TREATMENT POLICY 04

SUBJECT: **Off-Site Dosing and Extranet Use Requirements for Opioid Treatment Programs**

ISSUED: September 1, 2004, revised March 1, 2006, revised November 13, 2006, revised October 1, 2024

EFFECTIVE: February 1, 2025

PURPOSE:
The purpose of this policy is to clarify the rules and procedures pertaining to off-site dosing of medication for opioid use disorders (MOUD), and guidance on using the Substance Abuse and Mental Health Services Administration (SAMHSA) Extranet site for submission of all exception requests.

SCOPE:
This policy pertains to:

1. The allowance of take-home doses for patients receiving MOUD for opioid use disorder (OUD) within an Opioid Treatment Program (OTP) based on patient-centered care, progress in treatment/recovery, and assessment by the practitioner and OTP care team.
2. The application of the six considerations identified in 42 CFR Part 8 (2024) as they apply to take-home doses.
3. The required use of the SAMHSA extranet system for off-site dosing as it applies to patients who are receiving MOUD for an OUD in an OTP in Michigan, regardless of the funding source.

Due to the complexities of off-site usage, the circumstances of the individual patient, and the variety of rules and regulations involved, in situations where there is a conflict between state and federal rules not otherwise addressed in this policy, the most stringent rule applies.

BACKGROUND:
The use of Food and Drug Administration (FDA) approved medications (methadone, buprenorphine, and naltrexone) in the treatment of OUD through an OTP is highly regulated. Patients must initially attend the OTP frequently for induction, dose modification, on-site monitoring and supervised dispensing of their medication until they achieve stability in their dose, have worked with practitioners and counselors to develop a care plan specifically targeted to their needs, and have demonstrated the capacity to manage medication take-homes in a manner that is safe to themselves, persons in their immediate circle, and the community. The prevention of medication diversion is an additional safety consideration related to take-home medication.

Previously, patients needed to meet specified criteria before off site was allowed. Prior to revisions to 42 CFR Part 8 (2024) qualifications for off-site dosing included:

- Time in treatment,
- Periods of sustained abstinence from illicit substance use,
- Conduct and comportment within the OTP, and
- Required attendance at key treatment functions.

However, experience, research, and challenges with access to and retention in OUD treatment have shown the need to revise the standards. Greater importance has been placed on an individualized pace, patient engagement, personalized accomplishments, and individual and community safety. This allows for greater flexibility in creating plans of care that promote individualized treatment goals and recovery activities such as employment or education, while also eliminating the stigma and barrier of frequent OTP visits for individuals.

DEFINITIONS:

Comprehensive Treatment: treatment that includes the continued use of MOUD provided in conjunction with an individualized range of appropriate harm reduction, (OUD) medical (with other medical issues outside the scope of OTP medical responsibilities being referred to other providers), therapeutic services, and recovery support services.

Medication Assisted Treatment (MAT): this term is being phased out in favor of MOUD. Historically it has been used to identify services that include the use of medications in combination with counseling and behavioral therapies for the treatment of substance use disorders.

Medications for Opioid Use Disorders (MOUD): The use of FDA-approved medications as the treatment for people diagnosed with opioid use disorder.

Opioid Treatment Program: a program engaged in opioid use disorder treatment with the use of medication, medical and rehabilitative services. Only OTPs can use opioid agonist medications, are also able to use other MOUDs, and are expected to offer adequate medical, therapeutic, vocational, educational and other assessment, and treatment services either onsite or by referral to an outside agency or practitioner.

Care Plan: a plan of service for individualized treatment and recovery that outlines attainable treatment goals that have been identified and agreed upon between the patient and the OTP clinical team, and which specifies the services to be provided, as well as the proposed frequency and schedule for their provision.

Treatment/Recovery Plan: (New direction in federal regulations for OTPs has transitioned to the use of “Care Plan” and away from treatment or recovery plan. As a result, that language will be used within this policy and definitions for all are provided.)

direct and active client involvement in establishing the goals and expectations for treatment and recovery, and what barriers need to be removed, or problems resolved to help a person achieve their goals. Treatment/Recovery planning requires an understanding that each person is unique, and each treatment/recovery plan must be developed based on the individual needs, goals, desires, and strengths of each client and be specific to the diagnostic impression and assessment.

REQUIREMENTS:
All Opioid Treatment Programs are required to be:

- Licensed by the Department of Licensing and Regulatory Affairs.
- Registered with the Drug Enforcement Administration.
- Accredited by a SAMHSA approved accrediting body.
- Certified by SAMHSA (having been approved by the State Opioid Treatment Authority).

Certification requests are submitted through the SAMHSA Extranet System, and all OTP's must register with this system.

OTP program physicians/practitioners and other designated OTP staff must assess a patient's readiness for managing off-site dosing as it relates to their personal safety, their Care Plan, potential risk, and the protection of the community and safety of public health prior to granting off-site doses of medication. An individual's participation and progress towards personally identified treatment goals, personal circumstances, as well as emergency/intervening events or incidents, or physical/medical issues are used to evaluate and determine the number of MOUD doses allowed off site. Exceptions to these rules are allowed and must be submitted within the Extranet system for review and approval prior to dispensing medication for off-site dosing.

"Failure to submit the Form SMA-168 exception request and obtain approval from the State Opioid Treatment Authority and SAMHSA prior to providing care that deviates from the federal opioid treatment standards constitutes a serious regulatory violation. This type of violation may threaten an OTP's accreditation and certification and bring it out of compliance with state and federal regulations," (Opioid Treatment Exception Request). If a program is unsure if the care it intends to provide for a patient is in compliance, then the program should submit a Form SMA-168 exception request through the SAMHSA OTP Extranet site (OTP Extranet - Login)

Off-Site Dosing
Any patient in comprehensive treatment may receive their individualized take-home doses as ordered for days that the clinic is closed for business, including one weekend day (e.g., Sunday) and State and Federal holidays, no matter their length of time in treatment. OTP decisions on dispensing MOUD to patients for unsupervised use beyond approved OTP closures must be determined by an appropriately licensed OTP medical practitioner or the medical director. To determine which patients may receive

unsupervised medication doses the medical director or program medical practitioner must consider whether the therapeutic benefits of unsupervised doses outweigh the risks using the following criteria:

1. Absence of active substance use disorders, other physical or behavioral health conditions that increase the risk of patient harm as it relates to the potential for overdose, or the ability to function safely.
2. Regularity of attendance for supervised medication administration.
3. Absence of serious behavioral problems that endanger the patient, the public or others.
4. Absence of known recent diversion activity.
5. Ability to safely transport and store take-home medications.
6. Any other criteria that the medical director or medical practitioner considers relevant to the patient's safety and the public's health.

Dispensing restrictions *(do not apply to buprenorphine and buprenorphine products)*

- During **the first 14 days** of treatment, the take-home supply is limited to 7 days. It remains within the OTP practitioner's discretion to determine the number of take-home doses up to 7 days, but decisions must be based on the take home criteria. The rationale underlying the decision to provide unsupervised doses of methadone must be documented in the patient's clinical record.
- **After 15 days** of treatment, the take-home supply is limited to 14 days. It remains within the OTP practitioner's discretion to determine the number of take-home doses up to 14 days, but this determination must be based on the take home criteria. The rationale underlying the decision to provide unsupervised doses of methadone must be documented in the patient's clinical record.
- **After 31 days** of treatment, the take-home supply provided to a patient is not to exceed 28 days. It remains within the OTP practitioner's discretion to determine the number of take-home doses up to 28 days, but this determination must be based on the take home criteria. The rationale underlying the decision to provide unsupervised doses of methadone must be documented in the patient's clinical record.

Documentation of the patient's ability to manage off-site dosing, and the dosing schedule must be documented in the patient's medical record and addressed in the care plan. Dosage adjustments, additional counseling sessions, specialized treatment groups, or assessment for another level of care must be considered as part of an assistive and collaborative patient-staff relationship, not for the utilization of punitive sanctions.

Diversion of take-home medications:
OTPs must maintain current procedures adequate to identify the theft or diversion of take-home medications, including labeling containers with the OTP's name, address, and telephone number. Programs also must ensure that each individual take-home dose is packaged in a manner that is designed to reduce the risk of accidental

ingestion, including child-proof containers (Poison Prevention Packaging Act, Pub. L. 91-601 (15 U.S.C. 1471 et seq.)). Programs must provide education to each patient on:

- Safely transporting medication from the OTP to their place of residence.
- Safe storage of take-home doses at the individual's place of residence, including child and household safety precautions.

The provision of this education should be documented in the patient's clinical record. The patient's off-site dosing schedule is to be reviewed in conjunction with their individualized care plan every ninety days while the client receives doses for off-site use.

This requirement does not preclude distribution of legal harm reduction supplies that allow an individual to test their personal drug supply for adulteration with substances that increase the risk of overdose.

Product Preparation:

Methadone for off-site dosing must be dispensed in a liquid, oral form and formulated in such a way to minimize use by injection. The methadone must contain a preservative, so refrigeration is not required.

Methadone must be dispensed in disposable, single use bottles, and must be packaged in childproof containers pursuant to section 3 of the Poison Prevention Packaging Act, 15 USC Part 1471. In cases when clients take medication twice daily (split dosing), two separate childproof containers must be utilized. These efforts will help minimize the likelihood of accidental ingestion by children.

Buprenorphine/naloxone must be packaged in childproof manner/containers and labeled similar to methadone.

Vivitrol for the treatment of MOUD is an extended-release injectable formulation of Naltrexone, administered as an intramuscular gluteal injection once a month. Injectable naltrexone is administered only by a medical professional (e.g., physician, nurse, physician assistant, etc.) who can administer IM (gluteal) injections. Injectable naltrexone comes in a kit that contains a vial of naltrexone as a dry powder that must be reconstituted with a liquid diluent immediately before use. All preparation is conducted by the practitioner administering the medication. Additional information regarding the use of Naltrexone as an MOUD can be found on SAMHS's website. Because the dosing process for this medication and the fact that no additional doses leave the practitioners office there are no requirements for childproof packaging

Medication for Off-Site Administration must be labeled as follows:

- Name of the medication.
- The strength of the medication.
- The quantity dispensed.

- The OTP's name, address, and phone number.
- Patient's name or code number.
- Medical director's/prescriber's name.
- Directions for use.
- The date dispensed and the date to be used.
- A cautionary statement that the medication should be kept out of the reach of children.
- Statement that this medication is only intended for the person to whom it was prescribed.

If it is determined that the patient is not able to be responsible for doses, other arrangements must be made for them to be dosed on site at their current OTP or at another OTP. If a patient needs to go to another program to be dosed, coordination between both programs is required to ensure the patient is only dosing at one OTP for days when the patient's OTP of record is closed.

The Use of Toxicology Testing/Drug screening Services

Toxicology Testing/Drug screening Services is a clinical tool that is used to inform the treatment process and must be conducted in a way that is respectful of the individual and in accordance with clinical and professional standards. Results of these screenings must never be used punitively. Drug testing is one of the 'tools' used in the determination of take-home allowances for individuals receiving MOUD for OUD. Urine-saliva toxicology screens require the following:

- OTPs must use drug tests that have received the FDA's marketing authorization for commonly used and misused substances that may impact patient safety, recovery, or otherwise complicate substance use disorder treatment. The requirement to use drug tests that have received the FDA's marketing authorization is limited to random drug testing using samples obtained from patients, including urine or saliva.
- Drug testing must occur at a frequency that is in accordance with generally accepted clinical practice and as indicated by a patient's response to and stability in treatment, but no fewer than eight random drug tests per year per patient, allowing for extenuating circumstances at the individual patient level.

When conducting toxicology testing/drug screen services for the presence/absence of current or recent drugs used, a testing panel that includes the following must be used: alcohol (due to toxicity of mixing alcohol and methadone), methadone, methadone metabolites, buprenorphine, buprenorphine metabolite (or norbuprenorphine), opioids including fentanyl, amphetamines (including methamphetamine), cocaine, cannabinoids/THC, benzodiazepines, and any other drugs as appropriate for individual patients and regional prevalence, such as xylazine. Furthermore, specimens obtained for toxicology screens/drug screen services collected at the OTP must be processed by a certified lab. Tests that allow for in-house reading are not acceptable for this process.

If alcohol is suspected at the time of dosing, testing must be conducted by the use of a Breathalyzer or other standard testing means.

Patients who appear to be under the influence of any drug or alcohol must not be dosed until safe to do so. Patients should not be allowed to drive under this condition. Positive testing incidents for alcohol/marijuana/any illicit substance, this includes prescription medications for which there is no prescription, must be addressed in the patient's care plan.

The need to verify toxicology tests or the need for more frequent toxicology tests must be a clinical decision made by the care team, with final approval by the medical director, if they are not the practitioner involved with the care team and noted in the patient chart. Legally prescribed medications that have been verified, including controlled substances, and marijuana with a Michigan Medical Marijuana Card (MMMC) in the patient's name (citing the prescriber, the medical purpose for the card, and the date of expiration), are not considered illicit substances. The OTP verification can also include a copy of the prescription label, a printout from the pharmacy, or the information recorded in the chart from viewing the patient's prescription bottle. The date and source of verification must be documented in the patient chart and initialed by the staff person responsible for obtaining the verification. The OTP is also responsible for checking the Michigan Automated Prescription System (MAPS) for additional or unreported prescriptions. Prescription medication documentation must be updated in the patient's chart at the first opportunity after patient receives renewal of, or a new prescription. The use of alcohol or other contraindicated medication in association with the prescribed MOUD requires review by the practitioner. All medications are to be considered within the context of coordinating care with other prescribing healthcare providers, and the safety considerations of granting off-site dosing privileges.

<u>Marijuana Use While Participating in MOUD for OUD</u>
Current Regulatory and Informed Status Pertaining to Marijuana:

- DEA Scheduling - examples of Schedule I drugs are: heroin, Lysergic acid diethylamide (LSD), marijuana, etc. (The DEA considers marijuana a controlled substance and follows the federal position that its use is illegal)
- FDA Recommendation: FDA has determined that cannabis has a legitimate medical use and should be moved from Schedule I to Schedule III
- MCL-Section 333.7212 – Michigan legislature (2) Marihuana, including pharmaceutical grade cannabis, is a schedule 2 controlled substance if it is manufactured, obtained, stored, dispensed, possessed, grown, or disposed of in compliance with this act and as authorized by federal authority.
- Pharmacist.com – Cannabis, which contains tetrahydrocannabinol (THC) and CBD, has been investigated in the treatment of multiple disease states, yet federally, remains a Schedule I drug and is therefore considered to be a "drug with no current acceptable medical use." November 7, 2023

- In Michigan, marijuana use is legal for persons aged 21 and older, however can still significantly impact an individual's recovery and the safety and efficacy of their MOUD treatment. Things that must be considered when assessing marijuana use and/or positive toxicology screens/drug screens include, but are not limited to:

1. The four bulleted regulatory and informed status items pertaining to marijuana.
2. The results of toxicology screening/drug screening services showing positive for THC.
3. Whether the patient has a current, valid MMMC prescribed for medical reasons by a physician.
4. The impact of continued use of a scheduled, mood alerting substance on a patient's physiological and psychological recovery.
5. SAMHSA Grant Funds Marijuana Restrictions - SAMHSA grant funds may not be used to purchase, prescribe, or provide marijuana or treatment using marijuana. See, e.g., 45 CFR § 75.300(a) (requiring HHS to ensure that Federal funding is expended in full accordance with U.S. statutory and public policy requirements); 21 U.S.C. 812(c)(10) and 841 (prohibiting the possession, manufacture, sale, purchase or distribution of marijuana).

Additional guidance on the take-home criteria is available in the Federal Guidelines for Opioid Treatment Programs.

Patients must receive a copy of the clinic's rules pertaining to responsible handling of off-site doses and the reasons for revoking them. Clinic rules must include criteria for off-site dosing. A form signed by the client acknowledging receipt of this information must be included in the client file.

Exception Requests for Off-Site Dosing

Programs must submit an exception request for approval of any deviation from the federal opioid treatment standards in 42 CFR Part 8. There are numerous circumstances for which an exception request is required for off-site dosing. Exception Request Justifications Identified on the Extranet Form (SMA-168) include: Family Emergency, Incarceration, Funeral, Vacation, Transportation Hardship, Step/Level Change, Employment, Medical, Long-Term Care Facility, Other Residential Treatment, Homebound, Split Dose, Weather Crisis.

When submitting a request through the Extranet:

1. The SMA-168 form must be completed in its entirety – all information requested must be filled in.
2. A justification offered on the form must be identified/selected.
3. If selecting "Other" as the justification, the explanation must detail what "Other" is referencing.

4. Optional justifications for the exception request or potential reasons for the selection of “Other” may be identified on the list of Temporary Off-Site Dosing offered below but are not limited to these examples and the list below.

Temporary Off-Site Dosing

Special circumstances such as a patient’s physical/medical needs or other exceptional/exigent circumstances, situations in which a program is closed such as Sundays and Holidays, or emergency situations may result in cases when the client is allowed to dose off site for a limited time. Temporary Off-Site Dosing needs may encompass the following areas:

1. Physical/Medical necessity
   If a patient’s practitioner provides written documentation that reduced attendance at the clinic is necessary due to physical/medical necessity of the patient and the OTP practitioner concurs, off-site dosing is allowed without prior MDHHS/SOTA approval within CSAT/DPT guidelines.

   The written documentation from the patient’s practitioner must include a medical diagnosis and whether the condition is permanent or temporary. If the condition is temporary, the date the patient can return to their usual clinic attendance must be indicated. Whenever possible, the patient’s personal physician and the OTP practitioner should coordinate care including the prescribing of medication that interacts with the various MOUDs.

   Temporary exceptions need to be reviewed and reissued if the exception is needed beyond the initial time frame. All exceptions must be reviewed during the required 90-day OTP physician’s review. All documentation must be maintained in the patient’s chart.

2. Exceptional/Exigent Circumstances:
   MOUD for off-site dosing may be given to a patient who has an exceptional/exigent circumstance as indicated in this section and who, in the reasonable clinical judgment of the program practitioner, is responsible in the handling of MOUD. The exceptional/exigent circumstance must be clearly documented, and any supportive documentation should be included in the patient’s chart. Some examples of exceptional/exigent circumstances may include employment schedule conflicts; educational training schedule conflicts; medical or mental health appointment conflicts; appointments with other agencies relative to the client’s treatment goals.

   Travel hardship is another example - (at least 60 miles or 60 minutes one way from an OTP). The actual mileage must be documented in the patient’s chart with the city of origin listed.

3. Emergency Situations
   OTPs must have written plans and procedures which include how dosing patients on-site, as well as dispensing doses for off-site use, will be accomplished in emergency situations. Emergency situations include power failures, software failures, natural disasters, and other situations in which the OTP cannot operate as usual. This plan must also include how the security of the medication and patient records will be maintained.

Additional Issues that Require Off-Site Dosing

- Infectious disease and associated issues
  - Third party pick-up
  - Quarantine/Recovery Take Homes
  - Curbside dosing
  - Home Delivery – following limited exposure guidelines
- OTP Closure due to
  - Additional days of closure in extension to allowed federal/state approved holidays
  - OTP facility emergencies, i.e., damage to the physical structure, flood, fire, storm, etc
  - Facility restoration, operations, repair, or general maintenance
  - Weather conditions (forecasted) posing safety concerns – when requesting closure for weather conditions OTPs must:
    - Request closure in advance of weather event.
    - Indicate the type of anticipated weather (heavy snow, freezing rain, frigid temperatures) and include clip/screenshot of official weather alert/warning.
  - Power failures
  - Natural disasters
  - Other

Provider delivered or third-party delivery of medication doses for patients under the following circumstances:

- Physical/Medical Necessity
- Home-bound
- Short/Long term rehabilitation
- Residential treatment
- Incarcerated/within Carceral facilities
- Exceptional/exigent circumstances for patients not eligible for take-homes or the number needed for the circumstance, such as:
  - Funeral
  - Employment schedule conflicts/work mandate
  - Educational training schedule conflicts
  - Medical/mental health appointments/procedures
  - Legal issues/court appearances, etc

- Appointments with other agencies relative to the patient's treatment goals

Split Dosing - The final rule does not specify requirements of any additional testing or documentation beyond that of routine clinical practice, which includes, but are not limited to:

- Confirmed Pregnancy
- EKG to assess Long QT Syndrome
- Peak and Trough to assess rapid metabolization
- Other (please specify)

The use of clinical verification is applied as indicated by the needs of the patient.

Requirement pertaining to 'third party pick-up':
The medical director (with input from the care team if desired) must determine if the identified 3rd party is appropriate to handle the medication on behalf of the patient. Appropriate discretion must be used by the medical director or designated practitioner in making this determination. There are no specific prerequisites or disqualifiers related to the third-party designee. The medical director/practitioner approval of the designee must be identified on the exception request.

For those who are considered appropriate for off-site dosing, the OTP does not need to submit an exception request for the following circumstances:

- Approval of standard take-homes.
- Increase in step levels of standard take-homes provided they follow 42 CFR Part 8.
- Reduction of standard take-homes.
- Recission of previously granted standard take-homes.
- Modification of onsite dosing days/pick-up days.
- One time addition to the number of take-homes (not to exceed the maximum number allowed [28 days] by 42 CFR Part 8.
- Continuation of split dosing beyond the initially requested period if same medical conditions exist.
- Vacation – up to 14 days without submitting exception with practitioner approval.
- Funeral
- Employment schedule conflicts
- Educational/work training schedule conflicts
- Medical or mental health appointment conflicts
- Court required attendance
- Appointments with other agencies relative to the patient's treatment goals/care plan.

Those not appropriate for off-site dosing will need an exception request submitted.

Important note: within the patient file there must be an explanation of why the patient has been given the number of take-home doses allowed by the schedule identified in 42 CFR Part 8. The note must be clear and thorough and align with one or more of the six

criteria identified 42 CFR Part 8 (i)(2). The criteria can be found on page 4 of this document.

How to Submit an Exception Request

Utilizing SAMHSA OTP Extranet website, exception requests must be made by using electronic Form SMA-168: Exception Request and Record of Justification. All submissions are reviewed by both the State Opioid Treatment Authority and SAMHSA. All OTPs have an account on the SAMHSA OTP Extranet website. Exceptions can only be submitted by an OTP's qualifying practitioner(s) who have submitting and approval authority.

Security

The patient is expected to secure all take home medication in a locked box prior to leaving the OTP. It is expected that the patient stores this box in a manner that will prevent the key or combination from being readily available to children or others who could be harmed from accidental use and to prevent diversion to or by third parties. Clients should be able to explain the process that will be used to secure the medications that are taken home when asked by an OTP staff member. This process should be recorded in the client's record and updated when the client's take home status is reviewed every ninety days. Empty bottles are to be returned to the OTP in the locked box for proper disposal. Patients with unused or missed doses should be advised on proper disposal methods of the excess medication. Failure to do so could result in revocation of take-home privileges. Results of the clinical review process for take-homes must be recorded in the patient's chart.

Allowable Program Closures

The SMA-168 request must be submitted for each individual OTP.

- Sunday
  - OTPs may be closed on Sundays without prior approval from MDHHS/SOTA.
- Holiday Observances
  - OTPs may be closed for the following holidays without prior MDHHS/SOTA approval. No additional days may be added to the identified holiday date without prior approval. Should the holiday fall on a Sunday, OTPs may be closed the following Monday without prior MDHHS/SOTA approval.
    - New Year's Day
    - Martin Luther King, Jr. Birthday
    - Presidents' Day
    - Memorial Day
    - Juneteenth
    - Independence Day
    - Labor Day
    - Veteran's Day

- Thanksgiving Day
- Christmas Day

Any patient in comprehensive - treatment that includes the continued use of MOUD provided in conjunction with an individualized range of appropriate harm reduction, (OUD) medical (with other medical issues outside the scope of OTP medical responsibilities being referred to other providers), therapeutic services, and recovery support services - may receive their individualized take-home doses as ordered for days that the clinic is closed for business, including one weekend day (e.g., Sunday) and State and Federal holidays, no matter their length of time in treatment.

A day in which the OTP has abbreviated hours in which MOUD will be dispensed to patients not eligible for or not stable for take-homes will not be considered as a program closure.

PROCEDURE:
MDHHS/SOTA Approval Required is required for any patient taking medication out of the country must have MDHHS/SOTA approval. Note: medication transported out of the country is subject to that country's jurisdiction and it is the responsibility of the patient to research and abide by the country's rule.

Submission Of Exception Requests:
For all exception requests, OTPs must access the SAMHSA Extranet system and use form SMA-168 to identify and submit the request(s).

Delivery of MOUD to a Patient by a Third Party
A "MDHHS/OTP Delivery of MOUD to a Patient by a Third Party" form must be completed for each requested episode of a third-party pick-up/delivery and maintained at the program. A copy of the form signed by the person receiving the MOUD must be returned to the program so that the chain of custody can be documented before another supply is issued. A maximum of 14 doses at a time may be delivered to/for a patient for self-administration. The MOUD must be secured in a locked box before leaving the OTP. Empty bottles are to be returned to the OTP in the locked box for proper disposal. Patients with unused or missed doses should be advised on proper disposal methods of the excess medication. The third-party pick-up form/Chain of Custody Form can be found on the MDHHS/SUGE (Substance Abuse, Gambling and Epidemiology Section) website. MDHHS-6187.dotx (https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.michigan.gov%2Fmdhhs%2F-%2Fmedia%2FProject%2FWebsites%2Fmdhhs%2FKeeping-Michigan-Healthy%2FBH-DD%2FRecovery-and-Substance-Use%2FMDHHS-6187.dotx%3Frev%3D487a7115621b4a5ea50ccc25267ad95c%26hash%3D7719CE5A0BD2C136A4E06E6F4C5B86DB&wdOrigin=BROWSELINK)

Delivery of MOUD to Another Facility

A "MDHHS/OTP Delivery of MOUD to Another Facility Form" (MDHHS-6188.dotx https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.michigan.gov%2Fmdhhs%2F-%2Fmedia%2FProject%2FWebsites%2Fmdhhs%2FKeeping-Michigan-Healthy%2FBH-DD%2FRecovery-and-Substance-Use%2FMDHHS-6188.dotx%3Frev%3D9f6e7d3e44934e68ac173560a618269e%26hash%3DAF671B8484E23FB3AD06417258B1399A&wdOrigin=BROWSELINK) must be completed for each requested episode of a third-party pick-up/delivery and maintained at the program. A copy of the form signed by the person receiving the MOUD must be returned to the program so that the chain of custody can be documented before another supply is issued. A staff member of the facility (extended care, residential, carceral, etc.) in which the client is housed may obtain a maximum of seven doses at a time within a jail/carceral setting, and a maximum of 14 doses at a time may be delivered to/for a patient in a residential treatment or long-term care facility. The facility will transport or receive from transport, secure, and administer the MOUD, as well as dispose of empty and missed dose bottles following medication disposal guidelines, according to that facility's protocols for the use of medications that are controlled substances. Any unused doses remaining at the time of the patient's release/departure/discharge are the property of the patient and must be given to them when leaving as with all personal property.

Remaining doses of an individual's prescribed medication cannot be kept/retained by the temporary attending facility, regardless of the type of facility – including jail/carceral facilities. The OTP is not able to supply additional doses until the full time period covered by the delivered doses has elapsed. Please see references for additional information related to the issue.

Violating rules related to the release of personal prescriptions to inmates can lead to several consequences:

1. **Legal Action**: The jail or its staff could face lawsuits for failing to provide necessary medication, potentially resulting in fines or other legal penalties.
2. **Regulatory Penalties**: Regulatory bodies may impose fines or other sanctions on the facility for non-compliance with health and safety regulations.
3. **Reputational Damage**: The facility could suffer reputational harm, affecting its relationship with the community and other stakeholders.
4. **Internal Disciplinary Actions**: Staff members involved in the violation could face disciplinary actions, including suspension or termination.

These consequences aim to ensure that inmates receive the care they need and that facilities adhere to legal and ethical standards.

Monitoring For Compliance

Site visits/compliance reviews of OTPs by MDHHS and PIHPs will include a review of documentation verifying that patient assessment for off-site dosing complies with 42 CFR Part 8 criteria and practitioner risk assessment. Alteration or recension of off-site dosing privileges will be reviewed/reconsidered, when the patient has not maintained

alignment with the criteria to have off-site dosing or has not continued to display progress in their recovery or demonstrate responsibility and safety for continued off-site dosing. OTPs must have a system to readily identify those patient's issued doses for off-site use.

REFERENCES:

Certification of Opioid Treatment Programs: United States Code of Federal Regulations, Title 42, Part 8, Washington, D.C.
https://federalregister.gov/d/2024-01693

Division of Pharmacologic Therapies. (2002). *Patient Exceptions SMA-168-Exception Request and Record of Justification under 42 CFR § 8.12.* Retrieved from the Substance Abuse and Mental Health Services Administration website at https://www.samhsa.gov/medications-substance-use-disorders/otp-resources/submit-exception-request

Drug Enforcement Agency Education Requirements for the Prescribing of Buprenorphine. American Society of Addiction Medicine DEA Education Requirements https://www.asam.org/education/dea-education-requirements

Labeling and Dispensing of Prescription Medication. *Public Health Code:* 1978 Public Act 369, as amended, Article 6. MCL 333.17745, Michigan Legislature, 1977-78 Legislative Session, Lansing, Michigan. (September 30, 1978).
http://www.legislature.mi.gov/mileg.aspx?page=getObject&objectName=mcl-333-17745

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Resources:
Rights for Individuals who are Incarcerated: A Federal Court Ruling May Nudge More Jails And Prisons To Offer Addiction Meds: Shots - Health News: NPR

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