NEW YORK STATE | Office of Addiction Services and Supports

OASAS. Every Step of the Way.

GUIDELINES FOR OPIOID TREATMENT PROGRAMS WORKING WITH CORRECTIONAL FACILITIES

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Contents

INTRODUCTION

Authorities such as the American Medical Association, the American Society of Addiction Medicine, and the American Academy of Addiction Psychiatry, recognize that Medication for Opioid Use Disorder (MOUD) is ***the standard of care*** for the treatment of opioid use disorder (OUD). New York State has been actively working to break down barriers and to ensure equity for marginalized populations and communities across the state. Included in those efforts is a new law (Chapter 432 of 2021) effective October 7, 2022, requiring that county and state-operated correctional facilities to ensure access to the range of U.S. Food and Drug Administration (FDA) approved medications to treat substance use disorders (SUD). These guidelines will provide information to State and Local Correctional Facilities, as well as Opioid Treatment Programs (OTPs) who are providing methadone for incarcerated individuals within correctional settings at the local and state level including: enrollment, medical information/responsibilities, transportation of medication, record keeping, and contact with patients will be covered.

Chapter 432 of the Laws of 2021 amends the corrections law and adds a new section to the mental hygiene law. Paragraph 2 of section 19.18-c of the New York State Mental Hygiene Law outlines requirements for corrections-based service provision as follows:

2. The services to be provided by such program shall be in accordance with plans developed by participating local governmental units, in collaboration with county sheriffs, taking into account local needs and available resources. These plans must be approved by the commissioner
and shall include, but not be limited to, the following:

(a) Alcohol, benzodiazepine, heroin and opioid withdrawal management;

(b) At least one formulation of every form of medication assisted treatments approved for the treatment of a substance use disorder by the Federal Food and Drug Administration necessary to ensure that each individual participating in the program receives the particular form found to be the most effective at treating and meeting their individual needs. The commissioner may allow jails a limited exemption to providing opioid full agonist treatment medications where the commissioner determines that no providers that have received the required accreditation are located within a reasonable distance of the facility. Jails that do not have the resources available to meet standards set forth herein may apply to the commissioner for a limited exception allowing such jail to enter into an agreement with a community- or jail-based program offering substance use disorder treatment and transition services to provide such services to individuals in such jails. Any such determination shall be reviewed on a regular basis;

(c) Group and individual counseling and clinical support;

(d) Peer support;

(e) Discharge planning; and

(f) Re-entry and transitional supports.

OVERVIEW OF MODEL

As opioid related overdose rates continue to rise, it is imperative that New York State provides access to critical life-saving treatment, particularly for our most vulnerable populations. Without appropriate care and services, incarcerated individuals with an opioid use disorder, may suffer severe withdrawal symptoms and illness. We also know that upon release, individuals reentering the community are at a much greater risk for overdose and death.

These are devastating but avoidable consequences for individuals entering the criminal justice system. In most cases, it is appropriate to reinitiate medication for opioid use disorder treatment if they recently ceased their treatment or to begin treatment if the individual is not currently using medication to treat their opioid use disorder.

Methadone, an FDA approved medication to treat opioid use disorder, is subject to many laws and regulatory requirements that need to be addressed for the medication to be provided to incarcerated individuals. Opioid Treatment Programs (OTPs) are regulated by the Drug Enforcement Agency (DEA), Substance Abuse and Mental Health Services Administration (SAMHSA), NYS Office of Addiction Services and Supports (OASAS), and NYS Bureau of Narcotic Enforcement (BNE). The laws and regulations are very strict and address various storage, administration, record keeping, medical, and clinical requirements.

There are several ways that incarcerated individuals may access their medication:

1. Individuals may be transported to a local OTP on a daily basis.
2. Mobile Medication Units (MMUs) can dispense the medication on-site at the correctional facility. The MMU is required to dispense directly from the vehicle to the individual. This would necessitate access to a secure area for the MMU.
3. Establishing an OTP or an Additional Medication Location for a community OTP in the correctional facility.
4. Obtaining the medication from a community OTP, transporting it to the correctional facility and providing it to the incarcerated patient.

This document focuses primarily on the fourth option outlined above – transporting medication from a community-based OTP to a Correctional Facility. To provide methadone on-site to an incarcerated individual, the Correctional Facility and the OTP must enter into an agreement with a local OTP for the OTP to provide methadone for incarcerated individuals. The OTP would issue a medication order and provide the medication to the correctional facility. OTPs are permitted, pursuant to federal rules, to provide "take home doses" for individuals who are incarcerated.

Federal Guidelines for Opioid Treatment Programs (SAMHSA, 2015)[1] govern the provision of OTP services and specifically address incarcerated individuals:

Provision of Medication to Patients Who Are Incarcerated, in Residential Treatment, Medically Compromised, or Homebound

> *During the course of medication-assisted treatment, there may be occasions when a patient is unable to report to the program for routine observed ingestion of medication. This absence may occur because of illness, pregnancy, **incarceration**, participation in residential treatment, lack of transportation, and the like. When these situations occur, continuing the patient's treatment safely while also ensuring appropriate handling and delivery of medication to the patient is a challenge for clinical staff. One solution is to use a chain-of-custody record, which is a document containing the signatures of all people who have handled the medication. This record also should contain spaces for the patient to initial each day that the medication is administered, as well as spaces for the initials of the person who administered the medication. The patient and the person administering the medication should contact the program immediately if the medication seems altered in any way.*
>
> *When the patient is unable to report to the program as required, a responsible person maintains a chain-of-custody record and takes charge of the medication, placing it under lock and key at the offsite location. The same holds true for incarceration facilities and nursing homes that do not have methadone in stock.*

The US Department of Justice, Drug Enforcement Agency, Diversion Control Division has issued guidance identifying statutory and regulatory guidance and recommended practices. The Narcotic Treatment Program (NTP) Manual[2] provides, in part:

> ***12.2 Correctional Facilities***
>
> *Staff employed by the correctional facility may take custody from the NTP of a locked container that holds patient-specific medications. The transporting staff, who should not have a key to the locked container, will deliver the medication to the facility and hand off to its nursing staff. The NTP and the facility need to implement controls to prevent diversion, including chain of custody documentation and appropriate secure storage that complies with state laws. The facility personnel who dispense or administer the medication to the inmate must fit into one of the four categories set forth in 21 CFR*

[1] Federal Guidelines for Opioid Treatment Programs (SAMHSA, 2015)
[2] DEA, Narcotic Treatment Program Regulations, Revised 2022

1301.74(i)[3]*. Each of the facility staff who transport or dispense the medication should be made an agent of the NTP through a formal written agreement.*

The OTP shall individually package and label medication doses for incarcerated patients based on a medication order issued by the medical staff at the OTP. When the OTP individually packages and labels the medication doses for incarcerated patients, this is referred to as "take home" doses. Depending on scheduling, the OTP normally would provide seven (7) days of medication for each individual. The local correctional facility shall arrange for an appropriate staff member to pick up the medication at the OTP. The OTP staff places the medication in a locked tote box. Only the OTP and the nursing staff at the local correctional facility would have the key to the tote box. The driver transporting the medication is not permitted have a key. When the medication arrives at the correctional facility, it is inventoried by the nursing staff and stored in a double locked box.

Some correctional facilities may have a NYS DOH 3a Institutional Dispenser Limited License. The correctional facility must follow all requirements for maintaining controlled substances (security, medication counts, etc.) consistent with 3a requirements. In this model, no additional license is needed by the correctional facility to provide methadone to incarcerated individuals.

Federal regulations describe the circumstances and requirements for an OTP that is working with a local correctional facility, providing, in part:

The Federal Opioid Treatment Standards - Required services

42 CFR §8.12(f) (1) General. OTPs shall provide adequate medical, counseling, vocational, educational, and other assessment and treatment services. These services must be available at the primary facility, ***except where the program sponsor has entered into a formal, documented agreement with a private or public agency, organization, practitioner, or institution to provide these services to patients enrolled in the OTP****. The program sponsor, in any event, must be able to document that these services are fully and reasonably available to patients.*

[3] 21 CFR 1301.74(i) Narcotics dispensed or administered at a narcotic treatment program will be dispensed or administered directly to the patient by either
(1) the licensed practitioner,
(2) a registered nurse under the direction of the licensed practitioner,
(3) a licensed practical nurse under the direction of the licensed practitioner, or
(4) a pharmacist under the direction of the licensed practitioner.

Pursuant to this regulation, the correctional facility is the institution that can provide services to the incarcerated patients on behalf of the OTP. An example of the formal agreement is included in the Appendix B.

Operational Considerations

Medication Orders

Pursuant to Federal rules and regulations, only a prescriber employed at a certified OTP can order methadone to treat opioid use disorder (OUD). There are limited exceptions, to be discussed later in this document. The OTP prescriber will write a medical order for the methadone for the patient. The order is sent to the correctional facility where the correctional facility's prescriber reviews the order, and then writes an order authorizing the nursing/facility staff to provide the incarcerated patient with the medication. Correctional facility staff may only provide medication consistent with the executed order of the OTP prescriber. Any changes in the dosage must be done by the OTP prescriber who will create a new medical order. The correctional facility must include copies of all methadone orders in the incarcerated individual's medical record. The OTP prescriber will consult with the correctional facility medical and nursing staff for any questions related to dosage. **The correctional facility medical and nursing staff should never alter the medication dosage independently. Any changes to medication dosing may only be issued by the appropriate OTP prescriber.**

There may be cases where an incarcerated individual is already a patient at a particular OTP but may need to obtain their medication from an alternative OTP while incarcerated. This can occur due to logistical reasons such as distance between the correctional facility and the home OTP. An OTP in greater proximity to the correctional facility may "guest dose" an incarcerated patient that is from another OTP. The originating OTP would send a copy of the medication order and other critical information to the new prescribing OTP, so that the medication can be provided to the correctional facility as "take home" doses. If a change in the dosage is indicated, the medication order change must be produced by the originating OTP.

Take Home Exception – Process for Approval

The OTP must obtain an Exception from Office of Addiction Services and Support (OASAS) to provide "take home" doses to an incarcerated individual. The OTP must submit an exception request (Form SMA-168) to SAMHSA. Instructions and the form can be found on this website:

SAMHSA Take Home Exception Requests

OASAS will be automatically notified by SAMHSA when a Take Home Exception has been submitted. OASAS will then review and approve the Exception.

Medication Preparation/Transportation

The OTP is responsible for individually packaging and appropriately labeling "take home" medication doses in child resistant packaging. The will designate correctional facility staff as agents to pick up and transport the medication. There is no requirement related to the qualifications or number of people who must pick up the medication. For example, one person is sufficient. **The OTP must execute a "Designated Agent" agreement to identify all Correctional Facility staff responsible for transporting the medication from the OTP to the correctional facility Additionally, all correctional facility staff who handle, store and deliver the medication should identified and designated.** A sample OTP Agent Designation agreement is provided in APPENDIX C]

Medication must be placed in a locked tote for transportation to the correctional facility. OTP nursing staff and the correctional facility should have the only keys to the tote. The transporting individual(s) should not have a key. The OTP staff must place signed documentation regarding the number of doses per patient in the tote, to be inventoried at the correctional facility by correctional facility staff. The OTP and the correctional facility staff shall maintain and document a detailed accounting of all medications transferred between the facilities.

Medication Storage

Methadone has specific storage requirements, per federal statute, rules and regulations. The medication must be stored in a controlled substance cabinet that is a steel constructed, stationary, locked, double cabinet (pursuant to correctional facility's NYS DOH 3a license). Both cabinets must have key-locked doors with separate keys; refrigeration is not required. An inventory of all controlled substances, including methadone (a Schedule II drug), shall be prepared and maintained in accordance with Part 80.50 (c) (1) of Title 10 of the New York Code of Rules and Regulations (NYCRR) and Section 1301.72(a) of Title 21 of the Code of Federal Regulations (CFR). APPENDIX E provides relevant excerpts of the above referenced state and federal regulations. Additionally, 10 NYCRR Part 80.50(c)(1) provides, in part:

> *(c) Working stocks of controlled substances for institutional dispensers without a registered pharmacy, treatment programs, license holders engaging in research, instructional activities, and chemical analysis shall be securely kept as follows:*
>
> > *(1) Schedule I, II, III and IV controlled substances shall be kept in stationary, locked double cabinets. Both cabinets, inner and outer, shall have key-locked doors with separate keys; spring locks or combination dial locks are not acceptable. For new construction, cabinets shall be made of steel or other approved metal.*

Providing the Medication

According to Chairman's Memorandum No. 8-98 issued by the New York State Commission on Corrections (hereinafter the Chairman's Memorandum) which is provided for references as APPENDIX H[4], there are two processes for providing medication to incarcerated patient's: "delivery" and "administration". [Note: this memo only applies to local correctional facilities. The NYS Department of Corrections and Community Supervision has its own policies regarding the matter]. They are described below.

Delivery of Medication

Pursuant to Chairman's Memorandum health care providers or correction officers may deliver medication in a correctional setting. **Delivery** means giving an individual a single unit of medication from a pharmacy/OTP-prepared and labeled container. This includes unit dose packages which are sometimes referred to as "blister packs." If prescribed liquid medication is available from the pharmacy/OTP in a single dose unit, this may be delivered by correction officers as well. A correction officer cannot dilute or mix liquid medication (e.g., mix in juice). A correction officer can only deliver medication from a pharmacy/OTP-prepared container.

Administration of Medication

Pursuant to the Chairman's Memorandum, only authorized licensed health care providers within the correctional setting can **administer** medication. Administration includes distinguishing between various types and dosages, following specific medical orders (e.g., hold medication if pulse less than 60; or give medication every four hours as necessary for pain), substituting equivalent medications, and executing a prescriber's telephone or written orders.

The delivery/administration of the medication must be documented in the medication administration record (MAR). A copy of the MAR should be sent to the OTP on a weekly basis.

APPENDIX H, Opinion of OASAS General Counsel, has been provided to address questions about the ability of nurses to administer methadone that has been poured by another nurse.

[4] New York State Commission of Corrections, Chairman's Memorandum No. 8-98, May 26, 1998. (Attachment I)

Stock Medication

Federal regulations[5] allow for the correctional facility to obtain and maintain an amount of **stock methadone** which can be used when the regular medication from the OTP has not been obtained. Examples of this could be:

- A newly incarcerated individual is determined to be taking methadone and the medication will not be immediately available (e.g., weekends when the OTP is closed).
- There is a problem (e.g., weather and travel issues) that prevent the transportation of the medication from the OTP to the correctional facility.

Stock methadone should be ordered from the pharmaceutical distributor under either the correctional facility's DEA registration or the DEA registration of an appropriate prescriber employed by the correctional facility.

Methadone may be obtained in liquid and wafer formulations. The liquid usually comes as a concentrate which needs to be diluted. Dilution may only be performed by a licensed pharmacist. For the liquid formulation, a computerized dispensing machine is usually used to pour individual doses. As it is expected that use of stock methadone would be limited to very specific instances, using wafers might be more practical. Wafers come in a variety of doses and can be combined to create the dose needed. The wafers are dropped into a liquid (e.g., orange juice) and dissolved before administering to the patient. This process can only be performed by a licensed prescriber, pharmacist, or Registered Nurse.

Stock methadone must be stored in a secure cabinet separate from other medications for incarcerated patients.

Per Federal regulations[6], an initial physical exam is required to prescribe methadone. If the medical staff is not available to conduct the physical exam, the medication cannot be ordered.

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[5] 21 CFR *§* 1306.07(b) *Nothing in this section shall prohibit a physician who is not specifically registered to conduct a narcotic treatment program from administering (but not prescribing) narcotic drugs to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment. Not more than one day's medication may be administered to the person or for the person's use at one time. Such emergency treatment may be carried out for not more than three days and may not be renewed or extended.*

[6] 42 CFR *§ 8.12 (f) (2) Initial medical examination services. OTPs shall require each patient to undergo a complete, fully documented physical evaluation by a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician before admission to the OTP. The full medical*

Please note that providing medication from stock sources can only be done by a pharmacist or nurse. Non-nursing staff cannot provide medication from stock.

Medical and nursing staff access, particularly on weekends/holidays, may limit the ability to provide medication from stock. In that case, the correctional facility could provide ancillary medication to help manage opioid withdrawal until access to methadone is arranged (See When MOUD is Not Available).

Missed Doses

If an incarcerated patient misses three (3) or more doses of methadone, a dose adjustment may be needed. For any incarcerated patient missing three (3) or more doses of methadone, the correctional facility medical staff should notify the OTP. The OTP prescriber can then determine what dose the incarcerated patient should receive.

Spilled Medication

In cases where a patient's liquid medication is spilled, the correctional facility can:

1. Request that the OPT prepare a new dose if the OTP is close enough for facility staff to pick up a new dose that day.
2. Use emergency stock methadone for the spilled dose. This should be clearly documented in the record. (A nurse must pour the medication)

examination, including the results of serology and other tests, must be completed within 14 days following admission.

Medication Disposal

According to DEA requirements (APPENDIX E), any unused methadone shall be returned to the OTP for disposal. This would include methadone doses originally received from the OTP, as well as expired or surplus stock methadone[7]. The OTP shall adhere to all relevant regulations and procedures for the disposal of the medication. The amount of medication being returned to the OTP should be carefully documented to ensure that diversion cannot occur.

When MOUD is Not Available

In circumstances when MOUD is not available for an individual who is experiencing opioid withdrawal, practitioners can follow the:

American Society of Addiction Medicine (ASAM) guidelines to manage opioid withdrawal with ancillary medications[8]

[7] Per DEA communication 3/25/2022.

[8] The American Society of Addiction Medicine (ASAM) National Practice Guideline for the Treatment of Opioid Use Disorder 2020 Focused Update (accessed August 6, 2022.

OTP/CORRECTIONAL FACILITY Responsibilities

OTP Responsibilities

- The OTP shall enter the patient's name into the Central Registry
- The OTP does **NOT** enter the patient into the CDS system.
- The OTP maintains a record for the individual, noting diagnoses, dosage, relevant medical information, dates served,
- The OTP should make a referral to a community-based OTP when the patient is to be released. This effort is coordinated with the correctional facility and parole/probation staff if involved.

Correctional Facility Responsibilities

Per the OTP/Correctional Facility formal agreement (APPENDIX B), the correctional facility is responsible for providing medical, counseling, vocational, educational, and other assessment and treatment services.

Drug Testing

Federal regulation requires that all OTP patients have at least 8 random urine toxicology screens per year.

> *42 Part 8.12 (f) (6) Drug abuse testing services. OTPs must provide adequate testing or analysis for drugs of abuse, including at least eight random drug abuse tests per year, per patient in maintenance treatment, in accordance with generally accepted clinical practice. For patients in short-term detoxification treatment, the OTP shall perform at least one initial drug abuse test. For patients receiving long-term detoxification treatment, the program shall perform initial and monthly random tests on each patient.*
>
> The *Federal Guidelines for Opioid Treatment Programs (SAMHSA, 2015, p. 44)* provides additional context and considerations for testing and screening for substances:
>
> *"Although testing panels typically include opioids (including prescription opioid analgesic compounds), benzodiazepines, barbiturates, cocaine, marijuana, methadone (and its metabolites), buprenorphine, amphetamines, and alcohol, they are not limited to these substances. Clinicians should determine the drug-testing regimen by analyzing community drug-use patterns and individual medical indications. It is strongly recommended that benzodiazepines, barbiturates, and alcohol (using the ethyl glucuronide test) be included in drug screening and testing panels. Alcohol is the most widely used mood-altering substance in the United States, and benzodiazepines and barbiturates are often prescribed for detoxification and chronic seizure disorders. Detection of benzodiazepines, barbiturates, or alcohol is important in ongoing assessment, treatment planning, and medication management."*

These testing requirements can be met using multi-drug panel, CLIA waived test cups. The results should be recorded in the incarcerated patient's medical file, as well as shared with the OTP for their records.

GLOSSARY

ASAM - American Society of Addiction Medicine

BNE – NYS Bureau of Narcotics Enforcement

DEA – U.S. Drug Enforcement Administration

FDA – Food and Drug Administration

MAT – Medication for Addiction Treatment, formerly Medication Assisted Treatment

MOUD – Medication for Opioid Use Disorder

NTP – Narcotic Treatment Program, the Federal Term for an OTP

OASAS – NYS Office of Addiction Services and Supports

OTP – Opioid Treatment Program, also known as Methadone Maintenance Treatment Program

OUD – Opioid Use Disorder

SAMHSA - Substance Abuse and Mental Health Services Administration

APPENDIX A
SETTING UP METHADONE SERVICES IN A CORRECTIONAL FACILITY

SETTING UP METHADONE SERVICES IN A CORRECTIONAL FACILITY

QUICK GUIDE

The most common way for a correctional facility to offer methadone is to enter into an agreement with a community-based OTP (OASAS Certified Outpatient Program – Opioid Treatment Program)[9]. The correctional facility, along with the County Local Mental Hygiene Director, should contact the local OTP and discuss how to implement the program for the correctional facility. The discussion should include:

1. Process for identifying current and potential patients with an opioid use disorder (OUD) in the correctional facility.
2. Process for creating medication orders by the OTP to be shared with the correctional facility. Note that new cases (inductions) will require a face-to-face contact with the OTP prescriber.
3. Create and sign an agreement whereby the correctional facility agrees to:
    a. Provide some of the services normally provided by the OTP. This can include medical, counseling, toxicology, and education services.
    b. Names of correctional facility staff who are identified as being able to act as **agents** of the OTP in order to transfer medication doses from the OTP to the correctional facility, handle the medication and provide it to the patients. This would include all staff responsible for transporting the medication, nursing staff and other staff who may handle/monitor the medications.
4. Utilization of consent forms that are compliant with 42 CFR Part 2[10], federal confidentiality standards applicable to addiction treatment records, to facilitate information sharing between the correctional setting(s) and OTP(s). A sample 42 CFR Part 2 compliant consent form can be found here: TRS-2 Consent for Release of Information Concerning Patient With Substance Use Disorder .
5. Develop procedures for transfer –
    a. Nurses at the OTP dispense individually labeled bottles for each dose for each day.
    b. Bottles are inventoried and placed in a locked tote with the inventory.
    c. The correctional facility staff person picks up the tote. The staff person must NOT have a key to the tote.
    d. The nursing staff at the correctional facility receive and unlock the tote. They verify the inventory.

[9] Opioid Treatment Programs are certified by OASAS under 14 NYCRR Part 822 Outpatient - Opioid Treatment Program. These programs must also have a SAMHSA Certification, DEA registration and an accreditation from a SAMHSA recognized body (The Joint Commission, CARF, COA)

[10] 42 CFR Part 2 -- Confidentiality of Substance Use Disorder Patient Records

e. The medication is stored in a double-locked controlled substances box that is compliant with NYS DOH Bureau of Narcotic Enforcement and/or DEA regulations (See APPENDIX E).

6. Develop medication administration/distribution policies and procedures that include diversion mitigation strategies (e.g., checking the patient's mouth, having them eat a cracker and drink water after administering the medication, etc.)
7. Implement a medication administration record (MAR). Patients should initial the box that they have received their medications. This record can then be copied and sent to the OTP so that their records show the patient received the medication.
8. Develop communication expectations between the correctional facility and the OTP covering patient status, dosing amount concerns (too low or too high), notification of multiple missed doses, medical or mental health concerns, etc.
9. Work with the OTP on discharge planning to ensure that patients continue to receive treatment once released from custody.
10. Develop process to return unused medication back to the OTP for disposal.

The OTP should institute procedures to enter each case in the OTP Central Registry. [NOTE: cases do not need to be entered into OASAS Client Data System (CDS)]

APPENDIX B
OPIOID TREATMENT PROGRAM/COUNTY CORRECTIONAL FACILITY SERVICES AGREEMENT

OPIOID TREATMENT PROGRAM/COUNTY CORRECTIONAL FACILITY SERVICES AGREEMENT

This AGREEMENT is made between:

(Name, address of County Correctional Facility) hereinafter referred to as the Correctional Facility and:

(Name, address of Opioid Treatment Program), hereinafter referred to as the Opioid Treatment Program or OTP.

The Agreement serves to establish that the Correctional Facility will provide specified services on behalf of the OTP. This agreement is in accordance with the Federal Opioid Treatment Standards as established:

42 CFR §8.12(f). *Required services*

(1) *General.* OTPs shall provide adequate medical, counseling, vocational, educational, and other assessment and treatment services. These services must be available at the primary facility, **except where the program sponsor has entered into a formal, documented agreement with a private or public agency, organization, practitioner, or institution to provide these services to patients enrolled in the OTP**. The program sponsor, in any event, must be able to document that these services are fully and reasonably available to patients.

(2) *Initial medical examination services.* OTPs shall require each patient to undergo a complete, fully documented physical evaluation by a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician before admission to the OTP. The full medical examination, including the results of serology and other tests, must be completed within 14 days following admission.

(3) *Special services for pregnant patients.* OTPs must maintain current policies and procedures that reflect the special needs of patients who are pregnant. Prenatal care and other gender specific services or pregnant patients must be provided either by the OTP or by referral to appropriate healthcare providers.

(4) *Initial and periodic assessment services.* Each patient accepted for treatment at an OTP shall be assessed initially and periodically by qualified personnel to determine the most appropriate combination of services and treatment. The initial assessment must include preparation of a treatment plan that includes the patient's short-term goals and the tasks the patient must perform to complete the short-term goals; the patient's requirements for education, vocational rehabilitation, and employment; and the medical, psychosocial, economic, legal, or other supportive services that a patient needs. The treatment plan also must identify the frequency with which these services are to be provided. The plan must be

reviewed and updated to reflect that patient's personal history, his or her current needs for medical, social, and psychological services, and his or her current needs for education, vocational rehabilitation, and employment services.

Transfer of Medication

Per United State Drug Enforcement Administration (DEA) direction, Correctional Facility staff who have been approved to function as **agents** on behalf of the OTP, are able to pick up medication at the OTP provided that:

1. The medication is inventoried, and the resulting inventory list and medication are placed in a locked tote by the OTP nursing staff.
2. The transporting staff person does not have a key to the tote.
3. When the medication arrives at the Correctional Facility, the nursing staff unlocks and opens the tote to confirm the inventory. Once confirmed, nursing staff sign the form indicating that the inventory is complete. A copy of the form is forwarded to the OTP, the original is maintained at the Correctional Facility.

Responsibility Areas

Opioid Treatment Program

1. Creating medical order for methadone dose
2. Packaging individually labeled doses of methadone for OTP patients incarcerated at the facility
3. Loading and locking the methadone transport tote
4. Maintaining record of methadone doses sent to facility
5. Maintaining copy of medication administration record (MAR) documentation from facility
6. Maintenance of a treatment plan indicating that patient is receiving MAT from the OTP, while other services are provided by Correctional Facility
7. Enter patient information into Lighthouse Central Registry

Correctional Facility

1. Medical services for patients, including physical exam, treatment of other conditions, medication for other conditions, etc.
2. Provide OTP with medical information, particularly regarding medical conditions and medications
3. SUD counseling services in accordance with the needs of individual
4. Toxicology testing
5. Counseling on preventing exposure to, and the transmission of, human immunodeficiency virus (HIV) and hepatitis C virus (HCV) diseases for each patient
6. Maintenance of medication records including the medical order from the OTP, the MAR, the required controlled substances records, and any spilled medications
7. Provision of community re-entry support when patient is nearing release
8. Treatment plan/record indicating that the patient has been prescribed methadone from the OTP and that other counseling services are provided by Correctional Facility.
9. Provides staff/vehicle to pick up the medication and return the empty tote to OTP on, at a minimum, a weekly basis.

Opioid Treatment Program and Correctional Facility

1. Advise of change(s) in the patient's medical condition, including symptoms related to over/under dosing, health status, relocation, dosage change, missed doses, and serious side effects
2. Ongoing regular communication between program administrators, medical and nursing staff regarding program operation, issues, and changes.

Continuing Care Planning

The Correctional Facility's discharge planner should work with the OTP to develop the plan for the incarcerated patient's release. The plan should be developed as soon as medication services begin. This is particularly important for non-sentenced individuals who may be released from custody at any time.

As soon as possible, the plan should identify which OTP the individual would be referred to upon release. A consent to release information should be obtained so that the OTP and the Correctional Facility can make a referral to the identified OTP to ensure continuity of services.

This Agreement shall, at the option of either party, become immediately null and void and have no effect if either party fails to perform in accordance with said provisions contained herein.

This Agreement shall commence on __ _____. Either party may terminate this Agreement by giving written notification of said intent to cancel, to the other party. Such notification would result in immediate cancellation.

THIS AGREEMENT is dated the _____ day of _____, 20__.

_____

County Correctional Facility Superintendent Date

_____

OTP Authorizing Signature Date

APPENDIX C
OTP DESIGNATED AGENT AGREEMENT

OTP DESIGNATED AGENT AGREEMENT

The United States Drug Enforcement Administration has instructed that Correctional Facility staff persons may transport individually labeled doses of methadone from the OTP to the Correctional Facility, store and provide the medication to patients as long as they are designated to be **agents** of the OTP. Under no circumstances should the agent have a key to access the locked box that the medication is stored in.

By signing this document, the facility staff attest that they will adhere to all statutory and regulatory policies and procedures related to the transportation, storage, and provision of the medication. Upon approval from the OTP, these staff members shall be designated as agents of the OTP.

Facility Staff Person Name/Role	Signature	Date

Submitted by:

_____

Correctional Facility Administrator Signature Date

Approved by:

_____

OTP Director Signature Date

APPENDIX D
42 CFR § 8.12 FEDERAL OPIOID TREATMENT STANDARDS

§ 8.12 FEDERAL OPIOID TREATMENT STANDARDS

(a) General. OTPs must provide treatment in accordance with the standards in this section and must comply with these standards as a condition of certification.

(b)Administrative and organizational structure. An OTP's organizational structure and facilities shall be adequate to ensure quality patient care and to meet the requirements of all pertinent Federal, State, and local laws and regulations. At a minimum, each OTP shall formally designate a program sponsor and medical director. The program sponsor shall agree on behalf of the OTP to adhere to all requirements set forth in this part and any regulations regarding the use of opioid agonist treatment medications in the treatment of opioid use disorder which may be promulgated in the future. The medical director shall assume responsibility for administering all medical services performed by the OTP. In addition, the medical director shall be responsible for ensuring that the OTP is in compliance with all applicable Federal, State, and local laws and regulations.

(c) Continuous quality improvement.

(1) An OTP must maintain current quality assurance and quality control plans that include, among other things, annual reviews of program policies and procedures and ongoing assessment of patient outcomes.

(2) An OTP must maintain a current “Diversion Control Plan” or “DCP” as part of its quality assurance program that contains specific measures to reduce the possibility of diversion of controlled substances from legitimate treatment use and that assigns specific responsibility to the medical and administrative staff of the OTP for carrying out the diversion control measures and functions described in the DCP.

(d) Staff credentials. Each person engaged in the treatment of opioid use disorder must have sufficient education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. All physicians, nurses, and other licensed professional care providers, including addiction counselors, must comply with the credentialing requirements of their respective professions.

(e) Patient admission criteria -

(1) Maintenance treatment. An OTP shall maintain current procedures designed to ensure that patients are admitted to maintenance treatment by qualified personnel who have determined, using accepted medical criteria such as those listed in the Diagnostic and Statistical Manual for Mental Disorders (DSM-IV), that the person is currently addicted to an opioid drug, and that the person became addicted at least 1 year before admission for treatment. In addition, a program physician shall ensure that each patient voluntarily chooses maintenance treatment and that all relevant facts concerning the use of the opioid drug are

clearly and adequately explained to the patient, and that each patient provides informed written consent to treatment.

(2) Maintenance treatment for persons under age 18. A person under 18 years of age is required to have had two documented unsuccessful attempts at short-term detoxification or drug-free treatment within a 12-month period to be eligible for maintenance treatment. No person under 18 years of age may be admitted to maintenance treatment unless a parent, legal guardian, or responsible adult designated by the relevant State authority consents in writing to such treatment.

(3) Maintenance treatment admission exceptions. If clinically appropriate, the program physician may waive the requirement of a 1-year history of addiction under paragraph (e)(1) of this section, for patients released from penal institutions (within 6 months after release), for pregnant patients (program physician must certify pregnancy), and for previously treated patients (up to 2 years after discharge).

(4) Detoxification treatment. An OTP shall maintain current procedures that are designed to ensure that patients are admitted to short- or long-term detoxification treatment by qualified personnel, such as a program physician, who determines that such treatment is appropriate for the specific patient by applying established diagnostic criteria. Patients with two or more unsuccessful detoxification episodes within a 12-month period must be assessed by the OTP physician for other forms of treatment. A program shall not admit a patient for more than two detoxification treatment episodes in one year.

(f) Required services -

(1) General. OTPs shall provide adequate medical, counseling, vocational, educational, and other assessment and treatment services. These services must be available at the primary facility, except where the program sponsor has entered into a formal, documented agreement with a private or public agency, organization, practitioner, or institution to provide these services to patients enrolled in the OTP. The program sponsor, in any event, must be able to document that these services are fully and reasonably available to patients.

(2) Initial medical examination services. OTPs shall require each patient to undergo a complete, fully documented physical evaluation by a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician, before admission to the OTP. The full medical examination, including the results of serology and other tests, must be completed within 14 days following admission.

(3) Special services for pregnant patients. OTPs must maintain current policies and procedures that reflect the special needs of patients who are pregnant.

Prenatal care and other gender specific services or pregnant patients must be provided either by the OTP or by referral to appropriate healthcare providers.

(4) Initial and periodic assessment services. Each patient accepted for treatment at an OTP shall be assessed initially and periodically by qualified personnel to determine the most appropriate combination of services and treatment. The initial assessment must include preparation of a treatment plan that includes the patient's short-term goals and the tasks the patient must perform to complete the short-term goals; the patient's requirements for education, vocational rehabilitation, and employment; and the medical, psychosocial, economic, legal, or other supportive services that a patient needs. The treatment plan also must identify the frequency with which these services are to be provided. The plan must be reviewed and updated to reflect that patient's personal history, his or her current needs for medical, social, and psychological services, and his or her current needs for education, vocational rehabilitation, and employment services.

(5) Counseling services.

(i) OTPs must provide adequate substance abuse counseling to each patient as clinically necessary. This counseling shall be provided by a program counselor, qualified by education, training, or experience to assess the psychological and sociological background of patients, to contribute to the appropriate treatment plan for the patient and to monitor patient progress.

(ii) OTPs must provide counseling on preventing exposure to, and the transmission of, human immunodeficiency virus (HIV) disease for each patient admitted or readmitted to maintenance or detoxification treatment.

(iii) OTPs must provide directly, or through referral to adequate and reasonably accessible community resources, vocational rehabilitation, education, and employment services for patients who either request such services or who have been determined by the program staff to be in need of such services.

(6) Drug abuse testing services. OTPs must provide adequate testing or analysis for drugs of abuse, including at least eight random drug abuse tests per year, per patient in maintenance treatment, in accordance with generally accepted clinical practice. For patients in short-term detoxification treatment, the OTP shall perform at least one initial drug abuse test. For patients receiving long-term detoxification treatment, the program shall perform initial and monthly random tests on each patient.

(g) Recordkeeping and patient confidentiality.

(1) OTPs shall establish and maintain a recordkeeping system that is adequate to document and monitor patient care. This system is required to comply with all Federal and State reporting requirements relevant to opioid drugs approved for use in treatment of opioid use disorder. All records are required to be kept confidential in accordance with all applicable Federal and State requirements.

(2) OTPs shall include, as an essential part of the recordkeeping system, documentation in each patient's record that the OTP made a good faith effort to review whether or not the patient is enrolled any other OTP. A patient enrolled in an OTP shall not be permitted to obtain treatment in any other OTP except in exceptional circumstances. If the medical director or program physician of the OTP in which the patient is enrolled determines that such exceptional circumstances exist, the patient may be granted permission to seek treatment at another OTP, provided the justification for finding exceptional circumstances is noted in the patient's record both at the OTP in which the patient is enrolled and at the OTP that will provide the treatment.

(h) Medication administration, dispensing, and use.

(1) OTPs must ensure that opioid agonist treatment medications are administered or dispensed only by a practitioner licensed under the appropriate State law and registered under the appropriate State and Federal laws to administer or dispense opioid drugs, or by an agent of such a practitioner, supervised by and under the order of the licensed practitioner. This agent is required to be a pharmacist, registered nurse, or licensed practical nurse, or any other healthcare professional authorized by Federal and State law to administer or dispense opioid drugs.

(2) OTPs shall use only those opioid agonist treatment medications that are approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for use in the treatment of opioid use disorder. In addition, OTPs who are fully compliant with the protocol of an investigational use of a drug and other conditions set forth in the application may administer a drug that has been authorized by the Food and Drug Administration under an investigational new drug application under section 505(i) of the Federal Food, Drug, and Cosmetic Act for investigational use in the treatment of opioid use disorder. Currently the following opioid agonist treatment medications will be considered to be approved by the Food and Drug Administration for use in the treatment of opioid use disorder:

(i) Methadone;

(ii) Levomethadyl acetate (LAAM); and

(iii) Buprenorphine and buprenorphine combination products that have been approved for use in the treatment of opioid use disorder.

(3) OTPs shall maintain current procedures that are adequate to ensure that the following dosage form and initial dosing requirements are met:

(i) Methadone shall be administered or dispensed only in oral form and shall be formulated in such a way as to reduce its potential for parenteral abuse.

(ii) For each new patient enrolled in a program, the initial dose of methadone shall not exceed 30 milligrams and the total dose for the first day shall not exceed 40 milligrams, unless the program physician documents in the patient's record that 40 milligrams did not suppress opioid abstinence symptoms.

(4) OTPs shall maintain current procedures adequate to ensure that each opioid agonist treatment medication used by the program is administered and dispensed in accordance with its approved product labeling. Dosing and administration decisions shall be made by a program physician familiar with the most up-to-date product labeling. These procedures must ensure that any significant deviations from the approved labeling, including deviations with regard to dose, frequency, or the conditions of use described in the approved labeling, are specifically documented in the patient's record.

(i) Unsupervised or "take-home" use. To limit the potential for diversion of opioid agonist treatment medications to the illicit market, opioid agonist treatment medications dispensed to patients for unsupervised use shall be subject to the following requirements.

(1) Any patient in comprehensive maintenance treatment may receive a single take-home dose for a day that the clinic is closed for business, including Sundays and State and Federal holidays.

(2) Treatment program decisions on dispensing opioid treatment medications to patients for unsupervised use beyond that set forth in paragraph (i)(1) of this section, shall be determined by the medical director. In determining which patients may be permitted unsupervised use, the medical director shall consider the following take-home criteria in determining whether a patient is responsible in handling opioid drugs for unsupervised use.

(i) Absence of recent abuse of drugs (opioid or nonnarcotic), including alcohol;

(ii) Regularity of clinic attendance;

(iii) Absence of serious behavioral problems at the clinic;

(iv) Absence of known recent criminal activity, e.g., drug dealing;

(v) Stability of the patient's home environment and social relationships;

(vi) Length of time in comprehensive maintenance treatment;

(vii) Assurance that take-home medication can be safely stored within the patient's home; and

(viii) Whether the rehabilitative benefit the patient derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion.

Such determinations and the basis for such determinations consistent with the criteria outlined in paragraph (i)(2) of this section shall be documented in the patient's medical record. If it is determined that a patient is responsible in handling opioid drugs, the dispensing restrictions set forth in paragraphs (i)(3)(i) through (vi) of this section apply. The dispensing restrictions set forth in paragraphs (i)(3)(i) through (vi) of this section do not apply to buprenorphine and buprenorphine products listed under paragraph (h)(2)(iii) of this section.

During the first 90 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) is limited to a single dose each week and the patient shall ingest all other doses under appropriate supervision as provided for under the regulations in this subpart.

In the second 90 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) are two doses per week.

(iii) In the third 90 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) are three doses per week.

(iv) In the remaining months of the first year, a patient may be given a maximum 6-day supply of take-home medication.

(v) After 1 year of continuous treatment, a patient may be given a maximum 2-week supply of take-home medication.

(vi) After 2 years of continuous treatment, a patient may be given a maximum one-month supply of take-home medication, but must make monthly visits.

No medications shall be dispensed to patients in short-term detoxification treatment or interim maintenance treatment for unsupervised or take-home use.

(5) 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 take-home supplies are packaged in a manner that is designed to reduce the risk of accidental

ingestion, including child-proof containers (see Poison Prevention Packaging Act, Public Law 91-601 (15 U.S.C. 1471et seq.)).

(j) Interim maintenance treatment.

(1) The program sponsor of a public or nonprofit private OTP may place an individual, who is eligible for admission to comprehensive maintenance treatment, in interim maintenance treatment if the individual cannot be placed in a public or nonprofit private comprehensive program within a reasonable geographic area and within 14 days of the individual's application for admission to comprehensive maintenance treatment. An initial and at least two other urine screens shall be taken from interim patients during the maximum of 120 days permitted for such treatment. A program shall establish and follow reasonable criteria for establishing priorities for transferring patients from interim maintenance to comprehensive maintenance treatment. These transfer criteria shall be in writing and shall include, at a minimum, a preference for pregnant women in admitting patients to interim maintenance and in transferring patients from interim maintenance to comprehensive maintenance treatment. Interim maintenance shall be provided in a manner consistent with all applicable Federal and State laws, including sections 1923, 1927(a), and 1976 of the Public Health Service Act (21 U.S.C. 300x-23, 300x-27(a), and 300y-11).

(2) The program shall notify the State health officer when a patient begins interim maintenance treatment, when a patient leaves interim maintenance treatment, and before the date of mandatory transfer to a comprehensive program, and shall document such notifications.

(3) SAMHSA may revoke the interim maintenance authorization for programs that fail to comply with the provisions of this paragraph (j). Likewise, SAMHSA will consider revoking the interim maintenance authorization of a program if the State in which the program operates is not in compliance with the provisions of § 8.11(g).

(4) All requirements for comprehensive maintenance treatment apply to interim maintenance treatment with the following exceptions:

(i) The opioid agonist treatment medication is required to be administered daily under observation;

(ii) Unsupervised or “take-home” use is not allowed;

(iii) An initial treatment plan and periodic treatment plan evaluations are not required;

(iv) A primary counselor is not required to be assigned to the patient;

(v) Interim maintenance cannot be provided for longer than 120 days in any 12-month period; and

(vi) Rehabilitative, education, and other counseling services described in paragraphs (f)(4), (f)(5)(i), and (f)(5)(iii) of this section are not required to be provided to the patient.

[66 FR 4090, Jan. 17, 2001, as amended at 68 FR 27939, May 22, 2003; 77 FR 72761, Dec. 6, 2012; 80 FR 34838, June 18, 2015]

APPENDIX E
MEDICATION STORAGE REGULATIONS

MEDICATION STORAGE REGULATIONS

NYS DEPARTMENT OF HEALTH REGULATION

10 NYCRR 80.50 (c) (1)

> *(c) Working stocks of controlled substances for institutional dispensers without a registered pharmacy, treatment programs, license holders engaging in research, instructional activities, and chemical analysis shall be securely kept as follows:*
>
> > *(1) Schedule I, II, III and IV controlled substances shall be kept in stationary, locked double cabinets. Both cabinets, inner and outer, shall have key-locked doors with separate keys; spring locks or combination dial locks are not acceptable. For new construction, cabinets shall be made of steel or other approved metal.*

DEA RULE

21 CFR 1301.72(a): Physical security controls for non-practitioners; narcotic treatment programs; and compounders for narcotic treatment programs; mobile narcotic treatment programs; storage areas.

Schedules I and II. Raw material, bulk materials awaiting further processing, finished products which are controlled substances listed in Schedule I or II (except GHB that is manufactured or distributed in accordance with an exemption under section 505(i) of the Federal Food Drug and Cosmetic Act which shall be subject to the requirements of paragraph (b) of this section), and sealed mail-back packages and inner liners acquired in accordance with part 1317 of this chapter, shall be stored in one of the following secured areas:

(1) Where small quantities permit, a safe or steel cabinet;

(i) Which safe or steel cabinet shall have the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques;

(ii) Which safe or steel cabinet, if it weighs less than 750 pounds, is bolted or cemented to the floor or wall in such a way that it cannot be readily removed; and

(iii) Which safe or steel cabinet, if necessary, depending upon the quantities and type of controlled substances stored, is equipped with an alarm system which, upon attempted unauthorized entry, shall transmit a signal directly to a central protection company or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Administrator may approve.

APPENDIX F
DEA CORRESPONDENCE ON OPIOID TREATMENT IN CORRECTIONAL SETTINGS

U. S. Department of Justice

Drug Enforcement Administration

8701 Morrissette Drive
Springfield, Virginia 22152

www.dea.gov

Steve Hanson, Associate Commissioner

New York State Office of Addiction Services and Support

1450 Western Avenue

Albany, New York 12203

Steve.Hanson@oasas.ny.gov

Dear Mr. Hanson:

This is in response to your email dated October 15, 2021, to the Drug Enforcement Administration (DEA), and a subsequent telephone conversation that occurred on December 7, 2021, with DEA's New York Field Division's Diversion Program Manager Juana Hill, and members of DEA's Policy Section and Chief Counsel's Office. Your email states that New York State (NYS) has recently enacted a statute that mandates access to the U.S. Food and Drug Administration's (FDA)-approved medications for addiction treatment for any incarcerated individual where the medication is indicated and access to methadone treatment is a key component of the required services. You state that NYS has 57 county jails and 50 state correctional facilities located across the state. Many of these facilities are in rural areas where there are currently no operating Narcotic Treatment Programs (NTP). To obtain the medications, county jails will be required to enter into agreements with the nearest NTPs to maintain incarcerated individuals on their medication.

During the December 7, 2021 conference call, you submitted six questions in addition to the previously submitted seven questions and provided some clarity regarding your proposed Hub and Spoke business model and related questions. It is our understanding that all proposed Hub and Spoke components and locations will register with DEA as NTPs in order to provide Medication Assisted Treatment (MAT) to your inmates. You also envisioned another model where you will contract with NTPs outside of your Hub and Spoke network to provide MAT to inmates at jails in rural or underserved areas.

Consistent with the Administrative Procedure Act and DEA policy, the agency generally refrains from providing interpretations of the law and regulations in letters to individuals. Where DEA does

provide such interpretations, it is generally in a guidance document published on the agency's website so that it is available for review by all interested members of the public. However, DEA is able to respond to the following questions. DEA appreciates the opportunity to address your inquiry and apologizes for our delayed response.

QUESTION #1: Can corrections officers serve as "Responsible Others" to pick up prepared "take home" doses of methadone and transport them securely to the jail, or correctional facility?

This question relates to you contracting with outside DEA-registered NTPs that would provide MAT services to smaller jail facilities. You provided the following scenario and state that when an incarcerated individual is a patient at an NTP, they are not able to leave the jail to appear at the NTP. Particularly when there are multiple NTP patients in a correctional facility, the most efficient and secure method to transport medication is for a corrections officer (New York Corrections Officers are sworn peace officers who have had extensive background checks and training) to travel to the NTP. They would then take custody of a locked container that holds the individually labeled doses of medication prepared by the NTP staff. The officer would not have a key to the container. The officer would then transport the container to the facility, where it would be handed to the facility nursing staff. A "chain of custody" document would be maintained to ensure that there is no diversion of the medication. The medication would then be appropriately stored and secured in compliance with state laws regarding the storage of controlled substances. The correctional facility staff would observe the incarcerated individual taking their medication each day.

Regarding your proposed scenario, additional doses may be given into the custody of the jail, or the correctional facility's authorized personnel, to be secured at the jail or correctional facility for administering or dispensing to each of these patients as indicated by the medical director. You would also need to obtain authorization by the medical director of the NTP and ensure the proposal was in accordance with the Substance Abuse and Mental Health Services Administration (SAMHSA) regulations under 42 CFR part 8. Alternatively, the jail or correctional facility may transport patients to the NTP to receive FDA approved drugs for use in maintenance or detoxification treatment. If permitted by the state opioid treatment authorities, patients may be taken to the NTP to be administered an initial dose.

DEA believes that the NYS Office of Addiction Services and Support proposal would comply with the Controlled Substances Act (CSA) provided that the correctional officers, employed by the jail or correctional facility, who take possession of the methadone and or buprenorphine at the NTP and deliver it to the jail or correctional facility, are made agents of the NTP through a formal written agreement. 21 USC 802(3). This agreement must specify the scope of the jail or correctional facility personnel's authority and duties. The CSA provides that individuals serving as an agent or employee of any registered distributor or dispenser of any controlled substance need not register and may lawfully possess any controlled substance if such agent or employee is acting in the usual course of business or employment. 21 USC 822(c)(1).

Your email further proposes that the jail or correctional facility personnel who dispense the methadone daily at the jail will be designated as agents of the NTP. DEA recommends that they be so designated in writing. Further, the correctional facility personnel who actually dispense or administer the treatment must be either (1) the licensed practitioner, (2) a registered nurse under the direction of the licensed practitioner, (3) a licensed practical nurse under the direction of the licensed practitioner, or (4) a pharmacist under the direction of the licensed practitioner. 21 CFR 1301.74(i).

QUESTION #2: Can DEA-registered "Additional Medications Locations" obtain stock methadone from the distributor or manufacturer for dispensing to incarcerated individuals?

During our follow up phone conversation, you stated the NYS Department of Corrections and Community Supervision (DOCCS) is pursuing a "Hub and Spoke" model for NTP operations. The plan is to obtain a DEA registration, SAMHSA certification, and National Commission on Correctional Health Care (NCCHS) accreditation for the operation of one or more NTP programs. It is likely that, initially, DOCCS would have two NTPs, one at a male reception facility (Downstate Correctional Facility) and another at a female reception facility (Bedford Hills Correctional Facility). These facilities would serve as the "hubs." Incarcerated individuals in need of methadone maintenance treatment would be evaluated by the NTP's staff at these facilities and a medical order for the medication would be issued.

After a short stay at a reception facility, inmates would likely be transferred to another facility and then potentially a third or more depending on the person's needs and required level of security.

According to our phone conversation, these subsequent facilities would serve as the "spokes."

DOCCS would like to identify a number of these "spoke" facilities as "Additional Medication Locations" (AML) as described by SAMHSA. These sites would be included under the SAMHSA certification of the "hub" NTP and registered with DEA as an NTP. Medical staff at the AML sites would function under the supervision of the NTP Medical Director. After registering with DEA as an NTP, the spoke facility would order methadone directly from the distributor or manufacturer.

All inventories, records, and reports for the administration and dispensing of FDA-approved medications, as outlined by DEA regulations, must be kept at the NTP's DEA-registered location for at least two years. 21 U.S.C. 827; 21 CFR part 1304.

QUESTION #8: Can DEA distinguish between "dispensing," "administering," and "monitored self-administration" of controlled substances?

The CSA defines the term "dispense" to mean "to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling, or

compounding necessary to prepare the substance for such delivery." 21 U.S.C. 802(10). The term "dispenser" means "a practitioner who so delivers a controlled substance to an ultimate user or research subject." Id.

The term "administer" refers to "the direct application of a controlled substance to the body of a patient or research subject by - (A) a practitioner (or, in his presence, by his authorized agent), or (B) the patient or research subject at the direction and in the presence of the practitioner, whether such application is by injection, inhalation, ingestion, or any other means." 21 U.S.C. 802(2).

Neither the CSA nor its implementing regulations define the term "Monitored Self administration."

QUESTION #11: If medication is provided to persons in correctional facilities, with the medication being individually bottled and labeled, what is the proper way(s) for the unused medication to be disposed of?

This question relates to you contracting with outside registered NTPs that would provide MAT services to your jails geographically located far distances in rural areas. The designated jails or correctional institutions would return any medications not administered and or dispensed to inmates back to the NTP. The authorized NTP personnel will adequately secure the medication at the NTP in accordance with DEA regulations, 21 CFR 1317, for the purposes of disposal. All inventories, records, and reports for the administration and dispensing of FDA-approved medications, as outlined by DEA regulations, must be kept at the NTP's DEA-registered location for at least two years, 21 CFR part 1304.

Throughout the COVID-19 public health emergency, DEA has worked with our partners from other federal, state, and local agencies, and together DEA has taken great strides to ensure

Americans have continued access to the medications they need. Please refer to DEA's Guidance Document Portal for more information on DEA's efforts with respect to medication assisted treatment.

Additionally, on Monday June 28, 2021, a final rule was published in the *Federal Register*, Federal Register / Vol. 86, No. 121 / Monday, June 28, 2021 / Rules and Regulations, titled

"Registration Requirements for Narcotic Treatment Programs with Mobile Components." This Final Rule revised the existing regulations at 21 CFR 1301.13 (e)(4), regarding NTPs to allow a mobile component associated with the registered program (in the state that the registrant is registered in) to repeatedly dispense narcotic drugs in schedules II-V (including buprenorphine), at remote locations for the purpose of maintenance or detoxification treatment, without obtaining separate registrations at those remote locations thereby allowing a larger population greater access to MAT and other services. The addition of this permanent mobile component will also address the needs of patients residing in rural areas who cannot travel great distances to see their providers. A copy of this final rule is attached for your convenience.

I trust this letter adequately addresses your inquiry. For information regarding DEA's Diversion Control Division, please visit www.DEAdiversion.usdoj.gov. If you have any additional questions on this issue, or any other, please contact the Diversion Control Division Policy Section at (571) 362-3260.

Sincerely,

Thomas W. Prevoznik
Deputy Assistant Administrator
Diversion Control Division

APPENDIX G
NYS OASAS OPINION OF COUNSEL: NURSING PRACTICES IN OASAS CERTIFIED PART 822 OPIOID TREATMENT PROGRAMS (OTPS) & MAT FOR INCARCERATED INDIVIDUALS

Nursing practices in OASAS certified Part 822 Opioid Treatment Programs (OTPs) & MAT for incarcerated individuals

Nursing practices in OASAS certified Part 822 Opioid Treatment Programs (OTPs)

OASAS OTPs are an integral part of the spectrum of treatment modalities available to New York residents struggling with Opioid Use Disorder (OUD). OTPs provide urgently needed relief to an individual with OUD who is immediately assessed, admitted and dosed with appropriate medications to relieve any withdrawal symptoms. Many individuals with OUD are able to achieve sustained recovery when maintained on an appropriate dose of methadone and with supportive services available when needed. Over time individuals who have appeared for daily methadone dosing, provided acceptable toxicology and met treatment goals can be evaluated for "take home" methadone dosing. Take home dosing is always done in individual bottles with a single dose per bottle together with patient specific labeling. OTPs are certified by OASAS, licensed by the Drug Enforcement Administration (DEA) and Substance Abuse and Mental Health Services Administration Center for Substance Abuse Treatment (CSAT) and accredited by a federally approved accrediting body (The Joint Commission (TJC), Commission on Accreditation of Rehabilitation Facilities (CARF)). Physicians (MD), Registered Nurses (RN) and Licensed Practical Nurses (LPN) are an essential part of the medical staff of an OTP and critical to the various licenses and accreditations of an OTP. OASAS Part 822 regulations require an MD be present or available for consultation whenever an OTP is open. OTPs must have at least 2 full time nurses, at least 1 of whom is an RN, on staff. Programs exceeding 300 patients must have additional nurses. A nurse must be present whenever methadone is being provided to patients. OTPs must be open at least 6 days a week with flexible dosing hours. Physicians determine all patient dosages and schedules of administration of methadone and document them in a patient record. No changes to dose or administration may be made without a new order.

The practice of nursing is governed by the NYS Department of Education. NYS Education Law Section § 6902 defines the practice of nursing as follows:

Definition of practice of nursing. 1. The practice of the profession of nursing as a registered professional nurse is defined as diagnosing and treating human responses to actual or potential health problems through such services as case finding, health teaching, health counseling, and provision of care supportive to or restorative of life and well-being, and ***executing medical regimens*** prescribed by a licensed physician, dentist or another licensed health care provider legally authorized under this title and in accordance with the commissioner's regulations. ***A nursing regimen shall be consistent with and shall not vary any existing medical regimen.***

2. The practice of nursing as a licensed practical nurse is defined as performing tasks and responsibilities within the framework of case finding, health teaching, health counseling and provision of supportive and restorative care under the direction of a registered professional nurse,

licensed physician, dentist or other licensed health care provider legally authorized under this title and in accordance with the commissioner's regulations.

The ***medical regimen*** in an OTP for patients on methadone consists of an MD ordering a dose and schedule of methadone for each specific patient. This medical regimen is entered and stored in the medical record of an OTP by an RN. The vast majority, if not all OTPs in NY, utilize a computer based dispensing machine for dispensing of methadone. The machine is synchronized with the OTPs Electronic Medical record (EMR) such that the nurse administering methadone verifies the identity of the patient and confirms it in the EMR. Programs utilize RNs and LPNs to administer dispensed medications; however, LPNs are always supervised by an RN. The EMR then communicates patient information on dose to the dispensing machine which then dispenses the medication into a receptacle (cup or take home bottle). A single dose in a cup is provided to the patient (and may be accompanied by another cup with water or a similar beverage). The nurse watches the patient take the medication and then confirms, by visual inspection or asking patient to speak, that all medication had been taken. Patients then properly dispose of the cups (by returning to the nurse or placing in secure receptacles. Take home doses are communicated to the dispensing machine, which dispenses the dose and prints a label with necessary information (patient name, dose). Nurses prompt the dispensing machine to dispense as many single take home doses as have been ordered by the MD and place a label provided by the machine on each receptacle in accordance with the medical regimen provided. Take home doses are given to a patient. Patients must return empty take home bottles to the OTP after all doses have been taken. The nurse will ensure the appropriate number of bottles are returned consistent with the regimen ordered by the MD. Nurses do not measure or pour individual doses of methadone. Nurses do not complete labeling of any dose dispensed by a dispensing machine.

This long standing system of RN's and supervised LPNs completing a nursing regime that has been dictated by a prescribed medical regimen is appropriate and in accordance with state laws and the federal opioid treatment standards that require that "… opioid agonist treatment medications are administered or dispensed only by a practitioner licensed under the appropriate State law and registered under the appropriate State and Federal laws to administer or dispense opioid drugs, or by an agent of such a practitioner, supervised by and under the order of the licensed practitioner. *This agent is required to be a pharmacist, registered nurse, or licensed practical nurse*, or any other healthcare professional authorized by Federal and State law to administer or dispense opioid drugs." (emphasis added) 42 CFR Part 8.12.

MAT for incarcerated individuals

In NYs ongoing efforts to combat addiction and the opioid epidemic, OASAS and its OTPs have been engaged in partnership with the criminal justice system to ensure Medication Assisted Treatment (MAT), including Methadone, is available to inmates in public institutions (local jails and state prisons). Recently medical staff at NYS correctional facilities have been advised MAT is available in penal facilities, its use will be expanding and that they should familiarize themselves with the various versions of MAT. SAMHSA has recognized the importance of

continuing individuals that are otherwise unable to attend their OTP on their OTP regimen. In 2015 SAMHSA advised OTPs that in order to "ensure that the patient's treatment is continued safely while also ensuring appropriate handling and delivery of medication to the patient a possible solution is to use a chain-of-custody record, which is a document containing the signatures of all people who have handled the medication. This record also should contain spaces for the patient to initial each day that the medication is administered, as well as spaces for the initials of the person who administered the medication. The patient and the medical professional administering the medication should contact the program immediately if the medication seems altered in any way." See Substance Abuse and Mental Health Services Administration. *Federal Guidelines for Opioid Treatment Programs.* HHS Publication No. (SMA) XX-XXXX. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2015. Further, it is important to note that this NYS initiative is timely given the recent cases and settlements finding that denial of MAT to an incarcerated individual is a violation of such person's rights under the Americans with Disabilities Act.[11]

The process NYS has established for methadone administration at NYS correctional facilities involves a NYS Department of Corrections and Community Supervision (DOCCS) primary care medical provider completing a physical examination for an inmate as part of its MAT program. The DOCCS medical provider consults with an OTP and the physician at the OTP provides an order for methadone for a MAT eligible inmate. The DOCCS medical provider orders that DOCCS staff follow the medical regime for methadone ordered by the OTP physician. The methadone is transported by correctional facilities staff in locked boxes where the daily medication is placed for each inmate, such medication having been dispensed from the OTP dispensing machine in accordance with the physician's prescribed regimen. Upon arrival at the correctional facility the locked box is stored by medical staff and the daily doses of methadone are administered according to labeling and the prescribed regimen. The staff transporting the methadone do not have keys to access the medication in the locked box, the only staff having keys to the locked box are medical staff at the OTP and the correctional facility. Used medication receptacles are returned to the OTP. This routine generally occurs weekly.

The process NYS has established for ensuring inmates have access to MAT is in line with federal law and guidelines and state professional practice laws. All medication is prescribed by licensed practitioners according to medical regimen and there is no opportunity for deviation from such regimen. Further, appropriate steps have been taken to ensure medication is not diverted or altered in any way through a chain of custody process.

[11] See Smith v Aroostic County, No. 19-1340 (1st Cir. 2019); Pesce v Coppinger, Case 1:18-cv-11972-DJC Document 57 (USDC Mass 2018); *Kortlever v. Whatcom County et. al*, Case 2:18-cv-00823-JLR Document 35-1 Filed 04/29/19 settlement agreement at: https://www.aclu-wa.org/docs/settlement-agreement-1

Thus, it is the opinion of OASAS Counsel that the practices utilized by OTPs to provide methadone to both incarcerated individuals and those not incarcerated comply with the professional practice laws and regulations.

Sincerely,

Robert A. Kent, General Counsel

APPENDIX H
COMMISSION ON CORRECTIONS CHAIRMAN'S MEMORANDUM MEDICATION PROCEDURES IN LOCAL CORRECTIONAL FACILITIES (8/1998)
[NOTE: THIS DOES NOT APPLY TO STATE CORRECTIONAL FACILITIES]

CHAIRMAN'S MEMORANDUM NO. 8-98

May 26, 1998

TO: SHERIFFS, JAIL ADMINISTRATORS, COMMISSIONERS OF CORRECTION, MEDICAL COORDINATORS

RE: Medication Procedures in Local Correctional Facilities

Section 6801 of the Education Law, in defining the practice of pharmacy, states that pharmacy is "... the preparing, compounding, preserving or dispensing of drugs, medicines, and therapeutic devices on the basis of prescription or other legal authority." Likewise, a pharmacy is defined as "any place, other than a registered store, in which drugs, prescriptions or poisons are compounded, preserved, dispensed or retailed, or in which such drugs, prescriptions or poisons are by advertising or otherwise offered for sale at retail." (Section 6802 Education Law)

In cases where large bulk stocks or supplies of medication are maintained at the facility, such a facility may be operating a pharmacy to which the requirements of the Education Law would apply. Physicians, Physician's assistants and nurse practitioners typically authorize such medication through the writing of a prescription, and the prescription is filled from stock supplies. Section 6803 of the Education Law states "only a person licensed or otherwise authorized under this article shall practice pharmacy or use the title 'pharmacist' or any derivative." There is no statutory authorization for nurses to fill prescriptions. Education Law requirements do not prohibit a physician from supplying his patients with such drugs as the physician deems appropriate, provided that such drugs are dispensed in a container labeled with the name of the patient and dispenser, directions for use, date of delivery and other information required by law (section 6807(b) of the Education Law), but such dispensing is limited to pharmacists and physicians.

New York State Commission of Correction
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Alan J. Croce, Chairman/Commissioner
Thomas J. Goldrick, Commissioner
Patricia R. Tappan, Commissioner

Health care providers or correction officers can deliver medication in a correctional setting. "Delivery" means giving an individual a single unit of medication from a pharmacy-prepared and labeled container. This includes unit dose packages which are sometimes referred to as "blister packs." If prescribed liquid medication is available from the pharmacy in a single dose unit, this could be delivered by correction officers as well. An officer cannot dilute or mix liquid medication (e.g., mix in juice).

Health care providers cannot pour and label a unit of medication for a correction officer to deliver at a later date. An officer can only deliver medication from a pharmacy-prepared container. Administration of Medication

Only authorized licensed health care providers can "administer" medication. The administration of medication would include activities which require distinguishing between various types and dosages of medications or medications ordered with specific parameters (e.g., hold medication is pulse less than 60; or give medication every four hours if necessary for pain).

Administration also includes substituting equivalent medications or executing a physician's telephone or written orders.

Medication administration is solely the function of authorized health care providers in a correctional setting.

Finally, no one, licensed or not, may administer or deliver medication prescribed and dispensed for one named individual to another individual.

_____

Alan J. Croce
Chairman/Commissioner

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RESOURCES

NYS OASAS Outpatient/Opioid Treatment Regulations

NYS OASAS PART 822 Outpatient/Opioid Treatment Programs

National Commission on Correctional Health Care – Correctional Facility-Based MAT: Promising Practices, Guidelines and Resources

NCCHC Jail Based MAT: Promising Practices, Guidelines and Resources

SAMHSA Guidelines for OTP Programs

Federal Guidelines for Opioid Treatment Programs | SAMHSA Publications and Digital Products

NYS Controlled Substances Law:

NYS Department of Health Controlled Substance Regulations

US DEA Narcotic Treatment Program Manual:

DEA, Narcotic Treatment Program Regulations, Revised 2022

NYS OASAS Opinion of Counsel: Nursing practices in OASAS certified Part 822 Opioid Treatment Programs (OTPs) & MAT for incarcerated individuals

NYS Opinion of Counsel - Nursing Practices Certified Opioid Treatment Programs (2019)