Medication Assisted Treatment in Residential Treatment Facilities

CONTENTS:

State of California—Health and Human Services Agency
Department of Health Care Services

JENNIFER KENT
DIRECTOR

GAVIN NEWSOM
GOVERNOR

January 22, 2019

Hello,

The California Department of Health Care Services (DHCS) is excited to announce the release of a toolkit aimed at informing and engaging licensed residential treatment facilities about medication assisted treatment (MAT). MAT is an evidence-based treatment for clients with opioid use disorder and alcohol use disorder. As of January 2019, clients in licensed residential treatment facilities are required to have access to MAT.

This toolkit contains information about the benefits of MAT, the process and requirements for providing access to MAT in licensed residential treatment facilities, and information on how practitioners can apply for a Drug Addiction Treatment Act (DATA) 2000 waiver to prescribe buprenorphine.

In this toolkit, you will find the following documents:

- Part 1: Basic Overview of MAT
- Part 2: MAT in Residential Treatment Facilities
- Part 3: Obtaining a DATA 2000 Waiver
- Appendix: Sample Incidental Medical Services (IMS) Submission Documents

The appendix is a compilation of DHCS approved sample documents related to the IMS approval process. Facilities that choose to provide IMS are not required to use the sample documents included in this folder, but we hope they will be helpful to you and your organization should you choose to apply to provide IMS for your clients.

This toolkit was made possible through support from our partners at the California Health Care Foundation and Harbage Consulting.

An electronic copy of the toolkit is accessible here: bit.ly/DHCSMATResources

Thank you.

Sincerely,

Marlies Perez
Division Chief, Substance Use Disorder Compliance Division
Department of Health Care Services

What is Medication Assisted Treatment (MAT)?

Evidence-based treatment for patients in need

MAT is the use of United States Food and Drug Administration (FDA)-approved medications, in combination with counseling and behavioral therapies, to provide a "whole-patient" approach to the treatment of substance use disorders. MAT is an evidence-based treatment for clients with opioid use disorders (i.e. addiction to heroin, illicit fentanyl, or prescription pain medications) and clients with alcohol use disorders.

The addition of MAT has been shown to significantly reduce the rate of relapse, compared to abstinence-based treatment. For opioid use disorders (OUD), use of methadone or buprenorphine cuts overdose rates by half or more, and reduces rates of HIV and hepatitis C transmission.[1] While MAT is considered standard of care for clients with opioid use disorders and alcohol use disorders, there is no FDA-approved MAT for other substance use disorders available currently.

Clients should have access to MAT while living in a residential treatment facility. Residential treatment facilities are not allowed to deny admission to potential clients because they have a valid prescription from a licensed health care professional for an FDA-approved medication for MAT.[2]

In addition, residential treatment without medication for clients with OUD puts them at high risk of overdose after departure.

Residential treatment facilities can provide access to MAT for their clients in treatment, either within the facility (through incidental medical services) or in the community, through relationships with opioid treatment programs, community health centers, or other MAT access points.

WHAT IS MAT?

FDA-approved medication + Counseling and behavioral therapies = Whole patient approach to treatment

REDUCED RATE OF RELAPSE

MAT has been shown to reduce the rate of relapse, compared to abstinence-based treatment.

DHCS

This resource was created by Harbage Consulting with support from the California Health Care Foundation.

[1] National Institute on Drug Abuse, "Effective Treatments for Opioid Addiction," available at bit.ly/2o7VWxE.

[2] SB 992, 2018. Available at bit.ly/2pXyq9K.

What FDA-approved medications are commonly used in MAT?

MAT FOR OPIOID USE DISORDER

Buprenorphine and buprenorphine products: Medication that inhibits the action of other opioids, prevents cravings and withdrawal symptoms, and dramatically lowers the risk of overdose. Offered as a daily dissolving tablet or film placed under the tongue or inside the cheek, as a monthly injection, or as a 6-month implant under the skin. Buprenorphine can be prescribed by a properly trained and waivered physician, nurse practitioner, or physician assistant in a primary care office or other setting, as well as in an opioid treatment program. Long-term maintenance (at least two years) cuts overdose rates in half; short-term treatment without continued MAT increases overdose rates and is not considered standard of care.

Methadone: Medication that prevents cravings and withdrawal symptoms and reduces the risk of overdose so long as it is administered in a controlled environment (such as an opioid treatment program). Methadone increases overdose risk if used illicitly or when prescribed for pain management, and it does not inhibit the effect of other narcotics. Offered as a daily liquid dispensed only in highly regulated specialty opioid treatment programs, also known as narcotic treatment programs.

Naltrexone: Medication that blocks the effects of opioids while reducing cravings. Offered as a daily pill or monthly injection. Naltrexone has been shown to reduce the risk of overdose in short-term trials; longer term trials do not yet show an impact on mortality. Naltrexone is not a controlled substance and can be prescribed or administered in any health care or SUD setting.

MAT FOR ALCOHOL USE DISORDER

Naltrexone: Medication that blocks the euphoric effects and feelings of intoxication and reduces cravings. Naltrexone is proven to reduce drinking days and amount of drinking per episode. Offered as a daily pill or monthly injection.

Acamprosate: Medication to reduce cravings for clients who have already stopped drinking. It does not help with withdrawal symptoms but does reduce cravings. Clients can continue taking this medication during relapse. Offered as a tablet taken three times a day.

Disulfiram: Medication that acts as a deterrent to drinking since combining it with alcohol causes physical illness. Clients can't drink while taking this medication, but it can be combined with other forms of treatment. Offered as daily pill.

NOTE: The medications listed here are not inclusive of all the FDA-approved medications used in MAT.

NALOXONE FOR OPIOID OVERDOSE

Naloxone is a life-saving medication that reverses an opioid overdose. Naloxone is safe for lay people to use, as it is harmless if misused, and has no effect on an individual if opioids are not present in their system. Naloxone blocks opioid receptor sites, reversing the toxic effects of the overdose, restarting breathing and waking people up from unconsciousness.

Naloxone can be given by intranasal spray or injection (in the muscle, under the skin, or in a vein) and should be given when someone appears to have overdosed (unconscious, with slowed breathing, or if breathing has stopped). Residential treatment facilities should keep naloxone onsite in the case of emergencies.

For more information on naloxone, see Mental Health and Substance Use Disorders Services Information Notice 17-048, bit.ly/2AAQcoD.

80% of people with OUD who receive treatment in a residential facility without MAT relapse within 2 years.

How does MAT help the client?

MAT stabilizes brain chemistry — taking clients out of the cycle of cravings and withdrawal, which can last for years after the last drug use. This allows clients to engage in treatment and benefit from behavioral health interventions, like counseling.

Along with helping to stabilize clients in their recovery process, long-term medication maintenance is important to prevent relapse. Some clients may continue with MAT for the rest of their lives. Others can be tapered off MAT under the supervision of a medical professional after 1-2 years. It all depends on the individual needs of each client and how severe and long-lasting the addiction has been.

The rate of relapse for a client with OUD who receives treatment in a residential treatment facility without MAT is 80% within two years – this means only 1 out of 5 patients can transition to recovery without using medications (and they are at high risk of death from overdose if they relapse).[3] Buprenorphine and methadone cut overdose death rates in half or more, lowering opioid use, decreasing HIV and hepatitis C risk, and reducing arrest and incarceration.[4] Detox alone usually does not work for OUD: the longer clients stay in treatment, the greater their chance of long-term survival.[5]

BENEFITS of MAT

- Reduce or eliminate withdrawal symptoms
- Reduce or eliminate cravings
- Block the euphoric effects of opioids & alcohol
- Normalize brain chemistry that drives motivation & bonding with others

VIDEO

See this video to understand how MAT works on the brain, and why OUD treatment works better with medications.

YouTube

bit.ly/2zL87s0

[3] Bart, Gavin. "Maintenance Medication for Opiate Addiction: The Foundation of Recovery," Journal of Addictive Diseases 31.3 (2012): 207–225. Available at bit.ly/2LFUFLK.

[4] American Society of Addiction Medicine, "Medication-Assisted Treatment with Buprenorphine: Assessing the Evidence." Available at bit.ly/2Vp5eaH.

[5] Mathers, Bradley M et al. "Mortality among People Who Inject Drugs: A Systematic Review and Meta-Analysis." Bulletin of the World Health Organization 91.2 (2013): 102–123. Available at bit.ly/2s0NQLG;

Corsi, Karen et al., "Opiate substitute treatment is associated with increased overall survival among injecting drug users." Evidence-Based Mental Health 13 (2010): 111. Available at bit.ly/2Qft5Wa;

Cornish, Rosie et al. "Risk of death during and after opiate substitution treatment in primary care: prospective observational study in UK General Practice Research Database." British Medical Journal 341 (2010): 5475. Available at bit.ly/2BSb7Eg;

Kimber, Jo et al. "Survival and cessation in injecting drug users: prospective observational study of outcomes and effect of opiate substitution treatment." British Medical Journal 341 (2010): 3172. Available at bit.ly/2Ar8tFt.

What is the length of treatment?

While every client is different, research shows that clients on MAT for more than 1-2 years have the best rates of long-term success. However, length of treatment can vary depending on the client, and some clients may be on MAT for the rest of their lives. There is no right or wrong length of time – it all depends on the needs and preferences of the client.

Research shows that the best results occur when a client receives medication for as long as it provides a benefit, known as "maintenance treatment." Ongoing maintenance treatment minimizes cravings and reduces the risk of relapse, allowing clients to focus on other aspects of their life, like finding a job or taking care of family. Ongoing maintenance treatment for opioid or alcohol use disorders is no different than taking medicine to control high blood pressure, high cholesterol, or diabetes.

Who pays for MAT?

MAT is covered by public (Medi-Cal/Medicare) and private insurance. It can also be paid for out-of-pocket.

For Medi-Cal clients, MAT can be covered in two ways: through an SUD treatment provider in the Drug Medi-Cal program or through the Medi-Cal managed care plan (for the prescriber) and the Medi-Cal Fee for Service Program (for the prescription obtained at a pharmacy).

It is always important to have a conversation with the client to help them explore treatment options that are sustainable and affordable.

What are the rights of clients in a residential treatment facility related to MAT access?

Clients should have access to MAT while living in a licensed residential treatment facility.

Residential treatment facilities are not allowed to deny admission to potential clients simply because they have a valid prescription from a licensed health care professional for an FDA-approved medication for MAT and are not allowed to discharge someone from treatment for seeking or obtaining FDA-approved medications from a medical provider.[6]

Additionally, there are federal laws that prohibit discrimination against clients receiving MAT. Clients in recovery from addiction, including those in MAT, are protected from discrimination in employment, housing, public accommodations, and access to government services by the following laws:

- Americans with Disabilities Act (ADA)
- Fair Housing Act (FHA)
- Workforce Investment Act (WIA)

[6] SB 992, 2018. Available at bit.ly/2pXyq9K.

Where can clients be referred to for MAT if it is not offered in my facility?

Clients must be allowed access to medications prescribed for MAT, even if the facility is not directly providing MAT onsite.

Clients may be referred to practitioners authorized to provide MAT. For a list of practitioners authorized to treat opioid dependency with buprenorphine by zip code, see bit.ly/2BfWXPR. For a list of methadone clinics, see bit.ly/2DcFpU6.

MAT may be offered in a variety of settings, including:

1 **Licensed Narcotic Treatment Programs (NTPs):** NTPs provide MAT, as well as medication management, counseling and recovery services. NTPs are the only settings licensed to offer methadone to treat OUD. Many also offer other medications.

2 **Outpatient SUD Treatment Programs:** Outpatient treatment programs operated by the county or private organizations offer counseling and recovery services and may offer MAT.

3 **Primary Care Settings:** MAT can be provided in doctor's offices, community clinics, federally qualified health centers, and other primary care settings. Buprenorphine can be prescribed or administered by a qualified practitioner who completes additional training and receives a DATA 2000 waiver. Naltrexone can be prescribed without a waiver.

4 **Emergency Departments and Hospitals:** Any provider in a hospital or emergency department may administer buprenorphine (give to the patient to take under observation) for up to three days in order to relieve acute withdrawal symptoms and facilitate patient referral to treatment. Providers with the DATA 2000 waiver can prescribe buprenorphine to patients in the hospital or emergency department by phone or through a prescription to be filled at a pharmacy.[7]

5 **Licensed Residential Treatment Facilities:** Licensed residential treatment facilities may offer MAT using incidental medical services (IMS). For more information, see Part 2.

DATA 2000 WAIVERS

Clinicians must take a standardized course (8 hours for physicians, 24 hours for nurse practitioners and physician assistants) and apply for a federal "waiver" to prescribe buprenorphine for addiction. For more information about DATA 2000 waivers, see Part 3.

How does MAT relate to the client's overall care?

If a client in your facility is on MAT, it is critical that his or her medical provider monitors other medications that the client is taking. For example, certain medications used in MAT can be risky when combined with anxiety medications, including benzodiazepines (e.g., Xanax, Valium).

Care coordination with outside providers that may be prescribing additional medications is therefore crucial to ensuring client safety. For residential facilities that choose not to prescribe and administer MAT onsite, a referral network to appropriate health care providers should be established to ensure that clients have access to all forms of FDA-approved treatments.

[7] Herring, Andrew A. "Emergency Department Medication-Assisted Treatment of Opioid Addiction," California Health Care Foundation, August 2016, bit.ly/2VkBsDL.

What are some of the common misconceptions about MAT?

Despite research showing the effectiveness of MAT for patients with opioid and alcohol use disorders, stigma against clients using MAT remains prevalent. Some of the common misconceptions include the belief that MAT merely substitutes one drug for another, and that abstinence is a "better" approach (see "Challenging the Myths about MAT" from National Council for Behavioral Health for research refuting common misconceptions).[8]

Abstinence approaches are two to three times as likely to result in an overdose death, and this is why it is so important for all drug treatment providers to embrace MAT as standard of care for people with opioid use disorder.

Only 1 out of 5 of people with OUD can achieve two years of abstinence without medications, and those who relapse are at high risk of death.[9] Once someone has overdosed once, the chance of dying in the next year is one in ten.[10]

Furthermore, increased access to MAT can reduce a client's risk of contracting HIV and hepatitis C.[11]

MAT for those addicted to opioids and alcohol is no different than medication for other chronic conditions like diabetes or heart disease, where patients may rely on their medications either short term or throughout the course of their lifetime to help them lead healthy, productive lives.

Where can I find more information?

For more information, please reference the following resources:

- Part 2: MAT in Residential Facilities – To learn more about how MAT can be offered in a residential treatment facility setting.
- Part 3: Obtaining a DATA 2000 Waiver – If you are interested in obtaining a DATA 2000 waiver to prescribe buprenorphine.
- Treatment Improvement Protocol 63: Medications for Opioid Use Disorder: bit.ly/2s4Wys0.
- Treatment Improvement Protocol 49: Incorporating Alcohol Pharmacotherapies into Medical Practice: bit.ly/2EYtURi.

[8] National Council for Behavioral Health, "Challenging the Myths about MAT for Opioid Use Disorder," available at bit.ly/2O3ECIy.

[9] Bart, Gavin. "Maintenance Medication for Opiate Addiction: The Foundation of Recovery," Journal of Addictive Diseases 31.3 (2012): 207–225. Available at bit.ly/2LFUFLK.

[10] Mattick, Richard P. et al., "Methadone Maintenance Therapy Versus No Opioid Replacement Therapy for Opioid Dependence," Cochrane Database of Systematic Reviews 3 (2009). Available at bit.ly/2AnBT7B;

Comer, Sandra D. et al., "Injectable, Sustained-Release Naltrexone for the Treatment of Opioid Dependence: A Randomized, Placebo-Controlled Trial," Archives of General Psychiatry 63, no. 2 (2006): 210–218. Available at bit.ly/2AoSuaV;

Fudala, Paul J. et al., "Office-Based Treatment of Opiate Addiction With a Sublingual-Tablet Formulation of Buprenorphine and Naloxone," New England Journal of Medicine 349, no. 10 (2003): 949–58, available at bit.ly/2s0ORU0.

[11] Schwartz, Robert P. et al., "Opioid Agonist Treatments and Heroin Overdose Deaths in Baltimore, Maryland, 1995-2009," American Journal of Public Health 103, no. 5 (2013): 917-22, available at bit.ly/2sZ4yyo.

What are the benefits of offering MAT at residential treatment facilities?

Research shows a wide variety of benefits from Medication Assisted Treatment (MAT), including but not limited to: decreased opioid use, decreased opioid-related overdose deaths, decreased criminal activity, decreased infectious disease transmission, and increased social functioning and retention in treatment.[1]

Many of the clients currently being served through residential treatment facilities are in treatment for opioid or alcohol use disorders, and would greatly benefit from MAT on their path to recovery. MAT can complement the counseling and support services that clients receive in residential treatment facilities.

Residential treatment facilities may be the only place where clients have access to this treatment. While residential treatment facilities in California do not have to prescribe or administer MAT directly, doing so may greatly assist their clients in reaching recovery.

It is never too early or too late to talk to your clients about MAT and the available treatment options to help them on their path to recovery. MAT should be started as early as possible to prevent relapse and overdose during the initial withdrawal process.

HOW TO TALK TO CLIENTS ABOUT MAT

ASK. Ask clients if they have ever considered using medication to stop their cravings for opioids or alcohol. Ask about their feelings towards using medications to assist in recovery. Counteract myths with facts to combat stigma, when necessary.

INFORM. Describe MAT options that may be available to the client and inform them about the benefits of MAT. As always, look for opportunities to combat stigma.

ENCOURAGE. Recommend that they consult with a medical provider to learn more. Provide referrals and linkages to external providers if MAT is not available onsite. Provide training and support to staff so they provide consistent messages, and do not undermine MAT access through stigmatizing messages.

This resource was created by Harbage Consulting with support from the California Health Care Foundation.

[1] National Institute on Drug Abuse, "Effective Treatments for Opioid Addiction," available at bit.ly/2o7VWxE.

Can MAT be provided within residential treatment facilities?

Yes. If a residential treatment facility wants to offer MAT services onsite, this can be done upon approval from the Department of Health Care Services (DHCS) to provide incidental medical services (IMS). The process for receiving DHCS approval to provide IMS is available in Mental Health and Substance Use Disorders Services (MHSUDS) Information Notice 18-031 (bit.ly/2PuHan8) and is also discussed in this document.

However, residential treatment facilities do not need to be IMS-approved in order to allow patients to access their medications for MAT. Residential treatment facilities are not allowed to deny admission to potential clients, or to discharge current clients, because they have a valid prescription for an FDA-approved medication for MAT. Residential facilities that choose not to be IMS-approved, a referral network to appropriate health care providers should be established to ensure that clients have access to MAT.

Residential treatment facilities should also have policies in place to ensure that clients have access to the medications they have been prescribed for any condition.

MAT ACCESS

Residential treatment facilities do not need to be IMS-approved in order to allow patients to access their medications for MAT.

What are Incidental Medical Services?

IMS are services provided at a licensed residential facility by a health care practitioner, or staff under the supervision of a health care practitioner, that address medical issues associated with detoxification, treatment, or recovery services.

See MHSUDS Information Notice 18-031 (bit.ly/2PuHan8) for more details on protocols for the provision of each of these services.

THE SERVICES THAT MUST BE PROVIDED

- Obtaining medical histories
- Monitoring health status
- Testing associated with detoxification from alcohol or drugs
- Providing alcohol or drug abuse recovery or treatment services
- Overseeing patient self-administered medications
- Treating substance use disorders, including detoxification and medication maintenance

What do residential treatment facilities need to do to provide IMS?

To provide IMS, residential treatment facilities must apply to DHCS for approval. New facilities must complete the Initial Treatment Provider Application (DHCS 6002, bit.ly/2RUCSCf); existing facilities must complete a Supplemental Application (DHCS 5255, bit.ly/2qNGUky).

Both new and existing facilities must submit all required documentation and fees, in addition to their application.

DHCS APPROVAL REQUIRED

Both new and existing facilities must submit all required documentation and fees, in addition to their application.

REQUIRED DOCUMENTATION

- **Fee** (MHSUD Information Notice No: 14-022, bit.ly/2FlCJGB).
- **Fire clearance form STD 850.**
- **Floor plan.**
- **Facility Staffing Data** (DHCS 5050, bit.ly/2DDyu7L), including all facility staff who provide or oversee IMS.
- **Job descriptions** for each staff position at the facility.
- **Health Care Practitioner** (HCP) **Incidental Medical Services Acknowledgement** (DHCS 5256, bit.ly/2siCX8j) for HCP's who provide or oversee IMS.
- Copy of all HCP's **valid licenses to practice in California** and **proof of addiction medicine training**.
- **Organizational chart,** includes all facility staff.
- **Services and Activities** — written description, including IMS.
- **Program description**, including IMS.
- **Admission, Readmission, and Intake Criteria**, including IMS.
- **Admission Agreement**, including IMS.
- **Detoxification Services** (if applicable) – Policies and procedures, including IMS.
- **Medication Policy** – Policy, procedures, and tasks for all forms of prescribed and over-the-counter medications (including MAT).
- **Incidental Medical Services** — Policies, procedures, and tasks for IMS.

NOTE: Reference the appendix for sample IMS submission documents.

What are the requirements for licensed residential facilities that provide IMS?

1 Facilities should have a health care practitioner who can provide services onsite. The practitioner must be licensed in California and have training in addiction medicine. For more information on provider training for buprenorphine, see Part 3.

2 Facilities must have a room where IMS can be provided. The IMS room does not need to have a sink but facilities must verify that the room where IMS will be provided meets minimum requirements — those requirements are:

- The room must be enclosed with permanent walls;
- It must contain a cabinet for the storage of medical equipment;
- It must have a locked cabinet for medications; and
- It must have a separate locked cabinet for narcotics.

3 Facilities must have policies and procedures in place for the provision of IMS. Detailed information about policy and procedure requirements for each IMS service is available in MHSUDS Information Notice 18-031 (bit.ly/2PuHan8).

How can I provide access to MAT without becoming approved for IMS?

Residential treatment facilities do not need to be IMS-approved in order to allow clients to access their medications for MAT. To ensure clients have access to MAT, residential treatment facilities should:

- **Create a Client-Focused Referral Network.** Create relationships with prescribing partners in your area for the populations you serve, which may include:
  - Clients with public insurance, who may be eligible for Medi-Cal, Drug Medi-Cal, and other social services and supports
  - Clients with private insurance, who may be eligible for services through their insurance network
  - Self-pay or uninsured clients, who may be eligible for programs and services supported by grants and other funding
- **Establish Policies and Procedures for Client MAT Medications.** These policies and procedures must allow clients to access their MAT medications while in the residential treatment facility. Policies and procedures may relate to:
  - MAT medication storage, such as the need for locked cabinets or where MAT medications may be stored
  - Processes for overseeing and documenting self-administration of MAT medications
  - Processes for disposing of unused or expired MAT medications
  - Staff training and qualifications related to overseeing MAT medication administration

Examples of such policies can be found in the IMS appendix.

Where can I find more information?

For more information, please reference the following resources:

- The appendix, which contains sample IMS submission documents.
- Part 1: Basic Overview of MAT – To learn more about MAT and the positive impact it can have on clients.
- Part 3: Obtaining a DATA 2000 Waiver – If you are interested in obtaining a DATA 2000 waiver to prescribe buprenorphine.
- DHCS website – Access a variety of resources pertaining to licensing and certification on the DHCS website, bit.ly/2MNgny8.

What is the benefit of obtaining a DATA 2000 Waiver?

A Drug Addiction Treatment Act (DATA) 2000 Waiver allows practitioners to prescribe buprenorphine. Buprenorphine is a type of medication used in MAT to help people recover from opioid use disorders. Unlike methadone, which can only be administered in an opioid treatment program such as a Narcotic Treatment Program (NTP) or Medication Unit (MU), buprenorphine can be prescribed and dispensed to clients by qualified practitioners in other health care settings. Prescribers include physicians, nurse practitioners, and physician assistants that have received a DATA 2000 Waiver.

With the passage of the SUPPORT for Patients and Communities Act in 2018, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives are also qualified practitioners.[1]

The Drug Addiction Treatment Act of 2000 allows these practitioners to prescribe buprenorphine and other Schedule III, IV, and V narcotic medications outside of opioid treatment program settings, including medical offices, emergency rooms, hospitals, and other settings.

DATA 2000 WAIVER

Allows providers to prescribe buprenorphine outside of opioid treatment programs.

DHCS

This resource was created by Harbage Consulting with support from the California Health Care Foundation.

[1] SUPPORT for Patients and Communities Act, H.R.6, Sec. 3201, available at bit.ly/2QeY98A.

What steps must physicians take to obtain a DATA 2000 Waiver?[2, 3]

MEET THE CRITERIA TO QUALIFY

Physicians must be qualified to apply for the waiver. DATA 2000 defines a "qualifying physician" as one who is:

- Licensed under state law.
- Registered with the Drug Enforcement Administration (DEA) to dispense controlled substances.
- Required to treat no more than 30 patients at a time within the first year and may treat up to 100 or 275 at a time (if certain qualifications are met) after the first year.[4]
- Capable of referring patients to counseling services.
- Completes training and/or certification requirements.
- Additionally, physicians must either be board-certified in addiction medicine, or complete required 8-hour training for the treatment and management of patients with opioid use disorders. Many of these trainings are available free and online.

COMPLETE TRAINING AND CERTIFICATION REQUIREMENTS

Under the DATA 2000 requirements, physicians must complete an 8-hour training to qualify for a waiver to prescribe and dispense buprenorphine. The Substance Abuse and Mental Health Services Administration (SAMHSA) maintains a list of supported continuing medical education (CME) courses that can help physicians qualify to prescribe buprenorphine in an office setting. See the "Where Can I Find More Information" section on Page 5 for more details.

APPLY FOR THE WAIVER

Physicians can take the following steps to apply for a DATA 2000 Waiver:

- ☑ Ensure you meet and have documentation showing you are a qualifying physician.
- ☑ Complete the required 8-hour training to prescribe and dispense buprenorphine.
- ☑ Fill out the SAMHSA Buprenorphine Waiver Notification form: bit.ly/2oj0A0D.
- ☑ Send SAMHSA all supporting documentation, including an 8-hour training certificate, via email to infobuprenorphine@samhsa.hhs.gov or via fax to (301) 576-5237.

---

[2] Substance Abuse and Mental Health Services Administration, "Buprenorphine Waiver Management," available at bit.ly/2L2vulh.

[3] Substance Abuse and Mental Health Services Administration, "Qualify for a Physician Waiver," available at bit.ly/2nqA8xS.

[4] The first year cap of 30 patients may be increased up to 100 in the first year for physicians who are certified in addiction medicine or addiction psychiatry, or that work in an approved MAT facility. SUPPORT for Patients and Communities Act, H.R.6, Sec. 3201, available at bit.ly/2QeY98A.

CONTINUED: WHAT STEPS MUST PHYSICIANS TAKE TO OBTAIN A DATA 2000 WAIVER?

WAIT FOR APPROVAL

SAMHSA conducts an application review within 45 days of receipt. Once the application process is approved, SAMHSA will email a letter to the applicant that confirms their waiver and includes a prescribing identification number for the physician to use.

EXPEDITED APPLICATIONS

Physicians may also request to provide treatment while their waiver application ('notification') is under review. To do this:

- Check the box "New Notification, with the intent to immediately facilitate treatment of an individual (one) patient" on the SAMHSA Buprenorphine Waiver Notification form.
- Meet criteria for obtaining a waiver (i.e., valid medical license, valid DEA registration number, completed training requirements).
- Contact the SAMHSA Center for Substance Abuse Treatment (CSAT)'s Buprenorphine Information Center (866)-BUP-CSAT to verify that the notification has been received and inform CSAT of your intention to begin treatment for one patient.

WAIVER RESTRICTIONS FOR PHYSICIANS

Once a physician has been granted a waiver to prescribe buprenorphine, they may have a maximum of 30 patients in opioid dependence treatment at a time for the first year. This cap can be increased to 100 in the first year for physicians who are certified in addiction medicine or addiction psychiatry, or who work in an approved MAT facility.[5] One year after the initial notification is submitted, the physician may submit a second notification of the need and intent to treat up to 100 patients at a time. Physicians with board certification in addiction medicine, or those meeting certain requirements (24/7 call coverage, electronic health record use, access to case management services, prescription drug monitoring programs (PDMP) registration, and acceptance of third-party insurance payment) may apply to treat 275 patients at a time.[6]

---

[5] SUPPORT for Patients and Communities Act, H.R.6, Sec. 3201, available at bit.ly/2QeY98A.

[6] More information on requirements for providers treating up to 275 patients is available at bit.ly/2LL5yMw.

What steps must NPs & PAs take to obtain a DATA 2000 Waiver?[7]

COMPLETE TRAINING AND CERTIFICATION REQUIREMENTS

The Comprehensive Addiction and Recovery Act (CARA) requires that nurse practitioners (NPs) and physician assistants (PAs) complete at least 24 hours of initial training to be eligible for a prescribing waiver for up to 30 patients. The 24 hours of initial training must cover each of the following topics:[8]

- Opioid maintenance and detoxification
- Appropriate clinical use of all drugs approved by the FDA for the treatment of opioid use disorder
- Initial and periodic patient assessments (including substance use monitoring)
- Individualized treatment planning, overdose reversal, and relapse prevention
- Counseling and recovery support services
- Staffing roles and considerations
- Diversion control
- Other best practices, as identified by the U.S. Secretary of Health and Human Services

SAMHSA also requires that the 24 hours of initial training is provided by one of the following organizations:

- The American Society of Addiction Medicine
- American Academy of Addiction Psychiatry
- American Medical Association
- American Osteopathic Association
- American Nurses Credentialing Center
- American Psychiatric Association
- American Association of Nurse Practitioners
- American Academy of Physician Assistants
- Any other organization that the U.S. Secretary of Health and Human Services determines is appropriate.

In addition, NPs and PAs may take the following training courses:

- An 8-hour training to qualify for a waiver to prescribe and dispense buprenorphine. SAMHSA maintains a list of supported CME courses that can help providers qualify to prescribe buprenorphine in an office setting. See "Where Can I Find More Information" section on Page 5 for more details.

- An additional 16 hours of free training offered by SAMHSA through the Providers' Clinical Support System for Medication Assisted Treatment (PCSS-MAT). See the "Where Can I Find More Information" section on Page 5 for more details.

[7] Substance Abuse and Mental Health Services Administration, "Qualify for Nurse Practitioners (NPs) and Physician Assistants (PAs) Waiver," available at bit.ly/2JmTDmq.

[8] 21 USC 823(g)(2)(G)(ii)(IV).

CONTINUED: WHAT STEPS MUST NPs & PAs TAKE TO OBTAIN A DATA 2000 WAIVER?

APPLY FOR THE WAIVER

NPs and PAs can take these steps to apply for a DATA 2000 waiver for up to 30 patients at a time:

☑ Complete the 24-hour training to become an eligible prescriber.

☑ Fill out the SAMHSA Buprenorphine Waiver Notification form: bit.ly/2oj0A0D.

☑ Send SAMHSA all supporting documentation via email to infobuprenorphine@samhsa.hhs.gov or fax to (301) 576-5237.

WAIT FOR APPROVAL

SAMHSA conducts an application review within 45 days of receipt. Once the application process is approved, SAMHSA will email a letter to the applicant that confirms their waiver and includes a prescribing identification number for the NP or PA to use.

NP and PA waiver applications are forwarded to the Drug Enforcement Administration (DEA) and assigned a special identification number. DEA regulations require both this number and the NP or PA's regular DEA registration number to be included on all buprenorphine prescriptions for opioid dependency treatment.

NOTE: Expedited applications are not available for NPs and PAs.

Where can I find more information?

For more information, please reference the following resources:

- Part 1: Basic Overview of MAT – To learn more about MAT and the positive impact it can have on clients.
- Part 2: MAT in Residential Facilities – To learn more about how MAT can be offered in a residential treatment facility setting.
- Free Online DATA Waiver Training Course for Physicians: bit.ly/2QCwEdn

OTHER RESOURCES

Supported CME Course: bit.ly/2vBgVAq.

NP and PA MAT Waiver Training: bit.ly/2PTxORy.

SAMHSA MAT of OUD Pocket Guide: bit.ly/2DluisI.

SAMHSA MAT App: bit.ly/2D2IxQW.

California Health Care Foundation Opioid Safety Network: bit.ly/2qTVt6l.

Clinical Guidelines & Research:

- Clinical Use of Extended-Release Injectable Naltrexone in the Treatment of Opioid Use Disorder: A Brief Guide: bit.ly/2K5tQjk.
- General Principles for the Use of Pharmacological Agents to Treat Individuals with Co-Occurring Mental and Substance Use Disorders: bit.ly/2rcWTZB.
- Sublingual and Transmucosal Buprenorphine for Opioid Use Disorder: Review and Update: bit.ly/2RqTfGW.
- The ASAM Standards of Care for the Addiction Specialist Physician: bit.ly/2DjmmrD.

Appendix: Sample Documents for IMS Approval

This appendix provides examples of the types of policies and procedures that residential treatment facilities may submit for approval to provide Incidental Medical Services (IMS). They are not intended to supplant approved policies and procedures at licensed residential treatment facilities approved for IMS.

Program Description: Detoxification Services

[Program] provides a secure environment tailored to the client's individual needs. [Program] promotes a healthy, safe, and structured environment that focuses on helping the client recover and live a lifetime of sobriety. [Program] is dedicated to helping clients get the most out of their experience as they develop new skills for sobriety and healthy living that will last a lifetime.

[Program] is designed to serve adults over the age of 18 with alcohol and drug related problems. The detoxification program is built as a medically managed residential detoxification treatment model with significant social model features. The program does not provide medically monitored inpatient detoxification services but does provide incidental medical services (IMS). The IMS program includes the following categories, as defined by DHCS MHSUDS Information Notice 18-031:

1. Obtaining medical histories.
2. Monitoring health status to determine whether the health status warrants transfer of the client in order to receive urgent or emergent care.
3. Testing associated with detoxification from alcohol or drugs.
4. Providing alcoholism or drug abuse recovery or treatment services.
5. Over-seeing client self-administered medications.
6. Treating substance use disorders, including detoxification.

The detoxification program includes IMS, individual counseling, group sessions, and participation in educational sessions, based on the capability of the client to participate.

An assessment will be done by the approved IMS physician to determine the level of detoxification needed. The program will not admit clients whose withdrawal signs and symptoms are sufficiently severe to require medical and nursing care services. An alcohol and drug free environment is maintained at all times.

Admission, Readmission and Intake Criteria

Statement of Non-Discrimination of the Admission Process

[Program] will not discriminate in the provision of benefits or services and/or deny admission into the program on the basis of race, color, national origin, ethnic group identification, religion, age, sex, or disability, pursuant to Title VI of the Civil Rights Act of 1964 (Section 2000d, Title 42, United States Code); the Rehabilitation Act of 1973 (Section 794, Title 29, United States Code); the American Disability Act of 1990 (Section 12132, Title 42, United States Code); Section 11135 of the California Government Code; and Chapter 6 (commencing with Section 10800), Division 4, Title 9 of the California Code of Regulations.

Admission Criteria

Admission is open to individuals 18 years or older in need of residential or detoxification IMS for alcohol and/or drug related problems and not in need of medical treatment for a life-threatening illness or condition. The request for admission must be voluntary and made by the individual seeking services.

The admission process will include the Department of Health Care Services (DHCS) Client Health Care Questionnaire and Initial Screening Questions (DHCS 5103) form to be completed by a Health Care Practitioner (HCP), or staff under the supervision of an HCP, including a registered or certified counselor. The screening and assessment of the client must be performed within twenty-four (24) hours of admission. The DHCS 5103 form must be reviewed, in person, face-to-face, signed and dated by the client and program staff. The physician will review the screening, document social, psychological, physical, and/or behavioral problems related to alcohol and/or other drugs within twenty-four (24) hours of admission, and ultimately decides if the client is a good candidate for [Program]'s IMS services. If IMS is needed, the physician will complete, sign and date the IMS Certification Form (DHCS 4026).

[Program] doesn't discriminate in the provision of services. [Program] will not exclude those with hepatitis, HIV or AIDS. If an individual is in need of a higher level of care such as an inpatient detox, hospital, or any other services that [Program] is unable to provide, the individual will be referred for services elsewhere.

Clients referred by the courts are also accepted, and full disclosure is made to authorities, probation officers, social workers, and police if specific violation of court order or law is involved. Clients referred by the court are asked to sign consent forms granting permission of staff to make these disclosures when referral is made.

Readmission Criteria

The physician will ultimately decide if a client is appropriate for readmission to receive IMS services. The client must meet all admission criteria based on their individual needs, and whether or not readmission would be beneficial to the client in terms of an

overall treatment and recovery plan. An individual readmission interview with the client is scheduled with the physician to discuss readmission to receive IMS. An attempt is made to determine the appropriateness of readmission to the program. The client is provided an opportunity to discuss any problems that may have occurred during the last treatment episode.

If the client was discharged for threats of violence, a treatment team decision will make the determination if the client will be accepted back into the program. This will be done on a case-by-case basis, based on the severity of the situation: (1) If the client expresses willingness to comply with the rules of the program; and (2) The staff has determined that client may re-enter the program if there is no current threat to the safety of the program clients and staff. The client will then be placed on a behavioral contract.

If the client was discharged for physical acts of violence on another person or due to destruction of the facility property, the client will be ineligible for re-admission. The client will be given referrals to different treatment facilities.

If the decision is for readmission to receiving IMS services, the client shall be subject to the screening and intake procedures including drug and alcohol testing, and completion of a new admissions agreement by both client and admissions counselors.

Intake Criteria

Residential IMS services are open to individuals 18 years or older in need of treatment, who have not used alcohol and drugs for 24 hours. Detoxification and IMS services are open to persons requiring detox but not in need of a medical facility; this will be determined during the assessment process with the physician. Admission must be voluntary and made by the individual seeking services.

If the client is appropriate for treatment, the following information will be gathered:

- Social, economic, and family history.
- Education
- Criminal history, current and past legal status
- Medical history via the DHCS Client Health Care Questionnaire and Initial Screening Questions (DHCS 5103) form
- Alcohol and/or other drug history
- Previous treatment, including psychiatric care

The client attends orientation within 72 hours of admission, which describes functions and requirements of the program. [Program] has an inventory of community services that are available, and the client will be made aware of this inventory. This inventory includes but is not limited to hospitals, police, crisis centers, emergency facilities, county health, mental health, paramedics, doctors, detox facilities, inpatient programs, outpatient programs, and sober living facilities.

Admission Agreement

1. Program

1.1. Program Admission. Client will be voluntarily admitted into the addiction treatment and rehabilitation program ([Program]), subject to the obligations and representations of Client set forth in this agreement.

1.2. Program Services. Client consents to the following services, including, but not limited to, receiving assessment, evaluation, treatment plans, diet planning, diagnosis, detoxification (including IMS), counseling, lectures on substance abuse, family group therapy, vocational counseling, relapse prevention planning, topic discussions, group therapy, group outings and field trips, occasional drug testing and discharge planning in the program.

IMS includes the following services as defined by MHSUDS Information Notice No.: 18-031:

- Obtaining medical histories.
- Monitoring health status to determine whether the health status warrants transfer of the client in order to receive urgent or emergent care.
- Testing associated with detoxification from alcohol or drugs.
- Providing alcoholism or drug abuse recovery or treatment services.
- Over-seeing client self-administered medications.
- Treating substance use disorders, including detoxification.

2. Payment Provisions

2.1. Amount Assessed. Payment for these services will be charged to Client's insurance or paid in cash, in the amount of $___ per day for the detoxification IMS, and $___ per day for residential treatment services. Client understands that certain expenses, including, but not limited to, housing and transportation expenses, may not be covered by Client's insurance. [Program] will perform a verification check of Client's enrollment in health insurance and health insurance benefits; however, [Program] does not guarantee benefits and/or payment by Client's insurer for any of the services provided to Client.

2.2. Payment Schedule. [Program] will mail invoices for payment of all services and/or for reimbursement to an address provided by Client, at its discretion or when requested by client. Payment of an invoice is due within thirty (30) days of the receipt of the invoice.

2.3. Refund policy. [Program] is not obligated under any circumstance to issue a refund for any payments made by Client for services already rendered, but [Program] may issue a refund, in [Program]'s sole discretion.

3. **Conditions for Eviction.** Client understands and agrees that if Client does not adhere to the [Program] rules and regulations, an incident report may be documented by [Program]. An incident report may be documented by [Program] where:
   (a) Client fails to adhere to any of the [Program] rules
   (b) Client either verbally or physically disrespects [Program] employees or other clients or
   (c) Client refuses to attend daily meetings or treatment activities.

   Client understands and agrees that the situations described in (a) through (c) are not intended to be, nor are they, a comprehensive identification of all situations where [Program] may document an incident report. Client understands and agrees that there may be situations which are not expressly identified in this agreement that may result in [Program] documenting an incident report regarding Client.

   If more than 3 incident reports occur, staff will decide on a case-by-case basis what consequence is appropriate given the circumstances, including, but not limited to, suspension or termination from [Program].

4. **Client Relapse.** Client possession and/or use of alcohol or any unauthorized mind-altering substances may be grounds for termination from [Program]. Client relapses shall be reviewed on a case-by-case basis by the physician, referred to detoxification services if actively under the influence, and evaluated for medical appropriateness for continued treatment services.

5. **Termination.**

5.1. Termination by Client. Client may terminate his or her involvement in [Program] at any time, but understands that no guarantee of refund, partial or in full, shall be made to Client.

5.2. Termination by [Program]. [Program] reserves the right to immediately terminate this agreement without advance notice at any time upon its determination that: (a) Client has breached this agreement, (b) Client has engaged in illegal, uncontrollable, or dangerous conduct while in [Program], (c) Client’s continued involvement in [Program] presents a danger to the health or safety of [Program] staff or employees, other clients, or client, or (d) Client has violated or intends to violate any of [Program]'s rules, or any applicable laws, rules, or regulations.

If [Program] terminates this agreement, and Client is discharged from [Program], Client agrees to leave peacefully and understands that he or she will not be refunded any payments made to [Program] and that client will be liable to make payment for all services rendered.

6. **Amendments**. Any amendments or modifications of this agreement must be in writing and must be signed and executed by both parties to be effective.

Client hereby certifies, represents and warrants that as of the signing of this agreement:

a) Client has read and understands the foregoing agreement; and
b) Client is not under the influence of any intoxicants, depressants, or other substances that would otherwise influence the sobriety of the client, and client is of conscience and sound mind as of the signing of this Agreement.

IN WITNESS WHEREOF, the Parties have executed this agreement as of the Effective Date.

CLIENT

Client's Printed Name: _____

Client's Signature: _____

Date: _____

[Program]

Program Representative's Printed Name: _____

Program Representative's Signature: _____

Date: _____

Detoxification Policies and Procedures

[Program] detoxification program is designed to serve adults over the age of 18 with alcohol and drug related problems. The detoxification program includes incidental medical services (IMS), individual counseling, group sessions, and participation in educational sessions based on the capability of the client to participate.

An assessment will be done by the physician to determine the level of detoxification needed. The program will not enroll clients whose withdrawal signs and symptoms are sufficiently severe to require medical and nursing care services that must be performed in a licensed clinic or health facility.

Staffing

1. For every 15 clients receiving detoxification services there shall always be at least one staff member with a current cardiopulmonary resuscitation certificate and current first aid training trained to provide detoxification services on duty and awake at all times.
2. Withdrawal management programs are overseen by a physician with training and experience in detoxification and withdrawal management. The physician provides leadership, training, and consultation to the treatment team. The physician also maintains ongoing relationships with the medical community, supervises the medical quality review process, and oversees treatment protocols.

Practices

1. Staff will perform a face to face observation of each client receiving detoxification services at least every 30 minutes during the first 72 hours following admission.
    a. Documentation of observations and physical checks shall be recorded on the Detoxification Log and signed by the program staff. Detoxification Logs shall include the exact time the physical check was performed, and a complete description of what was observed.
        i. At minimum, authorized staff shall conduct weekly reviews of all documentation logs, including the Detoxification Log, as part of ongoing quality assurance.
    b. Only staff that has been trained in the provisions of detoxification services may conduct and record observations and physical checks. Training shall include information on detoxification medications, signs and symptoms that require referral to a higher level of care or emergent care. Copies of training records shall be kept in personnel files.
2. Only staff members trained to provide detoxification services shall be assigned to the observation of detoxification clients at all times.
3. After 24 hours, close observations and physical checks may be discontinued or reduced based upon a determination by a physician. Documentation of the information that supports a decrease in close observation and physical checks shall be recorded in the client’s file.

Medication Policy and Procedure

Receipt of Medications

1. Prescribed, over-the-counter, and medications for medication assisted treatment (i.e. medications for treating alcohol or opioid use disorder) are all allowable medications.
2. Medications received from a pharmacy, company representative, or by mail shall be handled only by authorized staff at the time of delivery.
3. [Program] will secure and inventory all medications entering its facilities on applicable medication logs. This includes: medications brought by the client upon admission, those brought to the client from outside the facility after admission, those picked up from home or the pharmacy by the client or staff, and controlled medications such as methadone take-home doses.
4. If a medication is brought in by a client, the following procedure is in place:
    a. The medication must be brought in the original bottle from the pharmacy and properly labeled. The health care practitioner (HCP), licensed, or certified staff must inspect the medication to ensure it is what it is labeled and is packaged appropriately.
    b. The physician must approve of the client's medication. If the physician does not approve of the medication the client has brought to the facility, the client will be informed of this and the medication will be ordered from the local pharmacy. All medications will be stored in the locked medication room and returned to the client at the time of discharge.
    c. If medications are brought in by the client, and discontinued by the physician, the prescribing HCP will be notified by staff via fax (if the client signs a release of information).
5. Under the designation and supervision of the prescribing physician and/or the supervisor, authorized staff shall be responsible for documenting medication in documentation binders, which shall be stored behind a locked area:
    a. Medication Self-Administration Log
    b. Medication Dispensing Log
    c. Disposal/Destroyed Medication Log
6. At minimum, authorized staff shall conduct weekly reviews of the medication storage areas and documentation logs (e.g. reconciliation of medications stored and medication logs) and work to reconcile any discrepancies.

Administration of Medications

To ensure safety and provide the highest quality of care to its clients, [Program] will ensure that the initiation of Medication Assisted Treatment (MAT) is implemented at the appropriate time and maintained during treatment, as determined by the physician. Examples of MAT medications include, but are not limited to, acamprosate, disulfiram, methadone, buprenorphine and naltrexone.

- All clients prescribed MAT will be seen face-to-face by the physician prior to the initiation of medications.
- Medications may include oral, injectable, and implantable subdermal formulations.
- All HCP, licensed, or certified staff will be trained on the use of the medications prior to working with clients.
- Stock or bulk prescription medications will not be stored at the licensed facility site.
- Surgical procedures will not be performed at the licensed facility site.
- All controlled medications will be kept in a separate locked bin or safe within a locked cabinet behind the locked door of the designated IMS room.

The [Program] physician will work with the client's primary care physician (if authorized by the client by signing a confidential release) to coordinate care for any complex conditions which may impact the client's success in treatment. For clients receiving methadone, the physician shall collaborate with a Narcotic Treatment Program (NTP) (if authorized by the client with a confidential release of information) to coordinate how the client will receive their medication. The physician will document coordination with the primary care physician or NTP in the client file within 24 hours.

The [Program] physician, working with the primary care physician (if any) will determine the level of MAT services required and an assessment will be conducted by the [Program] physician in the designated IMS room. The physician is allowed to administer an injectable or implantable subdermal MAT with the written consent of the client. An informed consent form must be completed prior to the administration of any injectable or subdermal (MAT) medications.

<u>Oral Medications</u>

Only qualified and trained staff have access to the medication storage area within the IMS room. All medications are stored in a locked cabinet in the designated IMS room. All Controlled medications are stored in a separate locked bin or safe in the designated IMS room and inventoried with each shift change to prevent diversion. Medications will also be routinely checked to ensure that they did not expire and are taken as prescribed.

Medications must be taken by clients within one hour of the time prescribed by the physician. The medication order consists of six parts, as follows:

1. The name of the client.
2. The date and time when the order is written.
3. The name of the medication to be self-administered and the reason.
4. The dosage.
5. The route and any special directives regarding its self-administration.
6. The time of self-administration and/or frequency.

Only one client at a time is allowed in the IMS medication room to take medication. For all medications dispensed, the client will be identified by checking the client's name and date of birth on the medication record and asking their name and date of birth prior to taking their medication. If a client does not come for their medications a staff member will remind the client of the need for their medications.

Staff will verify that the correct medication and the correct amount of medication were taken by the client. The staff and the client will sign the Medication Self-Administration Log to indicate that the client has taken the medication and also document in the client's chart within 24 hours. The medication log will include the following:

- Daily log that identifies all medications taken by the clients.
- List that describes all physicians' prescription orders written on a given day.
- All medications logged by staff on the form once they are prescribed by the physician.
- The dosage taken with staff initials and client's initials.
- Client refusal to take their medications (if applicable), and notification to physician.
- Staff monitoring of client self-administered medications.

Clients who are maintained on methadone will be supported in their methadone dosing either at their designated clinics or withtake-home doses. Take-home doses may be stored and transported using a lock box with keys, or a lock box with a combination lock. The box will be transported to the residential facility to be handled by authorized staff. The authorized staff will count the doses, document the count and secure the methadone in the lock box, within a locked cabinet.

Clients will take medication under the observation of trained staff. Training and competency for observation of client self-administration will be documented in the employee's personnel file. The staff and client will be educated regarding all aspects of the process required for the safe self-administration of medication. Clients will self-administer their medication as directed in the presence of and under the direct supervision of the qualified staff on duty. HCP's will document that a client has been educated and is appropriate to self-administer medications. The education will include, but not be limited to the following:

- Definition of a supervised self-administration medication system
- Staff's role in providing supervision and monitoring
- Safe storage of medication
- Side effects
- Monitoring the effectiveness of medication
- Issues to report to the HCP
- Situations requiring emergency intervention

Staff providing medications are trained by the HCP regarding medications and provide assistance in the self-administration of medications in the designated IMS room, only as follows:

1. Removing the container in which the client's medications are stored from the secured and locked medication storage area.
2. Handing the container in which the client's medications are stored, to the client whose identity is ascertained by facility staff, including a system to correctly identify the client and to ensure that the correct client receives the appropriate medication.
3. Observing the client self-administer their medication. Immediately report any unusual signs, reactions, symptoms, or actions on the part of the client that was observed to a medical care provider.
4. Retrieving the container in which the client's medications are stored and returning the container to a secure storage area.
5. The program staff who assists the client in the self-administration of the client's medication shall record and sign the Medication Self-Administration Log within the client’s medical record.
6. Prescription medications shall be stored in the original prescription container. Non-prescription medications shall be stored in the manufacturer's original container. All prescribed medications shall have a label that includes the client name, dosage, prescriber, name of pharmacy, medication name, strength, quantity, and expiration date. Sample medications given by the prescribing physician must have a prescription attached to them. No bulk prescription medications will be used or kept at the facility.
7. All medications for client's use shall be stored using appropriate temperatures as indicated by the manufacturers or prescription labeling. Medications required to be stored at room temperature shall be stored at a temperature between 59 degrees and 86 degrees Fahrenheit. Medications requiring refrigeration shall be stored in a secured and locked refrigerator between 36 degrees and 46 degrees Fahrenheit, or other required temperature range as specified on the prescription instructions and/or prescription materials.
8. Medications needing destruction will be stored in designated bins away from the rest of the client medications.
9. Any medication that requires refrigeration will be kept in a small refrigerator in the IMS room. The temperature of the refrigerator shall be checked daily and noted on the refrigerator log. No staff items can be stored in this refrigerator.
10. HCP or qualified staff will inspect the medication area daily. Any deficiencies will be reported to the physician immediately.

Injectable Medications

For injectable medications, the HCP will:

1. Perform hand hygiene by washing hands with soap and water and drying with single-use towels. After performing hand hygiene, well-fitting, non-sterile gloves will be placed on the hands.
2. Clean and inspect the injection site. Before injecting medication, HCP will inspect the skin to make sure there is no bruising, burns, swelling, hardness, or irritation in the area. HCP will alternate injection sites to prevent damage to an area with repeated injections. HCP will clean the skin with an alcohol swab and let the alcohol dry thoroughly before doing the injection.
3. Prepare the syringe with the medication. Before withdrawing medication from a vial and injecting, HCP will make sure it is the correct medication, at the correct dose, at the correct time, and in the right manner. A new needle and syringe will be used with every injection.
4. Draw air into the syringe and draw back the plunger to fill the syringe with air up to the dose that will be injected.
5. Insert air into the vial. This is done by removing the cap from the needle and pushing the needle through the rubber stopper at the top of the vial.
6. Withdraw the medication. This is done by turning the vial and syringe upside down so the needle points upward then pulling back on the plunger to withdraw the correct amount of medication.
7. Remove any air bubbles. HCP will tap the syringe to push any bubbles to the top and gently depress the plunger to push the air bubbles out.

Injectable medications will only be administered by the HCP, using the below procedures:

- HCP will perform hand hygiene by washing hands with soap and water and drying with single-use towels.
- After performing hand hygiene, well-fitting, non-sterile gloves will be placed on the hands.
- If the medication is stored in the refrigerator, it will be removed from the refrigerator about 30 minutes before injection so it can warm up to room temperature.
- Supplies will be placed on a clean, dry surface.
- The medication may be supplied in a pre-filled syringe that does not require mixing. If this is the case the HCP does not need to prime the syringe but will check for air bubbles and to see if the level of the medication is at the top of the needle.
- If the syringe is not pre-filled, HCP will prime the syringe to remove all the air from it, hold the syringe pointing upwards, and gently tap the sides to force any air bubbles to the top. HCP will push the plunger slowly until one or two

drops come out from the tip of the needle. This ensures that all air has been safely removed from the syringe.

- If the medication preparation requires mixing diluent (liquid) with dry powder, HCP will follow the directions as specified in the medication information instructions.
- For pen devices, HCP will refer to the medication guide or package insert or website from the manufacturer for injection instructions specific to the device, as each one is different.
- Any sharp materials, including needles used will be secured and disposed of in a puncture-proof container and disposed in accordance with the State of California Cal Recycle and/or local government medical waste requirements.

Subcutaneous Injections

A subcutaneous injection involves depositing medication into the fatty tissue directly beneath the skin using a short injection needle. Body sites typically include the upper arm, abdomen, or the top of the thigh. The injection site should be alternated to prevent damage to an area with repeated injections. Any medications that are subcutaneous will be conducted by the HCP using the following procedures:

1. HCP will perform hand hygiene by washing hands with soap and water and drying with single-use towels. After performing hand hygiene, well-fitting, non-sterile gloves will be placed on the hands.
8. Prior to giving the injection, HCP will clean the injection site with an alcohol wipe starting at the puncture site, using firm pressure and working outward in a circular motion, and let the alcohol dry thoroughly before doing the injection.
2. HCP will remove the needle cover, being careful not to touch the needle.
3. HCP will gently pinch one to two inches of the skin at the injection site.
4. Holding the syringe straight up from the injection site, HCP will insert the needle using a quick motion.
5. HCP will inject the medication by pushing the plunger until the syringe is empty.
6. HCP will remove the needle gently but quickly and apply pressure to the injection site with an alcohol wipe and apply a bandage if necessary.

After Injection

- Used needle and syringe will be discarded into a puncture-resistant sharps container.
- Other used items will be discarded into the appropriate category of waste.
- HCP will perform hand hygiene again, as described above.

Licensed or certified staff will document in the client file within 24 hrs.

Intramuscular Injections

An intramuscular injection involves depositing medication into deep, muscle tissue using an injection needle longer than those used for subcutaneous injections. Body sites typically include the mid-thigh or upper, outer quadrant of the buttocks. The injection site should be alternated to prevent damage to an area with repeated injections. Any intramuscular injections will be conducted by the HCP using the following procedures:

1. HCP will remove the needle cover, being careful not to touch the needle.
2. With a thumb and index finger, HCP will stretch the skin of the injection site slightly. HCP will ask the client to relax the muscle, as injecting into tense muscles will be more painful.
3. Holding the syringe straight up from the injection site, HCP will insert the needle using a quick motion.
4. HCP will inject the medication by pushing the plunger until the syringe is empty.
5. HCP will remove the needle gently but quickly and apply pressure to the injection site with an alcohol wipe. HCP will apply a bandage if necessary.

After Injection

- Used needle and syringe will be discarded into a puncture-resistant sharps container.
- Other used items will be discarded into the appropriate category of waste.
- HCP will perform hand hygiene again, as described above

Licensed or certified staff will document in the client file within 24 hrs.

Preparing an Auto-Injector

Any auto-injector pens will be conducted by the HCP using the following procedures:

1. If using a pen delivery system, HCP will attach the needle to the pen.
2. For first time use, HCP will need to prime the pen to push out extra air in the delivery system.
3. HCP will dial a small dose (usually 2 units or 0.02 ml, or as indicated by the package instructions) and push the button to expel the primer.
4. HCP will dial the correct dose and prepare for injection.
5. HCP will inject the medication.
    a. HCP will take a pinch of skin between the thumb and index finger and hold it.
    b. HCP will inject the needle into the pinched skin at a 90-degree angle. This will be done quickly, but without great force.
    c. HCP will inject the entire amount of medication.
    d. HCP will let go of the pinched skin and withdraw the needle, then discard the used needle in a puncture-resistant sharps container.

e. HCP will use gauze to apply light pressure to the injection site. If there is any bleeding, it should be very minor.

After Injection:

- Used needle and syringe will be discarded into a puncture-resistant sharps container.
- Other used items will be discarded into the appropriate category of waste.
- HCP will perform hand hygiene again, as described above

Licensed or certified staff will document in the client file within 24 hrs.

Disposal of Medications

No expired, contaminated, or deteriorated medications, or used syringes will be kept on [Program] premises. Staff follow the procedures listed below for disposal of these items:

1. Medications that have expired shall be disposed of within fourteen (14) working days of the expiration date by authorized staff.
2. Medications that are contaminated or have deteriorated shall be disposed of within fourteen (14) working days of discovery by authorized staff.
3. Unused medication will be sent with the client at discharge if approved by the physician. If not approved, the unused medication will be destroyed under the destruction policies outlined here.
4. All used syringes and other medical sharps will be discarded in rigid sharps containers and when ¾ full will be disposed of as hazardous waste through a contract with a third-party vendor.
5. Authorized staff shall place all medications to be destroyed in a designated, destruction bin that is rigid-sided, sealable and secure, which will be either transported to, or picked up by a third-party contractor, for proper destruction.
6. Each medication that is to be discarded shall be listed in a Disposal/Destroyed Medication Log. The receipt and destruction of the medication(s) by the third-party vendor shall be noted on the Disposal/Destroyed Medication Log. In the case of destroying medications not removed by the client upon departure, staff shall sign a record, to be retained in the client's file for at least three years, and that lists the following:
   a. Name of the client
   b. The prescription number and the name of the pharmacy
   c. The medication name, strength and quantity destroyed
   d. The date of destruction.
7. At minimum, authorized staff shall conduct weekly reviews of the medication storage areas and documentation logs (e.g. reconciliation of medications stored and medication logs) and work to reconcile any discrepancies.

Disposal of Controlled Medications

Authorized staff must follow the procedures listed below for the disposal of controlled medications:

1. Controlled medications that need to be disposed of will be collected by authorized staff.
2. All identifying client information from the controlled medication will be removed.
3. Two authorized staff members will empty controlled medications into a designated, destruction bin that is rigid-sided, sealable, and secure. One authorized staff member will dispose of the medication and the other authorized staff member will witness disposal.
4. Disposal of controlled medications will be documented in the Disposal/Destroyed Medication Log by authorized staff member disposing of the controlled medications and co-signed by witnessing authorized staff member. The controlled medications are disposed of through a contract with a third-party vendor.

Disposal of Illegal Substances

1. Illegal substances will be discarded in the presence of two authorized staff members into a designated destruction bin, that is rigid-sided, sealable and secure. The bin is maintained in a locked closet until it can be collected and disposed of through a contract with a third-party vendor.
2. Disposal of illegal substances will be documented in the Disposal/Destroyed Medication Log by authorized staff members disposing of the controlled medications and co-signed by vendor at pick up.

Incidental Medical Services Policy and Procedures

AB 848 was enacted in 2016, and authorized residential, non-medical, alcohol and drug treatment facilities licensed by the Department of Health Care Services (DHCS) to provide incidental medical services (IMS). IMS are approved services provided by a health care practitioner (HCP) or staff working under the supervision of an HCP, which address medical issues associated with either detoxification or the provision of alcohol or substance use recovery or treatment services.

IMS are limited to services that are not required to be performed in a licensed clinic or licensed health facility (as defined in Section 1200 or 1250) and can safely be provided in compliance with the community standard of practice at the licensed alcohol or substance use recovery or treatment facility. IMS does not include the provision of general primary care. IMS must be related to the client's process of moving into long-term recovery.

The [Program] IMS includes the following categories, as defined by regulation:

1. Obtaining medical histories.
2. Monitoring health status to determine whether the health status warrants transfer of the client in order to receive urgent or emergent care.
3. Testing associated with detoxification from alcohol or drugs.
4. Providing alcoholism or drug abuse recovery or treatment services.
5. Overseeing client self-administered medications.
6. Treating substance use disorders, including detoxification.

[Program] has a dedicated room for IMS. The room is equipped with supplies and [Program] facility has the required first aid kits and locked/secured medication room for self-administration of medications. No individual who requires 24-hour medical care will be admitted into the facility.

1. Obtaining Medical Histories

Prior to admission and prior to receiving any IMS, the HCP, licensed, or certified counselor, and the individual will complete the Client Health Questionnaire and Initial Screening Form (DHCS 5103) in person. All individuals will disclose the following during the intake process on the Client Health Questionnaire and Initial Screening Questions Form:

- All prescribed medications they are currently taking;
- Major medical illnesses. Individuals currently taking anti-depressants will be able to continue to take these medications while participating in the program;
- Injuries;
- Hospitalizations;
- Allergies;
- Substance abuse history, including past withdrawal episodes; and

- Psychiatric comorbidity.

After completion, the DHCS 5103 form will be signed by the individual and an HCP, or a staff member under the supervision of an HCP, including a registered or certified counselor in the assigned IMS room. This form is reviewed to ensure the individual is appropriate for treatment at this facility, whether the individual is currently intoxicated, the type and severity of the withdrawal syndrome, as well as an assessment of information regarding past withdrawal episodes.

Physician review of the Client Health Questionnaire and Initial Screening Questions Form (DHCS 5103) will occur within 24 hours of admission including a face-to-face assessment in the assigned IMS room. If IMS is needed, the physician will complete, sign and date the IMS Certification Form (DHCS 4026).

All IMS will be documented in the client file within 24 hours. Upon completion of the intake process, the client will sign and date the admission agreement; the original will be placed in the client file within 24 hours and the client will receive a copy.

2. Monitoring Health Status

[Program] continuously monitors the health status of clients to determine whether their health status warrants transfer to receive urgent or emergent care. The physician will conduct a face-to-face physical within 24 hours of admission in the designated IMS room. The physician will document the results and final determination on the IMS Certification Form (DHCS 4026); the physician will provide the original form to [Program] staff to place in the client file within 24 hours.

Upon admission, the following assessments will be conducted at the facility:

- A face-to-face physical exam within 24 hours of admission is performed by the physician in designated IMS room and documented in the client's file.
- Instant/rapid read alcohol and drug screens are conducted on site by [Program] staff who are specifically trained in these testing procedures and have demonstrated competency to perform these functions. All test results will be read by the physician or HCP and recorded in the client file; the testing materials will be disposed of in the waste basket or the hazardous waste bin after they are read.
- Vital signs are performed by [Program] staff that are trained and have demonstrated competency to perform these functions. Competency will be documented in their personnel file.
- All treatment staff are trained to monitor detoxification levels using the Clinical Institute Withdrawal Assessment / Clinical Opioid Withdrawal Scale (CIWA/COWS)
    - At intake and during the course of treatment, staff will document the client's signs and symptoms using a CIWA/COWs form with the clients file

or electronic medical record (EMR). The following will be filled out starting at the time of intake:

- Signs and symptoms will be documented in the clients file every 30 minutes for a minimum of the first 72 hours.
- Temperature will be taken for the first 72 hours.
- Client will be visually evaluated every 30 minutes for the first 72 hours of their stay for signs of breathing by watching chest rises. Following the first 72 hours, clients will be visually evaluated hourly for signs of breathing for the duration of their stay.
- CIWA and/or COWS will be completed every 4 hours for clients on Detox Protocol. After the client is off Detox Protocol and cleared by the physician, vitals will be obtained twice a day and documented in the client's file/EMR.
- Any signs and symptoms of auditory or visual hallucinations will require the physician or HCP to be contacted.
- COWS score greater than 30 requires the physician to be immediately contacted and possible referral to an outside hospital will be made at the discretion of the physician.
- CIWA score greater than 15 requires the physician to be contacted and the CIWA will be taken every hour. If CIWA score does not decrease within the next 3 hours with appropriate medications, proper referral to an outside hospital and transportation shall take place.
- If the CIWA score reaches 19, then 911 and the physician will be called.
- Prescribed medications shall be provided to the client by self-administration, if approved by the physician.
- Eligibility of readmission to the IMS program of a previously discharged client will be decided by the physician.

- The medical history collects and documents details about the physical health status of the client, particularly those aspects that will have a direct impact on the course of withdrawal, this includes current medications, major medical illnesses, injuries, surgeries, hospitalizations, and allergies. The medical history shall include substance use disorders and psychiatric comorbidity.

If it is determined at intake or at any time during the course of treatment that a client's current health status is beyond the scope of the residential license, the physician, HCP, or qualified staff functioning under the direction of the HCP, must immediately transfer the resident where they can receive urgent or emergent care. Any referral made by [Program], either prior to or after admission, will be documented in the client's file within 24 hours. The physician will determine if client's health status warrants re-admission into the IMS program and will sign and date the final determination within 24 hours.

Emergency, Medical & Psychiatric Referrals

The [Program] treatment program is designed to assist the individual with recovery; however, the individual needs and problems may be of such a complex nature that [Program] cannot provide all necessary services.

During the admission process, clients that are assessed to need services not provided by [Program] are referred to the appropriate external services. Requests for referrals made by the client shall also be granted. Any referrals, whether requested by staff or client, shall be documented in the client file and [Program] staff with the permission of the client to initiate telephone contact with the appropriate community service provider to make necessary arrangements.

[Program] staff conducting the intake and admission will be culturally competent in their interactions with all clients, without stigmatizing. They will communicate [Program] policies and procedures and make the appropriate referrals. Any client that exhibits signs of medical or psychiatric issues shall be referred to the appropriate services. [Program] staff will ensure that clients receive referrals to needed medical or dental services.

Emergency services shall be referred, as follows:

- Medical Emergency - accidents, acute illness, need for transport to emergency room and/or questionable need for immediate medical or nursing intervention.
- Behavioral Emergency - uncontrollable behavior, need to transport to the emergency room, identified need for crisis intervention, or restrictive intervention, which last for more than ten minutes.
- Other emergency - natural disaster, building or utilities (water, power, heater, etc.).
- Staffing problems - Inability of [Program] to provide required staffing, staff emergency situations, employee misconduct (allegations of abuse, not following direction, absences, inability to work, etc.).

3. Testing Associated with Detoxification

The physician shall order laboratory testing of clients, if appropriate, after review of their medical history and exam. Qualified staff may perform testing in the IMS room of the facility.

The physician or HCP has the responsibility of reviewing and determining test results. All test results, regardless of type, will be signed (or initialed) and dated by the physician or HCP, with a copy of the results in the client record within 24 hours from receipt.

Testing of clients is conducted to monitor the stabilization of the client through the treatment process. Testing will include the administration of tuberculosis testing; results of blood/urine testing may result in also testing for HIV, hepatitis, drug/alcohol testing, or

any other testing/screenings that may have a direct impact on the provision of alcohol and/or drug services.

Testing Procedures

IMS testing will be ordered by the physician, including laboratory tests. [Program] will ensure that all non-medical staff will be fully trained (with duties on their duty statement) for any testing that may be performed by these staff members.

All licensed, certified or registered employees conducting any testing will be required to be aware of minimum standards, as stated below:

- Performs routine laboratory procedures such as preparation of lab sheet and basic preparation of testing materials.
- Conducts non-technical routine laboratory tests and procedures under the direction of professional staff.
- Opens, separates, numbers and arranges specimens for laboratory examination and trace results.
- Maintains simple laboratory records and inventory for supplies and reagents.
- Maintains laboratory equipment and supplies by cleaning and maintaining quality assurance records.
- Maintains a clean and sanitary work area in accordance with standard laboratory practice and procedures.

It is the policy of [Program] to provide guidelines and procedures to assist in the surveillance, prevention, and control of the spread of communicable diseases and infections, especially "priority risks" within the population served, including lice, conjunctivitis, HIV, hepatitis, scabies and TB. The physician is responsible for reading and making the final determination of any test results within five days from date of receipt.

Regardless of the type of screen conducted, hand hygiene procedures must be followed and include the use of alcohol-based hand rubs (containing 60-95% alcohol) and hand washing with soap and water. Alcohol-based hand rub is the preferred method for decontaminating hands, except when hands are visibly soiled (e.g., dirt, blood, body fluids), or after being in direct contact with clients with known or suspected infectious diarrhea (e.g., Clostridium difficile, norovirus), in which case soap and water should be used. Hand hygiene stations should be strategically placed to ensure easy access. All testing will either be conducted in the examination room or the bathroom (urine testing).

All testing results are read by the physician or HCP and documented in the client file within 24 hours of receipt.

Types of Testing

Toxicology for alcohol and drugs (blood draws)

A withdrawal of blood will only occur when and if the physician makes a request; this order will be documented in the client file. All blood draws will only be taken by an HCP acting within their scope of licensure.

The following list the procedures for blood draws:

1. The physician has requested an order for specific lab work.
2. Staff will inform the client that lab work has been ordered.
3. Staff will ask the client for cooperation.
4. The HCP will perform the following under their licensing scope of practice:
    a. Obtain two identifiers from the client.
    b. Validate that materials to be used are not expired, and proper equipment is present.
    c. Determine best location to obtain specimen.
    d. Practice aseptic technique throughout procedure.
    e. Wash hands before and wear gloves throughout procedure.
    f. Use alcohol to clean the site and allow to dry.
    g. Collect appropriate number and vials of blood, as ordered by the physician.
    h. Place cotton and tape on site of specimen collection to prevent further bleeding.
    i. Document the order and results in client file.

Urine drug screens

As part of the program rules, individuals must agree to submit to a random alcohol and/or drug urine or breathalyzer test. This may be conducted at intake or during the course of the program. To avoid contamination, samples will follow chain of custody procedures. All test results will be documented and placed in the client file within 24 hours.

After an individual is admitted to the program and during the admissions process, they will be subject to screenings for drugs and alcohol in order to make a proper assessment and render the appropriate level of treatment. Screenings will take place on-site in the IMS room. The physician will ultimately decide the course of treatment based on testing, exam and history gathered prior to admission.

The following procedures will be implemented to protect against falsification and/or contamination of a specimen collection and are to be followed for all tests:

1. The HCP or qualified staff shall inform the client just before testing.
2. The HCP or qualified staff and client will ensure the bottle ID Number is the same as the 'drug test log' number provided in the testing package.

3. The HCP or qualified staff shall use gloves to handle the specimen bottle; the bottle label shall specify the client's name, identification number, and date.
4. The client's name will be written on the 'Specimen Requisition' form.
5. The client will be required to submit to the urinalysis testing in the presence of a same-sex HCP or qualified staff.
6. The HCP or qualified staff will collect the bottle immediately, seal, and verify the information on the bottle, and verify the information on the 'Specimen Requisition' form matches the information on the bottle.
7. The HCP or qualified staff will place a copy of the 'Specimen Requisition' form in the client file.
8. All specimens shall be placed in the secure refrigerated area.
9. The urine specimen will be collected by the end of the day and sent to a contracted lab.
10. Upon receiving result, the counselor shall discuss positive results with the client in accordance with program rules; the counselor will indicate discussion on progress notes during an individual session with client.
11. The licensed or certified staff shall document results in the client file within 24 hours.
12. If required, results of all testing will only be released to the persons specified on the "Confidential Release of Information' form.
13. All test results shall be signed and dated by the physician or HCP and documented in the client file within 24 hours.

<u>Urine Collection Procedure:</u>

1. HCP or qualified staff will place the following information on the bottle label:
    a. Date of collection,
    b. Donor's name and/or identification numbers
    c. Collector's initials
2. HCP or qualified staff will provide the donor with a clean, unused urine specimen collection container and instruct the donor to fill the container at least half full (a minimum of 30 ml's).
    a. Unobserved Collection: HCP or qualified staff will allow the donor to enter and maintain privacy within the stall or partitioned area. The HCP or qualified staff will wait outside the collection area until the donor is finished urinating, and will complete the remainder of the test request form while collecting the specimen.
    b. Observed Collection: Staff will inform the donor that collection will occur under direct observation. HCP or qualified staff will accompany the donor into the collection lavatory at the IMS property (the collector must be the same sex). HCP or qualified staff will instruct the donor to urinate into the sample container with the witness observing urination, and complete the remainder of the test request form after the donor has completed collecting the specimen.

3. HCP or qualified staff will accept the specimen from the donor. The use of disposable gloves is mandatory when handling specimens.
4. Upon receipt of the specimen from the donor, HCP or qualified staff will immediately apply the temperature strip (if applicable) to the outside of the bottle. If using a drug screen test request form, they will record the urine temperature on the form.
    a. NOTE: Urine temperature should be measured within (4) four minutes of collection and should read between 90-100 F.

Collection Area Guidelines:

1. Storage area for collection supplies and related materials is secure.
2. Collection site facility is secure, well lit, and free of any areas where adulterants or substitute specimens can be hidden. The lavatory closest to the IMS room will be utilized.
3. There is a suitable clean surface for the collector to use as a work area.
4. Eliminate or secure all sources of water in the area where urination occurs. Bluing agent should be placed in the toilet tanks and bowls to prevent sample dilution.
5. Eliminate or secure all soap or detergent dispensers or any other potential adulterants.
6. A secured storage area should be available to ensure specimen security prior to transport to the laboratory.
7. A general log book should be maintained to record collected specimens.
8. Disposal is not necessary as all collected specimens are sent to an off-site laboratory.
9. Results of collected specimens will be read by physician or HCP within 7 days of collection.

Breathalyzer

The following is the procedure for performing a breathalyzer test. These tests may be performed by a member of staff that has been properly trained and does not have to be performed by an HCP:

1. Staff member will press the power button.
2. The unit will warm up; it will be ready when "blow" is indicated.
3. Staff will obtain a clean mouthpiece for each client.
4. Staff will ask the client to blow through the mouthpiece into the unit for 4 seconds, or until the unit beeps twice.
5. The results will be displayed for 15 seconds; if a second test is needed, staff will press the power button to turn the unit off and repeat steps 1 through 4.
6. Staff will record the results on the 'Drug Testing' form and place in client file within 24 hours from time of test.
7. The unit will automatically turn off after two minutes.

Confirmatory laboratory analysis for:

- Electrolyte disturbances
- Nutrition deficiencies
- Organ dysfunction
- Other markers impacted by substance use and withdrawal

Before collecting the specimen, staff will confirm the test(s) ordered and the client's identification and verify that pretest instructions or information, as applicable, have been provided. This includes:

- Test orders – HCP or qualified staff performing various tests should routinely confirm that the written test order is correct. If there is a question, check with the physician. Standing orders for certain tests might apply, but they should be documented.
- Client identification – HCP or qualified staff will identify the client before collecting the specimen. Because names can be similar and lead to confusion, use birth dates, middle initials, identification numbers, or other means to ensure the specimen is collected from the correct client.
- Pretest instructions – Some tests require special preparation on the client's part (e.g., a fasting state for glucose testing). HCP or qualified staff will provide the client with pretest instructions, when appropriate, and when special preparation is needed, verify that clients received instructions before testing. To determine if clients followed the instructions, HCP or qualified staff will ask them to explain how they prepared for the test.
- Pretest information – HCP or qualified staff will discuss factors, test limitations, or medical indications that can affect test results with the client, as appropriate, and provide pertinent information such as pamphlets supplied by the test manufacturer, when specified in the product insert.

4. Providing Alcoholism or Drug Abuse Recovery or Treatment Services

In order to provide IMS, the individual must sign an admission agreement that describes the IMS that [Program] is allowed to provide and that the physician, HCP or staff working under the supervision of an HCP will provide the services. The client shall receive a copy of the admission agreement, with a copy also placed in their file. The continuous monitoring of the client while in the IMS program will be done by the physician or HCP. As a result of their assessment of the client's health questionnaire and a physical examination, the HCP lists on the DHCS 4026 the specific alcohol and/or other drug abuse recovery treatment services to be provided by the program.

Upon completion of the form and signed by both the HCP and the client, the form is placed in the client's file and its contents are used to inform and create the client's treatment plan. The [Program] treatment staff continuously communicate with the physician and the client during the length of treatment and make adjustments to the treatment plan as needed.

Testing of clients is conducted to monitor the stabilization of the client through the treatment process. Testing will include the administration of tuberculosis testing; results of blood/urine testing may result in also testing for HIV, hepatitis, drug/alcohol testing, or any other testing/screenings that may have a direct impact on the provision of alcohol and/or drug services.

All IMS testing of clients is conducted to monitor the stabilization of the client through the treatment process. Testing will include the following:

- Administration of tuberculosis testing
- Testing for HIV, hepatitis depending on results of blood/urine testing
- Drug/alcohol testing
- Any other testing/screenings that may have a direct impact on the provision of alcohol and/or drug services.

Testing Procedures *(Refer to Section 3 for test procedures)*

Types of Testing *(Refer to Section 3 for types of testing)*

5. Overseeing Self-Administered Medications

Only qualified and trained staff have access to the medication storage area within the locked IMS room. All medications are stored in a locked cabinet in the designated IMS room. All controlled medications are stored in a separate locked bin or safe in the designated IMS room and inventoried with each shift change to prevent diversion. Medications will also be routinely checked to ensure that they did not expire.

The physician will determine the client's need and prescribe medication as appropriate as well as dictate the timeline for medication observation. Medications will be dispensed by the local pharmacy as ordered. Generics may be substituted if approved by the ordering physician. The physician will review the client's need for medication at least every 30 days. If a prescription is renewed, it is to be documented in the medical record. In the case of discontinuation, a written order by the physician is to be documented in the client medical record. Under no condition will medication be withheld for disciplinary reasons.

Medications must be taken by clients within one hour of the time prescribed by the physician. The medication order consists of six parts, as follows:

1. The name of the client.
2. The date and time when the order is written.
3. The name of the medication to be self-administered and the reason.
4. The dosage.
5. The route and any special directives regarding its self-administration.
6. The time of self-administration and/or frequency.

Process for Client Self-Administration

Only one client at a time is allowed in the IMS medication room to take medication. For all medications dispensed, the client will be identified by checking the client's name and date of birth on the medication record and asking their name and date of birth prior to taking their medication. If a client does not come for their medications a staff member will remind the client of the need for their medications.

Staff will verify that the correct medication and the correct amount of medication were taken by the client. The staff and the client will sign the Medication Self-Administration Log to indicate that the client has taken the medication and also document in the client's chart within 24 hours. The medication log will include the following:

- Daily log that identifies all medications taken by the clients.
- List that describes all physicians' prescription orders written on a given day.
- All medications logged by staff on form once they are prescribed by the physician.
- The dosage taken with staff initials and client's initials.
- Client refusal to take their medications (if applicable), and notification to physician.
- Staff monitoring of client self-administered medications.

Clients who are maintained on methadone will be supported in their methadone dosing either at their designated clinics or withtake-home doses. Take-home doses may be stored and transported using a lock box with keys, or a lock box with a combination lock. The box will be transported to the residential facility to be handled by authorized staff. The authorized staff will count the doses, document the count and secure the methadone in the lock box, within a locked cabinet.

Clients will take medication under the observation of trained staff. Training and competency of observation of client self-administration will be documented in the employees personnel file. The staff and client will be educated regarding all aspects of the process required for the safe self-administration of medication. Clients will self-administer their medication as directed in the presence of and under the direct supervision of the qualified staff on duty. HCPs will document that a client has been educated and is appropriate to self-administer medications. The education will include, but not be limited to the following:

- Definition of a supervised self-administration medication system
- Staff's role in providing supervision and monitoring
- Safe storage of medication
- Side effects
- Monitoring the effectiveness of medication
- Issues to report to the HCP
- Situations requiring emergency intervention

Staff providing medications are trained regarding medications and provide assistance in the self-administration of medications in the designated IMS room, only as follows:

1. Removing the container in which the client's medications are stored from the secured and locked medication storage area.
2. Handing the container in which the client's medications are stored, to the client whose identity is ascertained by facility staff, including a system to correctly identify the client and to ensure that the correct client receives the appropriate medication.
3. Observing the client self-administer their medication. Immediately report any unusual signs, reactions, symptoms, or actions on the part of the client to the HCP.
4. Retrieving the container in which the client's medications are stored and returning the container to a secure storage area.
5. The program staff who assists the client in the self-administration of the client's medication shall record and sign the client medication log within the client's medical record.
6. Prescription medications shall be stored in the original prescription container. Non-prescription medications shall be stored in the manufacturer's original container. All prescribed medications shall have a label that includes the client name, dosage, prescriber, name of pharmacy, medication name, strength, quantity, and expiration date. No bulk prescription medications will be used or kept at the facility.
7. All medications for client's use shall be stored using appropriate temperatures as indicated by the manufacturers or prescription labeling. Medications required to be stored at room temperature shall be stored at a temperature between 59 degrees and 86 degrees Fahrenheit. Medications requiring refrigeration shall be stored in a secured and locked refrigerator between 36 degrees and 46 degrees Fahrenheit, or other required temperature range as specified on the prescription instructions and/or prescription materials.
8. Medications needing destruction will be stored in designated bins away from the rest of the client medications.
9. Any medication that requires refrigeration will be kept in a small refrigerator in the IMS room. The temperature of the refrigerator shall be checked daily and noted on the refrigerator log. No staff items can be stored in this refrigerator.
10. HCP or qualified staff will inspect the medication area daily. Any deficiencies will be reported to the physician immediately.

<u>Documenting Medications</u>

Medications received from a pharmacy, company representative, or by mail shall be handled only by authorized staff at the time of delivery. [Program] will secure and inventory all medications entering its facilities on applicable medication logs. This includes: medications brought by the client upon admission, those brought to the client

from outside the facility after admission, those picked up from home or the pharmacy by the client or staff, and controlled medications such as methadone take-home doses.

If a medication is brought in by a client, the following procedure is in place:

- The medication must be brought in the original bottle from the pharmacy and properly labeled. The HCP, licensed, or certified staff must inspect the medication to ensure it is what it is labeled and is packaged appropriately.
- The physician must approve of the client's medication. If the physician does not approve the use of the client's own medication, the client will be informed of this and medication will be ordered from the local pharmacy. All medications will be stored in the locked medication room and returned to the client at the time of discharge.
- If medications are brought in by the client, and discontinued by the physician, the prescribing HCP will be notified by staff via fax (if the client signs a release of information).

Under the designation and supervision of the prescribing physician and/or the supervisor, authorized staff shall be responsible for documenting the below in medication documentation binders, which shall be stored behind a locked area:

- Medication Self-Administration Log
- Medication Dispensing Log
- Disposal/Destroyed Medication Log

At minimum, authorized staff shall conduct weekly reviews of the medication storage areas and documentation logs (e.g. reconciliation of medications stored and medication logs) and work to reconcile any discrepancies.

<u>Medication Destruction</u>

No expired, contaminated, or deteriorated medications, or used syringes will be kept on [Program] premises. Staff follow the procedures listed below for disposal of these items:

1. Medications that have expired shall be disposed of within fourteen (14) working days of the expiration date by authorized staff.
2. Medications that are contaminated or have deteriorated shall be disposed of within fourteen (14) working days of discovery by authorized staff.
3. Unused medication will be sent with the client at discharge if approved by the physician. If not approved, the unused medication will be destroyed under the destruction policies outlined here.
4. All used syringes and other medical sharps will be discarded in rigid sharps containers and when ¾ full will be disposed of as hazardous waste through a contract with a third-party vendor.

5. Authorized staff shall place all medications to be destroyed in a designated, destruction bin that is rigid-sided, sealable and secure, which will be either transported to, or picked up by a third-party contractor, for proper destruction.
6. Each medication that is to be discarded shall be listed in a Disposal/Destroyed Medication Log. The receipt and destruction of the medication(s) by the third-party vendor shall be noted on the Disposal/Destroyed Medication Log. In the case of destroying medications not removed by the client upon departure, staff shall sign a record, to be retained in the client for at least three years, and that lists the following:
    a. Name of the client
    b. The prescription number and the name of the pharmacy
    c. The medication name, strength and quantity destroyed
    d. The date of destruction.
7. At minimum, authorized staff shall conduct weekly reviews of the medication storage areas and documentation logs (e.g. reconciliation of medications stored and medication logs) and work to reconcile any discrepancies.

Authorized staff must follow the procedures listed below for the disposal of controlled medications:

1. Controlled medications that need to be disposed of will be collected by authorized staff.
2. All identifying client information from the controlled medication will be removed.
3. Two authorized staff members will empty controlled medications into a designated, destruction bin that is rigid-sided, sealable, and secure. One authorized staff member will dispose of the medication and the other authorized staff member will witness disposal.
4. Disposal of controlled medications will be documented in the Disposal/Destroyed Medication Log by authorized staff member disposing of the controlled medications and co-signed by witnessing authorized staff member. The controlled medications are disposed of through a contract with a third-party vendor.

<u>Medication Refusal</u>

If a client refuses to take their medication, the staff documents this on the medication sheet, notifies the physician (if not observed by the HCP), and documents in the client file within 24 hours. The physician may need to change or discontinue the medication. [Program] staff will put a copy of the adjustment or discontinuance documentation in the client file within 24 hrs. A client that refuses to take their medication may be discharged from the program; however, this decision will be made by the physician.

6. Treating Substance Use Disorders, Including Detoxification

To ensure safety and provide the highest quality of care to its clients, [Program] will ensure that the introduction of MAT is implemented at the appropriate time and maintained during treatment, as determined by the physician. Examples of MAT medications include, but are not limited to, acamprosate, disulfiram, methadone, buprenorphine and naltrexone.

- All clients prescribed MAT will be seen face-to-face by the physician prior to the initiation of medications.
- Medications may include oral and/or injectable, and implantable subdermal.
- All HCP, licensed, and certified staff will be trained on the use of the medications prior to working with clients.
- Stock or bulk prescription medications will not be stored at the licensed facility site.
- Surgical procedures will not be performed at the licensed facility site.
- No client who requires 24-hour medical care/monitoring will be admitted into the facility.
- [Program] IMS will not include intravenous solutions and medications.
- All controlled medications will be kept in a separate locked bin or safe within a locked cabinet behind the locked door of the designated IMS room.

The [Program] physician will work with the client's primary care physician (if authorized by the client by signing a confidential release) to coordinate care for any complex conditions which may impact the client's success in treatment. For clients receiving methadone, the physician shall collaborate with a Narcotic Treatment Program (NTP) (if authorized by the client with a confidential release of information) to coordinate how the client will receive their medication. The physician will document coordination with the primary care physician or NTP in the client file within 24 hours.

The [Program] physician, working with the primary care physician (if any) will determine the level of MAT services required and an assessment will be conducted by the [Program] physician in the designated IMS room. The physician is allowed to administer an injectable or implantable subdermal MAT with the written consent of the client. An informed consent form must be completed prior to the administration any injectable or subdermal (MAT) medications.

Oral Medications *(see Section 4 for Client Self-Administration)*

Injectable Medications

For injectable medications, the HCP will:

1. Perform hand hygiene by washing hands with soap and water and drying with single-use towels. After performing hand hygiene, well-fitting, non-sterile gloves will be placed on the hands.

2. Clean and inspect the injection site. Before injecting medication, HCP will inspect the skin to make sure there is no bruising, burns, swelling, hardness, or irritation in the area. HCP will alternate injection sites to prevent damage to an area with repeated injections. HCP will clean the skin with an alcohol swab and let the alcohol dry thoroughly before doing the injection.
3. Prepare the syringe with the medication. Before withdrawing medication from a vial and injecting, HCP will make sure it is the correct medication, at the correct dose, at the correct time, and in the right manner. A new needle and syringe will be used with every injection.
4. Draw air into the syringe and draw back the plunger to fill the syringe with air up to the dose that will be injected.
5. Insert air into the vial. This is done by removing the cap from the needle and pushing the needle through the rubber stopper at the top of the vial.
6. Withdraw the medication. This is done by turning the vial and syringe upside down so the needle points upward then pulling back on the plunger to withdraw the correct amount of medication.
7. Remove any air bubbles. HCP will tap the syringe to push any bubbles to the top and gently depress the plunger to push the air bubbles out.

Injectable medications will only be administered by the HCP, using the below procedures:

- HCP will perform hand hygiene; wash hands with soap and water, and dry with single-use towels.
- After performing hand hygiene, well-fitting, non-sterile gloves will be placed on the hands.
- If the medication is stored in the refrigerator, it will be removed from the refrigerator about 30 minutes before injection so it can warm up to room temperature.
- Supplies will be placed on a clean, dry surface.
- The medication may be supplied in a pre-filled syringe that does not require mixing. If this is the case the HCP does not need to prime the syringe but will check for air bubbles and to see if the level of the medication is at the top of the needle.
- If the syringe is not pre-filled, HCP will prime the syringe to remove all the air from it, hold the syringe pointing upwards, and gently tap the sides to force any air bubbles to the top. HCP will push the plunger slowly until one or two drops come out from the tip of the needle. This ensures that all air has been safely removed from the syringe.
- If the medication preparation requires mixing diluent (liquid) with dry powder, HCP will follow the directions as specified in the medication information instructions.

- For pen devices, HCP will refer to the medication guide or package insert or website from the manufacturer for injection instructions specific to the device, as each one is different.
- Any sharp materials, including needles used by a client for and/or during self-administration will be secured and disposed of in a puncture-proof container and disposed in accordance with the State of California Cal Recycle and/or local government medical waste requirements.

After Injection

- Used needle and syringe will be discarded into a puncture-resistant sharps container.
- Other used items will be discarded into the appropriate category of waste.
- HCP will perform hand hygiene again, as described above.

Subcutaneous Injections

A subcutaneous injection involves depositing medication into the fatty tissue directly beneath the skin using a short injection needle. Body sites typically include the upper arm, abdomen, or the top of the thigh. The injection site should be alternated to prevent damage to an area with repeated injections. Any medications that are subcutaneous will be conducted by the HCP using the following procedures:

1. HCP will perform hand hygiene by washing hands with soap and water and drying with single-use towels. After performing hand hygiene, well-fitting, non-sterile gloves will be placed on the hands.
9. Prior to giving the injection, HCP will clean the injection site with an alcohol wipe starting at the puncture site, using firm pressure and working outward in a circular motion, and let the alcohol dry thoroughly before doing the injection.
2. HCP will remove the needle cover, being careful not to touch the needle.
3. HCP will gently pinch one to two inches of the skin at the injection site.
4. Holding the syringe straight up from the injection site, HCP will insert the needle using a quick motion.
5. HCP will inject the medication by pushing the plunger until the syringe is empty.
6. HCP will remove the needle gently but quickly and apply pressure to the injection site with an alcohol wipe and apply a bandage if necessary.

After Injection

- Used needle and syringe will be discarded into a puncture-resistant sharps container.
- Other used items will be discarded into the appropriate category of waste.
- HCP will perform hand hygiene again, as described above.

Licensed or certified staff will document in the client file within 24 hrs.

Intramuscular Injections

An intramuscular injection involves depositing medication into deep, muscle tissue using an injection needle longer than those used for subcutaneous injections. Body sites typically include the mid-thigh or upper, outer quadrant of the buttocks. The injection site should be alternated to prevent damage to an area with repeated injections. Any intramuscular injections will be conducted by the HCP using the following procedures:

1. HCP will remove the needle cover, being careful not to touch the needle.
2. With a thumb and index finger, HCP will stretch the skin of the injection site slightly. HCP will ask the client to relax the muscle, as injecting into tense muscles will be more painful.
3. Holding the syringe straight up from the injection site, HCP will insert the needle using a quick motion.
4. HCP will inject the medication by pushing the plunger until the syringe is empty.
5. HCP will remove the needle gently but quickly and apply pressure to the injection site with an alcohol wipe. HCP will apply a bandage if necessary.

After Injection

- Used needle and syringe will be discarded into a puncture-resistant sharps container.
- Other used items will be discarded into the appropriate category of waste.
- HCP will perform hand hygiene again, as described above.

Licensed or certified staff will document in the client file within 24 hrs.

Preparing an Auto-Injector

Any auto-injector pens will be conducted by the HCP using the following procedures:

1. If using a pen delivery system, HCP will attach the needle to the pen.
2. For first time use, HCP will need to prime the pen to push out extra air in the delivery system.
3. HCP will dial a small dose (usually 2 units or 0.02 ml, or as indicated by the package instructions) and push the button to expel the primer.
4. HCP will dial the correct dose and prepare for injection.
5. HCP will inject the medication.
    a. HCP will take a pinch of skin between the thumb and index finger and hold it.
    b. HCP will inject the needle into the pinched skin at a 90-degree angle. This will be done quickly, but without great force.
    c. HCP will inject the entire amount of medication.
    d. HCP will let go of the pinched skin and withdraw the needle, then discard the used needle in a puncture-resistant sharps container.

e. HCP will use gauze to apply light pressure to the injection site. If there is any bleeding, it should be very minor.

After Injection:

- Used needle and syringe will be discarded into a puncture-resistant sharps container.
- Other used items will be discarded into the appropriate category of waste.
- HCP will perform hand hygiene again, as described above

Licensed or certified staff will document in the client file within 24 hrs.


DHCS
California Department of
Health Care Services