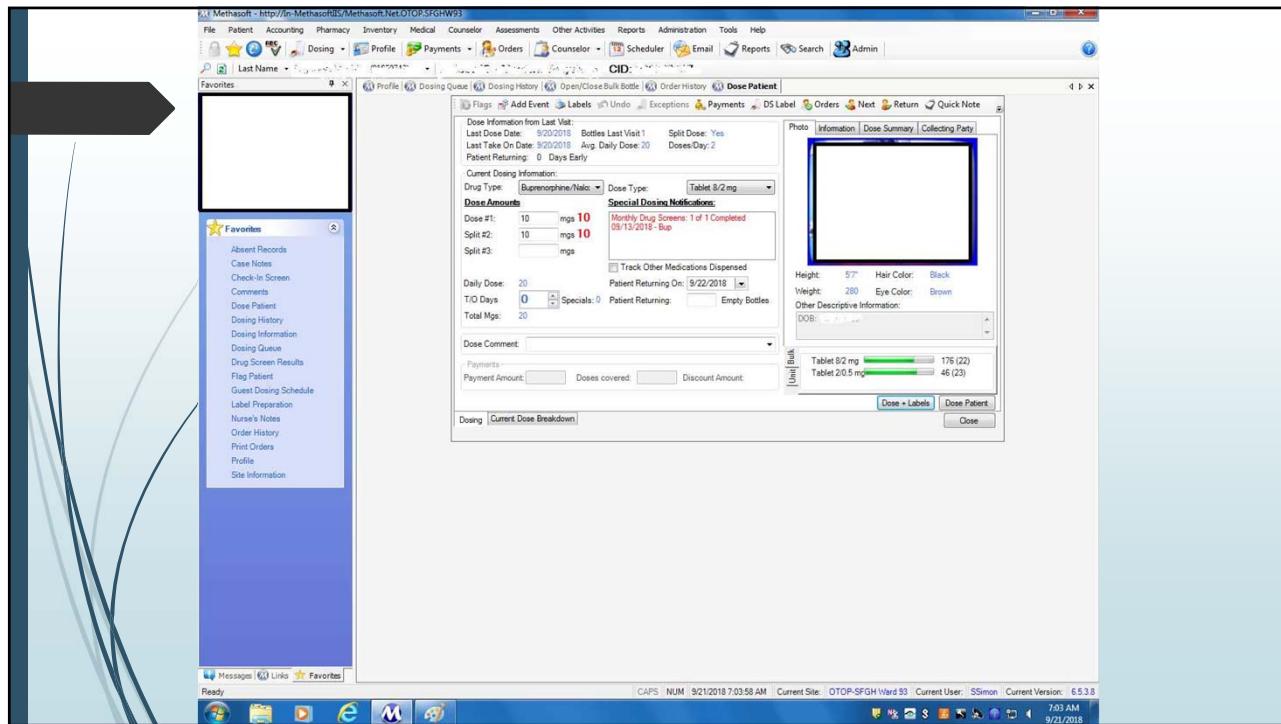
- ▶ 1. yes
- ▶ 2. no



Step four: set up dispensing and reconciliation

- ▶ MethaSoft is able to track dispensing of more than one type of medication, with corresponding dosing records and reconciliation.
- ▶ The following screen shots are from OTOP Ward 93, with patient identifiers erased. Courtesy of Hasija Sisic.
- ▶ Thank you, Hasija!





Step five: update the operations manual

IN 18-004 requires the following items to be present for each added medication. (This applies to disulfiram and naloxone as well.)

- ▶ **Estimated impact:** for example, how many new patients do you expect to treat with buprenorphine. How many patients do you expect would transfer from methadone to buprenorphine?
- ▶ **Patient selection criteria:** these are clinical judgement calls that will be discussed in webinar 2 on October 3rd, and this part of the protocol would be set by medical staff, under guidance of the Medical Director.
- ▶ **Patient orientation materials:** If you have a handbook, it needs to be updated. Since this is new in the OTPs, we expect patients will have lots of questions.
- ▶ **Procedures for dosing and storing:** Usually current procedures for methadone can be updated to include buprenorphine. (other medications such as disulfiram would not be stored in the safe). You may want to decide whether to crush the tablet if that's what you chose as the medication. It's harder to divert, and is absorbed faster.

How many patients on buprenorphine do you estimate by December 2018?

- ▶ We will likely have:
 1. 5-10 patients on buprenorphine
 2. 10-20 patients on buprenorphine
 3. 20-50 patients on buprenorphine
 4. over 50 patients on buprenorphine

Patient orientation materials some examples:

- Many patient and family materials have been prepared for the buprenorphine trainings over the years. I'm including a few examples here.
- The slides only contain part of the words and forms, the full versions are in attachments. These have been prepared for the buprenorphine trainings for office based buprenorphine, so you can tailor to your clinic population, or various reading levels, etc.

BUPRENORPHINE MAINTENANCE TREATMENT INFORMATION for FAMILY MEMBERS

Family members of patients who have been prescribed buprenorphine for treatment of addiction often have questions about this treatment.

What is an opioid?

Opioids are addictive narcotics in the same family as opium and heroin. This includes many prescription pain medications, such as Codeine, Vicodin, Demerol, Dilaudid, Morphine, Oxycontin, and Percodan. Methadone and buprenorphine are also opioids.

Why are opioids used to treat addiction?

Many family members wonder why doctors use buprenorphine to treat opiate addiction, since it is an opioid, as is heroin. Some of them ask, "Isn't this substituting one addiction for another?" But the two opioid medications used to treat addiction to heroin – methadone and buprenorphine – are not "just substitution." Many medical studies since 1965 show that maintenance treatment helps keep patients healthier, keeps them from getting into legal troubles, and prevents them from getting AIDS and hepatitis C.

What is the right dose of buprenorphine?

Family members of patients who have been addicted to heroin have watched as their loved ones use a drug that makes them high, or loaded, or have watched the painful withdrawal which occurs when the drug is not available. Sometimes the family has not seen the 'normal' person for years. They may have seen the patient misuse doctors' prescriptions for narcotics to get high. They are rightly concerned that the patient might misuse or take too much of the buprenorphine prescribed by the doctor. They may watch the patient and notice that the patient seems drowsy, or stimulated, or restless, and think that the buprenorphine will be just as bad as heroin.

Every opioid can have stimulating or sedating effects, especially in the first weeks of treatment. The 'right' dose of buprenorphine is the one that allows the patient to feel and act normally. It can sometimes take a few weeks to find the right dose. During the first few weeks, the dose may be too high, or too low, which can lead to withdrawal, daytime sleepiness, or trouble sleeping at night. The patient may ask that family members help keep track of the timing of these symptoms, and write them down. Then the doctor can use all these clues to adjust the amount and time of day for buprenorphine doses.

Once the right dose is found, it is important to take it on time in a regular way, so the patient's body and brain can work well.

BUPRENORPHINE MAINTENANCE TREATMENT

INFORMATION FOR PATIENTS

Specific information for patients who are considering treatment with buprenorphine

Addiction medicine doctors consider addiction to be a chronic disease and treat it accordingly. Buprenorphine is one of the medications which can be used to treat opioid addiction. Opioids are drugs like heroin, opium, morphine, codeine, oxycodone, hydrocodone, etc., which can be abused and lead to tolerance and dependence. This means that the user's body becomes accustomed to ever-higher amounts, and, when the drug is stopped, there are symptoms of withdrawal. Even after the worst physical part of withdrawal is over, some patients still don't feel right for a long time and may relapse to using drugs again, just to "feel normal."

Some of the medical research shows that after abusing drugs for a long time the brain is thrown off balance, and the goal of treatment is to encourage stability, both in the body and in the patient's life.



Not all patients who abuse opioids need medication to treat their addiction. Many addicted persons do very well with counseling, or residential therapeutic treatment, or in NA groups. But in some cases these approaches alone are not enough to keep the person stable, and maintenance medication is used. Maintenance medication is slower and longer acting in its effects on the brain than heroin or other drugs of abuse. This allows for a steadyng of brain function which is part of treatment. So the best way to use buprenorphine in maintenance treatment is to find the correct dose, where the patient feels normal, and keep that dose steady for a long time. This means taking the medication on a regular schedule as prescribed, in the same way as taking a blood pressure medication, or diabetes treatment.

Besides buprenorphine, methadone is also used as a maintenance medication to treat opioid addiction. This medication is also long acting and works by stabilizing the brain. This medication is given in specially licensed clinics called Opioid Treatment Programs, and its use is carefully regulated by federal and state agencies.

Buprenorphine also is bound by some regulations. For this reason, patients on buprenorphine will be asked to give urines for drug screens, and bring their bottles in for pill counts.



Buprenorphine is best started when the patient is suffering withdrawal, and the dose is adjusted over several days. It is given as a pill which dissolves under the tongue. The take-home buprenorphine pills also have a small amount of naloxone (Narcan) in them, which is an opioid antagonist. The purpose of the naloxone is to discourage illicit injection of the pill. The patient would not feel the effects of naloxone by mouth, but if it were dissolved and injected, it might cause severe withdrawal

*This section of the patient information handout has its own slide, because these are features of buprenorphine that affect patient flow, and the process of timing the first dose during intake.

Other protocol considerations

- ▶ For your operations manual to be complete, there are decisions about the medication and about patient flow that are unique to buprenorphine, and that are different from methadone.
- ▶ The induction process is a safety concern in methadone treatment because of the danger of over-medication as tissue stores build. The induction safety concern with buprenorphine is precipitated withdrawal. As the previous slide explains to the patient, they have to be in significant withdrawal before even a small dose, or they might get really 'sick'.
- ▶ You may want to have your intake staff or medical assistant learn to use a withdrawal scale, to help with timing of the first dose. The most common of these is the Clinical Opioid Withdrawal Scale, or COWS.

Clinical Opiate Withdrawal Scale (COWS)

Flow-sheet for measuring symptoms over a period of time during buprenorphine induction.

For each item, write in the number that best describes the patient's signs or symptom. 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 increase pulse rate would not add to the score.

Patient's Name: _____	Date: _____
Buprenorphine induction: Enter scores at time zero, 30min after first dose, 2 h after first dose, etc. Times: _____	
Resting Pulse Rate: (record beats per minute) 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 Sweating: over past ½ hour not accounted for by room temperature or patient activity. 0 no report of chills or flushing 1 subjective 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	

These are only the first two items on the scale, for the slide

About the regs

- The state monitors buprenorphine according to the federal regulations, 42CFR part 8. Exceptions may be granted to the time in treatment requirements for take-homes, because buprenorphine is considered to have a better 'safety profile' than methadone.
- The state is finalizing a new regs package for NTPs.

Register now for the second webinar on buprenorphine in OTP's

Implementing Buprenorphine in Opioid Treatment Programs: Clinical Issues

- Wednesday, October, 3 at 11:30 am
- Presenter: Judith Martin, MD
- Register at <https://cc.readytalk.com/r/n53cjgp29m5&eom>

This link will be mailed to you after the webinar.

Thank you!

- ▶ Comments, advice for colleagues, other questions?
- ▶ Note: the form examples are only partially copied in the slides, are attached as word documents in your email.