

CONTROLLED SUBSTANCE PATIENT PRESCRIPTION DISPOSAL

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive maintains policy and standards for disposal of patient-issued controlled substance medications at Department of Veterans Affairs (VA) medical facilities. Providing an environmentally responsible manner for Veterans to dispose of unwanted or unneeded medications improves medication safety in the home, reduces the chance of intentional or accidental poisonings, reduces the risk of diversion, and keeps pharmaceuticals from contaminating the environment.

2. SUMMARY OF MAJOR CHANGES: This VHA directive:

- a. Removes the requirement to establish a written local policy for all patient Controlled Substances take-back programs.
- b. Relocates Veteran Medication Disposal Options to Appendix A from the Policy section.

3. RELATED ISSUES: None.

4. RESPONSIBLE OFFICE: The Chief Consultant, Pharmacy Benefits Management (PBM) Service (12PBM) in the Office of Patient Care Services, is responsible for the content of this directive. Questions may be addressed to 202-461-7326.

5. RESCISSIONS: VHA Directive 1114, Controlled Substance Patient Prescription Disposal, dated September 9, 2016, is rescinded.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of January 2026. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

**BY THE DIRECTION OF THE OFFICE OF
THE UNDER SECRETARY FOR HEALTH:**

/s/ Beth Taylor, DHA
Assistant Under Secretary for Health
for Patient Care Services

NOTE: All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.

January 11, 2021

VHA DIRECTIVE 1114

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CONTENTS

CONTROLLED SUBSTANCE PATIENT PRESCRIPTION DISPOSAL

1. PURPOSE..... 1

2. BACKGROUND..... 1

3. DEFINITIONS 2

4. POLICY 3

5. RESPONSIBILITIES 3

6. VA MEDICAL FACILITY EMPLOYEE REQUIREMENTS 8

7. TRAINING 9

8. RECORDS MANAGEMENT..... 9

9. REFERENCES..... 9

APPENDIX A

VETERAN MEDICATION DISPOSAL OPTIONSA-1

APPENDIX B

SECURITY REQUIREMENTS FOR ON-SITE RECEPTACLESB-1

APPENDIX C

PHARMACY AND OPIOID TREATMENT PROGRAM RECORD KEEPING
REQUIREMENTS FOR COLLECTION RECEPTACLE INNER LINERS C-1

APPENDIX D

REQUIREMENTS FOR COLLECTION RECEPTACLE(S) MAINTAINED BY
PHARMACY AT LONG-TERM CARE FACILITIES D-1

CONTROLLED SUBSTANCE PATIENT PRESCRIPTION DISPOSAL

1. PURPOSE

This Veterans Health Administration (VHA) directive maintains policy and standards for patient issued controlled substance prescription medication disposal at Department of Veterans Affairs (VA) medical facilities. **AUTHORITY:** Title 38 United States Code (U.S.C.) § 7301(b); Title 21 Code of Federal Regulations (C.F.R.) § 1317.

2. BACKGROUND

a. On October 12, 2010, the Secure and Responsible Drug Disposal Act of 2010 (Disposal Act) was enacted (P.L. 111-273). Before the Disposal Act, ultimate users who wanted to dispose of unused, unwanted, or expired pharmaceutical controlled substances had limited disposal options.

b. The Disposal Act amended the CSA to authorize ultimate users to deliver their pharmaceutical controlled substances to another person for the purpose of disposal in accordance with regulations promulgated by the Attorney General (21 U.S.C. § 822(g), § 828(b)(3)). The DEA published a final rule, 79 FR 53520 (September 9, 2014) amending multiple parts of title 21 C.F.R. expanding the entities to whom ultimate users may transfer unused, unwanted, or expired pharmaceutical controlled substances for the purpose of disposal, as well as the methods by which such pharmaceutical controlled substances may be collected.

c. The goals of this final rule, are to set parameters for controlled substance diversion prevention that will encourage public and private entities to develop a variety of methods for collecting and destroying pharmaceutical controlled substances in a secure, convenient, and responsible manner, thus decreasing the supply of unused medications in homes. A second goal is to decrease the amount of pharmaceutical controlled substances introduced into the environment, particularly into public waters.

d. The final rule provides three voluntary options for ultimate user disposal: take-back events, mail-back programs, and collection receptacles. All of the collection methods are voluntary.

e. The final rule does not change the regulations for controlled substance institutional stock. Unusable or expired pharmacy controlled substance (CS) stock or stock in automated dispensing devices that have not been dispensed to a patient are considered inventory or stock of the registrant and therefore must be disposed of by the registrant in accordance with 21 C.F.R. § 1317.05. Likewise, a controlled substance dispensed for immediate administration pursuant to an order for medication in an institutional setting remains under the custody and control of that registered institution even if the substance is not fully exhausted (e.g., some of the substance remains in a vial, tube, transdermal patch, or syringe after administration but cannot or may not be further utilized, commonly referred to as “drug wastage” or “pharmaceutical wastage”). Such remaining substances must be properly recorded, stored, and destroyed in

accordance with DEA regulations and VHA Directive 1108.01, Controlled Substances Management, dated May 1, 2019.

3. DEFINITIONS

a. **Controlled Substance.** The term "controlled substance," as defined in 21 U.S.C. 802(6), means a drug or other substance, or immediate precursor, included in Schedule I, II, III, IV, or V of 21 U.S.C. § 812. 21 C.F.R. § 1308.11–308.15 provides a listing of each drug, substance, or immediate precursor for each schedule.

b. **Employee.** For purposes of this directive, as provided by 21 C.F.R. § 1300.05, employee means an employee as defined under the general common law of agency. The following criteria will determine whether a person is an employee of a registrant for the purpose of disposal: the person is directly paid by the registrant; subject to direct oversight by the registrant; required, as a condition of employment, to follow the registrant's procedures and guidelines pertaining to the handling of controlled substances; subject to receive a performance rating or performance evaluation on a regular/routine basis from the registrant; subject to disciplinary action by the registrant; and required to render services at the registrant's registered location. **NOTE:** *Contract employees and without compensation (WOC) employees that do not meet these criteria must not be involved in any aspects of managing on-site receptacles.*

c. **Law Enforcement Officer.** For purposes of this directive, as provided by 21 C.F.R. § 1300.05(b)(2), a law enforcement officer is a VA police officer authorized by VA to participate in collection activities conducted by VHA.

d. **Long-Term Care Facilities.** For purposes of this directive, as provided by 21 C.F.R. § 1300.01(b), a long-term care facility (LTCF) is a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients. For VA, this includes Community Living Centers, Mental Health Residential Rehabilitation Treatment Programs, VA domiciliaries, and other programs defined as extended care.

e. **On-site.** For purposes of this directive, as provided by 21 C.F.R. § 1300.05, on-site means located on or at the physical premises of the registrant's registered location. A controlled substance is destroyed on-site when destruction occurs on the physical premises of the destroying registrant's registered location. A hospital or clinic has an on-site pharmacy when it has a pharmacy located on the physical premises of the registrant's registered location. A Community-based Outpatient Clinic (CBOC) without a pharmacy is not considered on-site.

f. **Reverse Distributor.** For purposes of this directive, as provided by 21 U.S.C § 802(27), a reverse distributor is a registrant of the DEA who receives controlled substances acquired from another DEA registrant for the purpose of:

(1) Returning unwanted, unusable, or outdated controlled substances to the manufacturer or the manufacturer's agent; or

(2) Where necessary, processing such substances or arranging for processing such substances for disposal.

g. **Take Back Event.** For purposes of this directive, as provided by 21 C.F.R. § 1317.65, is a scheduled event for a registered collector to receive controlled substances from an ultimate user for the purpose of destruction.

h. **Ultimate User.** For purposes of this directive, as provided by 21 U.S.C. § 802(27), an ultimate user is a person who has lawfully obtained, and who possesses, a controlled substance for their own use or for the use of a member of their household or for an animal owned by them or by a member of their household.

i. **Mail-back program.** For purposes of this directive, as provided by 21 C.F.R. § 1317.70, is a disposal program where a VA medical facility partners with a collector to make postage paid mailing envelopes available to ultimate users to return unused or unwanted medications for destruction.

j. **Collector.** A DEA registrant or other entity authorized by DEA to receive unwanted or unused controlled substance from an ultimate user.

k. **Collection Receptacle.** A locked, secured, substantially constructed container where ultimate user can drop unwanted controlled substances.

4. POLICY

It is VHA policy that each VA medical facility or health care system (including associated VA community clinics) will provide at least one medication disposal option to Veterans consistent with DEA regulations and VHA policy to help prevent diversion and reduce the chance of intentional and accidental injury in the home from the accumulation of unwanted or unneeded medications. ***NOTE: See Appendix A for the disposal options available which are mailback envelopes, on-site collection receptacles managed by Pharmacy or collection receptacles managed by Security and Law Enforcement.***

5. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.

b. **Assistant Under Secretary for Health for Patient Care Services.** The Assistant Under Secretary for Health for Patient Care Services is responsible for supporting Pharmacy Benefits Management (PBM) Services with implementation and oversight of this directive.

c. **Assistant Under Secretary for Health for Operations.** The Assistant Under Secretary for Health for Operations is responsible for:

(1) Supporting the VISNs and VA medical facilities in implementation of a patient CS disposal program meeting the requirements of this directive.

(2) Communicating the contents of this directive to each of the Veterans Integrated Service Networks (VISNs).

(3) Assisting VISN Directors in resolving implementation and compliance challenges.

(4) Providing oversight of VISNs to ensure compliance with this directive and its effectiveness.

d. **Chief Consultant, Pharmacy Benefits Management Services.** The Chief Consultant, PBM Services is responsible for responding to inquiries from VA medical facility Pharmacy Chiefs regarding the implementation of this directive.

e. **Veterans Integrated Service Network Director.** The VISN Director is responsible for:

(1) Overseeing the implementation of patient CS medication disposal programs within their VISN.

(2) Ensuring that all VA medical facilities within the VISN comply with this directive and informing leadership when barriers to compliance are identified.

f. **VA Medical Facility Director.** The VA medical facility Director is responsible for:

(1) Implementing at least one option for patient disposal of controlled substances medications when appropriate and in settings that comply with 21 C.F.R. § 1317. An inter-professional approach must be utilized. Implemented programs must safely meet the needs of Veterans, provide efficiency for staff, minimize risk of diversion, and minimize costs. ***NOTE: Take-back events could be conducted in addition to one of the other options but should not be the only option available at a facility or healthcare system.***

(2) Providing oversight to ensure that VA medical center staff comply with this directive.

(3) Promoting a culture of “see something, say something” that encourages all managers and staff to report suspected diversion.

(4) Ensuring VA medical facility staff and trainees, with the exception of VA police and long-term care staff, do not take back or accept CS prescriptions from ultimate users (patients or family members, caregivers, or any other visitor). ***(NOTE: It is acceptable for staff to take temporary custody of a patient’s CS prescription(s) during admission, in the emergency department, or during procedural care when the patient is***

not able to retain custody and a family member or caregiver is not present to accept control of the CS medication. Process is defined locally for patient belongings, but temporary custody of controlled substances cannot be in pharmacy).

(5) Ensuring VA medical facility staff under their supervision do not dispose of pharmacy or hospital stock of CS in patient medication collection receptacles.

(6) Taking appropriate personnel action when VA medical facility staff are identified as accepting or taking CS prescriptions back from patients.

(7) Reporting, in accordance with the policy established in VHA Directive 1108.01, any suspected staff diversion of patient CS prescriptions and any loss or suspected diversion of on-site receptacle liners.

(8) Ensuring strong practices are established that maximize Veteran engagement and return on investment prior to instituting a program to provide mail-back envelopes to Veterans. See Appendix A. **NOTE:** *VA medical facilities must not conduct a mail-back program as mail-back programs require an on-site method of destruction. However, VA medical facilities may purchase mail-back envelopes from a DEA-authorized collector for distribution to Veterans.*

g. VA Medical Facility Clinical Executives and Managers. VA medical facility Clinical Executives and Managers are responsible for:

(1) Ensuring staff and trainees under their supervision, are aware that they cannot take or accept CS prescriptions back from patients or family members, caregivers, or any other visitor for the purpose of destruction. **NOTE:** *Staff must advise the person on available options provided by the VA medical facility and must distribute mail-back envelopes or direct (or walk) people to an on-site receptacle.*

(2) Ensuring staff and trainees under their supervision do not dispose of pharmacy or hospital stock of controlled substances in patient medication collection receptacles.

(3) Ideally on same day, but within one business day, reporting to their supervisor and VA medical facility Director any instances of staff accepting CS prescriptions back from Veterans or others for the purpose of destruction.

h. VA Medical Facility Chief of Police. The VA medical facility Chief of Police is responsible for:

(1) Following all applicable regulations if conducting a take-back event. See 21 C.F.R. § 1317.65. During a Take-Back Event the receptacle will be directly monitored by a VA police officer. **NOTE:** 21 C.F.R. § 1317.40 *prohibit pharmacies from conducting a take-back event.*

(2) Following DEA regulations and processes in Appendix B if VA Police are maintaining an on-site receptacle.

(3) Establishing a mechanism for destruction of filled receptacle liners, prior to implementing a program for on-site receptacles, under the control of VA Police. **NOTE:** *The services of a DEA-registered reverse distributor authorized to be a collector is the preferred method.*

(4) Reviewing and approving requests from the VA medical facility Chief of Pharmacy on the type of on-site receptacle to be used, where it will be installed, and the security method(s) for installation prior to implementing a program for on-site receptacles under the control of pharmacy.

(5) Reviewing and approving requests from the VA medical facility Mental Health Service Line Chief on the type of on-site receptacle to be used, where it will be installed and the security method(s) for installation prior to implementing a program for on-site receptacles under the control of the DEA registered Narcotic Treatment Program.

i. **VA Medical Facility Chief of Pharmacy.** The VA medical facility Chief of Pharmacy is responsible for:

(1) Ensuring that pharmacy staff do not dispose of expired or non-usable CS pharmacy stock or returned mail CS prescriptions in a patient collection receptacle or mail-back envelope. **NOTE:** *VHA Directive 1108.01 describes the policy and related DEA regulations for handling expired and non-usable controlled substances. Controlled substances returned in the mail as undeliverable are considered pharmacy stock as they did not reach the ultimate user.*

(2) Modifying the VA medical facility DEA registration to include the status of “collector” prior to establishing an on-site receptacle(s) or a receptacle at a VA LTCF under the control of pharmacy. **NOTE:** *On-site receptacles under the control of law enforcement do not require a modification to the VA medical facility DEA registration.*

(3) Modifying the VA medical facility DEA registration to remove the status of “collector” if the pharmacy stops on-site receptacle collection activities.

(4) Obtaining review and approval on the type of LTCF on-site receptacle to be used, where it will be installed, and the security method(s) for installation from the VA medical facility Chief of Police prior to implementing a program for on-site receptacles under the control of pharmacy.

(5) Establishing a mechanism for destruction of filled receptacle liners prior to implementing a program for on-site receptacles under the control of pharmacy. **NOTE:** *The services of a DEA registered reverse distributor authorized to be a collector is the preferred method.*

(6) Ensuring the small opening in the outer container of any collection receptacle maintained by pharmacy is locked or made otherwise inaccessible to the public when a pharmacy employee is not present (e.g., when the pharmacy is closed). **NOTE:** *If the receptacle is managed by VA Police, the opening does not need to be locked when the pharmacy is closed.*

(7) Following DEA regulations and processes in Appendix B if pharmacy is maintaining an on-site receptacle(s). Appendix D details requirements for LTCFs. **NOTE:** *Filled inner liners from off-site LTCFs and on-site LTC areas must not be brought to the VA medical facility pharmacy for storage and must be transferred to a reverse distributor for destruction within 3 business days of removal from the receptacle.*

(8) Ensuring staff and trainees are aware that they cannot take or accept CS prescriptions back from patients or family members, caregivers, or any other visitor.

(9) Ensuring staff advise the person on available options provided by the VA medical facility and distribute mail-back envelopes or direct (or walk) people to an on-site receptacle.

(10) Ideally on same day, but within one business day, reporting to their supervisor and the VA medical facility Director any instances of staff accepting CS prescriptions back from Veterans or others for the purpose of destruction.

(11) Reporting in accordance with the policy established in VHA Directive 1108.01 missing filled or empty inner liners and evidence of tampering of stored sealed liners for on-site receptacle(s) under the control of pharmacy.

(12) Ensuring mail-back envelopes purchased for distribution to Veterans are from a DEA-authorized collector and meet 21 C.F.R. § 1317.70 requirements. **NOTE:** *VA medical facilities must not conduct a mail-back program as mail-back programs require an on-site method of destruction. However, VA medical facilities may purchase mail-back envelopes from a DEA-authorized collector for distribution to Veterans.*

(13) Implementing strong practices that maximize Veteran engagement and return on investment prior to instituting a program to provide mail-back envelopes to Veterans and sharing resources available with staff on their use. See Appendix A. Examples of strong practices can be located on the PBM intranet through the link labeled "Medication Disposal for Patients": https://dvagov.sharepoint.com/sites/VHAPBM/Pharmacy_Operations/Patient%20Medication%20Disposal/Forms/AllItems.aspx. **NOTE:** *This is an internal VA website that is not available to the public.*

j. **VA Medical Facility Mental Health Service Line Chief or Equivalent Leader.**
The VA medical facility Mental Health Service Line Chief or equivalent leader is responsible for:

(1) Modifying the DEA Narcotic Treatment Program registration to include the status of "collector" prior to establishing an on-site receptacle located at a certified Opioid Treatment Program (OTP) and following all applicable regulations and processes in Appendix B for on-site receptacle(s) located at OTPs.

(2) Obtaining review and approval of the type of OTP on-site receptacle to be used, where it will be installed, and the security method(s) for installation from the VA medical facility Chief of Police prior to implementing a program for on-site receptacles under the

control of the DEA registered Narcotic Treatment Program. **NOTE:** *Receptacles located at a narcotic treatment program must be located in a room that does not contain any other controlled substances and is securely locked with controlled access.*

(3) Establishing a mechanism for destruction of filled receptacle liners prior to implementing a program for on-site receptacles under the control of the DEA registered Narcotic Treatment Program. **NOTE:** *The services of a DEA registered reverse distributor authorized to be a collector is the preferred method.*

(4) Ensuring a staff member accompanies the patient into the secured room where the receptacle is located.

(5) Ensuring staff advise the person on available options provided by the VA medical facility and distribute mail-back envelopes or direct (or walk) people to an on-site receptacle.

(6) Within 1 business day, reporting to their supervisor and the VA medical facility Director any instances of staff accepting CS prescriptions back from Veterans or others for the purpose of destruction.

(7) Reporting in accordance with the policy established in VHA Directive 1108.01 missing filled or empty inner liners and evidence of tampering of stored sealed liners for on-site receptacle(s) under the control of the DEA registered Narcotic Treatment Program.

6. VA MEDICAL FACILITY EMPLOYEE REQUIREMENTS

a. VA medical facility staff and trainees, with the exception of VA police and long-term care staff, must not take back or accept CS prescriptions from ultimate users (**NOTE:** *It is acceptable for staff to take temporary custody of a patient's CS prescription(s) during admission, in the emergency department, or during procedural care when the patient is not able to retain custody and a family member or caregiver is not present to accept control of the CS medication. Processes for handling the patient CS prescriptions under these circumstances must be defined in the applicable VA medical facility standard operating procedure(s) (e.g., admissions, patient care.) Under no circumstances should the patient CS medications be stored in pharmacy during temporary custody.*

b. VA medical facility staff must not dispose of pharmacy or hospital stock of CS in patient medication collection receptacles. **NOTE:** *DEA registrants cannot use the collection receptacles to dispose of unused controlled substances in their inventory or stock (21 C.F.R. § 1317.05 and § 1317.75). Pharmaceutical controlled substances remain under the custody and control of the DEA registrant if they are dispensed for immediate administration in the hospital or clinic pursuant to a provider order. If the medication is not fully used (e.g., half tablet or partial vial or syringe) after administration, then it must be destroyed and the destruction documented with the signatures of two authorized witnesses per VHA Directive 1108.01 staff must not place*

such remaining, unusable controlled substance in a collection receptacle as a means of disposal.

7. TRAINING

There are no formal training requirements associated with this directive. The communication slide deck will be available at https://dvagov.sharepoint.com/sites/VHAPBM/Pharmacy_Operations/Patient%20Medication%20Disposal/Forms/AllItems.aspx. **NOTE:** *This is an internal VA website that is not available to the public*

8. RECORDS MANAGEMENT

a. All records regardless of format (e.g., paper, electronic, electronic systems) created by this directive must be managed as required by the National Archives and Records Administration (NARA) approved records schedules found in VHA records Control Schedule 10-1. Questions regarding any aspect of records management should be addressed to the appropriate Records Manager or Records Liaison.

b. For receptacles under the control of VA police, the chain of custody for the liner is recorded on VA Form 3524, and in the green evidence ledger book. Hard copies of non-criminal Investigative Reports (IRs) for the final disposition of receptacles under the control of police must be maintained in the VA Police Records Control Schedule files.

c. Required documentation for filled and sealed inner liners turned over to a DEA authorized reverse distributor for any on-site receptacle under the control of pharmacy, OTP and VA Police must be maintained for a period of 3 years. This documentation can be electronic or hard copy and includes: the unique identification number of the sealed inner liner transferred; the size of the sealed inner liner transferred (e.g., 5-gallon, 10-gallon), the date of the transfer; and the name, address, and registration number of the reverse distributor to whom the controlled substances were transferred) must be recorded on VA Form 3524.

9. REFERENCES

a. P. L. 111-273.

b. 21 C.F.R. § 1300, § 1301, § 1304, § 1305, § 1307 and § 1317.

c. 79 FR 53520.

d. VA Handbook 0730, Security and Law Enforcement dated August 11, 2000.

e. VHA Directive 1108.01, Controlled Substances Management, dated May 1, 2019.

f. "Medication Disposal for Patients":

https://dvagov.sharepoint.com/sites/VHAPBM/Pharmacy_Operations/Patient%20Medication%20Disposal/Forms/AllItems.aspx

January 11, 2021

VHA DIRECTIVE 1114

[ation%20Disposal/Forms/AllItems.aspx](#). **NOTE:** *This is an internal VA website that is not available to the public.*

VETERAN MEDICATION DISPOSAL OPTIONS

1. In deciding what medication disposal option(s) to offer to Veterans, Department of Veterans Affairs (VA) medical facilities should solicit input from Primary Care, Nursing, Pharmacy, and Mental Health and Police services. To the degree possible, respect for Veterans' privacy must be considered in disposal procedures. Options that should be considered are:

a. VA medical facilities may purchase mail-back envelopes from a United States Drug Enforcement Agency (DEA) authorized collector for distribution to Veterans.

b. On-site receptacle maintained by the pharmacy under the responsibility of the Chief of Pharmacy.

c. On-site receptacle maintained by VA Police under the responsibility of the Chief of Police.

d. On-site receptacle maintained at a DEA-registered Narcotic Treatment Program under the responsibility of the Mental Health Service Line Chief or equivalent clinical leader.

e. Take-back events under the responsibility of the Chief of Police. **NOTE:** *In the final rule, only law enforcement may administer a take-back event. Take-back events could be conducted in addition to one of the other options but should not be the only option available at a facility or healthcare system.*

2. Resources to include sample tracking forms for inventory liners, receptacle signage, program marketing flyers and staff education have been developed to assist VA medical facilities in implementing an option. These resources can be located on the Pharmacy Benefits Management (PBM) intranet site through the link labeled "Medication Disposal for Patients" at:

https://dvagov.sharepoint.com/sites/VHAPBM/Pharmacy_Operations/Patient%20Medication%20Disposal/Forms/AllItems.aspx. **NOTE:** *This is an internal VA website that is not available to the public.*

SECURITY REQUIREMENTS AND PROCESSES FOR ON-SITE RECEPTACLES

The following requirements apply at any Department of Veterans Affairs (VA) medical facility that has chosen to operate on-site collection receptacles.

a. **Construction.** The collection receptacle must:

(1) Be a securely locked, substantially constructed container with a permanent outer container and a removable inner liner.

(2) Be substantially constructed of metal, resistant to brute force entry, and securely fastened to a permanent structure so that it cannot be removed.

(3) Include a small opening on the outer container that allows contents to be added to the inner liner but does not allow removal of the inner liner's contents.

(4) Have a securely locked access panel or door for removal of the inner liner. The access panel or door will be special keyed, and keys must be limited to VA Police or Pharmacy Service.

b. **Security.** The use of Security Surveillance TV cameras and an intrusion detection system on the receptacle are encouraged but not required.

c. **Signage.** The outer container of receptacles must prominently display a sign indicating that only Schedule II–V controlled and non-controlled substances, if a VA medical facility chooses to comingle substances, are acceptable substances and that controlled substances that are not lawfully possessed and other illicit or dangerous substances are not permitted. The signage must not transform the receptacle into a target for theft or diversion and discourage the use of receptacles for disposing of trash or other items. A template of the signage is available at:

https://dvagov.sharepoint.com/sites/VHAPBM/Pharmacy_Operations/Patient%20Medication%20Disposal/Forms/AllItems.aspx. ***NOTE:*** *This is an internal VA website that is not available to the public. Only ultimate users and other authorized non-registrant persons in lawful possession of a controlled substance in Schedule II, III, IV, or V may deposit such substances in a collection receptacle.*

d. **Location.** Receptacles must be permanently mounted in secure locations, as further provided for in (1)-(4) below depending on their location.

(1) VA Police Operations Rooms, as identified in VA Handbook 0730, Security and Law Enforcement, dated August 11, 2000, paragraph 5.b.(1). Such public contact points are normally located in high traffic areas of the primary medical care building at a VA medical facility.

(2) Receptacles under control of Pharmacy must be located in an area regularly monitored by employees and not in proximity to any area where emergency or urgent

care is provided. When an employee is not present (e.g., the pharmacy is closed) the opening to the receptacle must be locked or made otherwise inaccessible to the public.

NOTE: *If the receptacle is managed by VA Police, the opening does not need to be locked when the pharmacy is closed. Pharmacy must not place receptacles at a location that is not the registered location for the pharmacy (e.g., community clinic without an onsite pharmacy). On-site receptacles under the control of law enforcement do not require a modification to the facility DEA registration.*

(3) Receptacles located in on-site long-term care (LTC) areas or at off-site long-term care facilities (LTCFs) must be located in a secured area regularly monitored by LTC or LTCF employees, respectively. The opening to the receptacle must be locked or made otherwise inaccessible to the public when the receptacle is not being regularly monitored by these employees.

(4) Receptacles located at a narcotic treatment program must be located in a room that does not contain any other controlled substances and is securely locked with controlled access.

NOTE: *Pharmacy must not place receptacles at a location that is not the registered location for the pharmacy (e.g., community clinic without an onsite pharmacy). On-site receptacles under the control of law enforcement do not require a modification to the facility DEA registration.*

e. **Inner Liners.** Inner liners must meet the following requirements:

(1) The inner liner must be waterproof, tamper-evident, and tear resistant.

(2) The inner liner must be removable and sealable immediately upon removal without emptying or touching the contents.

(3) The contents of the inner liner must not be viewable from the outside when sealed.

(4) The size of the inner liner must be clearly marked on the outside of the liner (e.g., 5-gallon, 10-gallon).

(5) The inner liner must bear a permanent, unique identification number that enables the inner liner to be tracked.

f. **Process for Inner Liners:**

(1) **Pharmacy and Mental Health:**

(a) For receptacles under the control of Pharmacy or Mental Health, two employees must immediately seal the filled liner upon removal from the permanent outer container.

(b) The sealed inner liners should not be opened, x-rayed, analyzed, or otherwise penetrated.

(c) For Pharmacy receptacles, the filled and sealed inner liners are stored in the Pharmacy vault and promptly turned over to a reverse distributor for destruction. See Appendix D for storage requirements of filled and sealed inner liners in LTCFs. **NOTE:** *DEA does not define a time frame for “promptly”. Therefore, for the purpose of this directive, promptly is interpreted by VA to mean as soon as possible with storage not exceeding 30 calendar days.*

(d) For OTP receptacles, filled and sealed inner liners are stored securely at OTP and turned over to a reverse distributor for destruction as soon as possible, with storage not exceeding 30 calendar days.

(e) Documentation for inner liners for any on-site receptacle under the control of pharmacy or OTP are outlined in Appendix C and defines the requirements as listed in 21 C.F.R. § 1304.22(f).

(f) Maintain a running inventory of all liners (e.g., empty, in receptacle and sealed awaiting pick-up).

(2) Police:

(a) For receptacles under the control of police, a VA police officer removes and immediately seals the inner liner of filled containers initiating VA Form 3524, VA Police Property Held Evidence Record, and places them in the evidence locker for safekeeping, pending ultimate disposal. **NOTE:** *VA Police may not turn the liners over to Pharmacy Services for disposal.*

(b) For receptacles under the control of police, ensuring the chain of custody for the liner is recorded on VA Form 3524, and in the green evidence ledger book. The final disposition will result in a non-criminal Investigative Report (IR), with a hard copy in the VA Police Records Control Schedule files.

(c) Maintain required documentation for filled and sealed inner liners turned over to a DEA-authorized reverse distributor for any on-site receptacle under the control of VA Police. This documentation can be electronic or hard copy and includes: the unique identification number of the sealed inner liner transferred; the size of the sealed inner liner transferred (e.g., 5-gallon, 10-gallon) the date of the transfer; and the name, address, and registration number of the reverse distributor to whom the controlled substances were transferred must be recorded on VA Form 3524.

(d) The keys used to open and access the inner liner of receptacles under the control of VA Police are separately secured and an entry made into the Police Daily Journal each time the receptacle is opened.

(e) A report is made, in accordance with policy established in VHA Directive 1108.01 Controlled Substances Management, dated May 1, 2019, for any missing filled or empty inner liners and any evidence of tampering of stored sealed liners for on-site receptacle(s) under the control of VA Police.

**PHARMACY AND OPIOID TREATMENT PROGRAM RECORD KEEPING
REQUIREMENTS FOR COLLECTION RECEPTACLE INNER LINERS**

Records must be maintained for collection receptacle inner liners as defined in Title 21 Code of Federal Regulations (C.F.R.) § 1304.22(f) and in Veterans Health Administration (VHA) Records Control Schedule 10-1. The following information must be documented and maintained on file for a period of 3 years:

- a. Date each unused inner liner acquired, unique identification number and size (e.g., 5-gallon, 10-gallon) of each unused inner liner acquired;
- b. Date each inner liner is installed, the address of the location where each inner liner is installed, the unique identification number and size (e.g., 5-gallon, 10-gallon) of each installed inner liner, the registration number of the collector, and the names and signatures of the two employees that witnessed each installation;
- c. Date each inner liner is removed and sealed, the address of the location from which each inner liner is removed, the unique identification number and size (e.g., 5-gallon, 10-gallon) of each inner liner removed, the registration number of the collector, and the names and signatures of the two employees that witnessed each removal;
- d. Date each sealed inner liner is transferred to storage, the unique identification number and size (e.g., 5-gallon, 10-gallon) of each sealed inner liner stored, and the names and signatures of the two employees that transferred each sealed inner liner to storage; and
- e. Date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealed inner liner was transferred, the unique identification number and the size (e.g., 5-gallon, 10-gallon) of each sealed inner liner transferred, and the names and signatures of the two employees that transferred each sealed inner liner to the reverse distributor or distributor.

**REQUIREMENTS FOR COLLECTION RECEPTACLE(S) MAINTAINED BY
PHARMACY AT LONG-TERM CARE FACILITIES**

Only the Department of Veterans Affairs (VA) medical facility Pharmacy may install, manage, and maintain collection receptacles at off-site long-term care facilities (LTCFs) and in on-site long term care (LTC) areas and remove, seal, transfer, and store, or supervise the removal, sealing, transfer, and storage of sealed inner liners at LTCFs:

a. The installation, removal, transfer, and storage of inner liners must be performed either: by or under the supervision of one employee of the pharmacy and one supervisor-level employee of the LTCF (e.g., a charge nurse or supervisor) designated by the pharmacy; or, by or under the supervision of two employees of the authorized pharmacy.

b. Upon removal, sealed inner liners must only be stored at the LTCF for up to 3 business days in a securely locked, substantially constructed cabinet or a securely locked room with controlled access until transfer in accordance with Title 21 C.F.R. § 1317.05(c)(2)(iii).

c. A VA pharmacy must not operate a collection receptacle at a LTCF until its registration has been modified in accordance with 21 C.F.R. § 1301.51.

d. Staff at LTCFs may dispose of controlled substances in Schedules II, III, IV, and V on behalf of an ultimate user who resides, or has resided, at such LTCF by transferring those controlled substances into an authorized collection receptacle located at that LTCF. When disposing of such controlled substances by transferring those substances into a collection receptacle, such disposal shall occur immediately, but no longer than 3 business days after the discontinuation of use by the ultimate user. Discontinuation of use includes a permanent discontinuation of use as directed by the prescriber, as a result of the resident's transfer from the LTCF, or as a result of death.