

CONTROLLED SUBSTANCE PATIENT PRESCRIPTION DISPOSAL

- 1. REASON FOR ISSUE:** This Veterans Health Administration (VHA) directive establishes policy and procedures for disposal of patient-issued controlled substance medications.
- 2. SUMMARY OF CONTENT:** This VHA directive establishes policy and procedures for the disposal of patient-issued controlled substance medications.
- 3. RELATED ISSUES:** None.
- 4. RESPONSIBLE OFFICE:** The Chief Consultant, Pharmacy Benefits Management (PBM) Service (10P4P) 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:** None.
- 6. RECERTIFICATION:** This VHA directive is scheduled for recertification on or before the last working day of September 2021. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

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Under Secretary for Health

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CONTENTS

CONTROLLED SUBSTANCE PATIENT PRESCRIPTION DISPOSAL

1. PURPOSE..... 1

2. BACKGROUND..... 1

3. DEFINITIONS..... 2

4. POLICY 3

5. RESPONSIBILITIES 4

6. REFERENCES..... 10

APPENDIX A

SECURITY REQUIREMENTS FOR ON-SITE RECEPTACLESA-1

APPENDIX B

PHARMACY AND OTP RECORD KEEPING REQUIREMENTS FOR COLLECTION
RECEPTACLE INNER LINERSB-1

APPENDIX C

REQUIREMENTS FOR COLLECTION RECEPTACLE(S) MAINTAINED BY
PHARMACY AT LTCFs..... C-1

CONTROLLED SUBSTANCE PATIENT PRESCRIPTION DISPOSAL

1. PURPOSE

This Veterans Health Administration (VHA) directive establishes policy and procedures for patient issued controlled substance prescription medication disposal.

AUTHORITY: Title 21 United States Code (U.S.C.) 822(g) and 828(b)(3).

2. BACKGROUND

a. On October 12, 2010, the Secure and Responsible Drug Disposal Act of 2010 (Disposal Act) was enacted (Pub. L. 111-273, 124 Stat. 2858). Before the Disposal Act, ultimate users who wanted to dispose of unused, unwanted, or expired pharmaceutical controlled substances had limited disposal options. The Controlled Substances Act (CSA) only permitted ultimate users to destroy those substances themselves (e.g., by flushing or discarding), surrender them to law enforcement, or seek assistance from the United States Drug Enforcement Administration (DEA). These restrictions resulted in the accumulation of pharmaceutical controlled substances in household medicine cabinets that were available for abuse, misuse, diversion, and accidental ingestion. Disposal of Controlled Substances, 79 Fed. Reg. 53520 (Sept. 9, 2014) (to be codified at 21 C.F.R. pts. 1300, 1301, 1304, 1305, 1307 and 1317).

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. Title 21 United States Code (U.S.C.) 822(g), 828(b)(3). The DEA published a final rule, 79 FR 53520 (Sept. 9, 2014) (hereinafter, the rule), that expanded 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 goal of this rule, consistent with Congress's goal in the Disposal Act, is 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. Also, consistent with the Disposal Act's goal to decrease the amount of pharmaceutical controlled substances introduced into the environment, particularly into public waters, these regulations provide individuals with various additional options to dispose of their unwanted or unused pharmaceutical controlled substances beyond discarding or flushing the substances. As a result of these regulations, the DEA hopes that the supply of unused pharmaceutical controlled substances in the home will decrease, thereby reducing the risk of diversion or harm. *Id. at 53520-53521.*

d. The rule provides three voluntary options for ultimate user disposal: (1) Take-back events, (2) mail-back programs, and (3) collection receptacles. All of the collection methods are voluntary, and no person is required to establish or operate a disposal program. The rule also does not require ultimate users to utilize any of the three

methods for disposal of controlled substances. Specified entities may voluntarily administer any of the authorized collection methods in accordance with the regulations.

e. The 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 Title 21 Code of Federal Regulations (CFR) § 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 (e.g., 21 CFR § 1304.22(c)), all applicable federal laws, and VHA Handbook 1108.01, Controlled Substances (Pharmacy Stock).

3. DEFINITIONS

a. **Controlled Substance.** A controlled substance is a drug or other substance, or immediate precursor, that is regulated by federal law and considered controlled substances under the Controlled Substances Act (CSA). These substances are divided into five schedules and placed in their respective schedule based on whether they have a currently accepted medical use in treatment in the United States, their relative abuse potential, and their likelihood of causing dependence when abused. An updated and complete list of the schedules is published annually in 21 CFR §§ 1308.11 through 1308.15.

b. **Employee.** 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 may not be involved in any aspects of managing on-site receptacles.***

c. **Law Enforcement Officer.** Per the DEA rule (21 CFR 1300.05(b)(2)), a law enforcement officer is a VA police officer authorized by the Department of Veterans Affairs to participate in collection activities conducted by VHA.

d. **Long Term Care Facilities.** Per the DEA rule, Long Term Care Facility (LTCF) is defined at 21 CFR § 1300.01(b) and “means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident

patients.” For the purposes of VHA, this would include Community Living Centers, Mental Health Residential Rehabilitation Treatment Programs, VA domiciliaries and other programs defined as extended care.

e. **On-site.** Per the DEA regulations (21 CFR 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/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 would not be considered on-site.

f. **Reverse Distribute.** Reverse distribute means to acquire controlled substances or listed chemicals from another registrant or law enforcement for the purpose of return to the registered manufacturer or another registrant authorized by the manufacturer to accept returns on the manufacturer’s behalf; or for destruction.

g. **Reverse Distributor.** A reverse distributor is a person registered with the Drug Enforcement Administration as a reverse distributor.

h. **Ultimate User.** An ultimate user is defined by the Controlled Substance Act as a “person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household.” (See 21 U.S.C. 802(27)).

4. POLICY

It is VHA policy that each Department of Veterans Affairs (VA) medical facility (including associated VA community clinics) must evaluate all options in an inter-professional process and implement at least one practical, accessible, and secure option for patient disposal of controlled substances medications when appropriate and in settings that are applicable to the rule. To the degree possible, respect for Veterans’ privacy should be considered in disposal procedures. The process should include, at a minimum, input from primary care, nursing, pharmacy, and mental health and police services. Providing Veterans an option to dispose of unwanted/unneeded controlled substance medications in a secure manner will reduce the likelihood of diversion or harm. Options that should be considered are:

a. VA medical facilities may purchase mail-back envelopes from a 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 (21 CFR 1317.65), only law enforcement may conduct a Take Back Event.*

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

[https://vaww.cmopnational.va.gov/cmop/PBM/Medication Disposal for Patients/Forms/AllItems.aspx](https://vaww.cmopnational.va.gov/cmop/PBM/Medication%20Disposal%20for%20Patients/Forms/AllItems.aspx). **NOTE:** *This is an internal VA Web site that is not available to the public.*

5. RESPONSIBILITIES

a. **Deputy Under Secretary for Health for Operations and Management.** The Deputy Under Secretary for Health for Operations and Management is responsible for:

(1) Supporting the implementation of patient CS medication disposal programs across VHA.

(2) Working with the Director, VA Police and Security Service to:

(a) Define the security requirements for collection receptacles located within VA medical facilities and the storage of sealed filled inner liners (see Appendix A).

(b) Provide communication and education of VA Police Chiefs regarding the contents of the rule.

(c) Respond to questions from VA police field staff on the contents of this directive and the rule.

b. **Chief Consultant, Pharmacy Benefits Management Services.** The Chief Consultant, Pharmacy Benefits Management Services (PBM) is responsible for:

(1) Communication and education of VHA Pharmacy Chiefs regarding the contents of this directive and the rule.

(2) Responding to questions from VHA Pharmacy Chiefs on the contents of this directive and the rule.

c. **Veterans Integrated Service Network Director.** The Veterans Integrated Service Network (VISN) Director is responsible for supporting the implementation of patient CS medication disposal programs within their VISN.

d. **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 are applicable to the rule, and establishing a VA medical facility policy for all patient CS take-back programs implemented. An inter-professional approach should be utilized in accordance with this directive and the rule. Implemented programs and policy must follow the requirements in the final rule and should be designed to safely meet the needs of our Veterans, provide efficiency for staff, minimize risk of diversion, and minimize costs.

(2) Ensuring VA medical facility staff members and trainees, with the exception of VA police and long-term care staffs, are educated that they cannot take or accept CS prescriptions back from Veteran patients and/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/caregiver is not present to accept control of the CS medication. Processes for handling the patient CS prescriptions under these circumstances should be defined in the applicable VA medical facility policy (e.g., admissions, patient care, etc.) Under no circumstances should the patient CS medications be stored in pharmacy during temporary custody.*

(3) Ensuring VA medical facility staff members do not dispose of pharmacy or hospital stock of controlled substances in patient medication collection receptacles. **NOTE:** *The rule is clear that DEA registrants cannot use the collection receptacles to dispose of unused controlled substances in their inventory or stock. 21 CFR §§ 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 Handbook 1108.01 (Pharmacy Stock). Staff must not place such remaining, unusable controlled substance in a collection receptacle as a means of disposal. VA medical facility staff members must not place such remaining, unusable controlled substances in a collection receptacle as a means of disposal.*

(4) Taking appropriate personnel action when VA medical facility staff members are identified as accepting or taking CS prescriptions back from patients in violation of this policy and the rule.

(5) Reporting, in accordance with the procedures established in VHA Handbook 1108.01, Controlled Substances (Pharmacy Stock), any suspected staff diversion of patient CS prescriptions and any loss or suspected diversion of on-site receptacle liners.

(6) Ensuring strong practices are established and implemented that maximizes Veteran engagement and return on investment prior to instituting a program to provide mail-back envelopes to Veterans. **NOTE:** *VA medical facilities may not conduct a mail-back program as mail-back programs require an on-site method of destruction. 21 CF 1317.05. However, VA medical facilities may purchase mail-back envelopes from a DEA authorized collector for distribution to Veterans. Title 21 CFR 1317.70*

(7) Ensuring the VA medical facility DEA registration is modified to become authorized as a “collector” prior to establishing on-site receptacles under the control of pharmacy. *Title 21 CFR 1301.51. **NOTE:** On-site receptacles under the control of law enforcement do not require a modification to the facility DEA registration.*

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

e. **Facility Clinical Executives and Managers.** Facility Clinical Executives and Managers are responsible for:

(1) Ensuring staff and trainees, with the exception of long-term care staff, are educated that they cannot take or accept CS prescriptions back from Veteran patients and/or family members, caregivers or any other visitor for the purpose of destruction. **NOTE:** *Staff should educate the person on available options provided by the VA medical facility and may distribute mail-back envelopes and/or direct (or walk) people to an on-site receptacle.*

(2) Ensuring staff and trainees do not dispose of pharmacy or hospital stock of controlled substances in patient medication collection receptacles. **NOTE:** *The rule is clear that DEA registrants cannot use the collection receptacles to dispose of unused controlled substances in their inventory or stock. Title 21 CFR §§ 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 Handbook 1108.01, Controlled Substances (Pharmacy Stock), and in accordance with 21 CFR § 1304.22(c). Staff must not place such remaining, unusable controlled substance in a collection receptacle as a means of disposal. VA medical facility staff members must also not dispose of any controlled substances in inventory or stock in a collection receptacle as a means of disposal. Title 21 CFR §§ 1317.05 and 1317.75.*

(3) Promptly 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.

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

f. **Facility Chief of Police.** The facility Chief of Police is responsible for:

(1) Following all applicable regulations in the rule if conducting a Take-Back Event. During a Take-Back Event the receptacle will be directly monitored by a VA Police officer. **NOTE:** *Pharmacy may not conduct a take-back event per the final rule.*

(2) Following all applicable regulations in the rule if VA Police are maintaining an on-site receptacle.

(3) Review and approval of the security for on-site receptacle(s). **NOTE:** *This applies to any receptacle under the control of pharmacy as well as VA Police.*

(4) 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.*

(5) Receptacles under the control of police, ensuring 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 placing in the evidence locker for safekeeping, pending ultimate disposal.

(6) 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.

(7) Maintaining 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 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, etc.); 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.

(8) Ensuring 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

(9) Promptly reporting to the VA medical facility Director 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.

g. **Facility Chief of Pharmacy.** The facility Chief of Pharmacy is responsible for:

(1) Ensuring expired/non-usable CS pharmacy stock and returned mail CS prescriptions are not placed in a patient collection receptacle or mail-back envelope. **NOTE:** *VHA Handbook 1108.01, Controlled Substances (Pharmacy Stock), 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) Modification of the 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:** *Per 21 CFR 1317.75(d)(2)(i), on-site collection receptacles at a hospital or clinic shall be located in an area regularly monitored by employees, and shall not be located in the proximity of any area where emergency or urgent care is provided.*

Pharmacy may not place receptacles at a location that is not the registered location for the pharmacy (e.g., community clinic, etc.) with the exception of an off-site VA LTCF whose name and physical location were included in the application for DEA registration. Title 21 CFR 1301.51. .

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

(4) Obtaining review and approval on the type of on-site receptacle to be used, where it will be installed, and the security method(s) for installation from the 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).

(7) For receptacles under the control of pharmacy, ensuring two pharmacy employees immediately seal the filled liner upon removal from the permanent outer container. **NOTE:** *Per 21 CFR 1317.60(c), sealed inner liners shall not be opened, x-rayed, analyzed, or otherwise penetrated.*

(8) Ensuring filled and sealed inner liners are stored in the Pharmacy vault and promptly turned over to a reverse distributor for destruction. See Appendix C 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 shall be interpreted to be as soon as possible with storage not exceeding 30 days.*

(9) Maintaining required documentation for inner liners for any on-site receptacle under the control of pharmacy. Appendix B defines the requirements as listed in the rule.

(10) Maintaining a running inventory of all liners (e.g., empty, in receptacle or sealed/filled).

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

(12) For receptacles under the control of pharmacy, establishing a process that ensures security of the keys used to open and access the inner liner of the receptacle and tracks who accesses the keys.

(13) Ensuring staff and trainees are educated that they cannot take or accept CS prescriptions back from Veteran patients and/or family members, caregivers, or any other visitor. **NOTE:** *Staff should educate the person on available options provided by the facility and may distribute mail-back envelopes and/or direct (or walk) people to an on-site receptacle.*

(14) Promptly 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.

(15) Promptly reporting to the VA medical facility Director and Chief of Police missing filled or empty inner liners and evidence of tampering of stored sealed liners for on-site receptacle(s) under the control of pharmacy per the requirements defined in VHA Handbook 1108.01, Controlled Substances (Pharmacy Stock) for reporting any suspected theft, diversion, or suspicious loss of drugs.

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

(17) Ensuring mail-back envelopes purchased for distribution to Veterans are from a DEA authorized collector and meet the requirements in the final rule. **NOTE:** *VA medical facilities may 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.*

(18) Implementing strong practices that maximize Veteran engagement and return on investment prior to instituting a program to provide mail-back envelopes to Veterans and educating staff on their use.

h. **Facility Mental Health Service Line Chief or Equivalent Leader.** The facility Mental Health Service Line Chief or equivalent leader is responsible for:

(1) Modification of the DEA Narcotic Treatment Program registration as required by 21CFR 1301.51 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 in the rule for on-site receptacle(s) located at OTPs.

(2) Obtaining review and approval on the type of on-site receptacle to be used, where it will be installed and the security method(s) for installation from the facility Chief of Police prior to implementing a program for on-site receptacles under the control of the DEA registered Narcotic Treatment Program. **NOTE:** *Per 21 CFR 1317.75(d)(2)(ii), “Receptacles located at a narcotic treatment program shall 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 two employees immediately seal the filled liner upon removal from the permanent outer container. **NOTE:** *Per 21 CFR 1317.60 (c), sealed inner liners shall not be opened, x-rayed, analyzed, or otherwise penetrated.*

(5) Ensuring filled and sealed inner liners are stored securely at the OTP and promptly turned over to a reverse distributor for destruction. **NOTE:** *DEA does not define a time frame for “promptly”. Therefore, for the purpose of this directive, promptly shall be interpreted to be as soon as possible with storage not exceeding 30 days.*

(6) Maintaining required documentation for inner liners for any on-site receptacle under the control of the OTP. Appendix B defines the requirements as listed in the rule.

(7) Maintaining a running inventory of all liners (e.g., empty, in receptacle or sealed/filled).

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

(9) Ensuring staff and trainees are educated that they cannot take or accept CS prescriptions back from Veteran patients and/or family members, caregivers or any other visitor. **NOTE:** *Staff should educate the person on available options provided by the facility and may distribute mail-back envelopes and/or direct (or walk) people to an on-site receptacle.*

(10) Promptly 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) Promptly reporting missing filled or empty inner liners and evidence of tampering of stored sealed liners for on-site receptacle(s) per the requirements defined in VHA Handbook 1108.01, Controlled Substances (Pharmacy Stock) for reporting any suspected theft, diversion, or suspicious loss of drugs for on-site receptacle(s) under the control of the DEA registered Narcotic Treatment Program.

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

6. REFERENCES

- a. VHA Handbook 1108.01, Controlled Substances (Pharmacy Stock).
- b. Secure and Responsible Drug Disposal Act of 2010.
- c. 79 Federal Register 53520 (Sept. 9, 2014).

- d. 21 C.F.R. pts. 1300, 1301, 1304, 1305, 1307 and 1317.

SECURITY REQUIREMENTS FOR ON-SITE RECEPTACLES

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

a. **Construction.** The collection receptacle must meet the requirements in title 21 Code of Federal Regulations (CFR) 1317.75 and those set forth below:

(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 be 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 limited to VA Police or Pharmacy Service.

b. **Security.** The use of Security Surveillance TV (SSTV) cameras and an intrusion detection system on the receptacle is 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 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 should not transform the receptacle into a target for theft or diversion and discourage the use of receptacles for disposing of trash or other items. *(NOTE: 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 will 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, paragraph 5.b.(1). Such public contact points are normally located in high traffic areas of the primary medical care building at a facility.

(2) Receptacles under control of pharmacy may be located in an area regularly monitored by employees, and shall not be located in the proximity of 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 police, the opening does not need to be locked when the pharmacy is closed).*

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

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

e. **Inner Liners.** Inner liners must meet the requirements in 21 CFR 1317.60 to include:

(1) The inner liner shall be waterproof, tamper-evident, and tear resistant;

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

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

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

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

**PHARMACY AND OTP RECORD KEEPING REQUIREMENTS FOR COLLECTION
RECEPTACLE INNER LINERS**

Records must be maintained for collection receptacle inner liners as defined in the rule (title 21 Code of Federal Regulations (CFR) 1304.22(f)) and in VA's Record Control schedule. 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, etc.) 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, etc.) 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, etc.) 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, etc.) of each sealed inner liner stored, and the names and signatures of the two employees that transferred each sealed inner liner to storage;
- 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, etc.) 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 LTCFs**

Only Pharmacy may install, manage, and maintain collection receptacles at off-site LTCFs and in on-site LTC areas and remove, seal, transfer, and store, or supervise the removal, sealing, transfer, and storage of sealed inner liners at LTCFs per the requirements in title 21 Code of Federal Regulations (CFR) 1317.80(b):

a. The installation, removal, transfer, and storage of inner liners shall 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 may only be stored at the LTCF for up to three business days in a securely locked, substantially constructed cabinet or a securely locked room with controlled access until transfer in accordance with 21 CFR § 1317.05(c)(2)(iii).

c. A VA pharmacy shall not operate a collection receptacle at a LTCF until its registration has been modified in accordance with 21 CFR § 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 three 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.