NEW YORK STATE OF OPPORTUNITY. Department of Health

KATHY HOCHUL
Governor

JAMES V. McDONALD, M.D., M.P.H.
Commissioner

JOHANNE E. MORNE, M.S.
Executive Deputy Commissioner

Guidance for Residential Health Care Facilities Licensed as Class 3A Institutional Dispenser, Limited

The Bureau of Narcotic Enforcement (BNE) is providing this guidance for Residential Health Care Facilities (RHCF) licensed as Class 3A Institutional Dispensers, Limited facilities to assist in their development of policies and procedures for controlled substance drug disposal and destruction. Limited inventory in conjunction with proper disposal and destruction of controlled substances will help mitigate the potential for diversion.

Medications that are prescribed and dispensed to a patient are owned by the patient, known as the "end user" or "ultimate user". Class 3A licensees are given the lawful ability, through licensure, to take temporary custody of a patient's prescribed controlled substances. ***Once a patient is discharged, all medications prescribed to the patient that are in temporary custody of the Class 3A licensee, must be turned over to the patient at the time of discharge, unless they are discontinued by the practitioner who prescribed the medications***. Facilities are not legally allowed to retain possession of a patient's prescribed medications after discharge unless the medication has been discontinued by the prescriber. If patients are not provided with their medications upon discharge, they may not be able to obtain a refill of the controlled substance until the current prescription time period has ended. Upon a patient's death while residing at the facility, however, the licensee may retain possession of the patient's prescribed medications for the purposes of proper disposal.

The first step in reducing potential diversion of controlled substances is to reduce the amount of medication coming into a facility. Facilities should have a full understanding of their patient population and what their patients' medication needs are. To reduce the amount of medication at the facility, controlled substance prescriptions for patients in a hospice or a residential health care facility may be partially filled[1], or prescriptions may be issued for a shorter time period. Facilities are urged to have open dialogue with their medical directors and pharmacy consultants to be able to make informed and accurate decisions regarding the amounts of controlled substances entering the facility. For example, a rehabilitation facility with an average patient admission of 14 days usually does not need a 30-day supply of a medication for their patients. This is especially true for those medications utilized for pain management when, in many instances, the goal is to reduce the patient's use of these medications prior to discharge.

Drug Disposal/Destruction Methods

A. Long Term Care Facilities (LTCF) Pharmacy Collection Receptacles

A 2014 Drug Enforcement Administration (DEA) Rule allows authorized hospitals and retail pharmacies to maintain collection receptacles at Long Term Care Facilities (LTCF). According to the DEA, LTCF means a nursing home, retirement care, mental care or other facility or

[1] Title 10 NYCRR Parts 80.73 & 80.74

institution which provides extended health care to ***resident patients***[2]. Therefore, **not every Class 3A licensee may meet the qualifications required to be recognized by the DEA as a LTCF.**

Both controlled and non-controlled substances may be placed in a collection receptacle. Environmental Protection Agency-listed hazardous pharmaceuticals may be co-mingled with other medications in a DEA-approved collection receptacle, for the purpose of destroying an end user's medications.

A LTCF may only dispose of those controlled substances listed in Schedules II, III, IV, or V, are lawfully prescribed to an ultimate user who resides, or has resided, at the LTCF, and the facility has the lawful ability to have temporary possession of such medications under their BNE 3A license. Schedule I controlled substances, controlled substances that are not lawfully possessed by the resident ultimate user, and other illicit or dangerous substances are not permitted.[3]

At no time may a licensed 3A facility transport controlled substances or a filled drop box liner from the facility for any reason. Only a DEA registered Collector or common carrier may remove the filled liner from the 3A facility.

For more information on using this method of disposal/destruction, refer to Appendix A below.

NYS Drug Take Back Act

Pursuant to Public Health Law §§290-294, the New York State Drug Take Back Act (DTB) mandates that manufacturers establish, fund, and manage a New York State approved drug take back program(s) for the safe collection and disposal of unused covered drugs.

Licensed 3A LTCF's are eligible to participate in this program at little to no cost to the facility. For additional information on how your facility may be able to have a medication drop box installed through the DTB, please go to our web site at: https://www.health.ny.gov/professionals/narcotic/drug_take_back.htm.

B. Mail-Back Envelopes

The DEA allows ***residents*** of a LTCF to utilize a DEA-approved mail-back program[4]. A mail-back program may be conducted by a DEA-authorized collector. LTCFs cannot apply on their own to become a collector or administer a mail-back program. The LTCF may not use the mail-back packages or administer a mail-back program. ***The LTCF may not use any mail-back envelope program for the purpose of destruction of a licensed 3A's controlled substance inventory***.

On behalf of a LTCF resident, who has sole possession of their own controlled substances, a LTCF employee may place the resident's unwanted or unused controlled and non-controlled substances in a mail-back package, seal it, and immediately deposit it into the facility's outgoing

[2] 21 CFR 1300.01(b)
[3] 21 CFR 1317.30, 1317.70, & 1317.75(b)&(c)
[4] 21 CFR 1317.70

mail system[5]. The facility should have an internal tracking process for these envelopes until they leave the facility via USPS.

C. On-site Destruction

As specified in 10 NYCRR Section 80.51, the destruction of controlled substances shall mean that the substances have been ***rendered totally unrecoverable and beyond reclamation***. Single unit doses or partial doses remaining after the administration or attempted administration of a controlled substance may be destroyed on the premises of an institutional dispenser by a pharmacist or nurse provided that:

1. a notation is made in the patient administration record sheet; and
2. the destruction is witnessed by a second pharmacist or nurse or other responsible person designated by the administrator.

It is ultimately the responsibility of the pharmacist or nurse who is destroying the controlled substance, to assure that the method of destruction used renders the controlled substance totally unrecoverable and beyond reclamation.

All federal and state recordkeeping requirements must continue to be met.

Records of all transactions concerning the disposal or destruction of controlled substances, including shipping or tracking information, proof of receipt, and ultimate destruction from the company that owns the container, and receipts must be kept on-file at the 3A facility for a minimum of 5 years.

If a Class 3A facility wishes to utilize a DEA approved medication drop box as their method ongoing disposal method as part of their controlled substance diversion mitigation plan, they must request approval from BNE by submitting a written request to bnedestruction@health.ny.gov. This includes a DEA-approved medication drop box and those provided through the NYS Drug Take Back Program.

Additional information and forms on the Drug Take Back Act and the safe disposal of controlled substances, can be found at: https://www.health.ny.gov/professionals/narcotic/.

Onsite Sewering

While still a legal option in some locations, reducing the number of medications that are sewered should be limited as much as possible and should be a last resort method of destruction when all other options have been exhausted.

Facilities that are within a designated watershed area are not allowed to sewer medications. Please check with your local water district or municipality to determine if your facility is within designated watershed boundaries.

If sewering is the only available option, it should occur in an area that is not utilized for food preparation, such as a kitchen sink, and in an area not accessible by the public. Direct flushing of the medication should be used without prior alteration of the medication through dissolving,

[5] K Issue #5; Federal Register Vol 79 No. 174

boiling or other medication altering methods prior to sewering. Medications should not be mixed to make a “slurry” prior to sewering. Care should be taken to assure proper Personal Protective Equipment is utilized while sewering medications. All medications must be disposed in their original form without any alterations.

Additional Options

The commercial devices available on the market for drug destruction are continually changing. Some of these devices are only allowed at DEA registered facilities, which 3A licensees are not. It is imperative that a 3A LTCF that wishes to use one of these products, contacts BNE for assistance, before implementing a program that may not meet federal or state regulations.

Signatures on DOH Forms

All signatures must be legible. If any individual’s signature or credentials are not legible, the document will be denied, and an investigation will be initiated.

Electronic signatures or individual unique identifications are acceptable **ONLY** if it is specific to the signee using a unique identification and individualized password authentication. The signee’s credentials must also be present. This process must be outlined within the facility’s policies and procedures and made available to the Department at any time.

Methadone

Methadone is tightly regulated through the DEA and usually dispensed through a Narcotic Treatment Program (NTP), also known as an Opioid Treatment Program (OTP). NTP’s must be registered with the DEA to dispense methadone to end-users for the purpose of treating substance use disorders (SUD).

Methadone may also be prescribed by a practitioner for pain management. In many instances, this is used during end-of-life care.

Licensed 3A facilities are seeing more and more of their residents on methadone for SUD. The 3A licensed facility should have separate BNE approved storage for methadone used for SUD and separate storage for methadone used for pain management, both of which, must be kept separate from all other end-user controlled substances under the 3A license. This is to limit the number of staff that require access to each supply of methadone and thereby reducing the potentials for diversion.

When a 3A resident leaves the facility, all medications must be given to the end-user, unless they are discontinued by the practitioner. This also includes methadone whether it is prescribed for pain management or dispensed by an NTP for SUD.

BNE has found that some end-users are refusing to take their dispensed methadone with them or are otherwise leaving their methadone at the 3A facility when they leave the facility. This now leaves a 3A facility in a difficult situation. The only person who can legally possess that methadone, once the end-user leaves the 3A facility, is the end-user.

How does a 3A facility handle destruction and proper disposal of methadone?

If the methadone is dispensed from an NTP, it may be returned to the NTP if the NTP is a DEA registered Collector. There is no cost for an NTP to become a Collector. The NTP would then follow all DEA requirements for the proper disposition of the methadone. The 3A facility cannot transport the methadone. An agent of the NTP or other employee of the NTP may be allowed to transport the methadone to and from the NTP, but this must be specified in an MOU between the NTP and the 3A facility.

If an NTP is not a DEA registered Collector or the NTP otherwise refuses to take back the methadone, local law enforcement should be contacted to determine if they will come to the facility to pick-up the methadone, since it is now legally considered contraband. In many communities, law enforcement agencies may no longer be willing to accept abandoned controlled substances.

If the 3A facility still finds itself still in possession of the methadone, after attempting to return it to the dispensing NTP and contacting law enforcement, then the facility may submit a request to BNE for destruction following BNE's current process. The methadone can be listed on the DOH-166 or DOH-5733 forms. In most cases, the "**Reason for Destruction**" would be either "**Discontinued**" or "**Abandoned**". If a different reason must be used, then please include a letter with your destruction request as to why that reason needed to be used. For "**Source of Controlled Substance**", this would be the **name of the NTP or practitioner** who dispensed the methadone for the treatment of SUD.

The most appropriate onsite disposal method would be the utilization of a DEA approved collection receptacle that has been approved by BNE as the facility's ongoing method of destruction. Methadone can be placed in the drop box, but it must be in the original packaging so it will not leak or, if leaking, placed in a Zip Lock type back to prevent leakage.

APPENDIX A
Drug Disposal/Destruction
Long Term Care Facilities (LTCF) Pharmacy Collection Receptacles

The Drug Enforcement Administration (DEA) allows authorized hospitals/clinics and retail pharmacies to maintain collection receptacles at Long Term Care Facilities (LTCF). According to the DEA, LTCF means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to ***resident patients***[6]; therefore, **not every Class 3A licensee meets the qualifications required to be recognized by the DEA as a LTCF.**

Both controlled and non-controlled substances may be placed in the collection receptacle, and Environmental Protection Agency listed hazardous pharmaceuticals may be co-mingled with other medications in a DEA approved collection receptacle.

A LTCF may only dispose of those controlled substances listed in Schedules II, III, IV, or V that are lawfully possessed by an ultimate user who resides, or has resided, at the LTCF may be placed in the collection receptacle. Schedule I controlled substances, controlled substances that are not lawfully possessed by the ultimate user, and other illicit or dangerous substances are not permitted.[7]

Collection receptacles must meet the following requirements:

- Pharmacies servicing LTCFs can register with the DEA as a collector and place a collection receptacle at an LTCF. LTCFs cannot apply on their own to become a collector.

- An authorized pharmacy, registered with DEA as an authorized collector, may install, manage, and maintain a DEA approved collection receptacle at a LTCF.

- Receptacles located in an LTCF must be in a secured area, that is regularly monitored by residential health care facility employees.

- The collection receptacle must be securely fastened to a permanent structure and located in a secured area that is regularly monitored by LTCF supervisory staff.

- Regulations require the installation, removal, transfer, and storage of inner liners be performed by **one employee of the Collector and one supervisor-level nurse of the long-term care facility (e.g., a charge nurse or DON). If the facility does not have a nurse working at that time, the Administrator must be the employee from the facility.**

- Upon removal, sealed inner liners may be stored at the LTCF for up to three business days in a securely double locked, substantially constructed cabinet or a securely double locked room with controlled and limited access.

[6] 21 CFR 1300.01(b)
[7] 21 CFR 1317.30, 1317.70, & 1317.75(b)&(c)

LTCFs that will utilize a DEA approved collection receptacle as their ongoing method of disposal/destruction, must request approval from BNE by submitting the form "**Institutional Dispenser – Limited Medication Drop Box Request"**, DOH-5788, to bnedestruction@health.ny.gov. The request will contain the details of disposal/destruction, which, includes the following:

- Class 3A facility information including:
  - Facility name, BNE license number, address, and telephone number
  - Facility contact person name, and email address
  - Location of installed collection receptacle (including room#, etc.)
  - Copies of the facilities policies and procedures regarding all aspects of discontinued controlled substances and their destruction process

- Collector information (for pharmacy that maintains the collection receptacle) including:
  - Collectors name, address, and telephone number
  - Collectors contact person, and email address
  - Copy of the DEA Collector registration to collect controlled substances from ultimate users

The LTCF will receive a confirmation email from BNE with an approval or denial for this ongoing method of disposal/destruction. This approval will permit this method of disposal/destruction moving forward without prior approval requirements by BNE, and the facility will no longer be required to submit for pre-approval to BNE for a specific destruction date.

The LTCF will be required to:

- Store discontinued/unwanted controlled substances for no longer than 72-hours before placing in the drop box.
- Track all controlled substances that are transferred into the collection receptacle on the Controlled Substance Inventory for Drop Boxes in BNE Licensed Facilities (DOH-5733).
  - DOH-5733 was developed to be used as an "on-going" inventory tracking document. Each time a controlled substance is placed in a DEA/BNE approved receptacle, it is documented on this form at that time. Each inventory line must have a date and time when the controlled substance was placed into the collection receptacle.
- Ensure all controlled substances are transferred into the collection receptacle by a licensed healthcare provider who is properly licensed and authorized to administer controlled substances. This should be a nurse and one witness who both sign the appropriate inventory line on the DOH-5733. **All signatures must be printed and legible and include professional credentials. Initials and/or Illegible signatures will not be accepted.**
- Complete the Notification of Disposal/Destruction of Controlled Substances (DOH-5797) form:
  - Personnel removing the liner from the drop box must be an employee of the Collector, who owns and maintains the collection receptacle,

and a nurse in a supervisory capacity from the licensed facility – which verifies the presence of required personnel for the removal of the liner;
- If the 3A facility does not have nurses at the time the liner is removed, the Administrator for the facility must sign as the 3A Facility Supervisor
- Personnel conducting the disposal/destruction must sign *Statement of Disposal/Destruction* on the DOH-5797 and
- A copy of the BNE running inventory form (DOH-5733) must be submitted with the DOH-5797 along with the shipping/delivery receipt showing the liner reached its destination for final destruction.
- BNE will return the DOH-5797 with the destruction log number
    - **Synopsis:**
        - Filled liner removed from box by nurse supervisor and employee of the Collector;
        - Liner is stored in a in a securely locked, substantially constructed cabinet or a securely locked room with controlled access and diversion reduction policies are in-place;
        - Liner is shipped with tracking within 72 hours;
        - DOH-5797, DOH-5733, and completed tracking receipts are emailed to BNE; and
        - BNE will return with DD log number.

- Records of all transactions concerning the disposal/destruction of controlled substances, including shipping/tracking information, DOH-5797, DOH-5733, and receipts must be kept on-file at the 3A facility for 5 years.

- **At no time may a licensed 3A facility transport a filled drop box liner from the facility for any reason. Only a DEA registered Collector or common carrier may remove the filled liner from the 3A facility.**