Indian Health Service
Medication Assisted Treatment Using Telemedicine (Tele-MAT)
An Overview of Practical Considerations

Contents

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Background

The Indian Health Service (IHS) has demonstrated a continued commitment to increase access to culturally appropriate prevention, treatment, and recovery support services for Opioid Use Disorder (OUD). Key components of these approaches include:

- enhanced screening and early identification of OUD
- improved care coordination and patient referral for treatment
- enhanced workforce development strategies to increase education and resources surrounding medication use in the support of recovery

In some circumstances, IHS federal/Tribal/Urban (I/T/U) facilities may need to facilitate access to Medication Assisted Treatment (MAT) using telehealth treatment models when traditional office-based models are unavailable or inaccessible. Tele-MAT has the ability to increase access to patient assessment opportunities and prescribing services in order to further expand access to FDA-approved medications for OUD in Areas and communities where this practice has been difficult to establish or maintain and can also be used to augment existing recovery resources in rural communities. MAT service models should be carefully considered and designed to meet the needs of the local population.

Telehealth MAT models require additional coordination, attention, and resources to operate successfully. This document provides guidance to help providers and facilities establish an integrated Tele-MAT model within the Indian healthcare system.

This model is intended for the treatment of OUD with FDA-approved Office Based Treatment medications including buprenorphine-containing products and naltrexone. It is not intended to provide guidance for methadone treatment models that are restricted to DEA approved Opioid Treatment Programs.

Program Considerations:

1. PRESCRIBER RECOMMENDATIONS:

The following should be considered when vetting a potential Tele-MAT prescriber:

- Documentation demonstrating successful completion of relevant training on substance use disorders; fundamentals in conducting chemical dependency assessments; prescribing various MAT options of buprenorphine, buprenorphine/naloxone, naltrexone intramuscular injection, and/or other FDA-approved options available at the facility level.
- Registered as a current DATA-waived provider (possess a valid DEA X-license).
- If prescriber is working with a non-DEA licensed facility, without a DEA-licensed prescriber:
    - Registered with Indian Health Service as an Internet Eligible Controlled Substance Provider (IECSP)
    - Prescriber is eligible for this designation if the following are in place:
        1. Active and unrestricted State license
        2. Local medical staff clinical privileges fall under an appropriate scope of practice
        3. Active DEA registration to prescribe controlled substances, including an active DATA 2000 waiver to conduct maintenance and detoxification treatment using specifically approved schedule III, IV, or V controlled substance medications

Additional provider resources: https://www.ihs.gov/opioids/recovery/providers/

Laws Influencing Tele-Prescribing of Controlled Substances:

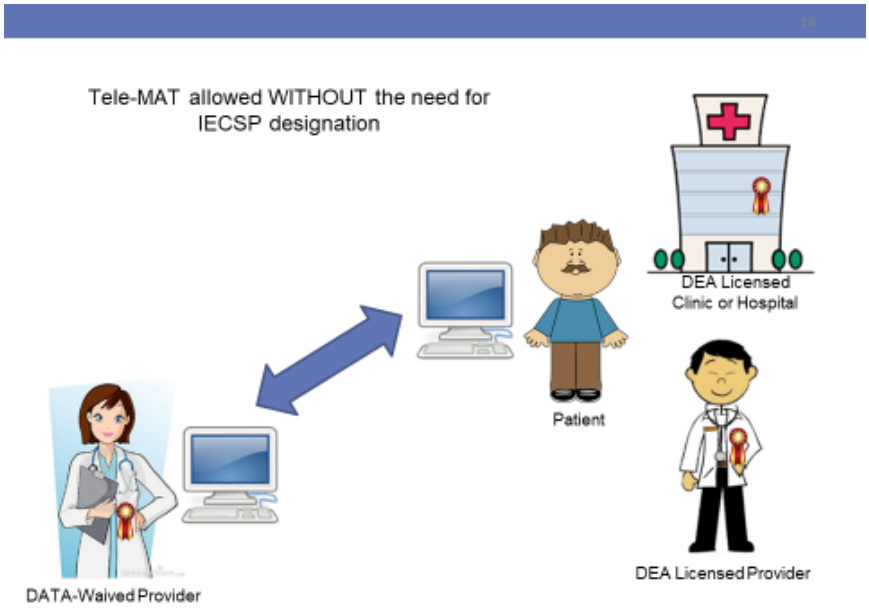
The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 seeks to prevent the illegal distribution and dispensing of controlled substances via the Internet, intended to reduce harm from Internet pharmacies. The general requirement is that the prescribing practitioner must have conducted at least one in-person medical evaluation of the patient. However, a DEA-registered practitioner acting within the United States is exempt from the requirement of an in-person medical evaluation as a prerequisite to prescribing or otherwise dispensing controlled substances by means of the Internet if the practitioner is engaging in the practice of telemedicine. For the purposes of these regulations, the "practice of telemedicine" means the practice of medicine in accordance with applicable Federal and State laws, by a practitioner (other than a pharmacist) who is at a location remote from the patient, and is communicating with the patient, or health care professional who is treating the patient using a telecommunications system (Graphic 1 example):

1. While the patient is being treated by, and physically located in, a DEA-registered hospital or clinic; and by a practitioner
    a. Who is acting in the usual course of professional practice
    AND
    b. Who is acting in accordance with applicant state law
    AND
    c. Is registered with the DEA in the State in which the patient is located

OR

2. While the patient is being treated by, and in the physical presence of, a DEA-registered practitioner
    a. Who is acting in the usual course of professional practice
    AND
    b. Who is acting in accordance with applicable state law
    AND
    c. Is registered with the DEA in the State in which the patient is located

Graphic 1 example:

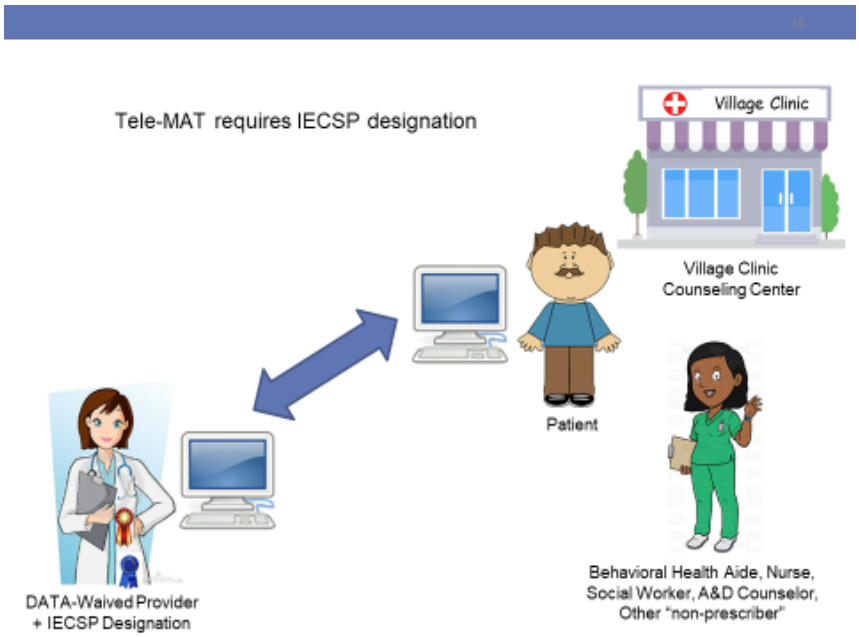


Due to the rural and isolated locations of many of our patients, the Act included further provisions to reduce potential barriers for IHS programs utilizing telemedicine models. If a DATA-waived provider is registered with Indian Health Service as an Internet Eligible Controlled Substance Provider (IECSP), they are able to provide services without the in-person medical evaluation and without the patient being physical located at a DEA-registered hospital/clinic or in the physical presence of a DEA-registered provider (Graphic 2 example).

The specific IHS telemedicine exception includes "a practitioner":

1. Who is an employee or contractor of the IHS, or is working for an Indian tribe or tribal organization under its contract or compact with the IHS under the Indian Self-Determination and Education Assistance Act (ISDEAA)
2. Who is acting within the scope of the employment, contract, or compact described in clause
3. Who is designated as an IECSP by the Secretary of Health and Human Services (HHS)

Graphic 2 example:



2. ADMINISTRATIVE CONSIDERATIONS:

The below represents recommendations and considerations and is not an inclusive list. A thorough gap analysis should be considered to identify potential barriers. Creation of a specific, comprehensive action plan may follow the analysis and may include the following:

- Establish a Telehealth Service Agreement between Tele-MAT provider/entity (Distant Site) and local, tribal or IHS facility (Originating Site).
    - Include details of what telehealth services will be provided to include the following:
        - identify the practitioner type that will be providing services
        - identify hours of operation
        - specify after-hours and emergency access
        - identify clerical and administrative support needs
        - specify hardware and network requirements
        - identify contingency plans to ensure continuity of operations in the event of IT systems failure
        - specify clinical documentation requirements, claims submission processes, and care coordination details. For additional information on telehealth deployment and use, consider consulting the IHS Telebehavioral Health Center of Excellence Toolkit
    - Ensure provider meets the Tele-MAT provider requirements
- Identify and address 'Originating Site' health system requirements
    - Hours of operation
    - Staffing needs (patient assessments, care coordination, administrative intake staff)
    - Clinic space/location
    - Technology capacity, infrastructure, equipment
    - Staffing support (establish workflows, training, evaluation/improvement processes)
- Ensure tele-prescriber is credentialed and has approved clinical privileges to manage OUD and prescribe the necessary medications
- Ensure tele-prescriber has access to the facility electronic health record
- Develop policy and procedures for MAT services at Originating Site
    - Address establishing care, appointments (scheduling, follow-up, no-shows, cancellations), patient assessments, patient release of information, induction procedures, lost medications, Urine Drug Screen monitoring, and responses to aberrant behaviors
    - Patient Informed Consent, treatment agreement, patient education material
    - Identify mechanisms to provide naloxone
    - Identify roles and responsibilities of facility staff and prescriber. See sample "Clinical Procedures Checklist" to assist with determining role-based responsibilities.
- Laboratory Considerations
    - Ensure availability of appropriate toxicology testing for substances, including testing for buprenorphine and its metabolites, confirmatory testing for benzodiazepines, along with testing for alcohol use. For more information on drug screening, please visit: https://ihs.cosocloud.com/p1w8ox2fkclv/?proto=true
- Staff Education
    - Ensure clinical staff is familiar with the use of MAT for OUD, including basics of office/home induction procedures and use of appropriate language surrounding patients with substance use disorder

- Referrals
    - Ability to provide or refer patients for behavioral health, addiction counseling, and/or other ancillary services as appropriate to support a holistic, whole-person approach to care and recovery
- Contingency Plan
    - Written plan for after-hours, holiday coverage, and other emergency situations
- Care Coordination and Wrap-around services
    - Maintain a current list of other available recovery resources and service providers within the community and surrounding areas
- Pharmacy/Medication procurement considerations
    - Ensure patient has access to MAT prescriptions
        - Prescription options available on the local formulary or utilization of an off-site pharmacy
    - Prescription transmission
    - Medication used for initial induction
        - Dispensed directly to patient by in-house or off-site pharmacy
        - Dispensed directly to clinical staff by in-house pharmacy
        - Consider coordination with off-site pharmacy, if necessary
        - Consider templated patient instructions for appropriate pick-up

3. PATIENT ELIGIBILTY FOR TELE-MAT:

- Patient is eligible for care at Indian Health Service facility
- Meets criteria for office-based MAT including diagnosis of OUD
- Patient has signed informed consent and treatment agreement
- Patient is motivated to fulfill required components of treatment (consent, laboratory tests, counseling, appointments, etc.)

4. TYPICAL TELE-MAT PATIENT CARE PATHWAY

1. Patient identified who may be eligible for MAT at local facility
2. Referral placed for Tele-provider to evaluate patient for eligibility of MAT services
3. Schedule MAT intake appointment
4. Intake appointment:
   The following elements are considered best practice when completing a thorough patient assessment; however, not all elements of care may be possible during the intake visit and may need to be further discussed at future appointments.
    - Patient history (including psycho/social history, current and past substance use)
    - Complete substance use disorder screening and withdrawal assessments: clinical opioid withdrawal scale (COWS), subjective opioid withdrawal scale (SOWS), objective opioid withdrawal scale (OOWS), craving assessment
        - Consider completing additional screenings and assessments of suicide, depression and anxiety prior to and throughout treatment
    - Confirm OUD diagnosis using *DSM-V* criteria
    - Prescription Drug Monitoring Program query results reviewed
    - Patient education documents (brochures, information sheets) about OUD and MAT provided and discussed with patient
    - Review and complete informed consent and treatment agreement paperwork
    - Provide education on opioid overdose and proper naloxone administration

        - Enter orders (could consider standing orders):
            - Prescription for naloxone
            - Toxicology test (Urine Drug Screen)
            - Labs (pregnancy test, LFTs, HIV, HCV, STIs)
    - Counsel on contraception methods for women of child-bearing age
    - Create individualized, patient treatment plan (consider bio, psycho, social and spiritual factors)
    - Coordinate care to appropriate services as needed (behavioral health, counseling, support/peer recovery, traditional or cultural medicine)
    - Induction
        - Office- or home-based induction
        - Buprenorphine/naloxone or naltrexone
            - Consider additional medications for symptomatic treatment of withdrawal as needed (comfort medications)
    - Schedule follow-up appointments

Additional Office Based Opioid Treatment Resources can be found at:
https://www.ihs.gov/opioids/recovery/obot/

Sample Clinical Procedures Checklist

CLINICAL PROCEDURES WHO PERFORMS THIS:	**PRESCRIBER**	**FACILITY**
Initial MAT consult and scheduling		
Review of eligibility for buprenorphine		
PDMP check (Prescription Drug Monitoring Program)		
Enter orders for toxicology testing		
Explain risks/benefits/alternatives/patient education		
Obtain informed consent and treatment agreement for MAT		
Collect specimen for toxicology		
Vital signs, screenings		
Withdrawal and Craving Assessments		
Intake documentation		
Enter orders for medication		
Induction		
Arrange follow-up appointment		
Close out consult		
Initial SUD counseling		
Follow-up SUD counseling		
Care Coordination		

Withdrawal Assessment:
Use the SOWS, OOWS and COWS, vital signs, and a targeted physical exam to document signs of withdrawal. The patient should exhibit signs of at least mild withdrawal (COWS > 5) prior to receiving the first dose of buprenorphine.

In addition to assessing for opioid withdrawal, also assess for substance **intoxication**, including but not limited to alcohol odor, nystagmus, patient disinhibition, or other altered mental status.

Lab testing: Urine drug toxicology test will be collected on the first day of initiation. Options include:

- Drug toxicology test analyzed by the local laboratory and/or
- Point-of-care-testing (POCT), such as urine dipstick testing, processed on site, if immediate results are required. Best used to verify substance use if in doubt or concerned by patient's report or presentation (confirm if this is available at facility)

Sample buprenorphine dosing for clinic induction:
Patients who are determined to be in at least mild opioid withdrawal and who do not have signs of intoxication from other substances should receive the following:

- For patients exhibiting **mild** withdrawal, give buprenorphine 2-4 mg sublingually (SL)
- For patients exhibiting **moderate** to **severe** withdrawal, give buprenorphine 4 mg SL. The sublingual tablet must dissolve completely under a moist tongue, which may take 5-10 minutes. Most patients experience relief of withdrawal symptoms or reduction in cravings within the first 15-20 minutes after taking the tablet (or film)

Re-evaluate patient after 30-60 minutes.

If there is no change in symptoms (no worsening), or symptoms are somewhat improved, an additional dose of buprenorphine 2-4 mg SL may be given. Reassess the patient again in 30-60 minutes for symptom relief. This process of providing an additional dose and reassessment may occur again, or the patient may be provided with two additional 4 mg take-home doses should withdrawal or marked craving recur in the evening. The total amount of buprenorphine provided on the first day of dosing is usually no more than 8mg.

A sudden exacerbation of opioid withdrawal symptoms after administering buprenorphine usually indicates the continued presence of other (full agonist) opioids. This is precipitated withdrawal, in that the buprenorphine displaces the agonist from the opioid receptor and precipitates withdrawal. If this occurs, discuss it with the patient and review the time of last opioid use. Give other medications (comfort medications) at the clinic for symptom management and instruct to return the following day for reevaluation.

Patients should return to clinic in the next 1-2 days for re-evaluation and upward dose titration. Some patients can be given a week's worth of medication on the day of induction and are able to be re-evaluated over the telephone during the first week of induction.

Sample Buprenorphine dosing for Home Induction:

Patients who are determined to be in at least mild opioid withdrawal and who do not have signs of intoxication from other substances should receive the following:

Day 1

- Start with 4mg dose if using SL film place ½ film under tongue, let complete dissolve which may take 5-10 minutes
- Most patients experience relief of withdrawal symptoms or reduction in cravings within the first 15-20 minutes after taking the tablet (or film).

If there is no change in symptoms (no worsening), or symptoms are somewhat improved, an additional dose of buprenorphine 4 mg SL may be given after an hour. The total amount of buprenorphine provided on the first day of dosing is usually no more than 8mg.

Day 2 up to Day 7

- Start with the total dose taken the day previously all at once in the morning
- May need to increase dose up to 16mg/day if symptoms of withdrawal continue

Patient should check-in with a trained clinic nurse or healthcare provider daily or as needed while titrating dose at home.

Counseling: Legislation mandates that all providers have *the ability to* refer buprenorphine-treated patients to further counseling. Adjunctive counseling that may be needed for induction includes:

- Counseling about use of opioids and/or other drugs of abuse
- Counseling targeting comorbid psychiatric conditions (e.g.: depression, PTSD)
- Intensive outpatient treatments
- Referrals to residential treatment programs and peer recovery support

Sample Naltrexone Treatment Plan

Checklist prior to Naltrexone Initiation

- Patient Treatment Information reviewed with patient verbally, in writing or both.
- Reinforce to the patient the need for frequent appointment adherence and confirm that this is realistic and manageable.
- Discuss counseling services that are available and expectations of the patient and provider.
- Review UDS, pregnancy test, and confirm that transaminases are < 5x normal and there is no sign of decompensated cirrhosis
- Detoxification from opioids should be completed prior to the administration of naltrexone to prevent precipitated or spontaneous withdrawal. The patient should be off short-acting opioids 5-7 days. If taking long-acting opioids such as methadone or buprenorphine, the patient should be off for at least 7-10 days.
- Detoxification from alcohol should occur prior to naltrexone initiation if a patient has a history of alcohol-related seizures, DTs, presence of moderate-severe withdrawal signs or symptoms, or as otherwise clinically indicated.
- Release of information (ROI) on file and documents related to recent past treatment in detox, Opioid Treatment Program (i.e., methadone program), or other treatment facility or office-based treatment reviewed.
- Medication education with focus on adverse effects such as injection site reactions and vulnerability to opioid overdose
- Patient is given information on f/u plan, clinic contact info, on what to do in case of questions after hours.
- Consider low dose oral naltrexone challenge for at risk patients whom you suspect may not have disclosed recent opioid use to avoid precipitated withdrawal

Naltrexone Maintenance

- Once stable, clinic visits required every 4 weeks if on Vivitrol (IM depot naltrexone) or earlier for supportive therapy.
- Refer to pharmacy for on-going maintenance therapy.
- Goal: Clinic visits every 28 days, occurring on the date of the patient's extended-release naltrexone injection.

Medications in Support of Recovery Treatment Agreement and Informed Consent

My Indian Health Service provider, _____, has prescribed _____ to treat my Opioid Use Disorder. This agreement is to outline our understanding of our roles and responsibilities regarding this treatment plan.

We here at [Insert I/T/U facility] are making a commitment to work with you in your efforts to engage in treatment, recovery and overall wellness. To help you in this work, we agree:

1. We will treat you with courtesy and respect. This includes making sure we discuss all medication concerns in private. We do not give out information about your medication without consent.
2. We will work with you to create a treatment plan that includes coordination with other service providers as well as regular appointments for follow-up visits for general wellness or special conditions.
3. We will take the time to make sure you understand how to safely take your medication.
4. We will make sure that this treatment is as safe as possible. We will check regularly to make sure you are not having bad side effects.
5. You will get clear instructions about how to contact your primary care team to discuss side effects, dosage change, or to report other prescriptions.
6. If we stop these medications because you have not followed this agreement we will:
    a. Explain to you why your medications are being stopped
    b. Continue to treat you and help you with your chronic condition in other ways.
    c. Treat you with the best medications in an emergency or for another problem.

I understand that:

____ (If take-home doses are prescribed) **I agree not to sell, share, or give my medication to another person.** Selling/sharing/ or giving my medications with others will result in immediate termination of my medications.

____(If take-home doses are prescribed) **I agree to comply with required film/pill counts and urine drug screens the day I am called, and to notify The XXXX immediately in case of lost, stolen or damaged medication.** Refills will not be prescribed earlier than scheduled. I will promptly report and bring in the pill bottle of any prescribed opioid and will dispose any unused medication.

_____I will comply with Urine Drug Testing. Refusing or tampering with a urine drug screen will result in discharge from treatment.

____ **I will keep XXXX informed of my current phone number** and notify my provider of any plan to be out of town.

____ **I agree to safely manage my prescriptions.** It is recommended I use a locked safe. Buprenorphine can cause death to children, other adults, or pets. I will call the poison control center or 911 immediately if anyone besides me takes the medication. I will report stolen medication to the police and bring in a police report. However, stolen medication will not be replaced.

____ **I agree to take my medications only as prescribed.** I will not adjust the dose on my own.

____ **I agree to discuss with my physician my prescribed medications including benzodiazepines (such as Valium, Klonopin, Ativan or Xanax), stimulants (such as Ritalin, Concerta, Adderall or Vyvanse) or other opioids. I may be asked to reduce or discontinue these medications.** Mixing buprenorphine with

some of the drugs listed above or with alcohol can be life threatening.

____ I agree to notify the clinic immediately in case of return to drug use, which can be life threatening. I will notify my doctor or counselor before any urine test shows drug use

___I agree to attend treatment sessions, complete assignments and show progress towards goals I will follow recommendations from my treatment team that will assist in my recovery.

My initials and signature below show that I have reviewed the following documents with staff, asked questions, and had my questions explained to me in terms I understand.

_____ The purpose, side effects, and risks and benefits of buprenorphine.
_____ My responsibilities while a client of medication-assisted treatment

By signing this Medications in Support of Recovery Treatment Agreement, I agree to abide by the terms of the agreement.

_____ _____ _____

Patient signature *Provider/Case Manager signature* *Date*

Return signed Agreement and Informed Consent to HIM