U.S. Department of Justice
Drug Enforcement Administration
Office of Diversion Control

April 2000

Narcotic Treatment Programs

Best Practice Guideline

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MESSAGE FROM THE ADMINISTRATOR

The Drug Enforcement Administration (DEA) is pleased to provide this guideline to assist in the understanding of the provisions of the Controlled Substances Act of 1970 (CSA) and in the implementation of the regulations as they apply to dosage reconciliation practices in narcotic treatment programs (NTPs). These guidelines should answer many of the questions that treatment programs have and should provide guidance to assist programs in complying with the regulations.

The NTP's role in the proper handling of controlled substances is critical both to the health of patients and to safeguarding against drug abuse and diversion. Programs' adherence to the law and understanding of the law's objectives play a valuable role in the protection of the public health and safety.

This guideline is the result of a collaborative effort of DEA and the American Methadone Treatment Association. It documents these organizations' mutual belief that the benefits of the therapeutic environment are enhanced by maintaining compliance with existing law.

Donnie R. Marshall
Acting Administrator

PREFACE

Drug abuse continues to be a significant problem in the United States. Preventing the diversion of legitimate drugs into the illicit market and the abuse of prescription medication, particularly controlled substances, is of great importance to DEA.

There are more than 1,000 NTPs registered with DEA, including methadone maintenance programs, methadone detoxification services, and compounders. The vast majority of these programs voluntarily comply with the Controlled Substances Act of 1970 (CSA) and its implementing regulations. The importance of proper control of the use of all approved narcotic replacement pharmacotherapies by NTP sponsors and staff cannot be overemphasized.

DEA policy and regulations require that all NTPs provide a complete and accurate accounting of all controlled substance medications received and dispensed. Factors that may affect a program's ability to maintain accurate inventory control and correct dispensing procedures include manufacturing standards for bottle fill, use of automatic dispensing pump equipment, effective integration of computer software programs, proper training of dispensing personnel, and accurate recordkeeping in the reconciliation of daily narcotic inventories. The purpose of these guidelines is to help NTPs interpret regulatory requirements and strengthen their ability to maintain accurate dispensing records in compliance with federal law.

It should be noted that some states have more stringent and/or additional requirements than those mandated by federal law. NTPs must comply with these more stringent and/or additional requirements. While the following guidelines include DEA regulatory requirements, NTPs should also consult with their State Methadone Authority, or its equivalent, to ensure compliance with state regulatory statutes.

ORGANIZATION OF THE GUIDELINES

The NTP guidelines that follow represent a joint initiative between DEA and the American Methadone Treatment Association. Their development grew out of the need to provide guidance to NTPs throughout the United States regarding common sense practices for the reconciliation of opioid replacement medications.

The guidelines provide information on a variety of issues related to compliance with DEA regulatory requirements and to the enhancement of NTP operations. Topics addressed range from procedures used when ordering and receiving medications and best practices for using automated dispensing systems, including the use of computer software in the dispensing/ reconciliation process, to recordkeeping and security requirements and procedures.

The guidelines can be used by NTP personnel to access specific information addressing issues or problems that arise during the day to day operation of the NTP. The intent of these guidelines is to ensure greater stability in the treatment process through the use of the same standard throughout the United States. Key management and dispensing personnel are encouraged to study the document as a whole.

In the text to follow, typeface and language are used to differentiate regulatory requirements from recommended practices.

- Recommended practices are presented in standard typeface and typically include the word "should" (e.g., "The designated staff member who receives a particular shipment should sign for the shipment only after all of the ordered medication has been accounted for.").

- The word "must" is typically used in presenting regulatory requirements, which are printed in italics. Further, the part and section of Title 21 of the Code of Federal Regulations (CFR) where a specific regulatory requirement is found is presented in brackets after the requirement (e.g., "*To order needed medication, a DEA Form-222 must be completed by the NTP.* [*21 CFR 1305.06*].").

This document also includes appendices which provide information to support material found in the body of the document. These include a compilation of questions that DEA is frequently asked - about the ordering and delivery of medication, recordkeeping, destruction of medication, security, and other issues - and the answers to these questions (Appendix A). There are also sample DEA forms (Appendix B) and a checklist that NTPs may use when preparing for a DEA investigation (Appendix C).

An appendix listing all local DEA diversion field offices also is included (Appendix D). When an NTP contacts the local DEA office to obtain information from or provide it to DEA personnel, callers should ask to speak with the "Diversion Group" of that office.

ACKNOWLEDGMENTS

The Drug Enforcement Administration would like to thank the many individuals who were involved in the development of these guidelines as well as those who reviewed drafts of this document at various stages of its development, including the American Methadone Treatment Association, the Center for Substance Abuse Treatment (CSAT), the Food and Drug Administration, and the State Methadone Authorities from Maryland and Virginia as well as various pharmaceutical companies, software manufacturers, and pump manufacturers.

Special recognition is given to CSAT which provided funding for the services of a professional writer/editor, and to the writer/editor for her efforts in completing this project.

In addition, special recognition is given to American Methadone Treatment Association's President and Board Members for their insight and expertise which proved to be invaluable to the success of this project.

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PART 1
REGISTRATION

At present, registering to become a narcotic treatment program (NTP) involves the State Methadone Authority (SMA), the Food and Drug Administration (FDA), and the Drug Enforcement Administration (DEA). Registration requires approval from all three of these agencies.

Key Elements of the Registration Process

The registration process includes:

- **Submission of Completed Applications to SMA, FDA, and DEA**

  - Contact the SMA for an application form and instructions and for information about applicable state regulations.

  - Contact FDA's Division of Scientific Investigations, Regulatory Management Branch, at 7520 Standish Place, Room 115, Rockville, MD 20855, Telephone number (888) 463-6332, for an application package for an NTP.

  - Contact the local DEA diversion field office to obtain the DEA application. (A copy of the DEA Form-363, "Application for Registration," is found in Appendix B. See Appendix D for a list of local DEA diversion field offices.)

- **Review of Applications by the SMA, FDA, and DEA**

- **Pre-Registration Review and/or Inspection Conducted by the SMA, FDA, and DEA**

  The SMA, FDA, and DEA each conduct a separate pre-registration review and/or inspection. The personnel conducting the inspections review relevant requirements with the applicant.

- **Approval**

  DEA may approve an application if the NTP has met all CSA recordkeeping and security requirements. However, a certificate of registration will not be issued until the SMA and FDA have licensed the applicant.

Other Sources of Information

SMA, FDA, and DEA personnel are available to answer questions about the registration process and requirements. In addition, the Center for Substance Abuse Treatment (CSAT) has published a monograph, entitled "Approval and Monitoring of Narcotic Treatment. A Guide on the Roles of Federal and State Agencies (Technical Assistance Publication No. 12)," which describes the registration process in detail. For a copy of this document, contact the National Clearinghouse for Alcohol and Drug Information at PO Box 2345, Rockville, MD 20847-2345, Telephone number (800) 729-6686.

PART 2
ORDERING MEDICATION

Once an NTP is registered by DEA the program will be provided an initial supply of "US Official Order Forms - Schedules I and II" (DEA Form-222). [21 CFR 1305.05(b)]. The forms must be used when ordering any schedule II medications (e.g., methadone, LAAM). [21 CFR 1305.03]. A copy of DEA Form-222 is found in Appendix B.

The following sections outline procedures for executing the order forms and offer recommendations for establishing a systematic ordering system to ensure that an adequate supply of medication is available. Procedures for responding to emergency situations, such as when a supply of the medication is needed and normal ordering procedures cannot be used, are also discussed.

Completing and Submitting the Order Form

Steps for completing and submitting a DEA Form-222 include the following:

- *To order needed medication, a DEA Form-222 must be completed by the NTP*. The following instructions for completing and executing order forms have been compiled from 21 CFR 1305.06, 1305.07, 1305.09, and 1305.11 as well as from the instructions located on the back of Copy 3 of the order form.

    - *Order forms must be prepared using a typewriter, pen, or indelible pencil*.

    - *No order form shall be filled if it (1) is not complete, legible, or properly prepared, executed, or endorsed, or (2) shows any alteration, erasure, or change of any description. A defective order form may not be corrected; it must be replaced by a new order form.*

      However, DEA has acknowledged that some minor changes may be accepted by a supplier. For instance, suppliers may correct order forms that contain minor errors (e.g., forms which are missing inconsequential information, or forms on which a purchaser has unintentionally inserted an incorrect date.

    - *The name and address of the supplier from whom the medication is being ordered must be entered on the order form.*

    - *Only one supplier may be entered on any order form.*

- *Only one item must be entered on each numbered line.* According to the instructions found on the back of Copy 3 of the order form, an item is any number of units of the same description, i.e., the same kind of medication and the same size container or the same number and size of dosage units.

- *The number of lines completed must be noted on the form.* A space is provided for the insertion of this information above the "date issued" block.

- *Each order form must be signed and dated by the person authorized to sign an application for registration/renewal application, and others designated by a power of attorney.*

  The power of attorney regulation is presented below. An example of the type of form that can be used as a power of attorney for DEA order forms and a sample notice of revocation of the power of attorney is found in Appendix B.

- According to the instructions found on the back of Copy 3 of the order form, the order form should be dated and signed as of the day it is submitted for filing.

Power of Attorney

Any purchaser may authorize one or more individuals, whether or not located at the registered location of the purchaser, to obtain and execute order forms on his/her behalf by executing a power of attorney for each such individual. The power of attorney shall be signed by the same person who signed the most recent application for registration or reregistration and by the individual being authorized to obtain and execute order forms. The power of attorney shall be filed with the executed order forms of the purchaser, and shall be retained for the same period as any order form bearing the signature of the attorney. The power of attorney shall be available for inspection together with other order form records. Any power of attorney may be revoked at any time by executing a notice of revocation, signed by the person who signed (or was authorized to sign) the power of attorney or by a successor, whoever signed the most recent application for registration or reregistration, and filing it with the power of attorney being revoked. [21 CFR 1305.07].

- *After filling in the information required to submit an order, the NTP sends Copies 1 and 2 of the DEA Form-222 to the supplier. The supplier retains Copy 1 for its records and submits Copy 2 to DEA. [21 CFR 1305.09(a),(d)].* At present, the forms should be mailed, not faxed, to the supplier (except in an emergency as discussed on page 6).

- *Order forms must be maintained separately from all other records. Copy 3 of the executed order forms and any attached statements or other related documents must be retained at the registered location printed on the order form. [21 CFR 1305.13(c)].* The NTP should establish and maintain a separate, readily retrievable file containing Copy 3 of all executed order forms.

- *The order forms must be retained for two years after the date of execution [21 CFR 1305.13(c)]*, or for the length of time required by the State Methadone Authority, whichever is the stricter requirement.

- *If an order cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60 days following the date of the order form. No order form is valid more than 60 days after its execution by the purchasing NTP. [21 CFR 1305.09(b)]*

- *Whenever a purchaser or supplier discovers that any used or unused order forms are stolen or lost, he/she must, immediately upon this discovery, report the theft or loss to the local DEA diversion field office, stating the serial number of each form. If the circumstances surrounding the theft or loss result in the purchaser (the NTP) being unable to state the serial numbers of the order forms, he/she must report, in lieu of the numbers of the forms, the date or approximate date the forms were issued to the NTP by DEA. [21 CFR 1305.12(b)].*

- *If any unused order form reported stolen or lost is subsequently recovered or found, the local DEA diversion field office must be immediately notified. [21 CFR 1305.12(b)].*

Establishing and Maintaining an Ordering System

To ensure that an adequate supply of medication is available to meet patient dosing requirements, it is recommended that programs establish and maintain a consistent ordering system. Important elements of such a system include the following:

- One NTP staff member should be designated to monitor medication inventory, complete order forms, and ensure that adequate supplies of medication and order forms are available at the program.

- The point in time at which an order for additional medication should be sent to the supplier should be determined by considering:
    - The number of patients in the program,
    - The average patient dose,
    - The capacity of the safe used by the program to store the medication, and
    - The usual length of time between the date an order form is mailed to the supplier and the date that the order is received by the program.

- The NTP's available supply of order forms (DEA Form-222) should be systematically monitored. To maintain an adequate supply, additional order forms may be requested from the local DEA diversion field office (see Appendix D).

  The NTP should anticipate a two to three week processing time before it receives the forms.

Emergency Orders

An emergency order occurs when an NTP does not have an adequate supply of medication in its inventory to meet patient dosing requirements, and would not be able to obtain the needed medication from the supplier in time to meet these requirements if normal ordering procedures were used. To address an emergency order when a DEA Form-222 is available, the NTP should arrange a transfer of medication from another NTP or other DEA registrant (i.e., hospital or pharmacy). If an order form is not available, the NTP should contact the local DEA diversion field office to authorize an emergency shipment and should also contact the supplier. Specific procedures to be used in these situations follow.

Procedures When an Order Form is Available

When an order form is available, the following actions should take place:

- The State Methadone Authority should be notified by the NTP supplying the medication that a transfer is being planned.

- *The NTP in need of medication must complete a DEA Form-222. [21 CFR 1305.03].*

- *On the order form, the NTP supplying the medication must be listed as the supplier. [21 CFR 1305.06(c)].*

- *There must be adequate security arrangements for the safe transfer of the medication to the receiving NTP. [21 CFR 1301.74(f)]*

- *The NTP in need of the medication must submit Copies 1 and 2 of DEA Form-222 to the NTP that is supplying the medication. [21 CFR 1305.09(a)].* The supplying NTP then transfers the quantity of medication indicated on the order form to the NTP in need of the medication.

- The NTP supplying the medication may wish to notify the local DEA diversion field office if a significant amount of medication is being transferred.

- *The NTP supplying the medication must retain Copy 1 for its records and submit Copy 2*

to the local DEA diversion field office. [21 CFR 1305.09(d)].

Procedures When an Order Form is Not Available

Specific procedures used when an order form is not available include the following:

- The NTP in need of medication should contact the local DEA diversion field office for assistance. The program should be prepared to provide DEA personnel with the name and phone number of a contact at the supplier, the NTP's DEA number, and the quantity of medication needed.

- The NTP should also contact the supplier to request the needed medication, and have the supplier contact the local DEA office to confirm that the emergency order was authorized. At that time, the supplier may ship the needed medication to the NTP.

- *Once the NTP receives their supply of DEA Form-222s, the NTP must submit an order form to document the emergency order authorized by DEA. [21 CFR 1305.03].* It is recommended that the order form reflect the actual date that the shipment of medication occurred.

- *The NTP in need of the medication then submits Copies 1 and 2 of the order form to the supplier, and retains Copy 3 for their records. [21 CFR 1305.09(a)].*

PART 3
RECEIVING MEDICATION

The following sections summarize procedures related to the receipt of the medication from the supplier, including the designation of NTP personnel responsible for receiving and storage of the medication, and procedures to be followed when a discrepancy or damage is identified at the time of delivery.

Designating NTP Personnel

Federal regulations require that medication deliveries to an NTP be received and secured by program personnel specifically designated for these tasks. *Acceptance of delivery of narcotic substances must be made only by a licensed practitioner employed at the NTP or by other authorized individuals designated in writing (excluding persons currently or previously dependent on narcotic drugs), who must sign for the narcotics. [21 CFR 1301.74(h)]*

- It is recommended that the NTP designate one staff member to have primary responsibility for receiving and securing the medication. The NTP also should identify additional program personnel who have authority to receive and store the medication at times when the individual designated to have primary responsibility is not available.

- *The NTP must maintain a written list of all designated personnel who have been authorized to receive and store the medication. [21 CFR 1301.74(h)].* This list should be updated whenever a change in designated personnel occurs.

General Procedures

When a shipment of the medication is delivered to the NTP:

- At the time of delivery, the designated staff member who receives the shipment should count the number of bottles in the shipment immediately and compare that number with the number found on the invoice.

- The designated staff member who receives a particular shipment should sign for the shipment only after all of the ordered medication has been accounted for.

- *If there are no discrepancies or damage and the medication is accepted as delivered, the designated staff member receiving the shipment must complete the right-hand column of Copy 3 of the DEA Form-222 that the NTP originally completed for the order, indicating the date of the delivery and the quantity received. [21 CFR 1305.09(e)].*

- It is recommended that NTP personnel who have been designated to receive shipments of medication initial the right hand column of the DEA Form-222, upon receipt of the medication.

- *The NTP must retain Copy 3 of all completed order forms as part of the program's records of receipts. [21 CFR 1305.13(a)].*

- *Order forms must be maintained separately from all other records and must be retained at the registered location for two years after the date of execution [21 CFR 1305.13(c)],* or for the length of time required by the State Methadone Authority, whichever is the stricter requirement.

Identification of Discrepancy/Damage to a Shipment

Procedures to be followed when a discrepancy or damage is found by the designated NTP staff at the time of delivery include the following:

- *When all or part of a shipment disappears, or never reaches its intended destination, the supplier is responsible for reporting any in-transit losses of controlled substances to DEA. An NTP is responsible for reporting any losses of controlled substances after a designated staff member has signed for and taken custody of a shipment. [21 CFR 1301.74(c)].*

  See the section entitled "Reporting Thefts and Losses of Controlled Substance Medication," in Part 6, "Recordkeeping," which discusses the filing of DEA Form-106, "Report of Theft or Loss of Controlled Substances."

- If, when checking a shipment at the time of receipt, the designated staff member receiving a shipment determines that there is a discrepancy between the amount of medication received and the amount ordered (i.e., a discrepancy that has not been explained by the supplier on the invoice included with the delivered order), the staff member should contact the supplier immediately for further instructions.

- When the designated staff member receiving a shipment determines that there has been damage to the medication, the staff member should contact the supplier immediately.

- The supplier should contact the appropriate DEA office immediately after being notified by the NTP of a discrepancy or damage found in a shipment.

- The supplier should contact the NTP to advise the program of the final determination regarding the discrepancy or damage.

- The NTP should document the discrepancy or damage to the shipment, related actions taken, and the final determination, which should be attached to Copy 3 of the relevant order form.

PART 4
DISPENSING/ADMINISTERING MEDICATION

The medication may be dispensed or administered manually or by using a computer system. Growing numbers of NTPs are using automated dispensing equipment in conjunction with computer software programs. Part 4 includes recommendations to assist NTPs to achieve maximum efficiency in the operation of these dispensing systems and in the use of computer software for dispensing the medication and/or for related recordkeeping.

At present, there are three forms of medication used in treatment: liquid, solid, and powdered. The NTP is advised to contact the State Methadone Authority to determine whether there are any specific prohibitions regarding the dispensing of any form of medication.

The recommendations presented below focus on procedures for dispensing/administering of liquid and solid medication. Those programs using powdered medication, which is converted to a liquid form prior to its utilization in treatment, should follow the recommendations presented below for liquid medication.

Using Automated Dispensing Pumps for Liquid Medication

The following sections present recommended procedures for maintaining and calibrating automated dispensing pumps.

Manufacturer's Instructions and Technical Assistance

- Read and follow the instructions in the manufacturer's manual prior to beginning operation.
- After beginning operation, follow the general care and usage instructions in the manufacturer's manual on a day-to-day basis.
- To prevent loss of the manufacturer's instruction manual and to ensure that it is available whenever it is needed, store the manual in a specific location in the NTP's medication area or administration office. Make an extra copy of the manual and store this back-up copy in a separate location.
- When questions pertaining to the operation and maintenance of the dispensing system arise, do not hesitate to contact the technical service department of the system manufacturer. The NTP should designate a specific individual to make such contacts.

Cleaning and Storing Equipment

- An automated dispensing system should be flushed with tepid, distilled water each day. (Tepid water is needed because excessively hot water can be corrosive to stainless steel equipment.)

- To prevent drying out of equipment, after flushing, distilled water should be left in the pump and tubing until the system is ready to be refilled with medication.

- Only authorized and trained personnel should purge the pump.

Calibrating the Equipment

Because manufacturers vary in their recommendations related to calibration of automated dispensing pump equipment, NTPs are advised to review the specific recommendations regarding calibration of pumps provided by the manufacturer of their pump. Some manufacturers recommend the use of volumetric flask calibration standards while others recommend the use of gravimetric calibration standards. In addition, some manufacturers recommend that pump equipment be recalibrated at the factory, while others deem on site recalibration to be appropriate. If recalibration is to be implemented at the NTP site, it is recommended that those NTP personnel who have been designated as responsible for recalibration be trained and certified by the pump manufacturer or the manufacturer's designee to ensure accurate calibration.

Other recommendations regarding calibration include the following:

- To minimize errors in the pumping of medication, automated dispensing pumps should be calibrated and serviced following the manufacturer's recommendations.

- Only certified, designated personnel should be involved in recalibrating equipment. These personnel should follow the manufacturer's recommendations and procedures during the recalibration process.

- The NTP should maintain a log documenting the history of pump recalibration.

- Pump output should be verified periodically, using either volumetric or gravimetric measures, as recommended by the pump's manufacturer.

- Graduated cylinders should not be used to verify bottle fill capacity. NTP personnel should not "dump" the contents of the bottles provided by the supplier into other containers in order to check bottle fill.

Maintaining and Replacing Tubing

- Tubing should be flushed and cleaned daily with tepid water.
- Tubing should be replaced when it begins to leak.
- Even when tubing appears to be in good condition, it should be replaced quarterly or at the time interval recommended by the manufacturer.
- Tubing should be replaced each time the NTP begins to use a different narcotic medication or narcotic medication from a different manufacturer in the pump system.
- The NTP should validate the pump's calibration after the tubing has been replaced.
- Replacement tubing should be obtained directly from the pump manufacturer or following the manufacturer's specific replacement recommendations.
- When an NTP purchases replacement tubing not precut to the appropriate length, and if active medication is dosed directly from the tubing (that is, there is no nozzle), it is important to cut the tubing cleanly and squarely (not at an angle) to prevent splashing, dripping, and/or diverting the fluid direction.

Using Computer Software for Dispensing/Related Recordkeeping

When using computer software packages, including software associated with the operation of automated dispensing pump and/or used for recordkeeping related to the dispensing of liquid or solid medication, NTPs should follow the specific recommendations of the companies which provide and install the computer hardware and software. General recommendations regarding the training of program personnel in the use of computer software and actions to be taken in the event of system emergencies follow.

Training in the Use of Software

- Designated NTP personnel should be trained by the software company before the NTP's use of computer equipment begins.
- Program management should ensure that new staff are trained in the use of the software either by existing program personnel, who have been previously trained by the software company, or by the software company itself.
- Training should be conducted by the software company for all designated dispensing personnel at least annually or whenever there is a major change in dispensing personnel.

Addressing System Emergencies

- When the automated system goes down, the vendor's software checklist should be consulted to be sure that procedures have been properly followed. NTPs are also advised to contact their software manufacturer.

- Each NTP should develop operating instructions for manual dispensing to be implemented in the event that the automated system goes down. The operating instructions should be developed before problems arise and NTP personnel should be trained in their use. These instructions should include procedures for bringing the system back on line and for updating the system.

- *Federal regulations require that NTPs maintain complete and accurate records. [21 CFR 1304.21(a) and (d)].* In order to comply with this regulation, NTPs must maintain dispensing information manually when the automated system becomes inoperable. Once the system is again operational, computer records must be updated to include information related to all manual dispensing that occurred while the system was inoperable. This information must be entered into the computer prior to closing.

- The NTP should maintain an off site back-up of all computer generated program information.

- The NTP should conduct periodic drills to prepare personnel for system emergencies.

Other Recommendations and Requirements

General procedures related to the dispensing and administering of solid or liquid medication include the following:

- *An NTP must provide effective security controls and procedures to guard against theft and diversion. [21 CFR 1301.71(a)].*

- A log of bottle numbers should be maintained.

- Medication should be used on a "first in/first out" basis.

PART 5
DISPOSAL OF MEDICATION

The following sections provide information to assist NTPs in differentiating between and responding to spillage and accountable losses of medication. Procedures for recording/reporting spillage and accountable losses and for destruction and disposal of medication are discussed.

Spillage and Accountable Loss

The procedures NTPs should follow when reporting/recording the destruction and disposal of individual doses of medication that are spilled differ from the procedures used when there are accountable losses of bulk inventory.

Spillage of Individual Patient Dose

When spillage of an individual patient dose occurs, the following should take place:

- The employee who spilled the medication or who witnessed a patient spilling the medication should immediately report the incident to a supervisor.
- After the spilling of medication has been reported to a supervisor, the medication should be properly disposed of.
- Documentation of spillage should be completed, indicating the drug, its strength and amount, and the date of spillage and signed by both the employee involved and a supervisor.
- Documentation of spillage should be maintained in a readily retrievable manner and reviewed periodically to determine if a pattern is developing.
- Documentation of spillage does not need to be sent to the local DEA diversion field office, but should be available for inspection by DEA.
- Any liquid or dust resulting from a spill or from the process of compounding diskettes **should not** be sent to DEA. Rather, these materials should be disposed of immediately in a manner that will prevent any further use of the medication, and should be witnessed by the employee involved and the supervisor.
- This disposal should be documented by the NTP and be maintained in their records in a readily retrievable manner.

Accountable Losses

Controlled substance bulk inventory lost through breakage, damage, or spillage (other than an individual patient dose) should be considered an accountable loss. *Disposal of such controlled substances must be in accordance with DEA requirements and must be reported on a DEA Form-41 (Registrants Inventory of Drugs Surrendered). [21 CFR 1307.21(a)].*
(See Appendix B).

General procedures for such disposal are reviewed in the section, "Disposal of Liquid or Solid Medication."

Disposal of Liquid or Solid Medication

NTPs that have medication requiring destruction should contact their local DEA diversion field office for authority and instructions related to the disposal of the substances. (Local DEA diversion field offices are listed in Appendix D).

Procedures related to destruction and disposal include the following:

- Any medication, regardless of form, should be destroyed if contaminated or beyond expiration date.

- An NTP using medication in solid form should gather and retain all recoverable chunks or chips of the medication.

- *Medication to be destroyed must be listed on the DEA Form-41. [21 CFR 1307.21(a)].*

- *The Special-Agent-in-Charge (SAC) at the local DEA diversion field office has the discretion to authorize the destruction of medication by an NTP, in a manner determined by the SAC. [21 CFR 1307*.21(b)].

If the local DEA diversion field office approves of the disposal, the office will instruct the NTP in the procedures to be followed. These may include the transfer of the medication to a registrant authorized to dispose of controlled substances, or by destruction in the presence of an individual from DEA or another authorized person.

PART 6
RECORDKEEPING

DEA requires that NTPs keep a record of all medication received, dispensed, administered, and destroyed. In addition, DEA requires that NTPs retain all records for two years from the date of execution. However, because some states require that records be retained for longer than two years, NTPs should contact the State Methadone Authority (SMA) for information about state requirements.

DEA requires that NTPs conduct an initial inventory of all stocks of controlled substance medications on hand on the date that the NTP begins operations. It is also required that, at least once every two years, each NTP conduct and document a physical inventory (called a "biennial inventory") of the medication on hand. These inventories must include all forms of medication on hand (i.e., liquid, tablet, diskette, or powder) as well as the quantity and strength of each medication.

During a DEA accountability investigation, the beginning inventory used in the audit must be an actual physical inventory taken by the NTP. The beginning inventory selected could either be the NTP's initial or biennial inventory.

The following sections summarize DEA recordkeeping and inventory requirements, provide an overview of DEA's accountability investigation, and recommended strategies for maintaining complete and accurate records in accordance with DEA regulations. Appendix C includes a list of all documents and information that an NTP is required to have available at the time of a DEA investigation.

Records for Compounding Controlled Substances

The sections that follow review DEA recordkeeping requirements related to the compounding of controlled substances.

Compounding for On-Site Use

All NTP sites that compound a bulk narcotic solution from bulk narcotic powder to liquid for on-site use must keep a separate batch record of the compounding. [21 CFR 1304.24(c)]

Compounding for Off-Site Use

Each NTP that is registered or authorized to compound narcotic drugs for off-site use in an NTP must maintain records which include the following information [21 CFR 1304.25]:

Bulk Form: *Records for each narcotic controlled substance in bulk form to be used in, or capable of use in, or being used in, the compounding of the same or other non-controlled substance in finished form must include the following information:*

- *Name of the substance*;

- *Quantity compounded in bulk form by the NTP, including the date, quantity, and batch or other identifying number of each batch compounded;*

- *Quantity and date received, including the name, address, and DEA number of the registrant from whom the substance was received;*

- *Quantity used to compound the same substance in finished form, including:*
    - *Date and batch or other identifying number of each compounding;*
    - *Quantity used in the compounding;*
    - *Finished form (i.e., 10 mg tablets or 10 mg concentration per fluid ounce);*
    - *Number of units of finished form compounded;*
    - *Quantity lost during compounding and the causes, if known;*
    - *Total quantity of the substance contained in the finished form;*
    - *Theoretical and actual yields; and*
    - *Any other information necessary to account for all controlled substances used in the compounding process;*

- *Quantity distributed in bulk form to other programs, including the date and quantity of each distribution and the name, address, and registration number of each program to whom a distribution was made; and*

- *Quantity disposed of by destruction, including the reason, date, and manner of destruction.*

For further information on procedures related to the destruction of medication, see the section entitled "Destruction of Liquid or Solid Medication," on page 16.

Finished Form: *Records for each narcotic substance in finished form must include the following information:*

- *Name of the substance;*

- *Finished form and the number of units or volume in each commercial container (i.e., 100-tablet bottle or 3 ml bottle);*

- *Number of containers of each such commercial finished form compounded from bulk form;*

- *Number of units of finished forms and/or commercial containers received from other persons, including the date or number of units and/or commercial containers in each receipt and the name, address, and DEA registration number of the person from whom the units were received;*

- *Number of units and/or commercial containers compounded by the NTP registrant from units in finished form received from others, including:*
    - *Date and batch or other identifying number of each compounding;*
    - *Operation performed (i.e., repackaging or relabeling);*
    - *Number of units of finished form used in the compound, the number compounded, and the number lost during compounding, with the causes, if known; and*
    - *Any other information necessary to account for all controlled substances used in the compounding process;*

- *Number of containers distributed to other programs, including the date, the number of containers in each distribution, and the name, address, and DEA registration number of the program to which the containers were distributed; and*

- *Number of units of finished forms and/or commercial containers destroyed in any manner by the NTP registrant, including the reason, the date, and manner of destruction.*

For further information on procedures related to the destruction of medication, see the section entitled "Disposal of Liquid or Solid Medication," on page 16.

Requirements for an Inventory

DEA requires that NTPs must conduct an initial inventory of all stocks of controlled substance medications on hand on the date that the NTP begins operations. In the event that no controlled substance medications are on hand at this time, this fact must then be noted in the NTP's initial inventory. [21 CFR 1304.11(b)].

DEA also requires that after the initial inventory is taken, NTPs must conduct a new physical inventory of all stocks of controlled substance medications on hand at least once every two years, which is identified as the official DEA biennial inventory. The biennial inventory may be conducted on any date within two years of the previous biennial inventory date. [21 CFR 1304.11(c)].

It is recommended, however, that NTPs conduct inventories at more frequent intervals in order to maintain adequate control over their needs and requirements.

The initial and biennial inventory must include the following information: [21 CFR 1304.11]:

- *Date the inventory is conducted,*
- *Time of day inventory is conducted, i.e., at the open or close of business, and*
- *Name, dosage form, strength, and quantity of each medication on hand at the time of the opening or closing inventory.*

It also is recommended that the initials of the individual who conducted the inventory be included in the written record of each inventory.

Receipts

See Part 3, "Receiving Medication," for information on recordkeeping procedures related to the receipt of medication from the supplier.

Dispensing Records

Each NTP must maintain a record of medication dispensing which contains the following information [21 CFR 1304.24(a)]:

- *Name of substance;*
- *Strength of substance;*
- *Dosage form;*
- *Date dispensed;*
- *Adequate identification of patient (consumer);*
- *Amount consumed;*
- *Amount and dosage form taken home by patient; and*
- *Dispenser's initials.*

Each NTP must maintain these records in a dispensing log. [21 CFR 1304.24(b)].

However, as an alternative to the maintaining a dispensing log, an NTP may use an automated/computerized data processing system for the storage and retrieval of the program's dispensing records, if the following conditions are met:

- The automated system maintains the information required in 21 CFR 1304.24(a),
- The automated system has the capability of producing a hard copy printout of the program's dispensing records,
- That an NTP print a hard copy of each day's dispensing log, which is then initialed appropriately by each person who dispensed medication to the program's patients, and
- That the automated system is approved by DEA.

Furthermore, if an NTP uses identification numbers or a similar system, rather than patient names and addresses for medication dispensing records, then that NTP has not "adequately identified" their patients as required by 21 CFR 1304.24(a). According to DEA policy, an NTP that uses such a system to identify its patients must maintain an up-to-date cross-index that associates each identification number with the name and address of the person to whom it refers. This list should be readily available for the auditing or verification of program records.

Computer Software Requirements for Maintaining Dispensing Records

When an NTP uses an automated data system to maintain dispensing records, *the computerized dispensing records must contain the information outlined in 21 CFR 1304.24(a).*

See the previous section regarding "dispensing record" requirements (manual as well as computerized).

It is also recommended that an NTP's computer software program be capable of producing accurate summary reports for any time frame selected by DEA personnel during an investigation. Further, if these summary reports are maintained in hard copy form, they should be kept in a systematically organized and centrally located file.

Reporting Theft and Loss of Controlled Substance Medication

Immediately upon discovery of a theft or significant loss of a controlled substance medication, the NTP must contact the local DEA diversion field office by telephone, facsimile, or with a brief written message explaining the circumstances. Further, a DEA Form-106, "Report of Theft or Loss of Controlled Substances", must be filed. [21 CFR 1201.74(c)]. The NTP should also notify the local police, as this may be required by state law.

The following sections review issues and procedures related to reporting the theft and loss of controlled substance medication.

Issues Related to Reporting Theft and Loss

- Although the regulations do not define the terms "upon discovery" and "significant loss," it is the responsibility of the NTP to use its best judgement to take appropriate action. What would constitute a significant loss for one program may be viewed as comparatively insignificant for another program.

- The loss of a small quantity of controlled substance, repeated over a period of time, may indicate a significant problem for a program even though the individual amounts of missing controlled substances are not, in and of themselves, significant.

- A program should be alert for suspicious or unexplained losses. Any signs of a break in, physical entry, or armed robbery should be reported.

- The burden of responsibility is on the NTP to identify a significant loss and make the required report to DEA. Some factors to consider for determining significant loss include:

    - The quantity missing (i.e., one tablet vs. one bottle)
    - The name and schedule of the missing medication
    - The abuse potential of the missing substance in your area
    - Is this the first time this loss has occurred? Has a similar loss occurred before?
    - Was this loss reported to local law enforcement authorities?

DEA Form-106 (Report of Theft or Loss of Controlled Substances)

The NTP must complete a DEA Form-106 to formally document the actual circumstances of a theft or significant loss and the quantities of controlled substances involved. [21 CFR 1301.74(c)]. However, in many cases, determining the actual circumstances may require some evaluation, review, and possible investigation. Issues and procedures related to the determination of whether and how to use DEA Form-106 include the following:

- If, after reviewing all the available information, it is determined that no theft or significant loss occurred, no DEA Form-106 need be filed. However, the NTP should notify DEA of the results of the investigation and maintain a record of the occurrence in its loss and theft file for future reference.

- If there is a question as to whether a theft or a significant loss has occurred, the NTP should contact the local DEA diversion field office.

- An NTP should not use a DEA Form-106 to adjust inventory.

An NTP should contact the local DEA diversion field office to obtain a DEA Form-106. A completed theft and loss form should include the following information:

- Name and address of NTP;
- DEA registration number;
- Date of theft;
- Local police department notified;
- Type of theft (night break in, armed robbery, etc.);
- Listing of symbols or other identifying markings (if any) used by NTP to mark containers; and
- Listing of controlled substances missing from theft or significant loss (name, quantity, and strength).

An NTP is required to prepare the form in triplicate, keep the third copy for its records, and send the first and second copies to the local DEA diversion field office.

DEA Accountability Investigations

A DEA accountability investigation is an unannounced investigation conducted by DEA personnel of an NTP's records and security measures of all controlled substances on hand.

Upon entering the premises, DEA personnel must (1) present their credentials, (2) state the purpose of their visit, and (3) present a written notice of their inspection authority (DEA Form 82 – Notice of Inspection of Controlled Premises) to the owner, operator, or agent in charge of the NTP. [21 CFR 1316.05].

Wherever possible, informed consent must consist of a written statement signed by the owner, operator, or agent in charge of the NTP, and witnessed by two persons. The written consent includes the following information [21 CFR 1316.08]:

That the owner, operator, or agent of the NTP:

- *Has been informed of his/her constitutional right not to have an administrative inspection without an Administrative Inspection Warrant (AIW),*
- *Has the right to refuse consent to such an inspection,*
- *Has been presented with a Notice of Inspection,*
- *Has given his/her consent voluntarily, without threats of any kind,*
- *May withdraw his/her consent at any time during the course of the inspection, and*
- *Has been informed that if anything of an incriminating nature is found, it may be seized and used against him/her in a criminal prosecution.*

In those cases in which informed consent is not given, or where consent is withdrawn, DEA personnel must obtain an AIW. [21 CFR 1316.08(a)]. If the owner, operator, or agent of an NTP refuses to permit the execution of an AIW, or impedes DEA personnel in the execution of an AIW, he/she is to be advised that such refusal or action constitutes a violation of the Controlled Substances Act of 1970. [21 CFR 1316.12].

Once DEA personnel have begun an accountability investigation, the owner, operator, or agent of the NTP must provide them with the following information [21 CFR 1301.74(c), 1304.11(b) and (c), 1305.09, 1305.13, and 1307.21]:

- *The initial inventory (if the NTP has been open for business less than two years, or upon request of DEA Investigators);*

- *The latest biennial inventory conducted (if the NTP has be in operation more than two years);*

- *Receipts (DEA Form-222s) of the medication received since the inventory was conducted; and*

- *Documentation of the amount of medication dispensed, spilled, returned to manufacturer, transferred to another NTP, missing due to theft or unexplained loss, destroyed since the inventory was conducted, or awaiting destruction.*

- It is also recommended that the NTP provide investigators with the most recent physical inventory. For a list of the documents required during a DEA investigation, see Appendix C.

Also during an accountability investigation, a "closing inventory" will be conducted. A closing inventory is a physical count of all the program's controlled substance medications on hand as of that date. The closing inventory will be verified by an official of the program, and should be done prior to or after the day's dispensing hours. In addition, it should be noted on the paperwork whether the closing inventory was taken at the opening or close of business hours.

DEA maintains a strict accountability policy regarding the reconciliation of all narcotic inventory medications. *All registered NTPs must provide an accurate and complete accounting of all narcotic medication that has been received, dispensed, returned, destroyed, reported lost/stolen, or otherwise disposed of. [21 CFR 1304.21].*

Maintaining Complete and Accurate Records

DEA regulation and policy require that NTPs provide complete and accurate records. In an effort to assist programs in their attempt to comply with these requirements, DEA strongly recommends that the following strategies be adopted:

- Ensure that employees understand how to operate relevant equipment, including computers;

- Maintain appropriate back-ups for computer and other recordkeeping systems; and

- Establish appropriate shut-down procedures to be used both at the time of dispenser shift changes and at the end of the work day.

DEA is aware that in dealing with liquid controlled substance medications, absolute accountability is not always attainable. An NTP's overall processes, procedures, and results will be taken into account in the evaluation of the outcomes of an investigation.

PART 7
SECURITY

Federal regulations address basic security requirements for NTPs. DEA is responsible for evaluating whether NTP security systems are in compliance with DEA regulations.

The following sections outline some of the factors that DEA considers in determining whether security systems are in compliance with security regulations and summarize specific requirements that pertain to the security of controlled substances in an NTP. Before making expenditures for a new or modified security system, existing and proposed NTPs are encouraged to contact their local DEA field diversion office to determine whether the proposed system is in compliance with the regulations. (Local DEA diversion field offices are listed in Appendix D).

DEA Security Regulations

DEA may exercise discretion regarding the degree of security required in NTPs based on such factors as the location of the program and the number of patients, security guards, physicians, and staff members connected with the program. [21 CFR 1301.74(l)].

In determining whether an NTP's security system complies with federal regulation, DEA considers several factors, including but not limited to the following [21 CFR 1301.71(b) and 1301.74(l)]:

- *Type (e.g., methadone, LAAM) and form (e.g., bulk powder, liquid, tablets) of controlled substances handled;*
- *Quantity of controlled substances handled;*
- *Location of the facility (e.g., high or low crime area);*
- *Type of building construction (e.g., brick or frame);*
- *Physical layout of the program interior (e.g., degree of separation of patient areas from medication dispensing and storage areas);*
- *Type of safe or vault used;*
- *Adequacy of electronic detection and alarm systems;*
- *Number of patients enrolled in the program;*
- *Availability of local police protection or private security; and*
- *Adequacy of key control systems and/or combination lock control systems.*

Security of Controlled Substance Stocks

The following sections summarize specific requirements related to NTP security.

Safes, Steel Cabinets, or Vaults

Requirements for safes, steel cabinets, or vaults include, but are not limited to, the following specifications or their equivalent. [21 CFR 1301.72(a)].

- *Safes, steel cabinets, or vaults must be constructed to withstand the following:*
    - *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.*

- *Safes and steel cabinets that weigh less than 750 lbs, must be bolted or cemented to the floor or wall in such a way that they cannot be readily removed.*

- *Safes and steel cabinets, if necessary, depending on the quantities and type of controlled substance medications stored, must be equipped with an alarm system, which upon unauthorized entry will transmit a signal directly to a central station protection company, a police department, or a 24-hour control station operated by the NTP.* It is recommended that each NTP contact their local DEA Diversion Field Office (see Appendix D) to determine if their program's safe/steel cabinet requires an alarm system.

- V*aults must be equipped with an alarm system, which upon unauthorized entry will transmit a signal directly to a central station protection company, a police department, or a 24-hour control station operated by the NTP.*

- *A vault must be constructed of 8 inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with 1/2-inch steel rods tied 6 inches on center, or the structural equivalent*.

- *A vault must be equipped with a self-closing and self-locking "day-gate", or its equivalent, if the vault remains open for frequent access.*

NTPs are advised to change security codes and dispensing area locks/keys and lock combinations when dispensing personnel resign or are terminated from employment.

Alarm Systems

Components of the alarm system must include [21 CFR 1301.72(a)]:

- *Contact switches on the door of the vault;*

- *A device designed to detect illegal entry into the vault (i.e., electrical lacing of walls, floors, and ceilings; sensitive ultra sonic equipment within the vault; or sound accumulator system); and*

- *Safes and steel cabinets, if necessary, depending on the quantities and type of controlled substance medications stored, must be equipped with an alarm system, which upon unauthorized entry will transmit a signal directly to a central station protection company, a police department, or a 24-hour control station operated by the NTP.* It is recommended that each NTP contact their local DEA Diversion Field Office (see Appendix D) to determine if their program's safe/steel cabinet requires an alarm system.

- V*aults must be equipped with an alarm system, which upon unauthorized entry will transmit a signal directly to a central station protection company, a police department, or a 24-hour control station operated by the NTP.*

For additional security of staff, patients, and medication, it is recommended that components of the alarms system also include:

- A perimeter alarm system covering doors and windows of the program; and

- Holdup alarms in strategic areas (i.e., the reception and dispensing areas).

Accessibility of Controlled Substances

Requirements pertaining to accessibility include the following:

- *The delivery of narcotic substances must only be accepted by a licensed practitioner employed at the facility or by other authorized individuals designated in writing (excluding persons currently or previously dependent on drugs), who must sign for the narcotics. [21 CFR 1301.74(h)]*

- *Patients must be required to wait in an area physically separated from the narcotic storage and dispensing area. [21 CFR 1301.74(j)].* The term "dispensing area" refers to the actual physical location where the dispensing occurs. It does not include any waiting or common areas.

- *Narcotics dispensed or administered at an NTP must be dispensed or administered only by the following individuals [21 CFR 1301.74(i)]:*

    - *A licensed practitioner;*
    - *A registered nurse under the direction of a licensed practitioner;*
    - *A licensed practical nurse under the direction of a licensed practitioner; or*
    - *A pharmacist under the direction of a licensed practitioner.*

- *The controlled substance storage areas must be accessible only to an absolute minimum of specifically authorized employees. [21 CFR 1301.72(d)]*

- *When it is necessary for employee maintenance personnel, nonemployee maintenance personnel, business guests, or visitors to be present in or pass through controlled substance storage areas or manufacturing areas during production of controlled substances (e.g., the compounding area), the registrant must provide adequate observation of the area by an employee specifically authorized in writing. [21 CFR 1301.72(d) and 1301.73(c)].*

It is recommended that the required documentation of those individuals authorized to have access to the dispensing area be easily retrievable and maintained in a central location.

The NTP should check with the State Methadone Authority, or its equivalent, to determine if there are any additional restrictions to access.

APPENDIX A

ANSWERS TO FREQUENTLY ASKED QUESTIONS

APPENDIX A
ANSWERS TO FREQUENTLY ASKED QUESTIONS

NTPs as well as other professionals concerned with narcotic addiction treatment often direct questions to DEA about the ordering and receipt of medication, addiction treatment outside a traditional NTP setting, destruction of medication, recordkeeping and security requirements, NTP personnel, and other issues. Frequently asked questions on these topics and their answers are found below.

For additional information on these topics it is recommended that you refer to the appropriate section of this document.

Ordering and Delivery

Q. Our program sends individual unit doses of medication to a satellite location. Must we use a DEA Form-222 (order forms)?

A. Yes. However, a program may wish to list the total quantity of medication transferred weekly (e.g., 150 doses x 30mg, or 4,500 mg), rather than listing the individual doses transferred on a daily basis to a satellite location. Before you begin to use this method to complete the order form you should obtain permission from your local DEA diversion field office. If you obtain permission to do this, it is recommended that an internal record documenting the actual transfer(s) be maintained, which should include the following:

- The date the transfer took place;
- The name of each satellite location;
- The amount of medication transferred to each satellite location; and
- The initials/signature of the NTP staff member who transferred the medication.

Q. A program has ordered methadone from their supplier. However, the shipment hasn't arrived and they are about to run out. Can we "lend" them a few bottles of methadone until their shipment arrives, without initiating a DEA Form-222?

A. No. You cannot "lend" them methadone, but you can transfer methadone to the other program to meet its immediate need. Every transfer of a Schedule II controlled substance must be documented on a DEA Form-222 and copies maintained as follows [21 CFR 1305.09(d), (e)]:

- Copy 1 must be retained by the NTP supplying the methadone;
- Copy 2 must be mailed to the local DEA diversion field office by the NTP supplying the methadone; and
- Copy 3 must be retained by the NTP receiving the methadone.

Q. Our program is almost out of methadone and cannot obtain any locally. What can we do?

A. Contact your local DEA diversion field office (see Appendix D). The office can authorize an emergency shipment of methadone from your supplier. The local office also will direct you as to the procedure that must be followed to obtain an emergency shipment.

Q. Our program has requested DEA Form-222s, but they have not arrived as yet and we are almost out of methadone. What can we do?

A. Contact your local DEA diversion field office (see Appendix D), which can trace your request for order forms and assist you in obtaining an emergency shipment.

Q. Who can accept delivery of methadone/LAAM at the NTP?

A. The acceptance of delivery of narcotic substances by an NTP must be made only by a licensed practitioner employed at the facility or other authorized individual designated in writing (excluding persons currently or previously dependent on narcotic drugs). The authorized individual must sign for the narcotics and place his/her specific title (if any) on any invoice.
[21 CFR 1301.74(h)].

Treatment Outside an NTP

Q. As a practicing physician, I want to open a Amedication unit@ in my office to dispense methadone to patients enrolled in an NTP. The methadone will not be stored overnight. Must I be registered with DEA?

A. Yes. Although FDA does not require a separate registration, you must have a separate DEA registration to conduct maintenance/detoxification treatment even though you do not store methadone overnight. It is the activity (dispensing/administering) that must be registered.
[21 CFR 1306.07(a)].

Q. I am a physician with a patient who is addicted to opioids. How can I treat this patient?

A. You may administer opioids to a patient for the purpose of relieving acute withdrawal symptoms while arrangements are made to refer your patient for addiction treatment, under the following conditions [21 CFR 1306.07(b)]:

- Not more than one day's medication may be administered or given to your patient at one time,
- This treatment may not be carried out for more than three days, and
- This three-day period cannot be renewed or extended.

Q. An NTP patient has been admitted to a hospital for treatment of a medical condition other than addiction. Can the hospital supply the treatment medication?

A. Yes. A physician, or authorized hospital staff, may administer or dispense narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction. [21 CFR 1306.07(c)].

Q. Can a patient in a Long Term Care Facility (LTCF) receive methadone for maintenance purposes?

A. If an LTCF is registered with DEA as a hospital/clinic, it need not be separately registered as an NTP to administer or dispense methadone as an adjunct to medical or surgical treatment of conditions other than addiction. [21 CFR 1306.07(c)]

If an LTCF that is not registered with DEA as a hospital/clinic has a patient who is also currently enrolled in a licensed NTP, the NTP may transfer medication to the LTCF with the approval of the State Methadone Authority.

If an individual not currently enrolled in an NTP is in an LTCF that is not registered with DEA as a hospital/clinic or an NTP, a practitioner may administer narcotic drugs to the individual for relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment. No more than one day's medication may be administered to the individual or for the individual's use at one time. Such emergency treatment may be carried out for no more than three days and may not be renewed or extended. [21 CFR 1306.07(b)]

Q. Can an "alcohol treatment center" (ATC) maintain and/or detoxify their patients with methadone from hospital pharmacy stock without a separate registration?

NOTE: Prior to admission into the ATC, these patients were enrolled in NTPs, and each patient currently receives a supply of methadone from his/her NTP.

A. Yes. Medical treatment has been interpreted by both DEA and FDA to include psychological as well as physiological treatment, and, as such, a primary psychiatric diagnosis of alcoholism would be considered medical treatment of a condition other than addiction. Treatment provided at ATCs registered with DEA as hospitals/clinics falls under the regulatory provision related to the administering/dispensing of narcotics for addiction treatment as an incidental adjunct to medical treatment of conditions other than addiction. [21 CFR 1306.07(c)].

An ATC which is not located in a hospital setting and equipped with pharmacy services may not be authorized to administer or dispense narcotics for treatment without separate registration as an NTP. Such an ATC, however, can administer methadone supplied by the NTP in which the patient is enrolled.

Q. May an inmate enrolled in an NTP have methadone administered by Department of Corrections medical staff, if the facility does not have a separate registration as an NTP?

A. Yes. Medical staff of the Department of Corrections may administer narcotic drugs to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made to have methadone supplied by the inmate's NTP. A separate registration would not be required provided that no more than one day's medication be administered to the person or for the person's use at one time. Such treatment is limited to three days and may not be renewed or extended. [21 CFR 1306.07(b)].

Q. May a Department of Corrections medical staff administer methadone to incarcerated, pregnant, opioid dependent women during the course of their pregnancy without a separate registration as an NTP?

A. Methadone may be administered in such circumstances when the following conditions are met. A practitioner, or authorized hospital staff, may administer or dispense narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction. Pregnancy is recognized as a medical condition by both DEA and FDA, and, therefore, this would be considered medical treatment of a condition other than addiction.

Such medical treatment is allowed "in a hospital" or institutional setting. However, the Department of Corrections must be licensed by both the state and DEA as a clinic, a hospital, or a hospital/clinic. [21 CFR 1306.07(c)]

Q. Does a nurse have the authority to administer methadone pursuant to a physician's medication order to an inmate?

A. Yes. If, as an agent of the practitioner, the nurse is so authorized by the state, she/he may act on behalf of, or at the direction of, the staff physician, pursuant to the physician's order for medication, and may administer the methadone to the inmate.

Q. Can I obtain an exception to a separate registration as an NTP to provide methadone maintenance to HIV infected opioid dependent patients who reside in nursing homes?

A. An HIV infected opioid dependent patient residing in a nursing home may receive medication only under the following conditions:

1) If the nursing home is not separately registered with DEA as an NTP, and the patient is currently enrolled in a licensed NTP, the NTP may deliver the patient's medication to the nursing home.

2) If the nursing home is registered with DEA as an institutional practitioner (hospital), a practitioner or authorized hospital staff may administer or dispense narcotics to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment. In this example, the primary medical condition is the patient's HIV infection. Therefore, medication could be dispensed to this patient as an incidental adjunct to his/her treatment.

Disposal of Medication

Q. Some methadone spilled in the NTP. How should this be reported?

A. When spillage of an individual patient dose occurs, the employee who spilled the medication or who witnessed a patient spilling the medication should immediately report the incident to a supervisor. The medication should then be properly disposed of. Documentation of spillage must be completed, indicating the drug, its strength and amount, and the date of spillage, and signed by both the employee involved and a supervisor. Documentation of spillage should be maintained in a readily retrievable manner and reviewed periodically to determine if a pattern is developing. Documentation of spillage does not need to be sent to the local DEA diversion field office, but should be available for inspection by DEA. [21 CFR 1304.21(a)].

Q. We have a bottle of methadone that has become contaminated. What should we do?

A. To obtain guidance on the destruction of any narcotic (except spills, as discussed above), contact the local DEA diversion field office listed in this manual (see Appendix D).
[21 CFR 1307.21(a)].

Q. What should we do with the empty bottles of methadone/LAAM?

A. The bottles should be rinsed out by the dispensing nurse before being disposed of in an appropriate manner.

Recordkeeping

Q. The state requires that I maintain records for three years, but DEA only requires two years. How long must I maintain records?

A. You must follow whichever requirement is stricter. In the example cited above, you would be required to maintain records for three years.

Q. Our program had some computer problems and lost some data. What should we do?

A. Any problems that involve loss of data should be recorded in writing to document any unusual occurrences. This documentation should be signed by those witnessing the incident. If it was possible to reconstruct the data using sign-in logs and other back-up documents, this should be mentioned in the incident report. The program should maintain a separate incident report file to be presented to investigators upon request. To reduce data loss in the future, your computer records should be backed up regularly using procedures recommended by your computer software supplier, so that only a minimal amount of data will be lost.

However, the loss of data should be minimal (no more than one day) as each NTP is required to maintain medication dispensing records in a dispensing log as outlined in 21 CFR 1304.24(b). Even those NTPs that use an automated/computerized data processing system for maintaining, storing, and retrieving dispensing record information are required to print a hard copy of each day's dispensing log, which is then initialed by each person who dispensed medication to patients. See Part 6, Recordkeeping, the section entitled "Dispensing Records" beginning on page 20 for additional information.

Q. Must we use patient names on dispensing records?

A. No. You may use patient identification numbers and maintain an up-to-date cross-index that associates each identifying number with the name and address of the person to whom it refers.

Security

Q. Our program would like to use a digital dialer for our alarm transmission to the central station. Is this permissible?

A. Digital dialers can easily be defeated and therefore are not usually acceptable as stand alone units. Any NTP wishing to modify their security should contact the local DEA Diversion Field Office (see Appendix D) for guidance prior to purchasing or installing any electronic security equipment.

Q. Should the alarm system be tested?

A. Yes. The system should be tested on a regular basis by testing the different sensors locally to make sure they are functioning and the sensitivity is appropriate. It is also recommended that, on a quarterly basis, the system be tested in conjunction with the central station. This is accomplished by notifying the alarm company that you are testing the alarm, and verifying that the central station received a signal from your location.

Q. Our hospital operates a small detoxification program within the hospital. Must we store the program's methadone in a burglary-resistant and alarmed safe? We normally stock less than 200 x 10 mg tablets.

A. DEA may exercise discretion regarding the degree of security required in addiction treatment programs based on such factors as the location of the program and the number of patients enrolled. [21 CFR 1301.74(l)]. Consult with your local DEA Diversion Field Office (see Appendix D) about specific security controls for your operation.

Personnel Issues

Q. Our program would like to hire an individual who had his DEA registration revoked for cause. If hired, this person would have access to controlled substances. Can our program hire this individual if his/her state license has been reinstated?

A. The program cannot employ anyone as an agent or employee **who will have access to controlled substances** if they have been convicted of a felony offense relating to controlled substances or, at any time, have had: (1) an application to obtain a DEA registration denied,
(2) a DEA registration revoked, or (3) surrendered a DEA registration for cause.

"For cause" means a surrender in lieu of, or as a consequence of, any federal or state administrative, civil, or criminal action resulting from an investigation of the individual's handling of controlled substances. [21 CFR 1301.76(a)].

However, an employer may request a waiver to employ such an individual in a position that will include access to controlled substances. Such a request should be addressed to:
DEA, Deputy Assistant Administrator, Office of Diversion Control, Washington, D.C. 20537.

Q. Is there any in-service training for NTP staff members available through DEA?

A. Contact your local DEA diversion field office to determine if training is available (see Appendix D).

Other Miscellaneous Issues

Q. Is it possible to use drugs other than methadone or LAAM for maintenance or detoxification purposes?

A. You can only use those opioids that are approved by FDA to maintain or detoxify an opioid

dependent individual. At this time, the Department of Health and Human Services and FDA have approved only methadone and LAAM for maintenance or detoxification treatment of narcotic addiction.

Q. An employee has been caught diverting controlled substances. What do we do?

A. Contact local law enforcement as well as the local DEA diversion field office to report the diversion and to obtain the required forms. If the employee is a licensed practitioner (MD, RN, or LPN), the state licensing authority also should be informed of the situation. [21 CFR 1301.76, 21 CFR 1301.91, 21 CFR 1301.92].

Q. A patient who is disabled and suffering with severe chronic pain became physically dependent on prescribed opiate pain medication. The patient enrolled in an NTP at the suggestion of a doctor as the only way to stay on the "pain medicine" legally. Is this the only way the patient can obtain enough medication to alleviate chronic pain?

A. No. If the doctor advised the patient that the only way to legally use "pain medicine" for a long period was to enroll in an NTP, he or she erred, even if the patient was physically dependent on the medication. The doctor can continue to prescribe narcotic medication for the treatment of pain. However, if treatment is for narcotic addiction, then the patient must be referred to an NTP. The key issue is whether the doctor referred the patient to the NTP because of pain or because of an addiction.

Q. Should an NTP replace tubing when it changes the source of the methadone product it uses?

A. It is best to replace tubing that has been compromised in any way. NTP personnel are advised to follow the recommendations of the pump manufacturer when the NTP changes from one methadone product to another.

APPENDIX B

FORMS

BLANK DEA FORM-363

APPLICATION FOR REGISTRATION

Under Narcotic Addict Treatment Act of 1974

OMB NO. 117-0015

DEA Form 363 (Nov. 1999)

READ INSTRUCTIONS BEFORE COMPLETING

USE BLACK INK

Name: Applicant or Program Name

(Last,

First, MI)

No registration will be issued unless a completed application form has been received (21 CFR 1301.13).

Tax Identification Number

Proposed Business Address (When using a P.O. Box you must also provide a street address)

City State Zip Code

Applicant's Business Phone Number Applicant's Fax Number

The Debt Collection Improvement Act of 1996 (PL 104-134) requires that you furnish your Federal Taxpayer Identifying Number to DEA. This number is required for debt collection procedures should your fee become uncollectable. If you do not have a Federal Taxpayer Identifying Number, use your Social Security Number.

REGISTRATION CLASSIFICATION:

1. BUSINESS ACTIVITY: (X only one)
   - N [X] Maintenance
   - P [X] Detox
   - R [X] Main & Detox
   - S [X] Compounder/ Maintenance
   - T [X] Compounder/ Detox
   - U [X] Compounder/ Main & Detox

2. DRUG SCHEDULES: (X all that apply)
   - [X] Schedule II
   - [X] Schedule III
   - [X] Schedule IV
   - [X] Schedule V

   DRUG CODES (Must indicate below the Narcotic Drug Code Number(s) for schedules checked)

   Methadone (9250)
   LAAM (9648)

3. INDICATE HERE IF YOU REQUIRE ORDER FORM BOOKS. [X]

4. SUPPLY ANY OTHER CURRENT DEA REGISTRATION NUMBERS

5. FDA No. APPLIED FOR: [X] Yes [X] No

6. ALL APPLICANTS MUST ANSWER THE FOLLOWING:

(a) Are you currently authorized to prescribe, distribute, dispense, conduct research, or otherwise handle the controlled substances in the schedules for which you are applying under the laws of the **state** or jurisdiction in which you are operating or propose to operate?

[X] Yes - State License No. [X] N/A [X] PENDING

ATTACH CHECK HERE

By completing this application, you are applying for registration or renewal or registration as a narcotic treatment program pursuant to the Controlled Substances Act of 1970, (PL 91-513), Title 21, United States Code, Section 823(f) and (g).

Note: The graphic illustrated above is only a depiction of the DEA Form-363. It is not intended to be used as an actual application form.

BLANK DEA FORM-363

APPLICATION FOR REGISTRATION

Under Narcotic Addict Treatment Act of 1974

OMB NO. 117-0015

DEA Form 363 (page 2) (Nov. 1999)

6. CONTINUED

(b) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law? ☒ YES ☒ NO

(c) Has the applicant ever surrendered or had a federal controlled substance registration revoked, suspended, restricted or denied? ☒ YES ☒ NO

(d) Has the applicant ever had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation? ☒ YES ☒ NO

(e) If the applicant is a corp, assoc, partnership or pharmacy has any person associated with the firm been convicted of a crime in connection w/ controlled substances under state or federal law, or ever surrendered or had a federal/state controlled substance registration revoked?

7. EXPLANATION FOR ANSWERING "YES" TO ITEMS 6(b), (c), (d), or (e)

Applicants who have answered "yes" to items 6(b), (c), (d), or (e) are required to submit a statement explaining such response(s). The space provided below should be used for this purpose. If additional space is needed, use as a separate sheet and return w/ application.

8. PAYMENT METHOD (X only one)

☒ VISA ☒ MASTER CARD ☒ CHECK ☒ U.S. MONEY ORDER

FEES ARE NOT REFUNDABLE

Credit Card Number | Expiration Date | SIGNATURE OF CARD HOLDER

9. CERTIFICATION FOR FEE EXEMPTION

☒ MARK THIS BLOCK **IF APPLICANT NAMED HEREON IS A FEDERAL, STATE, OR LOCAL GOVERNMENT OPERATED HOSPITAL, INSTITUTION, OR OFFICIAL.**

The undersigned hereby certifies that the applicant named hereon is a federal, state, or local government operated hospital, institution, or official, and is exempt from payment of the application fee.

Signature of Certifying Official **(other than applicant)** **Date**

Print or Type Name of Certifying Official

Print or Type Title of Certifying Official

10. APPLICANT SIGNATURE (must be an original signature in ink)

Signature Date

I hereby certify that the foregoing information furnished on this application is true and correct.

Print or Type Name

Print or Type Title (e.g., President, Dean, Procurement Officer, etc)

RETURN COMPLETE APPLICATION WITH FEE IN ATTACHED ENVELOPE

MAKE CHECK OR MONEY ORDER PAYABLE TO:
DRUG ENFORCEMENT ADMIN.

U.S. DEPT. OF JUSTICE
DRUG ENFORCEMENT ADMIN.
CENTRAL STATION
P.O. BOX 28083
WASHINGTON, D.C. 20038-8083

For INFORMATION, Call
1-800-882-9539

MAKE A COPY FOR YOUR RECORDS

Note: The graphic illustrated above is only a depiction of the DEA Form-363. It is not intended to be used as an actual application form.

BLANK DEA FORM-363a

RENEWAL

APPLICATION FOR DEA REGISTRATION

Under Narcotic Addict Treatment Act of 1974

OMB NO. 117-0015

DEA Form 363a (Nov. 1999)

No registration will be issued unless a completed application form has been received (21 CFR 1301.13).

READ INSTRUCTIONS BEFORE COMPLETING

USE BLACK INK

1. DRUG SCHEDULES: (X all that apply) ☒ Schedule II ☒ Schedule III ☒ Schedule IV ☒ Schedule V

DRUG CODES (Must indicate below the Narcotic Drug Code Number(s) for schedules checked)

Methadone (9250)
LAAM (9648)

2. INDICATE HERE IF YOU REQUIRE ORDER FORM BOOKS. ☒

3. FDA NUMBER

4. ALL APPLICANTS MUST ANSWER THE FOLLOWING:

(a) Are you currently authorized to prescribe, distribute, dispense, conduct research, or otherwise handle the controlled substances in the schedules for which you are applying under the laws of the **state** or jurisdiction in which you are operating or propose to operate?

☒ Yes - State License No. ☒ N/A ☒ PENDING

If you have answered yes to the following question(s) on previous applications, you must continue to answer yes and provide a state of explanation.

(b) Has the applicant ever been convicted of a crime in connection with controlled substances under state or federal law? ☒ Yes ☒ No

(c) Has the applicant ever surrendered or had a federal controlled substance registration revoked, suspended, restricted or denied? ☒ Yes ☒ No

(d) Has the applicant ever had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation?

(e) If the applicant is a corp., assoc., partnership, or pharmacy, has any officer, partner, stockholder or proprietor been convicted of a crime in connection with controlled substances under state or federal law, or ever surrendered or had a fed. Controlled substance registration revoked, suspended, denied, restricted, or placed on probation?

ATTACH CHECK HERE

5. EXPLANATION FOR ANSWERING "YES" TO ITEM(S) 4(b), (c), (d), or (e).

Applicants who have answered "yes" to items 4(b), (c), (d), or (e) are required to submit a statement explaining such response(s). The space provided below should be used for this purpose. If additional space is needed, use a separate sheet and return with application.

By completing this application, you are applying for registration or renewal or registration as a narcotic treatment program pursuant to the Controlled Substances Act of 1970, (PL 91-513), Title 21, United States Code, Section 823(f) and (g).

DEA REGISTRATION NUMBER

YOUR CURRENT REGISTRATION EXPIRES ON

ATTENTION

Note: The graphic illustrated above is only a depiction of the DEA Form-363a. It is not intended to be used as an actual application form.

BLANK DEA FORM-363a

APPLICATION FOR REGISTRATION

Under Narcotic Addict Treatment Act of 1974

OMB NO. 117-0015

DEA Form 363a (page 2) (Nov. 1999)

6. COMPLETE ANY MISSING OR INCORRECT INFORMATION:

Name: Applicant or Program Name

(Last,

First, MI)

Tax Identification Number

—

Proposed Business Address (When using a P.O. Box you must also provide a street address)

City State Zip Code —

Applicant's Business Phone Number — — Applicant's Fax Number — —

The Debt Collection Improvement Act of 1996 (PL 104-134) requires that you furnish your Federal Taxpayer Identifying Number to DEA. This number is required for debt collection procedures should your fee become uncollectable. If you do not have a Federal Taxpayer Identifying Number, use your Social Security Number.

7. PAYMENT METHOD (X only one)

FEES ARE NOT REFUNDABLE

☒ VISA ☒ MASTER CARD ☒ CHECK ☒ U.S. MONEY ORDER

Credit Card Number Expiration Date — SIGNATURE OF CARD HOLDER

8. CERTIFICATION FOR FEE EXEMPTION

☒ MARK THIS BLOCK **IF APPLICANT NAMED HEREON IS A FEDERAL, STATE, OR LOCAL GOVERNMENT OPERATED HOSPITAL, INSTITUTION, OR OFFICIAL.**

The undersigned hereby certifies that the applicant named hereon is a federal, state, or local government operated hospital, institution, or official, and is exempt from payment of the application fee.

Signature of Certifying Official **(other than applicant)** **Date**

Print or Type Name of Certifying Official

Print or Type Title of Certifying Official

9. APPLICANT SIGNATURE (must be an original signature in ink)

Signature Date

I hereby certify that the foregoing information furnished on this application is true and correct.

Print or Type Name

Print or Type Title (e.g., President, Dean, Procurement Officer, etc)

RETURN COMPLETE APPLICATION WITH FEE IN ATTACHED ENVELOPE

MAKE CHECK OR MONEY ORDER PAYABLE TO:
DRUG ENFORCEMENT ADMIN.

U.S. DEPT. OF JUSTICE
DRUG ENFORCEMENT ADMIN.
CENTRAL STATION
P.O. BOX 28083
WASHINGTON, D.C. 20038-8083

For INFORMATION, Call 1-800-882-9539

MAKE A COPY FOR YOUR RECORDS

Note: The graphic illustrated above is only a depiction of the DEA Form-363a. It is not intended to be used as an actual application form.

BLANK DEA FORM-222
U.S. OFFICIAL ORDER FORM - SCHEDULES I & II

See Reverse of PURCHASER'S Copy of Instructions	No order form may be issued for Schedule I and II substances unless a completed application form has been received, (21 CFR 1305.04).	OMB APPROVAL No. 1117-0010

TO: *(Name of Supplier)*	STREET ADDRESS
CITY and STATE / DATE	TO BE FILLED IN BY SUPPLIER SUPPLIERS DEA REGISTRATION No.

LINE No.	TO BE FILLED IN BY PURCHASER No. of Packages	Size of Package	Name of Item	National Drug Code	Packages Shipped	Date Shipped
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

◀ LAST LINE COMPLETED *(MUST BE 10 OR LESS)*	SIGNATURE OR PURCHASER OR ATTORNEY OR AGENT

Date Issued	DEA Registration No.	Name and Address of Registrant
Schedules		
Registered as a	No. of this Order Form	

DEA Form-222
(Oct. 1992)

U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II
DRUG ENFORCEMENT ADMINISTRATION
SUPPLIER'S Copy 1

Note: The graphic illustrated above is only a depiction of the DEA Form-222. It is not intended to be used as an actual order form.

BLANK DEA FORM-222

U.S. OFFICIAL ORDER FORM - SCHEDULES I & II

See Reverse of PURCHASER'S Copy of Instructions	No order form may be issued for Schedule I and II substances unless a completed application form has been received, (21 CFR 1305.04).	OMB APPROVAL No. 1117-0010

TO: *(Name of Supplier)*	STREET ADDRESS
CITY and STATE	DATE

TO BE FILLED IN BY SUPPLIER

SUPPLIERS DEA REGISTRATION No.

TO BE FILLED IN BY PURCHASER

LINE No.	No. of Packages	Size of Package	Name of Item	National Drug Code	Packages Shipped	Date Shipped
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

◀ LAST LINE COMPLETED *(MUST BE 10 OR LESS)*

SIGNATURE OR PURCHASER OR ATTORNEY OR AGENT

Date Issued	DEA Registration No.	Name and Address of Registrant
Schedules		
Registered as a	No. of this Order Form	

Shaded areas are pre-printed by DEA prior to mailing to the registrant.

DEA Form-222
(Oct. 1992)

U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II
DRUG ENFORCEMENT ADMINISTRATION
SUPPLIER'S Copy 1

Note: The graphic illustrated above is only a depiction of the DEA Form-222. It is not intended to be used as an actual order form.

SAMPLE DEA FORM-222

SHADED SECTIONS ARE PRE-PRINTED BY DEA

See Reverse of PURCHASER'S Copy of Instructions	No order form may be issued for Schedule I and II substances unless a completed application form has been received, (21 CFR 1305.04).	OMB APPROVAL No. 1117-0010

TO: *(Name of Supplier)*	STREET ADDRESS
CITY and STATE	DATE

TO BE FILLED IN BY SUPPLIER

SUPPLIERS DEA REGISTRATION No.

TO BE FILLED IN BY PURCHASER

LINE No.	No. of Packages	Size of Package	Name of Item	National Drug Code	Packages Shipped	Date Shipped
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

◀ LAST LINE COMPLETED *(MUST BE 10 OR LESS)*

SIGNATURE OR PURCHASER OR ATTORNEY OR AGENT

Date Issued	DEA Registration No.	Name and Address of Registrant
MM/DD/YYYY	RW0000000	Who Treatment Center 123 Whatever Lane Whereami, FL 12345
Schedules: 2		
Registered as a: NTP BOTH	No. of this Order Form: 1234567890	

*** TO BE USED FOR METHADONE AND LAAM ONLY ***

DEA Form-222
(Oct. 1992)

U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II

DRUG ENFORCEMENT ADMINISTRATION

SUPPLIER'S Copy 1

Note: The graphic illustrated above is only a depiction of the DEA Form-222. It is not intended to be used as an actual order form.

SAMPLE DEA FORM-222
SHADED SECTIONS ARE FILLED IN BY THE NTP WHEN PLACING AN ORDER

See Reverse of PURCHASER'S Copy of Instructions	No order form may be issued for Schedule I and II substances unless a completed application form has been received, (21 CFR 1305.04).	OMB APPROVAL No. 1117-0010

TO: *(Name of Supplier)* **Methadone Supplier**

STREET ADDRESS **21 Xyz Lane**

CITY and STATE **Anytown , FL 22312**

DATE **MM/DD/YYYY**

TO BE FILLED IN BY SUPPLIER

SUPPLIERS DEA REGISTRATION No.

TO BE FILLED IN BY PURCHASER

LINE No.	No. of Packages	Size of Package	Name of Item	National Drug Code	Packages Shipped	Date Shipped
1	25	946 ml	Methadone HCl 10mg/ml			
2	5	100	Methadone HCl Tablets 10mg			
3	20	4 x 25	Methadone HCl diskettes 40mg			
4						
5						
6						
7						
8						
9						
10						

3 ◀ LAST LINE COMPLETED *(MUST BE 10 OR LESS)*

SIGNATURE OF PURCHASER OR ATTORNEY OR AGENT *John Doe*

Date Issued **MM/DD/YYYY**

DEA Registration No. **RW0000000**

Name and Address of Registrant

Who Treatment Center
123 Whatever Lane
Whereami, FL 12345

Schedules **2**

Registered as a **NTP BOTH**

No. of this Order Form **1234567890**

***** TO BE USED FOR METHADONE AND LAAM ONLY *****

DEA Form-222
(Oct. 1992)

U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II
DRUG ENFORCEMENT ADMINISTRATION
SUPPLIER'S Copy 1

Note: The graphic illustrated above is only a depiction of the DEA Form-222. It is not intended to be used as an actual order form.

SAMPLE DEA FORM-222
SHADED SECTIONS ARE FILLED IN BY THE NTP
UPON RECEIPT OF AN ORDER

See Reverse of PURCHASER'S Copy of Instructions	No order form may be issued for Schedule I and II substances unless a completed application form has been received, (21 CFR 1305.04).	OMB APPROVAL No. 1117-0010

TO: *(Name of Supplier)* **Methadone Supplier**

STREET ADDRESS **21 Xyz Lane**

CITY and STATE **Anytown , FL 22312**

DATE **MM/DD/YYYY**

TO BE FILLED IN BY SUPPLIER

SUPPLIERS DEA REGISTRATION No.

TO BE FILLED IN BY PURCHASER

LINE No.	No. of Packages	Size of Package	Name of Item	National Drug Code	Packages Shipped	Date Shipped
1	25	946 ml	Methadone HCl 10mg/ml		25	M-D-Y
2	5	100	Methadone HCl Tablets 10mg		5	M-D-Y
3	20	4 x 25	Methadone HCl diskettes 40mg		20	M-D-Y
4						
5						
6						
7						
8						
9						
10						

3 ◀ LAST LINE COMPLETED *(MUST BE 10 OR LESS)*

SIGNATURE OR PURCHASER OR ATTORNEY OR AGENT *John Doe*

Date Issued **MM/DD/YYYY**

DEA Registration No. **RW0000000**

Name and Address of Registrant

Who Treatment Center
123 Whatever Lane
Whereami, FL 12345

Schedules **2**

Registered as a **NTP BOTH**

No. of this Order Form **1234567890**

***** TO BE USED FOR METHADONE AND LAAM ONLY *****

DEA Form-222
(Oct. 1992)

U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II
DRUG ENFORCEMENT ADMINISTRATION
SUPPLIER'S Copy 1

Note: The graphic illustrated above is only a depiction of the DEA Form-222. It is not intended to be used as an actual order form.

Suggested Format for the Power of Attorney Form

(see 21 CFR 1305.07)

_____ (Name of registrant)
_____ (Address of registrant)
_____ (DEA registration number)

I, _____ (name of person granting power), the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or Controlled Substances Import and Export Act, have made, constituted, and appointed, and by these presents, do make, constitute, and appoint _____ (name of attorney-in-fact), my true and lawful attorney for me in my name, place, and stead, to execute applications for books of official order forms and to sign such order forms in requisition for Schedule I and II controlled substances, in accordance with section 308 of the Controlled Substances Act (21 U.S.C. 828) and part 1305 of Title 21 of the Code of Federal Regulations. I hereby ratify and confirm all that said attorney shall lawfully do or cause to be done by virtue hereof.

_____
(Signature of person granting power)

I, _____ (name of attorney-in-fact), hereby affirm that I am the person named herein as attorney-in-fact and that the signature affixed hereto is my signature.

_____
(Signature of attorney-in-fact)

Witnesses:
1. _____.

2. _____.

Signed and dated on the _____ day of _____, (year), at _____.

Notice of Revocation

The foregoing power of attorney is hereby revoked by the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act of the Controlled Substances Import and Export Act. Written notice of this revocation has been given to the attorney-in-fact _____ this same day.

_____
(Signature of person revoking power)

Witnesses:
1. _____.

2. _____.

Signed and dated on the _____ day of _____, (year), at _____.

U.S. Department of Justice
Drug Enforcement Administration

REPORT OF THEFT OR LOSS OF CONTROLLED SUBSTANCES

Federal Regulations require registrants to submit a detailed report of any theft or loss of Controlled Substances to the Drug Enforcement Administration.

Complete the front and back of this form in triplicate. Forward the original and duplicate copies to the nearest DEA Office. Retain the triplicate copy for your records. Some states may also require a copy of this report.

OMB APPROVAL
No. 1117-0001

1. Name and Address of Registrant (include ZIP Code)

ZIP CODE

2. Phone No. (Include Area Code)

3. DEA Registration Number

2 ltr. prefix | 7 digit suffix

4. Date of Theft or Loss

5. Principal Business of Registrant (check one)
1 ☐ Pharmacy
2 ☐ Practitioner
3 ☐ Manufacturer
4 ☐ Hospital/Clinic
5 ☐ Distributor
6 ☐ Methadone Program
7 ☐ Other (specify) _____

6. County in which Registrant is located

7. Was Theft reported to Police?
☐ Yes ☐ No

8. Name and Telephone Number of Police Department (Include Area Code)

9. Number of Thefts or Losses Registrant has experienced in the past 24 months?

10. Type of Theft or Loss (Check one and complete items below as appropriate)
1 ☐ Night break-in
2 ☐ Armed robbery
3 ☐ Employee pilferage
4 ☐ Customer theft
5 ☐ Other (Explain)
6 ☐ Lost in transit (Complete Item 14)

11. If Armed Robbery, was anyone:
Killed? ☐ No ☐ Yes (How many) _____
Injured? ☐ No ☐ Yes (How many) _____

12. Purchase value to registrant of Controlled Substances taken?
$

13. Were any pharmaceuticals or merchandise taken?
☐ No ☐ Yes (est. value)
$

14. IF LOST IN TRANSIT, COMPLETE THE FOLLOWING:

A. Name of Common Carrier

B. Name of Consignee

C. Consignee's DEA Registration Number

D. Was the carton received by the customer?
☐ Yes ☐ No

E. If received, did it appear tampered with?
☐ Yes ☐ No

F. Have you experienced losses in transit from this same carrier in the past?
☐ No ☐ Yes (How many) _____

15. What identifying marks, symbols, or price codes were on the labels of these containers that would assist in identifying the products?

16. If Official Controlled Substance Order Forms (DEA-222) were stolen, give numbers.

17. What security measures have been taken to prevent future thefts or losses?

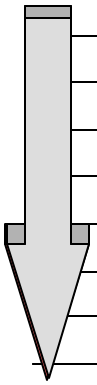
PRIVACY ACT INFORMATION

This section of the DEA-106 has been omitted due to space constraints.

Note: The graphic illustrated above is only a depiction of the DEA Form-106. It is not intended to be used as an actual Theft or Loss report.

DEA-106 (Dec. 1985) Pg. 2 **LIST OF CONTROLLED SUBSTANCES LOST**

Trade Name of Substance or Preparation	Name of Controlled Substance in Preparation	Dosage Strength and Form	Quantity
Examples: Desoxyn	**Methamphetamine Hydrochloride**	**5 mg Tablets**	**3 x 100**
Demerol	**Meperidine Hydrochloride**	**50 mg/ml Vial**	**5 x 30 ml**
Robitussin A-C	**Codeine Phosphate**	**2 mg/cc Liquid**	**12 pints**
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			
13.			
14.			
15.			
50.			



I certify that the foregoing information is correct to the best of my knowledge and belief

Signature Title Date

Note: The graphic illustrated above is only a depiction of the DEA Form-106. It is not intended to be used as an actual Theft or Loss report.

OMB Approval No. 1117-0007	U.S. Department of Justice/Drug Enforcement Administration **REGISTRANTS INVENTORY OF DRUGS SURRENDERED**	PACKAGE NO.

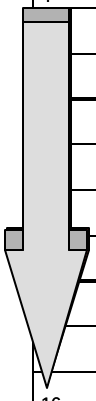
The following schedule is an inventory of controlled substances which is hereby surrendered to you for proper disposition.

FROM: (Include Name, Street, City, State and ZIP Code in space provided below.)

Signature of applicant or authorized agent
Registrant's DEA Number
Registrant's Telephone Number

NOTE: CERTIFIED MAIL (Return Receipt Requested) IS REQUIRED FOR SHIPMENTS OF DRUGS VIA U.S. POSTAL SERVICE. See instructions on reverse (page 2) of form.

NAME OF DRUG OR PREPARATION Registrants will fill in Columns 1,2,3, and 4 ONLY.	Number of Containers	CONTENTS (Number of grams, tablets, ounces or other units per container)	Controlled Substance Content (Each Unit)	FOR DEA USE ONLY		
				DISPOSITION	QUANTITY	
					GMS.	MGS.
1	**2**	**3**	**4**	**5**	**6**	**7**
Example: Methadone HCL Tablets, 10mg	1	100mg	10			
Example: Methadose 960 ml, 10mg/ml	1	960ml	10			
1						
2						
3						
4						
16						



Note: The graphic illustrated above is only a depiction of the DEA Form-41. It is not intended to be used as an actual Drug Disposal form.

DEA-41 (6/1986) Pg. 2

NAME OF DRUG OR PREPARATION Registrants will fill in Columns 1,2,3, and 4 ONLY.	Number of Con-tainers	CONTENTS (Number of grams, tablets, ounces or other units per container)	Controlled Substance Content (Each Unit)	FOR DEA USE ONLY		
				DISPOSITION	QUANTITY	
					GMS.	MGS.
1	2	3	4	5	6	7
17						
18						
19						
20						
21						
22						
23						
24						

The controlled substances surrendered in accordance with Title 21 of the Code of Federal Regulations, Section 1307.21, have been received in _____ packages purporting to contain the drugs listed on this inventory and have been: ** (1) Forwarded tape-sealed without opening; (2) Destroyed as indicated and the remainder forwarded tape-sealed after verifying the contents; (3) Forwarded tape-sealed after verifying contents.

DATE _____ DESTROYED BY: _____

** *Strike out lines not applicable.* WITNESSED BY: _____

INSTRUCTIONS

1. List the name of the drug in column 1, the number of containers in column 2, the size of each container in column 3, and in column 4 the controlled substance content of each unit described in column 3; e.g. morphine sulfate tabs, 3 pkgs, 100 tabs, 1/4 gr (16 mg) or morphine sulfate tabs, 1 pkg, 83 tabs, 1/2 gr (32 mg), etc.

2. All packages included on a single line should be identical in name, content, and controlled substance strength.

3. Prepare this form in quadruplicate. Mail two (2) copies of this form to the Special Agent in Charge, under separate cover. Enclose one additional copy in the shipment with the drugs. Retain one copy for your records. One copy will be returned to you as a receipt. No further receipt will be furnished to you unless specifically requested. Any further inquiries concerning these drugs should be addressed to the DEA District Office which serves your area.

4. There is no provision for payment of drugs surrendered. This is merely a service rendered to registrants enabling them to clear their stocks and records of unwanted items.

5. Drugs should be shipped tape-sealed via prepaid express or certified mail (**return receipt requested**) to Special Agent in Charge, Drug Enforcement Administration, of the DEA District Office which serves your area.

PRIVACY ACT INFORMATION

This section of the DEA-41 has been omitted due to space constraints

Note: The graphic illustrated above is only a depiction of the DEA Form-41. It is not intended to be used as an actual Drug Disposal form.

APPENDIX C

DEA INVESTIGATIONS:
REQUIRED DOCUMENTATION

DEA INVESTIGATIONS: REQUIRED DOCUMENTATION

Documents and information that NTPs are required to provide during a DEA investigation include the following:

1) List of all individuals having access to controlled substances (including full name, date of birth and Social Security number)

2) Designation in writing of all individuals who are authorized to accept medication shipments (including full name, date of birth, and Social Security number)

3) All licenses/permits issued to the program and practitioners, nurses, and pharmacists

4) Contract with alarm company that includes address, telephone number, current contact point, and services provided

5) Biennial inventory and any other inventories conducted by the program

6) All DEA-222 order forms, including:
   a) Order forms documenting receipt from supplier*
   b) Order forms documenting transfer to other sites or programs*
   c) Unexecuted, voided and cancelled order forms
   * *In instances where there are discrepancies between the amount ordered and the amount received, copies of invoices related to the order forms should be available.*

7) Manufacturing records for those programs that convert bulk powder to liquid, including:
   a) Batch records for powder to liquid conversion
   b) Batch records for bottling liquid medication
   c) ARCOS reports (where required)

8) Dispensing records for controlled substances, including:
   a) Computer summary for time period
   b) Any manual dispensing records
   c) Patient identification cross-index reference

9) Incident reports for investigation period

10) Report of Theft or Loss of Controlled Substances (DEA Form-106)

11) Registrants Inventory of Drugs Surrendered (DEA Form-41)

12) Powers of Attorney

During an investigation, the NTP also must provide an area where the investigators can work, which does not impede the operation of the program and allows for privacy. In addition, employees having access to methadone or having knowledge of the operation of the program should be available for interview.

APPENDIX D

DEA DIVERSION FIELD OFFICES

DEA DIVERSION FIELD OFFICES
AND
REGISTRATION ASSISTANTS

STATE	DIVERSION FIELD OFFICE	REGISTRATION OFFICE	DIVISION OFFICE
ALABAMA			
Northern	**DEA Birmingham RO** 234 Goodwin Crest, Suite 420W Birmingham, Alabama 35209 (205) 290-7150	**DEA New Orleans FD** (888) 514-7302* (888) 514-8051*	**DEA New Orleans FD** 3838 N. Causeway Blvd. Lakeway III, Suite 1800 Metairie, Louisiana 70002 (504) 840-1100
Southern	**DEA Mobile RO** 900 Western America Circle Suite 501 Mobile, Alabama 36609 (334) 441-5831	**DEA New Orleans FD** (888) 514-7302* (888) 514-8051*	**DEA New Orleans FD** (504) 840-1100
ALASKA	**DEA Seattle FD** 400 2nd Avenue West Seattle, Washington 98119 (206) 553-5990	**DEA Seattle FD** (888) 219-1418*	**DEA Seattle FD** 400 2nd Avenue West Seattle, Washington 98119 (206) 553-5990
ARIZONA			
Northern Central	**DEA Phoenix FD** 3010 N. 2nd St. Suite 301 Phoenix, Arizona 85012 (602) 664-5600	**DEA Phoenix FD** (800) 741-0902*	**DEA Phoenix FD** 3010 N. 2nd St. Suite 301 Phoenix, Arizona 85012 (602) 664-5600
Southern	**DEA Tucson DO** 3285 E. Hemisphere Loop Tucson, Arizona 85706 (520) 573-5500	**DEA Phoenix FD** (800) 741-0902*	**DEA Phoenix FD** (602) 664-5600
ARKANSAS	**DEA Little Rock RO** 10825 Financial Parkway Suite 317 Little Rock, Arkansas 72211 (501) 324-5981	**DEA New Orleans FD** (888) 514-7302* (888) 514-8051*	**DEA New Orleans FD** 3838 N. Causeway Blvd. Lakeway III, Suite 1800 Metairie, Louisiana 70002 (504) 840-1100

STATE	DIVERSION FIELD OFFICE	REGISTRATION OFFICE	DIVISION OFFICE
CALIFORNIA Central Coastal	**DEA San Francisco FD** 450 Golden Gate Ave. 14th Floor P.O. Box 36035 San Francisco, CA 94102 (415) 436-7854	**DEA San Francisco FD** (888) 304-3251*	**DEA San Francisco FD** 450 Golden Gate Ave. 14th Floor P.O. Box 36035 San Francisco, CA 94102 (415) 436-7854
	DEA San Jose RO One North First St., Suite 405 San Jose, California 95113 (408) 291-7235	**DEA San Francisco FD** (888) 304-3251*	**DEA San Francisco FD** (415) 436-7854
Central	**DEA Fresno RO** 2444 Main St., Suite 240 Fresno, California 93721 (559) 487-5402	**DEA San Francisco FD** (888) 304-3251*	**DEA San Francisco FD** (415) 436-7854
Northern	**DEA Oakland RO** 1301 Clay St., Suite 460N Box 70301 Oakland, California 94612 (510) 637-5600	**DEA San Francisco FD** (888) 304-3251*	**DEA San Francisco FD** (415) 436-7854
	DEA Sacramento DO 1860 Howe Ave., Suite 250 Sacramento, California 95825 (916) 566-7401	**DEA San Francisco FD** (888) 304-3251*	**DEA San Francisco FD** (415) 436-7854
South Central	**DEA Los Angeles FD** 255 East Temple St. 20th Floor Los Angeles, CA 90012 (213) 894-2650	**DEA Los Angeles FD** (888) 415-9822*	**DEA Los Angeles FD** 255 East Temple St. 20th Floor Los Angeles, CA 90012 (213) 894-2650
	DEA Riverside DO 4470 Olivewood Ave. Riverside, CA 92501-4155 (909) 328-6000	**DEA Los Angeles FD** (888) 415-9822*	**DEA Los Angeles FD** (213) 894-2650
CALIFORNIA Southern	**DEA San Diego FD** 4560 Viewridge Ave. San Diego, California 92123 (858) 616-4325	**DEA San Diego FD** (800) 284-1152*	**DEA San Diego FD** 4560 Viewridge Ave. San Diego, California 92123 (858) 616-4325

STATE	DIVERSION FIELD OFFICE	REGISTRATION OFFICE	DIVISION OFFICE
COLORADO	**DEA Denver FD** 115 Inverness Dr., East Englewood, Colorado 80112 (303) 705-7300	**DEA Denver FD** (800) 326-6900*	**DEA Denver FD** 115 Inverness Dr., East Englewood, Colorado 80112 (303) 705-7300
Southern	**DEA Colorado Springs RO** Plaza of the Rockies 111 S. Tejon, Suite 306 Colorado Springs, CO 80903 (719) 471-1749	**DEA Denver FD** (800) 326-6900*	**DEA Denver FD** (303) 705-7300
CONNECTICUT	**DEA Hartford RO** 450 Main St., Room 628 Hartford, Connecticut 06103 (860) 240-3700	**DEA Boston FD** (617) 557-2200	**DEA Boston FD** JFK Federal Building 15 New Sudbury St. Room E-400 Boston, Massachusetts 02203 (617) 557-2100
DELAWARE	**DEA Philadelphia FD** William J. Green Federal Bldg. 600 Arch St., Room 10224 Philadelphia, PA 19106 (215) 597-9540	**DEA Philadelphia FD** (888) 393-8231*	**DEA Philadelphia FD** William J. Green Fed. Bldg. 600 Arch St., Room 10224 Philadelphia, PA 19106 (215) 597-9540
DISTRICT OF COLUMBIA	**DEA Washington FD** Techworld Plaza 800 K St., NW, Suite 500 Washington, D.C. 20001 (202) 305-8800	**DEA Washington FD** (887) 801-7974* (202) 305-8888	**DEA Washington FD** Techworld Plaza 800 K St., NW, Suite 500 Washington, D.C. 20001 (202) 305-8800
FLORIDA Northern	**DEA Tallahassee RO** 3384 Capital Circle NE Tallahassee, Florida 32308 (850) 942-8417	**DEA Miami FD** (800) 667-9752*	**DEA Miami FD** 8400 NW 53rd St. Miami, Florida 33166 (305) 590-4980
Central	**DEA Orlando RO** Heathrow Business Center 300 International Pkwy, Ste 424 Heathrow, Florida 32746 (407) 333-7046	**DEA Miami FD** (800) 667-9752*	**DEA Miami FD** 8400 NW 53rd St. Miami, Florida 33166 (305) 590-4980

STATE	DIVERSION FIELD OFFICE	REGISTRATION OFFICE	DIVISION OFFICE
FLORIDA	**DEA Tampa DO**	**DEA Miami FD**	**DEA Miami FD**
West Central	4950 W. Kennedy Blvd. Suite 400 Tampa, Florida 33609 (813) 288-1290	(800) 667-9752*	(305) 590-4980
Southeastern	**DEA Miami FD** 8400 NW 53rd St. Miami, Florida 33166 (305) 590-4980	**DEA Miami FD** (800) 667-9752*	**DEA Miami FD** (305) 590-4980
GEORGIA	**DEA Atlanta FD** 75 Spring St., SW, Room 740 Atlanta, Georgia 30303 (404) 763-5861	**DEA Atlanta FD** (888) 219-7898*	**DEA Atlanta FD** 75 Spring St., SW, Rm 740 Atlanta, Georgia 30303 (404) 763-5861
Eastern	**DEA Savannah RO** 300 Drayton St., Suite 401 Savannah, Georgia 31401 (912) 652-4286	**DEA Atlanta FD** (888) 219-7898*	**DEA Atlanta FD** (404) 763-5861
HAWAII	**DEA Honolulu DO** P.O. Box 50163 300 Ala Moana Blvd. Room 3-147 Honolulu, Hawaii 96850 (808) 541-1930	**DEA Los Angeles FD** (888) 415-9822*	**DEA Los Angeles FD** 255 East Temple St. 20th Floor Los Angeles, CA 90012 (213) 894-2650
IDAHO	**DEA Seattle FD**	**DEA Seattle FD**	**DEA Seattle FD**
Northern	400 2nd Avenue West Seattle, Washington 98119 (206) 553-5990	(888) 219-4261*	400 2nd Avenue West Seattle, Washington 98119 (206) 553-5990
Southern	**DEA Boise RO** 607 North 8th St., Suite 400 Boise, Idaho 83702-5518 (208) 334-1620	**DEA Seattle FD** (888) 219-4261*	**DEA Seattle FD** 400 2nd Avenue West Seattle, Washington 98119 (206) 553-5990

STATE	DIVERSION FIELD OFFICE	REGISTRATION OFFICE	DIVISION OFFICE
ILLINOIS Northern Central	**DEA Chicago FD** Klyuczynski Federal Building 230 South Dearborn St. Suite 1200 Chicago, Illinois 60604 (312) 353-7875	**DEA Chicago FD** (800) 478-7630** (312) 353-1234	**DEA Chicago FD** Klyuczynski Federal Bldg. 230 South Dearborn St. Suite 1200 Chicago, Illinois 60604 (312) 353-7875
Central	**DEA Springfield RO** 400 West Monroe, Suite 302 Springfield, Illinois 62704 (217) 492-4504	**DEA Chicago FD** (800) 478-7630** (312) 353-1234	**DEA Chicago FD** (312) 353-7875
Southern	**DEA St. Louis FD** United Missouri Bank Building 7911 Forsyth Blvd., Suite 500 St. Louis, Missouri 63105 (314) 538-4600	**DEA St. Louis FD** (888) 803-1179*	**DEA St. Louis FD** United Missouri Bank Bldg. 7911 Forsyth Blvd., Ste. 500 St. Louis, Missouri 63105 (314) 538-4600
INDIANA	**DEA Indianapolis DO** 575 N. Pennsylvania, Room 408 Indianapolis, Indiana 46204 (317) 226-7977	**DEA Chicago FD** (800) 478-7642** (312) 353-1236	**DEA Chicago FD** Klyuczynski Federal Bldg. 230 South Dearborn St. (312) 353-7875
Northern	**DEA Merrillville RO** 1571 East 85th Ave., Suite 200 Merrillville, Indiana 46410 (219) 681-7000	**DEA Chicago FD** (800) 478-7642** (312) 353-1236	**DEA Chicago FD** (312) 353-7875
IOWA	**DEA Des Moines RO** Federal Building, Room 937 210 Walnut St. Des Moines, Iowa 50309 (515) 284-4709	**DEA St. Louis FD** (888) 803-1179*	**DEA St. Louis FD** United Missouri Bank Bldg. 7911 Forsyth Blvd. Suite 500 St. Louis, Missouri 63105 (314) 538-4600
KANSAS	**DEA Kansas City RO** 8600 Farley, Suite 200 Overland Park, Kansas 66212 (913) 652-9127	**DEA St. Louis FD** (888) 803-1179*	**DEA St. Louis FD** (314) 538-4600

STATE	DIVERSION FIELD OFFICE	REGISTRATION OFFICE	DIVISION OFFICE
KENTUCKY	**DEA Louisville RO** 1006 Federal Building 600 Dr. Martin Luther King Jr. Pl. Louisville, Kentucky 40202 (502) 582-5908	**DEA Detroit FD** (800) 230-6844*	**DEA Detroit FD** 431 Howard St. Detroit, Michigan 48226 (313) 234-4000
Southeastern	**DEA London RO** P.O. Box 5065 202 South Main St., 3rd Floor London, Kentucky 40741 (606) 862-4500	**DEA Detroit FD** (800) 230-6844*	**DEA Detroit FD** (313) 234-4000
LOUISIANA	**DEA New Orleans FD** 3838 N. Causeway Blvd. Lakeway III, Suite 1800 Metairie, Louisiana 70002 (504) 840-1100	**DEA New Orleans FD** (888) 514-7302* (888) 514-8051*	**DEA New Orleans FD** 3838 N. Causeway Blvd. Lakeway III, Suite 1800 Metairie, Louisiana 70002 (504) 840-1100
MAINE	**DEA Boston FD** JFK Federal Building 15 New Sudbury St., Room E-400 Boston, MA 02203-0131 (617) 557-2100	**DEA Boston FD** (617) 557-2200	**DEA Boston FD** JFK Federal Building 15 New Sudbury St., Room E-400 Boston, MA 02203-0131 (617) 557-2100
MARYLAND	**DEA Baltimore DO** 200 St. Paul Place, Suite 2222 Baltimore, MD 21202-2004 (410) 962-4800	**DEA Baltimore DO** (410) 962-7580	**DEA Washington FD** Techworld Plaza 800 K St., NW, Suite 500 Washington, D.C. 20001 (202) 305-8800
MASSACHUSETTS	**DEA Boston FD** JFK Federal Building 15 New Sudbury St., Room E-400 Boston, MA 02203-0131 (617) 557-2100	**DEA Boston FD** (617) 557-2200	**DEA Boston FD** JFK Federal Building 15 New Sudbury St., Room E-400 Boston, MA 02203-0131 (617) 557-2100
MICHIGAN	**DEA Detroit FD** 431 Howard St. Detroit, Michigan 48226 (313) 234-4000	**DEA Detroit FD** (800) 230-6844*	**DEA Detroit FD** 431 Howard St. Detroit, Michigan 48226 (313) 234-4000

STATE	DIVERSION FIELD OFFICE	REGISTRATION OFFICE	DIVISION OFFICE
MINNESOTA	**DEA Minneapolis/St. Paul RO** 330 Second Ave. S., Suite 450 Minneapolis, Minnesota 55401 (612) 348-1729	**DEA Chicago FD** (800) 478-7914** (312) 353-9166	**DEA Chicago FD** Klyuczynski Federal Bldg. 230 South Dearborn St., Suite 1200 Chicago, Illinois 60604 (312) 353-7875
MISSISSIPPI	**DEA Jackson DO** 100 W. Capitol St., Suite 1213 Jackson, Mississippi 39269 (601) 965-4400	**DEA New Orleans FD** (888) 514-7302*	**DEA New Orleans FD** 3838 N. Causeway Blvd. Lakeway III, Suite 1800 Metairie, Louisiana 70002 (504) 840-1100
MISSOURI Eastern	**DEA St. Louis FD** United Missouri Bank Building 7911 Forsyth Blvd., Suite 500 St. Louis, Missouri 63105 (314) 538-4600	**DEA St. Louis FD** (888) 803-1179*	**DEA St. Louis FD** United Missouri Bank Bldg. 7911 Forsyth Blvd., Ste. 500 St. Louis, Missouri 63105 (314) 538-4600
Western	DEA Kansas City RO 8600 Farley, Suite 200 Overland Park, Kansas 66212 (913) 652-9127	DEA St. Louis FD (888) 803-1179*	DEA St. Louis FD (314) 538-4600
MONTANA	**DEA Denver FD** 115 Inverness Dr., East Englewood, Colorado 80112 (303) 705-7300	**DEA Denver FD** (800) 326-6900*	**DEA Denver FD** 115 Inverness Dr., East Englewood, Colorado 80112 (303) 705-7300
NEBRASKA	**DEA Des Moines RO** Federal Building, Room 937 210 Walnut St. Des Moines, Iowa 50309 (515) 284-4709	**DEA St. Louis FD** (888) 803-1179*	**DEA St. Louis FD** United Missouri Bank Bldg. 7911 Forsyth Blvd., Ste. 500 St. Louis, Missouri 63105 (314) 538-4600
NEVADA	**DEA Las Vegas DO** 600 Las Vegas Blvd. S. Suite 640 Las Vegas, Nevada 89101 (702) 388-6635	**DEA Los Angeles FD** (888) 415-9822*	**DEA Los Angeles FD** 255 East Temple St. 20th Floor Los Angeles, CA 90012 (213) 894-2650

STATE	DIVERSION FIELD OFFICE	REGISTRATION OFFICE	DIVISION OFFICE
NEW HAMPSHIRE	**DEA Boston FD** JFK Federal Building 15 New Sudbury St., Room E-400 Boston, MA 02203-0131 (617) 557-2100	**DEA Boston FD** (617) 557-2200	**DEA Boston FD** JFK Federal Building 15 New Sudbury St., Room E-400 Boston, MA 02203-0131 (617) 557-2100
NEW JERSEY Central Northern	**DEA Newark FD** 80 Mulberry St., 2nd Floor Newark, New Jersey 07102 (973) 273-5060 or 273-5080	**DEA Newark FD** (888) 356-1071*	**DEA Newark FD** 80 Mulberry St., 2nd Floor Newark, New Jersey 07102 (973) 273-5060 or 273-5080
Southern	**DEA Camden RO** 1000 Crawford Place, Suite 200 Mt. Laurel, New Jersey 08054 (856) 968-4899	**DEA Newark FD** (888) 356-1071*	**DEA Newark FD** 80 Mulberry St., 2nd Floor Newark, New Jersey 07102 (973) 273-5060
NEW MEXICO	**DEA Albuquerque DO** 301 Martin Luther King Ave., NE Albuquerque, NM 87102 (505) 346-7419	**DEA Houston FD** (800) 743-0595*	**DEA El Paso FD** El Paso Federal Justice Cntr. 660 S. Mesa Hills Dr., Suite 2000 El Paso, Texas 79912 (915) 832-6000
NEW YORK	**DEA New York FD** 99 Tenth Ave. New York, New York 10011 (212) 337-3900	**DEA New York FD** (800) 877-1198* ext. 1593/1594	**DEA New York FD** 99 Tenth Ave. New York, New York 10011 (212) 337-3900
NEW YORK Central Western	**DEA Buffalo RO** 28 Church St., Suite 300 Buffalo, New York 14202 (716) 551-3391	**DEA New York FD** (800) 877-1198* Ext. 1593/1594	**DEA New York FD** 99 Tenth Ave. New York, New York 10011 (212) 337-3900
Long Island	**DEA Long Island DO** 175 Pinelawn Road, Suite 205 Melville, New York 11747 (631) 420-4540	**DEA New York FD** (800) 877-1198* ext. 1593/1594	**DEA New York FD** 99 Tenth Ave. New York, New York 10011 (212) 337-3900

STATE	DIVERSION FIELD OFFICE	REGISTRATION OFFICE	DIVISION OFFICE
NORTH CAROLINA	**DEA Greensboro RO** 1801 Stanley Road, Suite 201 Greensboro, NC 27407 (336) 547-4219	**DEA Atlanta FD** (888) 219-8689*	**DEA Atlanta FD** 75 Spring St., SW, Rm. 740 Atlanta, Georgia 30303 (404) 763-5861
NORTH DAKOTA	**DEA Minneapolis/St. Paul RO** 330 Second Ave. S., Suite 450 Minneapolis, Minnesota 55401 (612) 348-1729	**DEA Chicago FD** (800) 478-7914** (312) 353-9166	**DEA Chicago FD** Klyuczynski Federal Bldg. 230 South Dearborn St. Suite 1200 Chicago, Illinois 60604 (312) 353-7875
OHIO Northern	**DEA Cleveland RO** Courthouse Square 310 Lakeside Ave., Suite 395 Cleveland, Ohio 44113 (216) 552-3705	**DEA Detroit FD** (800) 230-6844*	**DEA Detroit FD** 431 Howard St. Detroit, Michigan 48226 (313) 234-4000
Central Southern	**DEA Columbus RO** 500 S. Front St., Suite 612 Columbus, Ohio 43215 (614) 469-2595	**DEA Detroit FD** (800) 230-6844*	**DEA Detroit FD** (313) 234-4000
Southern	**DEA Cincinnati RO** 36 East 7th St., Suite 1900 Cincinnati, Ohio 45202 (513) 684-3671	**DEA Detroit FD** (800) 230-6844*	**DEA Detroit FD** (313) 234-4000
OKLAHOMA Northeastern	**DEA Tulsa RO** Three Memorial Place 7615 E. 63rd Place, Suite 250 Tulsa, Oklahoma 74133 (918) 459-9600	**DEA Dallas FD** (214) 640-0849	**DEA Dallas FD** 1880 Regal Row Dallas, Texas 75235 (214) 640-0850
	DEA Oklahoma City DO 9900 Broadway Extension Oklahoma City, OK 73114 (405) 475-7556	**DEA Dallas FD** (214) 640-0849	**DEA Dallas FD** (214) 640-0850

STATE	DIVERSION FIELD OFFICE	REGISTRATION OFFICE	DIVISION OFFICE
OREGON	**DEA Portland DO** 1220 SW. 3rd Ave., Room 1525 Portland, Oregon 97204 (503) 326-2447	**DEA Seattle FD** (888) 219-4261*	**DEA Seattle FD** 400 2nd Avenue West Seattle, Washington 98119 (206) 553-5990
PENNSYLVANIA Eastern	**DEA Philadelphia FD** William J. Green Federal Bldg. 600 Arch St., Room 10224 Philadelphia, PA 19106 (215) 597-9540	**DEA Philadelphia FD** (888) 393-8231*	**DEA Philadelphia FD** William J. Green Federal Bldg 600 Arch St., Room 10224 Philadelphia, PA 19106 (215) 597-9540
Western	**DEA Pittsburgh RO** Federal Building 1000 Liberty Ave., Room 1328 Pittsburgh, Pennsylvania 15222 (412) 395-4502	**DEA Philadelphia FD** (888) 393-8231*	**DEA Philadelphia FD** (215) 597-9540
PUERTO RICO	**DEA Caribbean FD** P.O. Box 2167 San Juan, PR 00922-2167 (787) 775-1877	**DEA Caribbean FD** (787) 775-1766	**DEA Caribbean FD** P.O. Box 2167 San Juan, PR 00922-2167 (787) 775-1877
RHODE ISLAND	**DEA Boston FD** JFK Federal Building 15 New Sudbury St., Room E-400 Boston, MA 02203-0131 (617) 557-2100	**DEA Boston FD** (617) 557-2200	**DEA Boston FD** JFK Federal Building 15 New Sudbury St., Room E-400 Boston, MA 02203-0131 (617) 557-2100
SOUTH CAROLINA	**DEA Columbia DO** 1835 Assembly St., Suite 1229 Columbia, SC 29201 (803) 253-3441	**DEA Atlanta FD** (888) 219-8689*	**DEA Atlanta FD** 75 Spring St., SW, Rm. 740 Atlanta, Georgia 30303 (404) 763-5861
SOUTH DAKOTA	**DEA Des Moines RO** Federal Building, Room 937 210 Walnut St. Des Moines, Iowa 50309 (515) 284-4709	**DEA St. Louis FD** (888) 803-1179*	**DEA St. Louis FD** United Missouri Bank Bldg. 7911 Forsyth Blvd., Ste. 500 St. Louis, Missouri 63105 (314) 538-4600

STATE	DIVERSION FIELD OFFICE	REGISTRATION OFFICE	DIVISION OFFICE
TENNESSEE	**DEA Nashville DO** 801 Broadway, Suite 500 Nashville, Tennessee 37203 (615) 736-2559	**DEA Atlanta FD** (888) 219-7898*	**DEA Atlanta FD** 75 Spring St., SW, Room 740 Atlanta, Georgia 30303 (404) 763-5861
TEXAS Northern	**DEA Dallas FD** 1880 Regal Row Dallas, Texas 75235 (214) 640-0850	**DEA Dallas FD** (214) 640-0849	**DEA Dallas FD** 1880 Regal Row Dallas, Texas 75235 (214) 640-0850
	DEA Fort Worth RO 819 Taylor St., Room 13A33 Ft. Worth, Texas 76102 (817) 978-3455	**DEA Dallas FD** (214) 640-0849	**DEA Dallas FD** (214) 640-0850
Eastern Southern	**DEA Houston FD** 1433 West Loop S., Suite 600 Houston, Texas 77027-9506 (713) 693-3634	**DEA Houston FD** (800) 743-0595*	**DEA Houston FD** 1433 West Loop S., Ste. 600 Houston, Texas 77027-9506 (713) 693-3634
Central Western	**DEA San Antonio DO** 10127 Morocco, Suite 200 San Antonio, Texas 78216 (210) 525-2900	**DEA Houston FD** (800) 743-0595*	**DEA Houston FD** (713) 693-3634
Central	**DEA Waco Post of Duty** 6801 Sanger, Suite 2000 Waco, Texas 76710 (254) 741-1920	**DEA Houston FD** (800) 743-0595*	**DEA Houston FD** (713) 693-3634
Western	**DEA El Paso FD** El Paso Federal Justice Center 660 S. Mesa Hills Dr. Suite 2000 El Paso, Texas 79912 (915) 832-6000	**DEA Houston FD** (800) 743-0595*	**DEA El Paso FD** El Paso Federal Justice Cntr. 660 S. Mesa Hills Dr. Suite 2000 El Paso, Texas 79912 (915) 832-6000

STATE	DIVERSION FIELD OFFICE	REGISTRATION OFFICE	DIVISION OFFICE
UTAH	**DEA Salt Lake City RO** American Plaza III 47 W. 200 S., Room 401 Salt Lake City, Utah 84101 (801) 524-4156	**DEA Denver FD** (800) 326-6900*	**DEA Denver FD** 115 Inverness Dr., East Englewood, Colorado 80112 (303) 705-7300
VERMONT	**DEA Hartford RO** 450 Main St., Room 628 Hartford, Connecticut 06103 (860) 240-3700	**DEA Boston FD** (617) 557-2200	**DEA Boston FD** JFK Federal Building 15 New Sudbury St. Room E-400 Boston, MA 02203-0131 (617) 557-2100
VIRGIN ISLANDS	**DEA Caribbean FD** P.O. Box 2167 San Juan, PR 00922-2167 (787) 775-1877	**DEA Caribbean FD** (787) 775-1766	**DEA Caribbean FD** P.O. Box 2167 San Juan, PR 00922-2167 (787) 775-1877
VIRGINIA	**DEA Richmond RO** 8600 Staples Mills Road Richmond, Virginia 23228 (804) 771-8163	**DEA Washington FD** (877) 801-7974* (202) 305-8888	**DEA Washington FD** Techworld Plaza 800 K St., NW, Suite 500 Washington, D.C. 20001 (202) 305-8800
WASHINGTON	**DEA Seattle FD** 400 2nd Avenue West Seattle, Washington 98119 (206) 553-5990	**DEA Seattle FD** (888) 219-1418*	**DEA Seattle FD** 400 2nd Avenue West Seattle, Washington 98119 (206) 553-5990
WEST VIRGINIA	**DEA Charleston RO** Union Square 2 Monongalia St., Suite 202 Charleston, WV 25302 (304) 347-5209	**DEA Baltimore DO** (410) 962-7580	**DEA Washington FD** Techworld Plaza 800 K St., NW, Suite 500 Washington, D.C. 20001 (202) 305-8800
WISCONSIN	**DEA Milwaukee RO** 1000 N. Water St., Suite 1010 Milwaukee, Wisconsin 53202 (414) 297-3395	**DEA Chicago FD** (800) 478-7642** (312) 353-1236	**DEA Chicago FD** Klyuczynski Federal Bldg. 230 South Dearborn St. Suite 1200 Chicago, Illinois 60604 (312) 353-7875

STATE	DIVERSION FIELD OFFICE	REGISTRATION OFFICE	DIVISION OFFICE
WYOMING	**DEA Denver FD** 115 Inverness Dr., East Englewood, Colorado 80112 (303) 705-7300	**DEA Denver FD** (800) 326-6900*	**DEA Denver FD** 115 Inverness Dr., East Englewood, Colorado 80112 (303) 705-7300
HEADQUARTERS	**DEA Headquarters** Office of Diversion Control Registration Unit/ODRR Washington, DC 20537 (202) 307-7250	**DEA Headquarters** (800) 882-9539*	**DEA Headquarters** Office of Diversion Control Registration Unit/ODRR Washington, DC 20537 (202) 307-7250

FD - Field Division
DO - District Office
RO - Resident Office

* Toll free number.
** Must be in state to use toll free number.

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The Drug Enforcement Administration makes every effort to write clearly. If you have suggestions as to how to improve the clarity of this manual, call or write to the Drug Enforcement Administration, Office of Diversion Control, Liaison and Policy Section, Washington, D.C. 20537. Telephone number (202) 307-7297.

This publication is intended to provide guidance and information on the requirements of the Controlled Substances Act and its implementing regulations. If you require additional clarification or assistance, or wish to comment on any matter regarding DEA's requirements or regulatory activities, please contact your local DEA office Diversion Group. Every effort will be made to respond promptly to your inquiry.

Furthermore, please be aware that the Small Business and Agriculture Regulatory Enforcement Ombudsman and 10 Regional Fairness Boards were established to receive comments from small businesses about federal agency enforcement actions. The Ombudsman will annually evaluate the enforcement activities and rate each agency's responsiveness to small business. If you wish to comment on the enforcement actions of the DEA Diversion Program, call
1-888-REG-FAIR (1-888-7834-3247).

Additional information regarding DEA may be found on our web site at:
http://www.usdoj.gov/dea.