

CONTROLLED SUBSTANCES MANAGEMENT

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive provides procedures for maintaining accountability of all controlled substances and compliance with Drug Enforcement Administration (DEA) regulations.

2. SUMMARY OF MAJOR CHANGES: This directive incorporates VHA Handbook 1108.01, Controlled Substances (Pharmacy Stock), dated November 16, 2010, and has been updated based on recommendation and questions from the field, DEA survey findings, and identified vulnerabilities for diversion of controlled substances for non-legal purposes. These changes include:

- a. Changing the name of the policy to Controlled Substances Management.
- b. Adding definitions for Automated Dispensing Cabinet (ADC), Long Term Care Facility (LTCF), and off-site location.
- c. Adding responsibilities for the Deputy Under Secretary for Health for Operations and Management.
- d. Adding responsibilities for Associate Chief of Staff for Research and Development.
- e. Moving responsibilities for biennial inventory, record retention, use of VistA Controlled Substance software and reconciliation process for ADCs from VA medical facility Director to VA medical facility Chief of Pharmacy.
- f. Removing all appendices that contained forms. Staff should use the VA Forms website to ensure they are using the most recent version of a form.
- g. Removing specifications for electronic access control system and other security requirements. These are defined in VA Handbook 0730, Security and Law Enforcement, dated December 12, 2012, and staff should follow the most recent copy of that handbook.
- h. Updating requirement for reporting theft, loss, or suspected diversion of any high value drug.
- i. Removing requirements and information on par levels for inpatient dispensing as this information is already contained in VHA Directive 1108.06, Inpatient Pharmacy Services, dated February 8, 2017.
- j. Removing allowance for CPRS created or other locally created forms to be used for hand written controlled substance prescriptions. The only form that can be used for

handwritten controlled substance prescriptions is VA Form 10-2577F, Security Prescription Form or a State mandated controlled substance prescription form.

k. Clarifying the requirements for hard copy prescriptions, partial prescriptions, and biennial inventory.

l. Changing the requirement for all new pharmacy employees to view the TMS video "Employee Integrity and Pharmacy Security" from mandatory to recommended.

m. Adding a requirement for health care providers to ensure a valid prescription is handwritten or entered electronically for all controlled substances dispensed directly to the patient by the health care provider for take home.

n. Providing permissible pharmacist edits to hard copy controlled substance prescriptions.

o. Adding a requirement to transfer the hospital/clinic DEA registration to the Chief of Pharmacy upon the next renewal for those facilities that have an on-site pharmacy or stock controlled substances at an off-site location under the management of the Chief of Pharmacy.

p. Adding security requirements for compounded controlled substance injectable products, to include both syringes and bags, dispensed to patient care areas.

q. Changing the frequency of pharmacy required inventories from every 72 hours to twice a week.

3. RELATED ISSUES: Due to the time it will take to change or implement local policy and process requirements required in this directive, VA medical facilities are not expected to be in full compliance until six months after publication.

4. RESPONSIBLE OFFICE: The Chief Consultant, Pharmacy Benefits Management Services (10P4P), within the Office of Patient Care Services is responsible for the content of this directive. Questions may be addressed to 202-461-7362.

5. RESCISSIONS: VHA Handbook 1108.01, Controlled Substances (Pharmacy Stock), dated November 16, 2010, is rescinded.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of May 2024. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

May 1, 2019

VHA DIRECTIVE 1108.01

CERTIFIED BY:

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

/s/ Lucille B. Beck, PhD.
Deputy Under Secretary for Health for
Policy and Services

/s/ Lucille B. Beck, PhD.
Deputy Under Secretary for Health for
Policy and 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.*

DISTRIBUTION: Emailed to the VHA Publications Distribution List on May 28, 2019.

CONTENTS

CONTROLLED SUBSTANCES MANAGEMENT

1. PURPOSE..... 1

2. DEFINITIONS 1

3. POLICY 3

4. RESPONSIBILITIES 3

5. ORDERING AND RECEIVING CONTROLLED SUBSTANCES 15

6. INVENTORY OF CONTROLLED SUBSTANCES..... 16

7. CONTROLLED SUBSTANCES DISPENSING, NON-PHARMACY STOCK AREAS 17

8. CONTROLLED SUBSTANCES DISPENSING, OUTPATIENT SERVICES..... 19

9. DISPOSAL OF CONTROLLED SUBSTANCES STOCK 25

10. OPIOID TREATMENT PROGRAM 27

11. TRAINING 28

12. RECORDS MANAGEMENT..... 29

13. REFERENCES..... 29

APPENDIX A

REQUIREMENTS FOR USING COMMERCIAL CONTROLLED SUBSTANCE
MANAGEMENT SYSTEMSA-1

APPENDIX B

PROCEDURES FOR LOSS AND DIVERSION OF CONTROLLED SUBSTANCES...B-1

APPENDIX C

PERMISSIBLE PHARMACIST EDITS TO HARD COPY (HANDWRITTEN)
CONTROLLED SUBSTANCE PRESCRIPTIONS..... C-1

CONTROLLED SUBSTANCES MANAGEMENT

1. PURPOSE

This Veterans Health Administration (VHA) directive establishes the policy, responsibilities, and procedures to maintain accountability of all controlled substances and compliance with the Controlled Substance Act and Drug Enforcement Administration (DEA) regulations to minimize the risk for loss and diversion and enhance patient safety.

AUTHORITY: Title 21 United States Code (U.S.C.) 812 and 827; 38 U.S.C. 7301(b); Title 21 Code of Federal Regulations (CFR) Part 1300-END; and 38 CFR 17.38(a)(1)(iii).

2. DEFINITIONS

a. **Accountable Officer.** The Chief, Logistics Service is the Accountable Officer (AO) at a VA medical facility. At the Consolidated Mail Outpatient Pharmacy (CMOP) facilities, the Logistics Manager or other individual designated by the CMOP Director is the AO; the AO at a Clinical Research Pharmacy Coordinating Center (CRPCC) is designated by the VA medical facility Director. The AO's role is to be present and verify the receipt of controlled substances and the destruction or turn-in of drugs for destruction to a third party. The AO also maintains copies of all controlled substance invoices.

b. **Automated Dispensing Cabinet.** Automated Dispensing Cabinet (ADC) is a computerized drug storage device or cabinet that electronically dispenses medications in a controlled fashion and tracks medication use. They also are called a unit-based cabinet (UBC), an automated dispensing device (ADD), an automated dispensing unit (ADU), or an automated dispensing machine (ADM). Manufacturer names for ADCs include Omnicell, Pyxis, AcuDose, and MedSelect with many others commercially available.

c. **Clinical Research Pharmacy Coordinating Center.** The Clinical Research Pharmacy Coordinating Center (CRPCC), part of the VA Office of Research and Developments' Cooperative Studies Program, provides for the manufacturer, packaging, and distribution of all drugs in the Cooperative Studies Program and other affiliated Federal and collaborative research programs.

d. **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 CFR 1308.11 – 1308.15 provides a listing of each drug, substance, or immediate precursor for each schedule.

e. **Controlled Substances Coordinator.** A Controlled Substances Coordinator (CSC) is the individual appointed by the VA medical facility Director and responsible for the management of the controlled substances inspection program.

f. **Diversion.** Diversion means the diversion of controlled substances from legal and medically necessary uses towards uses that are illegal and typically not medically authorized or necessary. Diversion may occur at every point in the medication use

process and may involve theft by health care professionals. Drug diversion can result in patient harm, drug abuse, overdoses, and death.

g. **Evidence Bag.** An evidence bag is a clear plastic bag that can be permanently sealed, is generally tamper-evident, and allows marking (writing) on the bag.

h. **Long Term Care Facility.** Long Term Care Facility (LTCF) is defined in 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 this directive, this would include Community Living Centers (CLCs), Mental Health Residential Rehabilitation Treatment Programs, VA domiciliaries, and other programs defined as extended care.

i. **Off-Site Location.** An off-site location is any associated clinic or long-term care facility not located at the same physical address as the DEA registered medical facility.

j. **Opioid Treatment Program.** An opioid treatment program (OTP) is any opioid substance use disorder treatment program certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) in conformance with 42 CFR Part 8, to provide supervised assessment and medication-assisted treatment. Under these Federal regulations, OTPs are required to have current valid accreditation status, SAMHSA certification, and DEA registration before they can administer or dispense opioid drugs for the treatment of opioid substance use disorder. **NOTE: DEA Best Practice Guideline refers to OTPs as Narcotic Treatment Programs.**
<https://www.deadiversion.usdoj.gov/pubs/manuals/narcotic/index.html>.

k. **Prescription.** A prescription is an order for medication which is dispensed to or for an ultimate user. A prescription is not an order for medication which is dispensed for immediate administration to the ultimate user (i.e., an order to dispense a drug to an inpatient for immediate administration in a hospital is not a prescription).

l. **Provider.** For the purposes of this directive, a provider is any individual authorized by State licensure to prescribe controlled substances. VA providers must also have authorization from a VA medical facility in the form of clinical privileges, scope of practice, or as a postgraduate clinical trainee.

m. **Trainee.** Trainee is a general term to describe undergraduate, graduate, and post-graduate students, interns, residents, fellows, and VA advanced fellows including pre- and post-doctoral fellows. Trainees spend time at a VA medical facility for clinical or research training experiences to satisfy program or degree requirements. Trainee requirements can be found in VHA Directive 1400.09, Education of Physicians and Dentists, dated September 9, 2016; VHA Handbook 1400.07, Education of Advanced Fellows, dated February 26, 2016; and VHA Handbook 1400.08, Education of Associated Health Professions, dated February 26, 2016. Trainees are appointed under the statutory authorities of 38 U.S.C. 7405 or 38 U.S.C. 7406.

n. **Waste.** Waste refers to circumstances where controlled substances have been ordered for direct administration to a patient, the entire contents of the vial, syringe,

tablet, or other unit dose container is not administered. The remaining portion is considered waste.

o. **Working Stock.** Working stock refers to a small inventory of controlled substances that is removed from the main storage vault and stored in an alternate location in pharmacy for immediate access during dispensing activities. The storage device for working stock must have electronic access and preferably be an automated dispensing cabinet (e.g., Pyxis, Omnicell). Working stock should be limited to no more than a 5-day supply.

3. POLICY

It is VHA policy that management and accountability of all controlled substances Schedules I-V, to include procurement, transfer to another DEA registrant, storage, prescribing, administration, dispensing, waste, and disposal, will be in compliance with all laws and Federal regulations relevant to controlled substances and designed to minimize the risk for loss and diversion and enhance patient safety.

4. RESPONSIBILITIES

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

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

(1) Communicating the contents of this directive to each of the Veterans Integrated Services Networks (VISNs).

(2) Ensuring that each VISN Director has the sufficient resources to implement this directive in all VA medical facilities within that VISN.

(3) Providing oversight of VISNs to assure compliance with this directive, relevant standards, and applicable regulations.

(4) Ensuring that all controlled substances loss reports entered into the issue brief tracker system are forwarded to the Email group "VHAPBM Pharmacy Reporting Controlled Substance Diversion/Loss."

c. **Veterans Integrated Service Network Director.** Each VISN Director is responsible for ensuring that a comprehensive system for the management of controlled substances is maintained at each VA medical facility within the VISN.

d. **Consolidated Mail Outpatient Pharmacy National Director.** The National Consolidated Mail Outpatient Pharmacy (CMOP) Directors responsible for ensuring that a comprehensive system for the management of controlled substances is maintained at each CMOP that handles controlled substances.

e. **Clinical Research Pharmacy Coordinating Center Director.** The Clinical Research Pharmacy Coordinating Center (CRPCC) Director is responsible for ensuring that a comprehensive system for the management of controlled substances is maintained at the CRPCC.

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

(1) Ensuring that the requirements for provider DEA registration established in VHA Handbook 1108.05, Outpatient Pharmacy Services, dated August 1, 2016, are followed.

(2) Requiring uniform and complete compliance with Federal law and VHA policies on controlled substances for all staff involved in the handling and management of controlled substances.

(3) Ensuring there is a designated staff member responsible for assisting with the controlled substance monthly inspections, security, handling, and storage of controlled substances in areas not staffed by nursing or pharmacy personnel (e.g., research section).

(4) Defining in local policy a maximum time frame between removal of a controlled substance from stock in patient care areas to administration or return to stock. This time frame may vary for different areas of the VA medical facility. However, in general, for units and clinics it should not exceed 2 hours.

(5) Defining in local policy a maximum time frame between administration and wasting of the remaining contents to minimize the risk of diversion. This time frame may vary for different areas of the VA medical facility. For instance, wasting of partial doses on units and clinics can be accomplished almost immediately, whereas wasting in the operating room may not be able to be accomplished until the surgery case has ended.

(6) Ensuring that controlled substance loss, theft, or diversion occurring outside of the VA medical facility pharmacy is reported to the Chief of Pharmacy, and that reporting to DEA is completed as required in Federal regulations.

(7) Ensuring that the VA medical facility DEA registration is transferred to the Chief of Pharmacy upon the next renewal for those facilities that have an on-site pharmacy or that stock controlled substances at an off-site location under the management of the Chief of Pharmacy. ***NOTE: The DEA registrant (E-Signature name on the application) for clinics registered for the sole purpose of telehealth must be someone of authority at/over the clinic(s).***

g. **VA Medical Facility Chief of Pharmacy and Consolidated Mail Outpatient Pharmacy Director.** The VA medical facility Chief of Pharmacy and CMOP Director are responsible for ensuring that:

(1) All pharmacy requirements for ordering, receipt, storage, handling, dispensing, destruction, and security of controlled substances are followed.

(2) Written local standard operating procedures are established for the complete management of controlled substances within the pharmacy, to include ordering, receiving, storage, security, dispensing, destruction and loss reporting.

(3) All written local controlled substance policies, procedures, and records are in compliance with VHA, DEA, and Federal regulatory requirements (21 CFR Part 1300-END).

(4) A current copy of 21 CFR, Part 1300-END is retained in the pharmacy or electronically accessible to pharmacy staff.

(5) Disposal of records is in accordance with VHA's Records Control Schedule (RCS) 10-1. **NOTE:** *RCS 10-1, 7400.4, and 7400.5 currently requires all controlled substance records must be maintained for 3 years. Pharmacy staff must check the most current version of the RCS before disposing of records.*

(6) All new pharmacy employees receive training on Pharmacy Security and Integrity as part of the pharmacy employee orientation. This training must be documented in the employee orientation record or in the Talent Management System (TMS). **NOTE:** *The TMS video "Employee Integrity and Pharmacy Security" may be used to satisfy this requirement, and it is recommended that all new employees view this video.*

(7) All pharmacy technicians assigned to work in the vault have the duties specifically detailed in the functional statement and have objective competencies specific to the management of controlled substances in their performance plan.

(8) The VA medical facility DEA registration is transferred to the Chief of Pharmacy upon the next renewal for those facilities that have an on-site pharmacy or that stock controlled substances at an off-site location under the management of the Chief of Pharmacy. **NOTE:** *The DEA registrant (E-Signature name on the application) for clinics registered for the sole purpose of telehealth must be someone of authority at/over the clinic(s).*

(9) Security of controlled substances is maintained in accordance with the most recent version of VA Handbook 0730, Security and Law Enforcement, and as follows: **(NOTE:** *To help ensure new storage areas, access control and camera operations meet the requirements in VA Handbook 0730, the VA medical facility Chief of Police should be consulted prior to implementation.*)

(a) Storage of bulk inventory of controlled substances must be in the pharmacy vault or safe, unless a waiver is approved by the Office of the Chief Consultant, Pharmacy Benefits Management Services.

(b) If stored outside of the pharmacy vault, the working inventory of controlled substances must be stored in a secured locked cabinet or cart with electronic access or locked commercial automated dispensing system. It must not be dispersed with general pharmacy inventory.

(c) Controlled substances must not be stored in the warehouse with the exception of the All-Hazards Emergency Caches, which must be under the control of the VA medical facility pharmacy services and must meet the storage requirements of VA Handbook 0730; VHA Directive 0320.10, Inspection of VA All-Hazard Emergency Caches by the VHA Office of Emergency Management, dated July 26, 2017; and VHA Directive 1047(1), All-Hazards Emergency Caches, dated December 30, 2014.

(d) Controlled substance prescriptions filled and awaiting pick-up must be stored in a secured locked cabinet or in a cart with controlled electronic access if stored outside of the vault.

(10) The number of pharmacy staff who have access to scheduled drugs in all pharmacy locations (e.g., vault, filled prescriptions awaiting pick-up, working stock, ADCs) is limited based on work assignments related to controlled substances.

(11) Access to pharmacy controlled substances storage areas is monitored through an electronic access control system. **NOTE:** *Security cameras are highly recommended.*

(12) Employee electronic access to all pharmacy controlled substance storage areas located within the pharmacy, to include vault, working stock, filled prescriptions awaiting pick-up, cache, and ADCs, is maintained and reviewed on a regular basis, at a minimum quarterly, to identify unwarranted access (e.g., an employee accessing the inventory during scheduled time off or when assigned to a different area of the pharmacy). **NOTE:** *Administrator level access for ADCs should be limited with end-user access changes approved by the Chief of Pharmacy or designated supervisor.*

(13) Controlled substances are inventoried according to DEA regulations, as found in 21 CFR Part 1304.11, for the biennial physical inventory, as follows:

(a) Biennial physical inventory must be taken at least every 2 years on any date within the 2-year period of the previous biennial inventory.

(b) Documentation of the inventory of CII controlled substances must be separate from the inventory for CIII-V controlled substances.

(c) The biennial inventory must include all pharmacy controlled substance (CS) stock, all CS stock outside of the pharmacy including CS on floors, clinics, and research, CS prescriptions filled, but not picked up or mailed, CS drugs held for destruction and the pharmacy cache.

(d) For on-site patient medication disposal receptacles under the control of a pharmacy where the DEA registration was modified to add the status of "collector," the biennial inventory must include the quantity, unique identification number, and size of each unused collection receptacle liner and each sealed inner liner awaiting turn-over for destruction.

(e) The biennial inventory may be taken at the opening or closing of the business day. The inventory record must indicate the date, whether it was done at the opening or

closing of business, and the actual time each area was counted. The inventory record must be signed by the staff member(s) who completed the inventory.

(f) The biennial inventory must be stored in a separate file and clearly marked as the biennial inventory.

(g) A biennial inventory must be completed for each separate registration (e.g. CBOC, methadone clinic) and filed at the registered location.

(14) When a permanent change in the appointment of a VA medical facility Chief of Pharmacy or CMOP Director occurs, a complete inventory of controlled substances in each pharmacy under their control must be conducted. The VA medical facility or CMOP pharmacy inventory includes all stock of controlled substances that has not been dispensed to patients or distributed to areas outside of the pharmacy (e.g., clinics/wards). The inventory should also include verification of the drugs held for destruction and the pharmacy cache.

(a) The outgoing VA medical facility Chief of Pharmacy or CMOP Director and the designated or Acting VA medical facility Chief of Pharmacy or Acting CMOP Director, jointly conduct and record the inventory prior to transfer of responsibility. Additionally, the Acting VA medical facility Chief of Pharmacy or Acting CMOP Director, and incoming VA medical facility Chief of Pharmacy or incoming CMOP Director, are to jointly conduct and record the inventory upon transfer of permanent responsibility. In the event that only one individual is available (e.g., due to illness), the CSC conducts the inventory with that individual.

(b) A record of the inventory must be made on VA Form 10-2320 or an electronically generated inventory sheet for each drug inventoried; each VA Form 10-2320 or electronic equivalent must be signed and dated by both people conducting the inventory.

(c) Any inventory discrepancy is recorded and reported within 1 day per the procedures in Appendix B.

(15) The use of a two-person (facilitator and witness) signature system is used for all balance adjustments. **NOTE:** *The VistA Controlled Substance Package does not provide a mechanism to capture two signatures electronically and has limited characters to document the reason for the balance adjustment. An internally developed form or printed Email communication may be used to capture additional information and signatures. The documentation should be kept on file.*

(16) All balance adjustments are reviewed monthly, and a summary report is provided to the CSC as part of the monthly inspection process. During review, if any balance adjustment activity is indicative of possible diversion, the VA medical facility Chief of Pharmacy or designee must immediately report per the requirements in Appendix B.

(17) The number of VA medical facility pharmacy staff assigned the VistA PSDMGR security key, which allows a user to electronically perform controlled substance balance adjustments, is limited. **NOTE:** *Pharmacy staff involved in the monthly review of balance adjustments must not be assigned this security key.*

(18) The VistA PSDRPH security key is only issued to licensed pharmacists and the Pharmacy Informaticist (ADPAC) (who may not necessarily be a licensed pharmacist but requires this key to perform job duties).

(19) The VistA Controlled Substances Software is used for all controlled substances transactions. **NOTE:** *For the purposes of this directive, the CMOP has its own inventory management software and standard forms for controlled substance record keeping. Therefore, it is not held to VistA software or security key requirements.*

(a) All controlled substances ordered from a wholesaler or manufacturer must always be received in the VistA Controlled Substance Package per the requirements of paragraph 5, Ordering and Receiving Controlled Substances.

(b) The VistA Controlled Substance package must be fully implemented for all aspects of outpatient prescription processing and dispensing to include maintenance of perpetual inventory in the VistA Controlled Substance Package.

(c) A commercial automated controlled substance management system (e.g., Pyxis CII safe, OmniCell CSM) may be used for accountability and management of controlled substance stock used for dispensing to storage areas outside of the VA medical facility pharmacy (e.g., inpatient units, clinics) per the requirements defined in Appendix A.

(20) All controlled substances dispensed to and returned from, ADCs located in the VA medical facility outside of the pharmacy is reconciled by comparing VistA report to the ADC report when a commercial automated controlled substance management system is not used. **NOTE:** *VA medical facilities have experienced diversion during these process as the VistA inventory is not interfaced with the ADC inventory.*

(21) All DEA requirements for documentation are met, and the total quantity of the prescription is never exceeded if partials are issued for controlled substance prescriptions. **NOTE:** *It is highly recommended that local dispensing procedures limit issuing partials of controlled substance medications to those situations where a medication supply shortage would affect the care of the patient or a smaller supply is clinically indicated for patient safety.*

(22) Providing the CSC with a full list of the names of ADCs containing controlled substances and their corresponding NAOU name (if different) in VistA to ensure the controlled substance inspection program meets the requirements to inspect every controlled substance storage area every month.

(23) Promptly notifying the CSC anytime an ADC containing controlled substances is re-named, moved, newly installed or removed.

(24) A separate DEA registration is obtained for each off-site location where controlled substances are stored, administered, or dispensed. An off-site CBOC or Community Living Center (CLC) would require a separate DEA registration in order to stock controlled substance medications not prescribed and labeled for an individual patient. The DEA registration certificate (DEA Form 223) must be maintained at the registered location (i.e., the physical address noted on the certificate) in a secure location that is readily retrievable for inspection by an outside agency (see 21 CFR 1301.35(c)). **NOTE:** *VA has a waiver from DEA to place ADCs at Long Term Care Facilities without a pharmacy with the understanding there is dedicated on-site VA employed health care provider and pharmacist who works with the practitioner and other members of the team. DEA registrations for CLCs without an on-site pharmacy must be coordinated through the Office of the Chief Consultant, Pharmacy Benefits Management. The waiver allows the use of medication orders for controlled substances instead of prescriptions.*

(25) Documentation for all controlled substance stock transferred between DEA registered locations is completed according to DEA regulations and maintained on file, as follows:

(a) DEA Form 222 is required for the transfer of all CII medications.

(b) An invoice or receipt is required for all CIII-V medications. The document must include the names, addresses, and DEA registration numbers of the parties involved in the transfer; the drug name; dosage form; strength; quantity; and date transferred. The document should be signed by both the transferring and receiving parties, and it must be maintained on file.

(c) The main site can transfer up to 5 percent of total controlled substance stock without being registered as a supplier.

(26) Pharmacy staff ordering Schedule I and II controlled substances have been granted an individual power of attorney in accordance with 21 CFR 1305.05. The power of attorney is not submitted to DEA, but is filed locally and must be available for inspection by DEA.

(a) A record is maintained that lists each person granted power of attorney to sign controlled substances orders in accordance with 21 CFR 1311.45.

(b) The power of attorney is revoked in writing in accordance with 21 CFR 1303.05 if the person is no longer authorized to order controlled substances.

(c) For staff with Controlled Substance Ordering System (CSOS) certificates, the DEA Certification Authority is notified within 6 hours if the staff member has left employment or has had their privileges revoked in accordance with 21 CFR 1311.45.

(27) If using CSOS, the order is electronically received in the Prime Vendor system in accordance with 21 CFR 1305.22(g). This receiving file must be linked with the ordering file and saved to a shared pharmacy drive in a format (e.g., PDF) that is readily

retrievable. **NOTE:** *The Prime Vendor system provides instructions on how to link receipt to order and save.*

(28) If using DEA Form 222, receipt of Schedule I and II controlled substances is annotated on copy 3 of DEA Form 222 to include the number of commercial or bulk containers received and the dates received in accordance with 21 CFR 1305.13. **NOTE:** *DEA published a notice of proposed rule making in the Federal Register on 2/21/2019. In this notice, DEA is proposing to amend its regulations to implement a new single-sheet format for DEA Form 222. When regulations pertaining to DEA Form 222 change, pharmacy must follow the new regulations.*

(29) Orders are never electronically received in the Prime Vendor System until they are actually received and contents verified.

(30) A chain of custody is established and maintained for all returned controlled substances mailed prescriptions as described in paragraph 8.b.(6).

(31) All ADCs under the control of the VA medical facility or CMOP pharmacy are set up to force a password change in alignment with VHA security requirements for passwords. **NOTE:** *The current security requirement is every 90 days.*

(32) All trash containers in the VA medical facility or CMOP pharmacy vault have a lid, and trash is held in the vault until after the next physical inventory is verified.

(33) An electronic or handwritten prescription is received to support all controlled substances dispensed by a health care provider directly to a patient for take-home in the emergency department, urgent care, and all other clinics stocked with pre-packed stock for provider dispensing. **NOTE:** *The authority to dispense controlled substances is based on the health care provider's State of licensure. The Drug Enforcement Administration (DEA) document "Mid-Level Practitioners Authorization by State" is located at: https://www.deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf.*

(a) Verification of a prescription should be done daily for all removals of patient take-home controlled substance stock by reviewing removals from the ADC and checking for a prescription.

(b) A process must be in place to ensure the prescription is not filled and dispensed a second time.

(c) Stock medications to be dispensed by a health care provider for take-home by a patient should be pre-packed in child proof containers and appropriately labeled in accordance with outpatient prescription labeling requirements.

(34) Changes made to a hard copy (handwritten) prescription by a pharmacist have been clarified with the health care provider prior to making the change and that the change, date, and the name of person the pharmacist spoke to is documented on the prescription along with the pharmacist's signature. Permissible changes are detailed in Appendix C. **NOTE:** *A new prescription must be obtained from the health care provider for any edit(s) to an electronic prescription that "breaks the digital signature". This term*

is used to describe edits to electronic controlled substance prescriptions that result in a new order being generated by CPRS and VistA Outpatient Pharmacy.

(35) Pharmacy staff follow the requirements for storage of controlled substance patient medications during an admission and the requirements for accepting back patient controlled substance prescriptions for disposal as described in VHA Directive 1114, Controlled Substance Patient Prescription Disposal, dated September 9, 2016.

NOTE: *Patients participating in an investigational use study may return unused controlled substances received as part of that research to the registered dispenser from which the patient obtained the controlled substance (see 21 CFR 1317.85(b)).*

(36) All compounded controlled substance injectable products, to include both syringes and bags, dispensed to patient care areas must be sealed with a tamper-resistant cap and enclosed in a custom security bag with a serial number.

(a) The custom security bag must be transparent and contain the following information pre-printed on the label:

1. "Do not use if the security bag is not sealed properly or has signs of tampering."
2. "Do not use if the plastic cap on the port is missing or has signs of tampering."
3. "Do not use if the serial number on the security bag does not match the serial number written on the label of the IV bag."
4. "Call the pharmacy immediately to report any signs of tampering, security cap missing, or mismatch in numbers between the security bag and IV label."

(b) The security bag serial number must be written on the label of the compounded controlled substance IV by person doing the compounding.

(c) When checking, the pharmacist must verify the serial number on the label matches the serial number on the bag.

(d) Unused bags returned to pharmacy must be inspected by pharmacy staff, and any signs of tampering, missing security cap, or mismatch in numbers between the security bag and IV label must be reported immediately to the Chief of Pharmacy for further investigation and possible loss reporting per the requirements in Appendix B.

h. Clinical Research Pharmacy Coordinating Center Facility Director. The Clinical Research Pharmacy Coordinating Center (CRPCC) facility Director is responsible for ensuring that:

(1) The CRPCC facility is registered with the DEA as a "research" facility as defined in 21 CFR 1300-END.

(2) All written local controlled substance policies, procedures, and records are in compliance with VHA, DEA, and Federal regulatory requirements (see 21 CFR Part 1300-END).

(3) A current copy of 21 CFR Part 1300-END is retained in the CRPCC pharmacy or electronically accessible to CRPCC pharmacy staff.

(4) The CRPCC facility is authorized to be involved in the manufacture, testing, packaging, and distribution of Schedule I-V controlled substances.

(5) Each clinical study involving controlled substances is approved by an Institutional Review Board (IRB) and Research and Development Committee at each participating site prior to study drug distribution.

(6) The number of CRPCC pharmacy staff who have access to controlled substances is limited based on workload requirements for preparing, managing, and dispensing controlled substances.

(7) A biennial physical inventory of all controlled substances is conducted, and records are maintained in accordance with 21 CFR 1304.11.

(a) Documentation of the inventory of CII controlled substances must be separate from the inventory for CIII-V controlled substances.

(b) The biennial inventory may be taken at the opening or closing of the business day, and the inventory record must indicate when it was taken (opening or closing of the business day), the date it was taken, and the signature of the staff members who completed and validated the inventory.

(c) The biennial inventory must be stored in a separate file and clearly marked as the biennial inventory.

(8) Monthly physical inventories are conducted when there are controlled substances in stock and recorded on the appropriate CRPCC form. The physical inventory sheet should be signed and dated by the two people conducting the inventory.

(9) The CRPCC provides controlled substances to clinical studies at participating sites through the Pharmacy Service at each site to ensure inclusion in the controlled substance inspection program. A DEA Form 222 must be used for all Schedule I and II controlled substances.

(10) CRPCC staff ordering Schedule I and II controlled substances have been granted an individual power of attorney in accordance with 21 CFR 1305.05. The power of attorney must be signed by the same person who signed the most recent application for registration or renewal registration. The power of attorney is not submitted to DEA but is filed locally and must be available for inspection by DEA.

(11) A record is maintained that lists each person granted power of attorney to sign controlled substances orders in accordance with 21 CFR 1311.45.

(12) When a permanent change in the appointment of CRPCC facility Director occurs, a complete inventory of controlled substances in each pharmacy under their control must be conducted.

(a) The outgoing CRPCC Facility Director and the designated or CRPCC Facility Director, jointly conduct and record the inventory prior to transfer of responsibility. Additionally, the Acting CRPCC Facility Director and incoming CRPCC Facility Director are to jointly conduct and record the inventory upon transfer of permanent responsibility. In the event that only one individual is available (e.g., due to illness), the CSC conducts the inventory with that individual.

(b) A record of the inventory must be made each drug inventoried and must be signed and dated by both people conducting the inventory.

(c) Any inventory discrepancy is recorded and reported within 1 day to the affiliated VA Police Service.

(13) All controlled substances will be disposed of through an approved DEA-licensed destruction company.

i. **Clinical Leader.** The Clinical Leader (e.g., Associate Director for Patient Care Services, Chief of Staff) is responsible for ensuring that:

(1) All requirements for handling, storage, administration, and waste of controlled substances are followed in all areas under their purview.

(2) All required inventory verification counts outside of the inspection program requirements are performed if required in local VA medical facility policy. **NOTE:** *There are no requirements in national policy to perform routine inventories of controlled substances stored in non-pharmacy areas outside of the inspection program.*

(3) Security of controlled substances is maintained, and the storage area is appropriately secured in all VA medical facility approved storage and dispensing areas under their purview. **NOTE:** *VA Handbook 0730, Security and Law Enforcement, dated December 12, 2012, defines the security requirements for controlled substances stored outside of the VA medical facility pharmacy.*

(4) Staff witness and verify all controlled substance inventory delivered from the pharmacy.

j. **Associate Chief of Staff for Research and Development.** Associate Chief of Staff for Research and Development is responsible for ensuring that:

(1) All controlled substances for use in research (animal or human) conducted on VA property or facilities are ordered through and received by Pharmacy Service. **NOTE:** *In some circumstances, specialized veterinary controlled drugs used in animal research at a VA medical facility will not be available through vendors used pharmacy. In such a case, the Chief of Pharmacy should be consulted to ensure that the pharmacy is involved in arranging the purchase of or transfer of such drugs through a non-VA institution for use in the VA program. The ordering and procurement of such drugs is an ethical responsibility to maintain adequate care for laboratory animals used in VA research.*

(2) The Chief of Pharmacy is consulted when approved VA research is conducted at an affiliate institution or other non-VA location to determine whether controlled substances are to be obtained through the VA medical facility pharmacy.

(3) The research section initiates the purchase order with the designated fund control point and forwards it to pharmacy for authorization. **NOTE:** *All controlled substances purchases must be ordered separately from non-controlled drugs.*

(4) All use of veterinary controlled drugs in animal research shall be approved by the Institutional Animal Care and Use Program in consultation with the VA medical facility attending veterinarian.

k. **VA Provider Staff.** All VA providers are responsible for:

(1) Ensuring that all controlled substance prescriptions are issued for a legitimate medical purpose, acting in the usual course of professional practice.

(2) Full compliance with the Drug Addiction Treatment Act of 2000 (DATA 2000) when prescribing schedules III-V specific FDA approved narcotic controlled substances (e.g. buprenorphine-containing medications) for detoxification or maintenance treatment of opioid use disorder. **NOTE:** *The provider must obtain an individual DATA 2000 waiver and associated individual DEA license number.*

(3) Ordering electronically using the VistA e-prescribing software. When it is not possible to order electronically, the health care provider must use VA Form 10-2577F, Security Prescription Form or a State mandated controlled substance prescription form, to issue the controlled substance prescription.

(4) Ensuring that all paper (handwritten) prescriptions for controlled substances meet the requirements in Federal law by:

(a) Signing and hand stamping or printing their full name on all paper (handwritten) prescriptions.

(b) Writing the date of issue on the prescription. **NOTE:** *Prescriptions may not be post-dated or pre-dated.*

(c) Including drug name, strength, dosage form, quantity prescribed, direction for use, and number of refills (if any) authorized.

(d) Writing their individual DEA registration number or VA medical facility DEA number with individual suffix on all paper (handwritten) controlled substance prescriptions. **NOTE:** *VHA Handbook 1108.05, Outpatient Pharmacy Services, dated August 1, 2016, provides information on provider requirements for obtaining an individual DEA number and when a suffix may be used.*

(5) Immediately notifying the Chief of Staff, VA Police, and Chief of Pharmacy of lost, missing, or stolen prescription pads. **NOTE:** *Lost, missing, or stolen prescription pads*

must be reported as per the procedures for missing controlled substance medications in Appendix B.

(6) Ensuring that a prescription is entered electronically or handwritten for all controlled substances the provider dispenses directly to the patient for take home.

NOTE: *The authority to dispense controlled substances is based on the provider's State of licensure. Please refer to the DEA document, "Mid-Level Practitioners Authorization by State" at*

https://www.deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf This linked document is outside VA control and may not be conformant with Section 508 of the Rehabilitation Act of 1973.

5. ORDERING AND RECEIVING CONTROLLED SUBSTANCES

a. Ordering.

(1) All controlled substances must be ordered separately from non-controlled substances and must be ordered in compliance with 21 CFR Part 1305.

(2) Schedule I and II controlled substances must be ordered utilizing DEA Form 222, or electronically using the Controlled Substance Ordering System (CSOS).

(3) The delivery address on all orders for controlled substances must be the DEA-licensed location. **NOTE:** *CMOP facilities that use the services of a DEA registered re-packer for schedule CIII-V controlled substances may have orders shipped directly to the re-packer.*

b. Receiving.

(1) All orders for controlled substances must be delivered directly to the pharmacy or CRPCC facility in unopened shipping containers or boxes. Orders may be delivered directly to the OTP in unopened shipping containers or boxes instead of the pharmacy (see paragraph 10, Opioid Treatment Program).

(2) The opening of the container or box and the acknowledgment of receipt of the order must be performed in the pharmacy or CRPCC facility and witnessed by the Accountable Officer (AO), or designee, and the responsible pharmacy employee.

(3) Both employees must sign and date the invoice or packing slip to indicate receipt. A pharmacist must be one of the employees signing the receiving invoice.

(4) The AO, or designee, must verify that receipt of the controlled substance has been posted to pharmacy inventory in VistA at the VA medical facility, or in the facility inventory at the CMOP or CRPCC.

(a) The AO may visually view the uploading into VistA at the same time the order is checked in and denote verification into inventory on the invoice or packing slip when signed and dated; or

(b) The AO may compare the invoice(s) to a copy of the VistA inventory upload within 24 hours of checking in the order. In this instance, the AO must sign the copy of the VistA inventory upload. Logistics and Pharmacy must maintain a copy of the signed report on file for 3 years.

(5) Discrepancies must be reconciled with the AO before items are accepted into the pharmacy or CRPCC inventory. Any discrepancies noted are reported to the prime vendor or other supplier on the same day the discrepancy is discovered by the ordering official or pharmacy staff member.

6. INVENTORY OF CONTROLLED SUBSTANCES

a. **General.** A “perpetual” inventory of all pharmacy controlled substance stock to include vault and working stock must be maintained.

(1) A physical inventory must be conducted twice a week (3 days apart) and recorded on the appropriate electronically generated inventory sheet (or VA Form 10-2320). **NOTE:** *Automated Dispensing Cabinets that contain pharmacy stock and are located within the pharmacy are subject to these same inventory requirements. Drugs held for destruction in sealed evidence bags are not subject to these inventory requirements.*

(2) The last page of the physical inventory sheet must be signed by the person conducting the inventory. **NOTE:** *The electronically generated inventory sheet includes the date it was printed. This date denotes the date the inventory was conducted.*

b. **All Hazards Emergency Cache Controlled Substances.** The complete management of the All Hazards Emergency Cache controlled substances inventory includes:

(1) All cache controlled substances must be stored in containers that can be sealed with a numbered plastic lock. **NOTE:** *Cache stock may be stored in the pharmacy vault as long as it is in sealed containers with a numbered plastic lock and separate from other stock.*

(2) All controlled substances stored in sealed containers with a numbered plastic lock are exempt from the twice a week inventory requirement; however, the cache cart seal must be inspected twice weekly (3 days apart) to verify it is intact and the seal number is unchanged unless the VA medical facility has received a written waiver from the VHA Pharmacy Benefits Management Emergency Pharmacy Services (PBM/EPS) office. **NOTE:** *In accordance with VHA Dir 1047(1), All-Hazards Emergency Caches, dated December 20, 2014, waivers must be renewed every five years. NOTE: VHA Directive 1047(1) currently states the cache cart seal must be inspected every 72 hours. This Directive is currently under revision and will be changed to twice a week when republished. In the interim, the requirement of twice a week applies.*

(3) Lock numbers must be recorded, maintained on file, and made available to the controlled substance inspector during every monthly inspection.

(4) A physical count of all cache designated schedules II through V controlled substances must be completed quarterly.

(5) All controlled substances in a sealed cache cart must be inventoried each time the cart seal is broken or immediately upon discovery of a broken or suspicious looking cart seal or plastic lock.

(6) All controlled substances inventory must be entered into and maintained in the VistA Controlled Substance inventory software.

(7) All controlled substances in the cache must be included in DEA's required biennial inventory and the VA annual inventory.

(8) Any loss of a cache controlled substance must be immediately reported in accordance with Appendix B.

7. CONTROLLED SUBSTANCES DISPENSING, NON-PHARMACY STOCK AREAS

a. General.

(1) An electronic record of activity must be maintained in the VistA Controlled Substances Package for each item issued.

(2) Only Registered Nurses (RN), Advanced Practice Registered Nurses, Physician Assistants, physicians, or dentists (other than authorized pharmacy staff) are permitted to order controlled substances for stock. For controlled substance storage areas not staffed by these disciplines (e.g., research), the clinical leader for the area in collaboration with the Chief of Pharmacy must define who from that area is authorized to order controlled substances stock. **NOTE:** *It is recommended that this function be limited to licensed health care professionals whenever possible.*

(3) Only a pharmacy employee can issue a supply of controlled substances to a stock area outside of the pharmacy.

(4) When new inventory is received from pharmacy, a RN, or Licensed Practical Nurse (LPN), must witness and verify the receipt of controlled substances. For controlled substance storage areas not staffed by nursing, the clinical leader for the area in collaboration with the Chief of Pharmacy must define who from that area is authorized to witness and verify the receipt of controlled substances stock. **NOTE:** *It is recommended that this function be limited to licensed health care professionals whenever possible.*

(5) Any identified discrepancy in inventory during restock must be reported immediately to the Nurse Manager and Chief of Pharmacy for follow-up and resolution. If the discrepancy cannot be resolved within 1 business day it must be reported as suspected loss/diversion per the requirements in Appendix B.

(6) A pharmacist not involved in stocking or destocking of ADCs must reconcile all dispensing and return activity to and from ADCs located in the VA medical facility

outside of pharmacy by comparing VistA report to the ADC report when a commercial automated controlled substance management system is not used. **NOTE:** *VA medical facilities have experienced diversion during these process as the VistA inventory is not interfaced with the ADC inventory.*

(7) All controlled substances removed from an ADC and returned to the pharmacy must be either added back into the pharmacy inventory or processed for destruction within 1 business day.

(8) When a VA medical facility elects to utilize ADCs (e.g., AccuDose, Omnicell, Pyxis) for controlled substances, the equipment is to be interfaced with VistA, when possible, in order to receive patient and order specific information so that medications can be withdrawn only based on an existing order or for a specific patient in care areas where traditional medication orders are not used (e.g. anesthesia). This process is also referred to as setting the equipment to be “profiled”.

b. Dispensing Stock to Areas Without Automated Dispensing Cabinets(s).

(1) Pharmacy Service must electronically generate VA Form 10-2321, Narcotic Dispensing/Receiving Report which lists the name, strength, and quantity of each drug and the controlled substance area to be restocked. VA Form 10-2321 must list each item to be replenished; indicating the name, ward or clinic, strength, and quantity.

(2) When stock is delivered to the area, a RN, LPN, or other authorized staff must verify and sign VA Form 10-2321 or electronically receive in VistA, using the option “Receipt of Controlled Substance from Pharmacy”, acknowledging receipt of all controlled substances. For controlled substance storage areas not staffed by nursing, the clinical leader for the area in collaboration with the Chief of Pharmacy must define who is authorized to witness and verify the receipt of controlled substances stock. If receiving staff manually sign VA Form 10-2638, the pharmacy employee must then electronically receive the order to the stock area using the VistA option “Receipt of Controlled Substance from Pharmacy.”

(3) In areas where staff do not electronically document removal of doses using the VistA option “Sign Out Doses for Patient”, VA Form 10-2638, Controlled Substance Administration Record, (also commonly referred to as the “green sheet”) must accompany each drug issued. This form serves as the inventory record, and all stock removals and two signature waste must be documented on this form.

(4) In areas where staff electronically document stock removal and two signature waste using the VistA option “Sign Out Doses for Patient”, the VistA option “Label for Dispensing (Barcode)” must be used to print the dispensing drug barcode label.

(5) For dispensing of controlled medication related to approved VA research, documentation of administration must indicate the protocol number, date, and any other identifying information available to provide a satisfactory proof-of-use record for each dose of drug administered.

(6) When all stock is used, VA Form 10-2638 or the electronic barcode for areas using the VistA option "Sign Out doses for Patient" must be returned to pharmacy within 5 business days.

(7) Prior to completing VA Form 10-2638 in the Controlled Substance package and filing the form, a pharmacy employee must review the completed form for arithmetic errors, losses, or unusual or unwitnessed waste within 1 business day of receipt. For areas that use electronic documentation, a pharmacy employee must review the activity using the VistA option "Green Sheet History". Any identified discrepancies must be reported to the Chief of Pharmacy and Nurse Manager for resolution. If loss is identified, it must be reported per the procedures in appendix B.

(8) A pharmacy employee must complete VA-Form 10-2638 in the Controlled Substance package, using the option "Complete Green Sheet" within 1 business day of receipt of completed green sheet or the electronic barcode. **NOTE:** *This option removes the drug from the "Inspector's Log for Controlled Substances."*

8. CONTROLLED SUBSTANCES DISPENSING, OUTPATIENT SERVICES

a. General.

(1) Handwritten controlled substance prescriptions must be completed in accordance with 21 CFR 1306.05(a) and contain:

(a) Full name and address of the patient. Affixing an extra mailing label to the back of the prescription meets this requirement. To avoid using the reprint option which should be restricted, an extra label can be generated by entering "2" in the "copies" field when entering the prescription. **NOTE:** *A Post Office Box address may be used; Federal regulations do not require the physical address.*

(b) Drug name, strength, and dosage form.

(c) Quantity prescribed.

(d) Directions for use.

(e) DEA registration number of the health care provider. If the health care provider does not have an individual DEA number, the VA DEA registration number, and the provider's suffix must be on the prescription. **NOTE:** *VHA Handbook 1108.05 provides information on provider requirements for obtaining an individual DEA number and when a suffix may be used.*

(f) Name and address of the health care provider. The address of the health care provider should be the address where the provider is physically practicing. For example, if the provider is practicing at a CBOC, the address on the prescription should be the CBOC, not the main facility. A stamp may be used to add the address for health care providers.

(2) Controlled Substance prescriptions must be filed in accordance with 21 CFR 1304.04.

(a) All hard copy (non-electronic) prescriptions for Schedule II medications must be filed separately from all other prescriptions. It is recommended these be filed sequentially by prescription number to facilitate the controlled substance inspection program review requirement. There is no requirement to stamp the prescriptions with a red C.

(b) All hard copy (non-electronic) prescriptions for Schedule III-V medications may be filed together and should be filed separately from all other prescriptions. It is recommended these be filed sequentially by prescription number to facilitate the controlled substance inspection program review requirement. If filed separately from hard copy (non-electronic) non-controlled substance prescriptions, there is no requirement to stamp the prescription with a red C.

(c) Prescriptions should be filed each day in the appropriate file.

(d) Exemptions to Controlled Substances dispensing requirements in 21 CFR provisions 1306.25(a), 1306.22(b), and 1304.04, have been approved for CMOPs by a DEA waiver. Since no original or refill prescriptions are physically kept on site at the CMOP, DEA-record filing requirements for the actual prescription are not applicable to CMOP.

(3) Only CIII-V prescriptions may be transmitted to CMOP for filling and dispensing to the patient via mail carrier (per a DEA waiver letter dated July 13, 1999). CMOPs may not fill prescriptions and mail to the VA medical facility for dispensing to a patient. The Drug Enforcement Administration (DEA) letter waives the following provisions of 21 CFR:

(a) 1304.04 related to the storage of the original prescription other than at the registered location;

(b) 1306.22(b) with respect to the daily written verification of refills dispensed by a pharmacist; and

(c) 1306.25(a) regarding the sharing of real-time on-line database for pharmacies electronically transferring refill information.

(4) The prescription label of any drug listed as a "Controlled Substance" in Schedule II, III, IV, or V of the Controlled Substances Act must contain the following warning: "CAUTION: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."

(5) Pharmacy Service staff must verify the identity of the person picking up the outpatient-controlled substance prescription for outpatients or patients leaving the VA medical facility and must require the signature of such patient or their agent. **NOTE:** *DEA regulations limit dispensing of controlled substances to the patient or a member of the patient's household.*

(6) DEA regulations limit prescribing of controlled substances to those registrants allowed under law to make the decision to prescribe controlled substances.

(a) Pharmacists and technicians may not enter a controlled substance prescription for health care provider signature based on a Veteran request (either telephone or in person) or an expired refill document. A progress note or other form of communication may be sent to the health care provider advising of the Veteran request.

(b) Pharmacists and technicians may not enter a controlled substance prescription for health care provider signature because the original electronic prescription for controlled substance (EPCS) contained a typographical error or needed clarification. In these instances, the staff should contact the health care provider to enter a corrected EPCS prescription or provide a written prescription.

(c) Pharmacists, who work in a clinic (e.g., PACT, pain clinic) with the health care provider, evaluate patients, and provide recommendations on drug therapy, may enter a controlled substance prescription for health care provider signature. However, the pharmacist must not be involved in any aspect (to include processing) of dispensing of that prescription. In addition, there must be documentation in the medical record by the health care provider regarding the need for the medication. This may be accomplished through an addendum to the pharmacist note or in the health care provider note.

(d) Pharmacists whose State of licensure allows them to prescribe controlled substances, may enter and sign a controlled substance prescription in accordance with pharmacist State prescribing laws, scope of practice, and all other VHA and VA medical facility policies. As a health care provider, the pharmacist must document in the medical record the need for the medication. The prescribing pharmacist must not be involved in any aspect of dispensing that prescription.

(e) Patient-initiated requests for additional refills for prescriptions of Schedule III, IV or V medications may not be generated as unsigned electronic orders by automated telephone refill systems, internet-based refill requests, VistA-interfaced software or customer care call centers. Each of these examples bypasses the health care provider's obligation to make a medical decision of necessity to treat the patient with the medication. The appropriate and acceptable process is to inform the health care provider that the patient has requested such a refill. The health care provider's response may include writing a renewal prescription of the requested medication.

(7) All outpatient prescriptions for controlled substances not picked up at the outpatient window must be returned to stock or mailed to the patient with documentation of each step in the process. Pharmacy Service must maintain documentation to identify the disposition (whether mailed, dispensed at the pharmacy window, or returned to stock) of these prescriptions.

(8) All faxed or paper controlled substances prescriptions must contain the handwritten signature of the health care provider. Electronically signed paper or faxed prescriptions for controlled substances are not permissible.

(9) Quantity dispensing limits for outpatient prescriptions (CII-V) do not apply to research medications when the study protocol requires greater than the limit or when the drug cannot be dispensed in a 30 or 90-day supply (e.g. topical medication).

b. Mailed Prescriptions.

(1) Prescriptions for controlled substances can only be mailed in accordance with applicable DEA regulations. The shipping label attached to all controlled substances packages must have printed, as a return address, the local VA medical facility address where the prescription was generated. **NOTE:** *VA has a waiver dated April 12, 2010 from DEA to use the local VA medical facility address as the return address for controlled substance prescriptions dispensed by CMOP.*

(2) Controlled substances prescriptions may not be delivered or shipped to individuals in other countries without proper authorization. Any such delivery or shipment is an export under the Controlled Substance Act (CSA) and cannot be conducted unless the person sending the controlled substances has registered with DEA as an "exporter" (see 21 C.F.R. §§ 1301 and 1309) and has obtained the necessary permit(s) or submitted the necessary declaration(s) for export (21 C.F.R. §§ 1312 or 1313).

(3) All packages delivered to the United States Postal Service (USPS) mail carriers or by contracted shipper services must have a shipping label attached and be permanently sealed so its contents cannot be easily removed without detection. Packages containing a controlled substance, processed for mailing or shipping, cannot have any annotation on its shipping label that identifies its contents.

(4) Return receipt or "signature required" is not required for controlled substances. VA medical facilities should use special handling (e.g., return receipt, package delivery tracking, "signature required") for patients with an identified trend of claiming non-receipt when the package shows delivery or claiming missing tablets/capsules or prescription vial.

(5) CMOP facilities that do not process their own mailing and use other authorized delivery methods of shipping, must require documentation of the packages processing from the contracted mail consolidator and shipper that provides reconciliation of packages received and entered into the mail stream.

(6) A chain of custody must be maintained for mailed controlled substance prescriptions returned as undeliverable to the VA medical facility. **NOTE:** *It is highly recommended that packages be returned directly to the pharmacy when possible.*

(a) If returned to the mailroom, warehouse, or any area outside of the pharmacy, the package(s) must immediately be logged in and securely stored. Transfer to the pharmacy must occur within 1 business day and include the signature of staff from each service.

(b) If returned directly to the pharmacy, the package(s) must be immediately secured in the vault.

(c) Pharmacy Service may attempt to contact the patient to arrange pickup or re-mail of the returned prescription(s). If the patient cannot be contacted and arrangements cannot be made within 5 business days, the pharmacy staff must log the medication for disposal.

(d) Pharmacy Service must not place the contents of returned mailed prescriptions back into stock.

(e) Pharmacy Service must maintain a list of all returned controlled substance prescriptions which shows the ultimate disposition (e.g., re-mailed to patient, patient pick-up at the VA medical facility pharmacy, or logged for destruction).

c. Schedule II Dispensing.

(1) Schedule II controlled substances are to be dispensed in 30-day quantities or less. An individual health care provider may issue multiple handwritten prescriptions authorizing the patient to receive a total of up to a 90-day supply provided the following conditions are met:

(a) The patient is deemed competent to receive, have possession of, and present each subsequent prescription to the pharmacy at the appropriate time;

(b) Each separate prescription is issued for a legitimate medical purpose by an individual health care provider acting in the usual course of professional practice;

(c) The health care provider gives written instructions on each prescription indicating the earliest date on which the pharmacy may fill each prescription;

(d) The health care provider concludes that providing the patient with multiple prescriptions in this manner is safe and does not create an undue risk of drug diversion or misuse; and

(e) If the prescription is for an opioid, consent is documented as required in VHA Directive 1005(1), Informed Consent for Long-term Opioid Therapy for Pain, dated November 13, 2018.

(2) The refilling of a prescription for a Schedule II controlled substance is prohibited in accordance with 21 CFR 1306.12.

(3) For non-emergency situations, all hard copy (non-electronic) prescriptions for CII medications must be received by the dispensing pharmacy prior to dispensing the medications. CII prescriptions may not legally be dispensed based on a faxed copy. The pharmacy may use a fax copy to prepare the prescription; however, the original handwritten prescription must be received prior to dispensing. This applies to both non-VA health care providers as well as prescriptions written at VA CBOCs but dispensed at the main facility or another division.

(4) Consistent with 21 CFR 1306.11(d), in an emergency situation, as defined in 21 CFR 290.10, a pharmacist may dispense a controlled substance listed in Schedule II upon receiving oral authorization of a prescribing health care provider, provided that:

(a) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period.

(b) The prescription is immediately reduced to writing by the pharmacist and must contain all information required in 21 CFR 1306.05, except for the signature of the prescribing health care provider.

(c) If the prescribing health care provider is not known to the pharmacist, the pharmacist makes a reasonable effort to determine that the oral authorization came from a registered health care provider, which may include a callback to the prescribing health care provider using the phone number as listed in a telephone directory and/or other good faith efforts to ensure their identity.

(d) Within 7 days after authorizing an emergency oral prescription, the prescribing health care provider provides a written prescription for the emergency quantity prescribed to the VA medical facility pharmacy. The prescription shall have written on its face "Authorization for Emergency Dispensing" and the date of the oral order. The paper prescription may be delivered in person or by mail, but if delivered by mail, it must be postmarked within the 7-day period. Upon receipt, the dispensing pharmacist must attach this paper prescription to the oral emergency prescription. The pharmacist must notify the nearest DEA office if the prescribing health care provider fails to deliver a written prescription.

(5) When on-hand inventory is insufficient to fill the prescription in its entirety, a partial dispensing of a CII controlled substance may be done, as long as it is in compliance with current Federal regulations.

d. Schedule III-V Dispensing.

(1) Schedule III, IV, V controlled substances may be refilled in accordance with 21 CFR 1306.22. These prescriptions can be filled with a maximum of five refills if authorized by the health care provider over a 6-month period.

(2) Schedule III, IV, and V controlled substances are normally dispensed in 30-day quantities. If a VA medical facilities wishes to allow prescribing and dispensing of 90-day quantities of Non-narcotic Schedule III, Schedule IV, and Schedule V controlled substances criteria addressing patient safety, type of medication and patient monitoring must be jointly developed by health care providers and pharmacists.

(3) The partial filling of a prescription for a controlled substance listed in Schedule III, IV, or V is permissible under 21 CFR 1306.23, provided:

(a) Each partial filling is recorded in the same manner as a refilling;

(b) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed; and

(c) No dispensing occurs after 6 months after the date on which the prescription was issued.

NOTE: *The VistA Controlled Substance package does not accurately track total quantity dispensed when partials are dispensed. Therefore, pharmacists should not partial controlled substance prescriptions unless there is a medication supply shortage that would impact the care of the patient. In these cases, the pharmacist must ensure the partial filling will not result in exceeding the total quantity prescribed if refills or partials are processed in the future.*

9. DISPOSAL OF CONTROLLED SUBSTANCES STOCK

a. All controlled substances expired or otherwise determined to be unusable must be removed from active stock and stored separately until destroyed or turned over to a reverse distributor for destruction per the requirements of 21 CFR Part 1317. **NOTE:** *DEA regulations do not permit the VA medical facility pharmacy to accept controlled substances from VA Police or VA Office of Inspector General (OIG) for destruction post investigation.*

(1) Enter the medication on the VistA Controlled Substance Hold for Destruction Report in the VA medical facilities and the electronic accountability system in CMOP.

(2) Two VA pharmacy staff employees must verify the medication and place each item and a copy of the Hold for Destruction item report into an evidence bag and seal the bag.

(3) Write in ink on the evidence bag the destruction holding number, the date, name, and quantity of the controlled substance, and each employee will sign the bag.

b. Controlled substances held for destruction must be destroyed on-site or turned over to a DEA-licensed destruction company at least quarterly.

(1) All bags must be opened, and the contents must be verified by a member of the pharmacy staff in addition to the Accountable Officer (AO) at the time of destruction or at the transfer to a DEA-licensed destruction company.

(2) The AO, or designee, must be present to witness and verify counts of the controlled substances turn-in to the destruction company or when the destruction is performed on site. The AO, the pharmacist, and destruction company representative must sign the document listing the controlled substances transferred from VA to the destruction company. The pharmacist and the AO must sign DEA Form 41 if the destruction is performed on-site.

(3) At each destruction, a VA medical facility pharmacy supervisor must review all cancelled entries added to the Destruction Holding Report from the date of the last

destruction and verify the cancelled entries were for a legitimate reason and do not represent possible diversion.

c. When a distributor authorized by DEA to destroy controlled substances is utilized the distributor must provide a signed receipt for all CIII-V and DEA Form 222 for all CII drug products taken at the time of transfer. The receipt and DEA Form 222 must include drug name, dosage form, strength, quantity, and date of transfer and must be kept on file in accordance with VHA's Records Control Schedule (RCS) 10-1. **NOTE: RCS 10-1, 7400.4, and 7400.5 currently requires all controlled substance records must be maintained for 3 years. Pharmacy staff must check the most current version of the RCS before disposing of records.**

d. The Chief of Pharmacy or designee should consult with the DEA Special Agent in Charge for any planned method of on-site destruction prior to destroying controlled substances on-site to ensure the disposal method chosen meets the non-retrievable standard defined in law. See definition of non-retrievable at 21 CFR 1300.05.

e. For all controlled substances stock destroyed on site, the Chief of Pharmacy or designee must complete DEA Form 41 as required in 21 CFR 1317.05 and retain on file in accordance with VHA's Records Control Schedule (RCS) 10-1. **NOTE: RCS 10-1, 7400.4, and 7400.5 currently requires all controlled substance records must be maintained for 3 years. Pharmacy staff must check the most current version of the RCS before disposing of records.** A copy of the current form and instructions can be obtained from the DEA Web site:

http://www.deadiversion.usdoj.gov/21cfr_reports/surrend/. **NOTE: The VistA version of DEA Form 41 should not be substituted for the official DEA Form 41.**

f. Once the disposal of an item has occurred through either an on-site destruction or turn over to a reverse distributor, the "Destroy a Controlled Substance Drug" option in the VistA Controlled Substance package must be used to remove the items from the Destruction Holding Report.

g. Controlled substances dispensed for immediate administration to a patient in the VA medical facility setting and not fully used (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 "partial dose wasting") must be wasted.

(1) The DEA non-retrievable standard of destruction does not apply to wasting of partial doses. The method of wasting partial doses must be standardized in all areas of the VA medical facility. Impact on the environment and opportunity for diversion should be considered when choosing a method of destruction. The method of destruction and staff training must be in alignment with VHA Directive 7707, VHA Green Environmental Management System (GEMS) and Governing Environmental Policy Statement, and applicable Federal, State, and local environmental regulations and laws. For instance, there have been many reports of diversion from sharps containers of partial doses; therefore, this method should be avoided.

(2) Local policy must define a time frame between administration and wasting of the remaining contents to minimize the risk of diversion. This time frame may vary for different areas of the hospital. For instance, wasting of partial doses on units and clinics can be accomplished almost immediately, whereas wasting in the operating room may not be able to be accomplished until the surgery case has ended.

(3) All wasting of partial doses must be done by two staff members and documented. The documentation must include the amount given, the amount wasted, and the names of the two staff members.

(4) Whenever possible the two staff members performing the waste must be licensed health care providers. For areas that are only staffed with one licensed health care provider (e.g., only one RN or LPN on a unit), the VA medical facility Director may authorize other staff to witness waste of partial doses of controlled substances

10. OPIOID TREATMENT PROGRAM

a. Opioid treatment programs (OTPs) must be separately registered with the DEA and comply with all DEA record keeping requirements to include ordering, administration, dispensing, disposal, and biennial inventory.

b. All Methadone and buprenorphine for use in the opioid treatment program (OTP) must be ordered under the OTP DEA registration per the requirements for ordering and receiving in paragraph 5, Ordering and Receiving Controlled Substances. Stock may be delivered directly to the OTP in unopened shipping containers or boxes instead of the pharmacy. If stock is delivered directly to the OTP, there must be a pharmacist and AO involved in receiving the order. **NOTE:** *Buprenorphine dispensed by pharmacy per order or prescription of an authorized provider independent of the OTP should be ordered under the DEA registration of the VA medical facility.*

c. All stock ordered under the OTP DEA registration must be stored in the OTP and secured per the requirements of VA Handbook 0730, Security and Law Enforcement, dated December 12, 2012.

d. Methadone must be administered or dispensed only in oral form and formulated in such a way as to reduce its potential for parenteral misuse.

e. All unsupervised or take-home use of medication must meet the requirements in 42 CFR 8.12 and the current version of the SAMHSA Federal Guidelines for Opioid Treatment Programs. **NOTE:** *For ease of discrete transport home, OTPs should consider dispensing drug medication diskettes or tablets in one single bottle to patients who report to the clinic once or twice per month and receive a 15-30-day supply of medication. Programs should also consider medication diskettes or tablets for patients using air transportation. Dispensing dry medications mitigates any potential for bacterial growth in liquid media. Check SAMHSA's guidelines for most current information.*

f. Each take-home dose must be dispensed in a child resistant container and must be labeled with the:

- (1) Treatment center's name;
- (2) Center's address;
- (3) Telephone contact number; and
- (4) Physician's name.

g. Medication must be documented, such that it will display on the medication tab in CPRS to ensure other health care providers are aware the patient is receiving the medication, and appropriate order checks are generated when other medications are prescribed. **NOTE:** *This may be accomplished by documentation as an outpatient medication, non-VA medication, or clinic order. When choosing which area to document, evaluate the pros and cons of each to include how orders expire in each of these situations which may not generate order checks appropriately if not updated timely and the chance of the medication being renewed in error by a health care provider outside of OTP.*

h. All standalone commercial programs used to order and maintain inventory records must be interfaced with VistA if an interface is available.

i. All methadone and buprenorphine administration and dispensing may only be done upon the order (written or electronic) of an authorized OTP provider. **NOTE:** *Buprenorphine for medication assisted treatment of opioid use disorder may be prescribed by non-OTP providers who qualify and have received a waiver from DEA under 21 U.S.C. 823(g).*

j. Administration of prescribed opioid disorder treatment medications must be done by a pharmacist, Registered Nurse (RN), Licensed Practical Nurse (LPN), or any other health care provider authorized by Federal and State law to administer medications within an OTP.

k. Dispensing of take-home medications must be done by a health care provider authorized by Federal and State law to dispense medications in an OTP.

l. A dispensing log for all medications must be maintained per the requirements of 21 CFR 1304.24 in a readily retrievable manner to allow inspection by DEA.

11. TRAINING

The following training is required: All new VA medical facility and CMOP pharmacy employees receive training on Pharmacy Security and Integrity as part of new employee orientation. This training must be documented in the employee orientation record or in the Talent Management System (TMS). **NOTE:** *The TMS video "Employee Integrity and Pharmacy Security" may be used to satisfy this requirement, and it is recommended that all new employees view this video.*

12. RECORDS MANAGEMENT

All records regardless of format (paper, electronic, electronic systems) created in this directive shall be managed per the National Archives and Records Administration (NARA) approved records schedules found in VHA Records Control Schedule 10-1. If you have any questions regarding any aspect of records management, you should contact your facility Records Manager or your Records Liaison.

13. REFERENCES

- a. 21 U.S.C. 802.
- b. 21 U.S.C. 812 and 827.
- c. 21 U.S.C. 823.
- d. 38 U.S.C. 7301(b).
- e. 38 U.S.C. 7405.
- f. 38 U.S.C. 7406.
- g. 21 CFR 290.10.
- h. 21 CFR Part 1300-END.
- i. 38 CFR 17.38(a)(1)(iii).
- j. 42 CFR Part 8.
- k. 72 FR 64921.
- l. VA Handbook 0730, Security and Law Enforcement, dated December 12, 2012.
- m. VA Handbook 7002, Logistics Management, dated July 10, 2009.
- n. VHA Directive 0320.10, Inspection of VA All-Hazard Emergency Caches by the VHA Office of Emergency Management, dated July 26, 2017.
- o. VHA Directive 1005(1), Informed Consent for Long-term Opioid Therapy for Pain, dated November 13, 2018.
- p. VHA Directive 1047(1), All-Hazards Emergency Caches, dated December 30, 2014.
- q. VHA Directive 1114, Controlled Substance Patient Prescription Disposal, dated September 9, 2016.
- r. VHA Directive 1400.09, Education of Physicians and Dentists, dated September 9, 2016.

s. VHA Directive 7707, VHA Green Environmental Management System (GEMS) and Governing Environmental Policy Statement, dated December 29, 2015.

t. VHA Handbook 1108.05, Outpatient Pharmacy Services, dated August 1, 2016.

u. VHA Handbook 1400.07, Education of Advanced Fellows, dated February 26, 2016.

v. VHA Handbook 1400.08, Education of Associated Health Professions, dated February 26, 2016.

w. DEA, Office of Diversion Control, Pharmacist's Manual at https://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf

x. DEA waiver documents can be accessed on the PBM internal website at: <https://vaww.cmopnational.va.gov/cmop/PBM/Directives Policies and Information Letters/Controlled Substances Clarifications>. **NOTE:** *This is an internal VA Web site that is not available to the public.*

REQUIREMENTS FOR USING COMMERCIAL CONTROLLED SUBSTANCE MANAGEMENT SYSTEMS

Commercial Controlled Substance Management Systems may only be used to manage the inventory of controlled substance stock for dispensing to automated dispensing cabinets outside of the VA medical facility pharmacy. All outpatient controlled substance dispensing must be released and posted in the VistA software and an accurate inventory maintained in the VistA controlled substance package.

1. MANAGEMENT OF STOCK RECEIVED FROM WHOLESALER OR MANUFACTURER

a. All controlled substances must first be received into the VistA Controlled Substances Inventory per the requirements of paragraph 5, Ordering and Receiving Controlled Substances.

b. After the order has been received, the portion of the order that is designated as Automated Dispensing Cabinet (ADC) managed inventory will be removed from the VistA controlled substances package inventory using the balance adjustment option and manually added to the ADC managed software inventory on the same day the controlled substances are received from the wholesaler or manufacturer.

c. A staff member who did not perform the balance adjustment of the order must compare the balance adjustment report to the commercial software received inventory report and verify all items removed from the VistA inventory are entered into the commercial software inventory. One of the two staff members must be a registered pharmacist.

d. Both staff members will sign a copy of the ADC software inventory received report and a copy of the VistA balance adjustment report and attach to the vault copy of the invoice. These records must be maintained on file.

2. MANAGEMENT OF STOCK NEEDING TRANSFERRED BETWEEN THE VISTA INVENTORY AND THE COMMERCIAL CONTROLLED SUBSTANCE MANAGEMENT SYSTEM

a. In the event that the patient care needs require movement of controlled substances inventory from VistA to the commercial software after the date received from the wholesaler, the controlled substance will be removed from the VistA controlled substances inventory using the balance adjustment procedure and manually added to the ADC managed software inventory.

b. A staff member who did not perform the balance adjustment must compare the balance adjustment report to the commercial software received inventory report and verify all items removed from the VistA inventory are entered into the commercial software inventory. One of the two staff members must be a registered pharmacist.

Both staff members will sign a copy of the ADC software inventory received report and a copy of the VistA balance adjustment report. These records must be maintained on file.

c. The Pharmacy must have written standard operating procedures (SOP) for situations when someone is not available to perform a balance adjustment (e.g. off tours, weekends). The SOP must include:

(1) A requirement for the balance adjustment to be completed on the first working day someone is available.

(2) Detailed instructions on how to handle stock transfer for drugs that are not listed in the commercial controlled substance management inventory software.

(3) A notification mechanism that provides reliability. For example, a written note could be misplaced or someone may get busy and forget to write a note. Therefore, the notification mechanism(s) should involve a function(s) with the software that would be readily noticeable and clear instructions and communication mechanisms. This could include:

(a) Performing a cycle count to adjust the inventory upward. This would create a discrepancy the next time a count is performed.

(b) Putting a comment in the invoice field "transferring from outpatient VistA inventory." This would be noticeable under the medication activity when the next inventory was conducted.

(c) The use of a mail group composed of all staff with the ability to perform balance adjustments.

(4) Posting clear written instructions next to the commercial software terminal work area on what to do and who to notify.

3. MANAGEMENT OF STOCK FOR DESTRUCTION

a. Stock contained in the inventory of the commercial software that is expired or no longer usable must be processed for destruction through the VistA software package.

b. The stock must be removed from the commercial software inventory and balance adjusted into the VistA inventory. A different staff member will compare the balance adjustment report to the appropriate commercial software transaction report and verify all items removed from the commercial software inventory are entered into the VistA software inventory. One of the two staff members must be a registered pharmacist. Both staff members will sign a copy of the commercial software report and a copy of the VistA balance adjustment report. These records should be maintained on file for 3 years.

c. The drugs must then be processed for destruction per the requirements of paragraph 9, Disposal of Controlled Substance Stock.

4. QUALITY ASSURANCE MONITORS

At a minimum the following quality assurance monitors must be established to help detect any instances of diversion due to a lack of interface between the commercial system and VistA.

a. The ability of the commercial software to dispense prescriptions to an individual patient is disabled and can only be enabled by an administrator of the software. The administrator of the software must be one of the pharmacy leadership team and must not have the ability to perform balance adjustments in the controlled substance package.

b. At least weekly, a member of the pharmacy leadership team that does not have administrator access to the commercial software must run a report to check for any individual outpatient prescription dispensing activities. If any outpatient prescription dispensing activities are identified, a report must immediately be made to the Chief of Pharmacy and per the procedures in Appendix B.

c. Daily, Monday through Friday, a VA pharmacist supervisor must review the VistA Pharmacy Dispensing Report (PSD PRINT PHARM DISP) for the previous day for any instances of stock dispensed to a Narcotic Area of Use (NAOU) (e.g., ward, clinic, procedural area). For weekends and holidays, the report should be run the first business day after the weekend or holiday and cover all days since the report was last run. Any instances of dispensing activity to a NAOU must be immediately reported to the Chief of Pharmacy and per the procedures in Appendix B.

PROCEDURES FOR LOSS AND DIVERSION OF CONTROLLED SUBSTANCES**1. GENERAL**

a. In cases of accidental breakage or spillage within the pharmacy that is clearly observed but the controlled substances are not recoverable, pharmacy staff must document the circumstances of the breakage, and a pharmacy staff member and pharmacy supervisor must sign indicating what was witnessed and the circumstances and complete a balance adjustment electronically for the inventory records. This documentation must be maintained on file and be readily retrievable.

b. All prescription pad losses, controlled substances losses greater than five dosage forms and all controlled substances suspected diversion (any quantity) that occur within the medical facility or while under control of the transport carrier (e.g., United States Postal Service (USPS), United Parcel Service (UPS), FedEx) for prescriptions mailed from the VA medical facility must be reported into the VHA issue brief tracker system.

c. All controlled substances losses greater than five dosage forms and all controlled substances suspected diversion (any quantity) that occur within a Consolidated Mail Outpatient Pharmacy (CMOP) must be reported through the National CMOP Director to the Pharmacy Benefits Management Services Chief Consultant using the mail group: VHAPBM Pharmacy Reporting CS Diversion/Loss.

d. Prescriptions filled at a Consolidated Mail Outpatient Pharmacy (CMOP) and subsequently lost in the mail (never delivered to the patient), must only be reported on the CMOP website. **NOTE:** *The VA medical facility should not report these to the Drug Enforcement Administration (DEA), mail carrier, or Office of the Inspector General (OIG), and should not place into the issue brief tracker.*

e. The Department of Veterans Affairs (VA) Police, VA medical facility Director, VA medical facility Chief of Pharmacy or CMOP Director will notify the VA OIG of all controlled substances losses greater than five dosage forms and all controlled substances suspected diversion (any quantity). **NOTE:** *VA medical facility staff should discuss who will be responsible for reporting to ensure reporting is completed and to mitigate the risk of duplicate reporting.*

f. Information on all controlled substance losses must be given to the Controlled Substance Coordinator (CSC) for inclusion in the monthly and quarterly reports. **NOTE:** *If there is active investigation ongoing, providing information to the CSC may be delayed so that the investigation is not compromised.*

g. The VA medical facility Privacy Officer must be notified of packages lost or stolen while under the control of the transport carrier.

h. For losses identified as a shortage from the manufacturer of greater than five doses within one bottle or a reoccurring trend across multiple bottles from the same manufacturer, the manufacturer must also be notified and a Food and Drug

Administration (FDA) MedWatch form must be completed, checking the "Product Problem" box on the form.

i. When loss occurs outside of the pharmacy, the VA Police or VA medical facility Director must notify the Chief of Pharmacy immediately to initiate required Drug Enforcement Administration (DEA) reporting. **NOTE:** *Facilities are encouraged to establish a mail group for controlled substance loss or suspected diversion to facilitate communication across service lines and ensure all responsible parties are informed.*

j. The VA medical facility Chief of Pharmacy or local CMOP Director or designee must notify the DEA field office in writing within 1 business day of loss greater than five dosage forms and all controlled substances suspected diversion (any quantity) as required in 21 CFR 1301.76. **NOTE:** *If DEA Form 106 is filed within 1 business day, it serves as the notification to the DEA field office.*

k. Pharmacy staff must complete DEA Form 106 as required in 21 CFR 1301.76. **NOTE:** *There is no requirement to complete DEA Form 106 within 1 business day. The pharmacy may choose to wait until further fact finding is complete.*

(1) The number of losses reported must be tracked to ensure accurate reporting in the "number of theft or losses registrant has experienced in the last 24 months" field.

(2) For losses that occur while under the control of the transport carrier, "Lost in Transit" must be used in the "Type of theft/loss" field; "Ultimate User:" must be entered in the "Shipped to" field; and "DEA Number (shipped to)" field must be left blank. **NOTE:** *Do not include the patient name in the report.*

(3) If upon further investigation or fact finding it is determined no loss occurred, DEA Form 106 must be withdrawn.

(4) If upon further investigation or fact finding it is determined the amount of drug lost is different than initially reported, DEA Form 106 must be amended.

(5) The 10N Health System Specialists or issue brief tracking system will forward all controlled substance loss and diversion issue briefs to the Pharmacy Benefits Management Services Chief Consultant using the mail group: VHAPBM Pharmacy Reporting CS Diversion/Loss.

(6) At the Clinical Research Pharmacy Coordinating Center (CRPCC) facility, all controlled substance loss must be immediately reported to their affiliated VA medical facility Director, DEA, Director Cooperative Studies Program (CSP), and Chief Research and Development Officer and OIG

2. INTERNAL LOSS AND DIVERSION

a. All internal loss and diversion of controlled substances and prescription pads must be immediately reported by the VA staff member discovering the loss to their immediate supervisor.

(1) The supervisor may take up to 24 hours to resolve the loss (e.g., by reviewing dispensing or administration reports, taking a complete inventory, checking trash can, checking if drug was misstocked or misfiled).

(2) If the loss cannot be resolved within 24 hours or if diversion is suspected, the supervisor must immediately notify the VA medical facility Director and VA Police at VA medical facilities and the local CMOP Directors and VA facility Police service covering the CMOP at CMOP facilities, for investigation.

b. At the CRPCC facility, it must be immediately reported to their affiliated VA medical facility Director, DEA, Director CSP, Chief Research and Development Officer, and OIG.

c. Unresolved loss discovered by the controlled substance inspector during a controlled substance inspection must be immediately reported to the Controlled Substance Coordinator. If the nurse manager or pharmacy supervisor cannot resolve the loss with concurrence from the CSC within 24 hours, or if diversion is suspected, the CSC must immediately notify the VA Police and Director in the medical facilities and the CMOP Director at CMOP.

3. PATIENT REPORT OF RECEIVING LESS QUANTITY THAN PRESCRIBED OR MISSING MEDICATION FROM MAILED PACKAGE AFTER DELIVERY ACCEPTED

Patients reporting receiving less medication than prescribed (picked up at the VA medical facility or mailed) or missing medication vial from a mailed package should not be reported to the DEA. DEA regulations require reporting of loss of registrant stock. Once the patient receives the prescription, it is no longer considered registrant stock.

a. The health care provider should be notified through the entry of a CPRS progress note requiring health care provider co-signature of all unsupported patient claims (e.g., the package shows delivered, review of vault tapes show the prescription was filled correctly). The health care provider should review the relevant clinical information in making a decision to issue a new prescription prior to the scheduled due date.

b. A pharmacist must not provide the patient a partial fill of a controlled substance prescription in these circumstances and only dispense with a new prescription from the health care provider. The pharmacist must ensure they have a prescription on file to support all controlled substance dispensing. **NOTE:** *Pharmacy staff is encouraged to educate patients to refuse delivery of packages that show obvious signs of tampering.*

c. The Chief of Pharmacy and local CMOP Director (or designee) must ensure patient claims are tracked and trended as they could be indicative of internal diversion during the dispensing process. **NOTE:** *If significant or recurring trends are found or this is evidence of internal diversion, this information should be reported by issue brief into the issue tracker.*

May 1, 2019

**VHA DIRECTIVE 1108.01
APPENDIX B**

d. The Chief of Pharmacy and local CMOP Director (or designee) must report all patient claims to the mail transport carrier for prescriptions filled and mailed from their facility.

**PERMISSIBLE PHARMACIST EDITS TO HARD COPY (HANDWRITTEN)
CONTROLLED SUBSTANCE PRESCRIPTIONS**

1. BACKGROUND

a. On November 19, 2007, the Drug Enforcement Administration (DEA) published in the Federal Register (FR) the Final Rule entitled Issuance of Multiple Prescriptions for Schedule II Controlled Substances (72 FR 64921), which revised 21 CFR 1306.12 and 1306.14. In the preamble to that rule, DEA stated that "the essential elements of the [schedule II] prescription written by the practitioner (such as the name of the controlled substance, strength, dosage form, and quantity prescribed) may not be modified orally."

b. The instructions contained in the Rule's preamble are in opposition to DEA's previous policy which permitted the same changes a pharmacist may make to schedules III-V controlled substance prescriptions after oral consultation with the prescriber. DEA recognizes the resultant confusion regarding this conflict and plans to resolve this matter through a future rulemaking. Until that time, DEA has advised that pharmacists are instructed to adhere to State regulations or policy regarding those changes that a pharmacist may make to a schedule II prescription after oral consultation with the prescriber. When information is missing from or needs to be changed on a Schedule II controlled substance prescription, DEA expects pharmacists to use their professional judgment and knowledge of State and Federal laws and policies to decide whether it is appropriate to make changes to that prescription. In the absence of Federal regulations and the fact that the majority of Department of Veterans Affairs (VA) pharmacies are not licensed by a State, Veterans Health Administration (VHA) has established the following policy:

2. REQUIREMENTS

a. Only a registered pharmacist may make changes to a hard copy (handwritten) controlled substance prescription.

b. The pharmacist may add or change the dosage form, drug strength, directions for use, or drug quantity, only after oral consultation with and agreement of the prescribing health care provider.

c. All changes must be documented on the prescription to include the change, the person the pharmacist spoke with, the date and the signature of the pharmacist.

d. A pharmacist may not change the patient name, the controlled substance prescribed and the health care provider's name and signature.

e. For VA pharmacies licensed by a State, the pharmacist must also follow State law pertaining to editing controlled substance prescriptions and adhere to the more stringent regulation.