

Project 7883 - Proposed

Board of Pharmacy

Crisis Stabilization Services and Use of Automated Drug Dispensing Systems and Remote Dispensing Systems

18VAC110-20-200. Storage of drugs, devices, and controlled paraphernalia; expired drugs.

A. Prescriptions awaiting delivery. Prescriptions prepared for delivery to the patient may be placed in a secured area outside of the prescription department, not accessible to the public, where access to the prescriptions is restricted to individuals designated by the pharmacist. With the permission of the pharmacist, the prepared prescriptions may be transferred to the patient at a time when the pharmacist is not on duty. If a prescription is delivered at a time when the pharmacist is not on duty, written procedures shall be established and followed by the pharmacy that detail security of the dispensed prescriptions and a method of compliance with counseling requirements of § 54.1-3319 of the Code of Virginia. Additionally, a log shall be made and maintained of all prescriptions delivered to a patient when a pharmacist is not present to include the patient's name, prescription number, date of delivery, and signature of the person receiving the prescription. Such log shall be maintained for a period of one year. Notwithstanding the provisions of this subsection, prescriptions prepared for delivery to the patient may also be secured in an area outside of the prescription department in a remote dispensing system as defined in § 54.1-3401 of the Code of Virginia and pursuant to subsection A of 18VAC110-20-490.

B. Dispersion of Schedule II drugs. Schedule II drugs shall either be dispersed with other schedules of drugs or shall be maintained within a securely locked cabinet, drawer, or safe or maintained in a manner that combines the two methods for storage. The cabinet, drawer, or safe may remain unlocked during hours that the prescription department is open and a pharmacist is on duty.

C. Safeguards for controlled paraphernalia and Schedule VI medical devices. Controlled paraphernalia and Schedule VI medical devices shall not be placed in an area completely removed from the prescription department whereby patrons will have free access to such items or where the pharmacist cannot exercise reasonable supervision and control.

D. Expired, or otherwise adulterated or misbranded drugs; security. Any drug that has exceeded the expiration date or is otherwise adulterated or misbranded shall not be dispensed or sold; it shall be separated from the stock used for dispensing. Expired prescription drugs shall be maintained in a designated area within the prescription department until proper disposal.

18VAC110-20-275. Delivery of dispensed prescriptions.

A. Pursuant to § 54.1-3420.2 B of the Code of Virginia, in addition to direct hand delivery to a patient or patient's agent or delivery to a patient's residence, a pharmacy may deliver a dispensed prescription drug order for Schedule VI controlled substances to another pharmacy, to a practitioner of the healing arts licensed to practice pharmacy or to sell controlled substances, or to an authorized person or entity holding a controlled substances registration issued for this purpose in compliance with this section and any other applicable state or federal law. Prescription drug orders for Schedule II through Schedule V controlled substances may not be delivered to an alternate delivery location unless such delivery is authorized by federal law and regulations of the board.

B. Delivery to another pharmacy.

1. One pharmacy may fill prescriptions and deliver the prescriptions to a second pharmacy for patient pickup or direct delivery to the patient provided the two pharmacies have the same owner, or have a written contract or agreement specifying the services to be provided by each pharmacy, the responsibilities of each pharmacy, and the manner in which each pharmacy will comply with all applicable federal and state law.
2. Each pharmacy using such a drug delivery system shall maintain and comply with all procedures in a current policy and procedure manual that includes the following information:
 - a. A description of how each pharmacy will comply with all applicable federal and state law;
 - b. The procedure for maintaining required, retrievable dispensing records to include which pharmacy maintains the hard-copy prescription, which pharmacy maintains the active prescription record for refilling purposes, how each pharmacy will access prescription information necessary to carry out its assigned responsibilities, method of recordkeeping for identifying the pharmacist responsible for dispensing the prescription and counseling the patient, and how and where this information can be accessed upon request by the board;
 - c. The procedure for tracking the prescription during each stage of the filling, dispensing, and delivery process;
 - d. The procedure for identifying on the prescription label all pharmacies involved in filling and dispensing the prescription;
 - e. The policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information;
 - f. The policy and procedure for ensuring accuracy and accountability in the delivery process;
 - g. The procedure and recordkeeping for returning to the initiating pharmacy any prescriptions that are not delivered to the patient; and
 - h. The procedure for informing the patient and obtaining consent for using such a dispensing and delivery process.
3. Drugs waiting to be picked up at or delivered from the second pharmacy shall be stored in accordance with subsection A of 18VAC110-20-200 and subsection A of 18VAC110-20-490, if applicable.

C. Delivery to a practitioner of the healing arts licensed by the board to practice pharmacy or to sell controlled substances or other authorized person or entity holding a controlled substances registration authorized for this purpose.

1. A prescription may be delivered by a pharmacy to the office of such a practitioner or other authorized person provided there is a written contract or agreement between the two parties describing the procedures for such a delivery system and the responsibilities of each party.
2. Each pharmacy using this delivery system shall maintain a policy and procedure manual that includes the following information:
 - a. Procedure for tracking and ~~assuring~~ ensuring security, accountability, integrity, and accuracy of delivery for the dispensed prescription from the time it leaves the pharmacy until it is handed to the patient or agent of the patient;
 - b. Procedure for providing counseling;
 - c. Procedure and recordkeeping for return of any prescription medications not delivered to the patient;

- d. The procedure for ~~assuring~~ ensuring confidentiality of patient information; and
- e. The procedure for informing the patient and obtaining consent for using such a delivery process.

3. Prescriptions waiting to be picked up by a patient at the alternate site shall be stored in a lockable room or lockable cabinet, cart, remote dispensing system as defined in § 54.1-3401 of the Code of Virginia and pursuant to subsection A of 18VAC110-20-490, or other device that cannot be easily moved and that shall be locked at all times when not in use. Access shall be restricted to the licensed practitioner of the healing arts or the responsible party listed on the application for the controlled substances registration, or either person's designee.

D. The contracts or agreements and the policy and procedure manuals required by this section for alternate delivery shall be maintained both at the originating pharmacy as well as the alternate delivery site.

E. A controlled substances registration as an alternate delivery site shall only be issued to an entity without a prescriber or pharmacist present at all times the site is open if there is a valid patient health or safety reason not to deliver dispensed prescriptions directly to the patient and if compliance with all requirements for security, policies, and procedures can be reasonably ~~assured~~ ensured.

F. The pharmacy and alternate delivery site shall be exempt from compliance with subsections B through E of this section if (i) the alternate delivery site is a pharmacy, a practitioner of healing arts licensed by the board to practice pharmacy or sell controlled substances, or other entity holding a controlled substances registration for the purpose of delivering controlled substances; (ii) the alternate delivery site does not routinely receive deliveries from the pharmacy; and (iii) compliance with subsections B through E of this section would create a delay in delivery that may result in potential patient harm. However, the pharmacy and alternate delivery site shall comply with following requirements:

1. To ensure appropriate coordination of patient care, the pharmacy shall notify the alternate delivery site of the anticipated arrival date of the shipment, the exact address to where the drug was shipped, the name of the patient for whom the drug was dispensed, and any special storage requirements.
2. The pharmacy shall provide counseling or ensure a process is in place for the patient to receive counseling.
3. Prescriptions delivered to the alternate delivery site shall be stored in a lockable room or lockable cabinet, cart, remote dispensing system as defined in § 54.1-3401 of the Code of Virginia and pursuant to subsection A of 18VAC110-20-490, or other device that cannot be easily moved and that shall be locked at all times when not in use. Access shall be restricted to the licensed prescriber, pharmacist, or either person's designee.
4. The pharmacy shall provide a procedure for the return of any prescription drugs not delivered or subsequently administered to the patient.

G. A pharmacy shall not deliver dispensed drugs to a patient's residence that are intended to be subsequently transported by the patient or patient's agent to a hospital, medical clinic, prescriber's office, or pharmacy for administration and that require special storage, reconstitution or compounding prior to administration. An exception to this requirement may be made for patients with inherited bleeding disorders who may require therapy to prevent or treat bleeding episodes.

18VAC110-20-490. Automated devices for dispensing and administration of drugs.

A. A hospital, state facility as defined in § 37.2-100 of the Code of Virginia that is established pursuant to Title 37.2 of the Code of Virginia, facility as defined in § 37.2-100 of the Code of

Virginia that is licensed by the Department of Behavioral Health and Developmental Services and provides site-based crisis stabilization services, or other facility authorized by the board may use automated devices drug dispensing systems and remote dispensing systems for the dispensing and administration of drugs pursuant to § 54.1-3301 of the Code of Virginia and §§ 54.1-3401 and 54.1-3434.02 of the Drug Control Act and in accordance with 18VAC110-20-270, 18VAC110-20-420, or 18VAC110-20-460 as applicable. Unless prohibited under federal law, a remote dispensing system that solely stores drugs labeled and verified by the provider pharmacist for patients to obtain medication may be placed within close proximity of a permitted pharmacy or at a location issued a controlled substance registration pursuant to § 54.1-3420.2 of the Code of Virginia in a secure area under constant surveillance to ensure security of drugs, confidentiality of protected health information, and appropriate recordkeeping.

B. Policy and procedure manual; access codes.

1. Proper use of the automated drug dispensing devices system and remote dispensing system and means of compliance with requirements shall be set forth in the pharmacy's policy and procedure manual, which shall include provisions for granting and terminating user access.

2. Personnel allowed access to an automated drug dispensing device system and remote dispensing system shall have a specific access code that records or other means to record the identity of the person accessing the device. The device may verify access codes using biometric identification or other coded identification after the initial log-on in order to eliminate sharing or theft of access codes.

~~[3. If a key may be used to access the automated drug dispensing system or remote dispensing system and the provider pharmacy is not located within the facility, a key may be maintained in the possession of the director of nursing or an individual designated by the director of nursing who is licensed to administer medications.]~~

C. Distribution of drugs from the pharmacy.

1. Except when the automated drug dispensing system or remote dispensing system is used exclusively for administration of drugs for emergencies, a pharmacy located outside of the hospital or facility it services shall first obtain a controlled substance registration issued in the name of the pharmacy at the address of the hospital or facility and a registration from the Drug Enforcement Administration, if required, prior to stocking controlled substances in Schedules II through VI.

2. Drugs authorized pursuant to § 54.1-3434.02 of the Code of Virginia may be placed into and removed from automated drug dispensing systems or remote dispensing systems. Pharmacies servicing remote dispensing systems that package and label drugs for a specific patient may repackage drugs into bulk bins that are verified for accuracy by a pharmacist pursuant to 18VAC110-20-355. Pharmacies using a remote dispensing device that only stores patient-specific dispensed drugs for patients to obtain medication may place pharmacist-verified dispensed drug into the device.

3. Prior to removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in an automated drug dispensing device system or remote dispensing system. The delivery record shall include the date; drug name, dosage form, and strength; quantity; hospital or facility unit and a unique identifier for the specific device receiving the drug; initials of the person loading the automated drug dispensing device system or remote dispensing system; and initials of the pharmacist checking the drugs to be removed from the pharmacy and the delivery record for accuracy.

2. ~~4.~~ At the time of loading any Schedules II through V drug, the person loading will verify that the count of that drug in the automated drug dispensing device system or remote dispensing system is correct. Any discrepancy noted shall be recorded on the

delivery record and immediately reported to the pharmacist in charge, who shall be responsible for ensuring reconciliation of the discrepancy or properly reporting of a loss.

D. Distribution and dispensing of drugs from the device.

1. Automated drug dispensing devices in hospitals and remote dispensing systems shall be capable of producing a hard-copy record of distribution that shall show patient name, drug name and strength, dose withdrawn, date and time of withdrawal from the device, and identity of person withdrawing the drug. The record shall be filed in chronological order from date of issue or maintained electronically.

2. If an automated drug dispensing device system or remote dispensing system is used to obtain drugs for dispensing from an emergency room, a separate dispensing record is not required provided the automated record distinguishes dispensing from administration and records the identity of the physician who is dispensing.

3. Remote dispensing systems that dispense patient-specific drugs into an envelope shall satisfy compliance with 18VAC110-20-340 if the medication is assigned an expiration date of no more than 48 hours from the date of the packaging in an envelope.

4. Remote dispensing systems that dispense multiple medications into a single container for a specific patient shall include a medication description as set forth in 18VAC110-20-340 B on the label, medication envelope, or the medication run report.

5. Pharmacist verification of a patient-specific dispensed drug as required in 18VAC110-20-270 from a remote dispensing system is waived if a pharmacist verified the drug placed in the bulk bin that is placed in the device and the device incorporates sufficient technology to ensure accuracy of the dispensed drug.

E. Discrepancy reports. A discrepancy report for all Schedules II through V drugs and any drugs of concern, as defined in § 54.1-3456.1 of the Code of Virginia, shall be generated for each discrepancy in the count of a drug on hand in the device. Each such report shall be initiated or resolved by the PIC or ~~his~~ the PIC's designee within 72 hours of the time the discrepancy was discovered or, if determined to be a theft or an unusual loss of drugs, shall be immediately reported to the board in accordance with § 54.1-3404 E of the Drug Control Act.

F. Reviews and audits.

1. The PIC or ~~his~~ the PIC's designee shall conduct at least a monthly review for compliance with written policy and procedures that are consistent with § 54.1-3434.02 A of the Drug Control Act for security and use of the automated dispensing ~~devices~~ system and remote dispensing system, to include procedures for timely termination of access codes when applicable, accuracy of distribution and dispensing from the device, and proper recordkeeping.

2. The PIC or ~~his~~ the PIC's designee shall conduct at least a monthly audit to review distribution and dispensing of Schedules II through V drugs from each automated drug dispensing device system and remote dispensing system as follows:

a. The audit shall reconcile records of all quantities of Schedules II through V drugs dispensed from the pharmacy with records of all quantities loaded into each device to detect whether any drug recorded as removed from the pharmacy was diverted rather than placed in the proper device.

b. If a pharmacy has an ongoing method for perpetually monitoring drugs in Schedules II through V to ensure drugs dispensed from the pharmacy have been loaded into the device and not diverted, such as with the use of perpetual inventory management software, then the audit required in this subsection may be limited to the discrepancies or exceptions as identified by the method for perpetually monitoring the drugs.

3. The PIC or ~~his~~ the PIC's designee shall conduct at least a monthly audit to review the dispensing and administration records of Schedules II through V drugs from each automated drug dispensing device system and remote dispensing system as follows:

a. The audit shall include a review of administration and dispensing records, if applicable, for each device per month for possible diversion by fraudulent charting. The review shall include all Schedules II through V drugs administered and dispensed for a time period of not less than 24 consecutive hours during the audit period.

b. The hard-copy distribution, dispensing, and administration records printed out and reviewed in the audit shall be initialed and dated by the person conducting the audit. If nonpharmacist personnel conduct the audit, a pharmacist shall review the record and shall initial and date the record.

c. The PIC or ~~his~~ the PIC's designee shall be exempt from requirements of this audit if reconciliation software that provides a statistical analysis is used to generate reports at least monthly. The statistical analysis shall be based on:

(1) Peer-to-peer comparisons of use for that unit or department; and

(2) Monitoring of overrides and unresolved discrepancies.

d. The report shall be used to identify suspicious activity, which includes usage beyond three standard deviations in peer-to-peer comparisons. A focused audit of the suspicious activity and individuals associated with the activity shall be performed whenever suspicious activity is identified from the reports.

4. The PIC or ~~his~~ the PIC's designee shall maintain a record of compliance with the reviews and audits in accordance with subsection H of this section.

G. Inspections. Automated drug dispensing devices systems and remote dispensing systems shall be inspected monthly by pharmacy personnel to verify proper storage, proper location of drugs within the device, expiration dates, the security of drugs, and validity of access codes. The PIC or ~~his~~ the PIC's designee shall maintain documentation of the inspection in accordance with subsection H of this section. With the exception of a monthly physical review of look-alike and sound-alike drugs stored within matrix drawers or open access areas within the device, such monthly inspection shall not require physical inspection of the device if the device is capable of and performs the following:

1. At least daily monitoring of refrigerator or freezer storage with documented temperature ranges, variances, and resolutions;

2. Automatic identification and isolation of the location of each drug within the device using a machine readable product identifier, such as barcode technology, and generation of a report verifying the applicable settings;

3. Electronic tracking of drug expiration dates and generation of proactive reports allowing for the replacement of drugs prior to ~~their~~ the expiration date; and

4. Electronic detection of the opening of the device, identification of the person accessing the device, automatic denial of access to the device during malfunctions and mechanical errors, and generation of reports of any malfunction and mechanical error.

H. Records.

1. All records required by this section shall be maintained for a period of not less than two years. Records shall be maintained at the address of the pharmacy providing services to the hospital or facility except manual Schedule VI distribution records, reports auditing for indications of suspicious activity, and focused audits, all of which may be maintained in offsite storage or electronically as an electronic image that provides an

exact image of the document that is clearly legible provided such offsite or electronic records are retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

2. Distribution and delivery records and required initials may be generated or maintained electronically provided:

a. The system being used has the capability of recording an electronic signature that is a unique identifier and restricted to the individual required to initial or sign the record.

b. The records are maintained in a read-only format that cannot be altered after the information is recorded.

c. The system used is capable of producing a hard-copy printout of the records upon request.

3. Schedules II through V distribution and delivery records may also be stored off site or electronically in compliance with requirements of subdivision 1 of this subsection and if authorized by DEA or in federal law or regulation.

4. Hard-copy distribution, dispensing, and administration records that are printed and reviewed in conducting required audits may be maintained at an ~~off-site~~ offsite location or electronically provided they can be readily retrieved upon request; provided they are maintained in a read-only format that does not allow alteration of the records; and provided a separate log is maintained for a period of two years showing dates of audit and review, the identity of the automated drug dispensing device system or remote dispensing system being audited, the time period covered by the audit and review, and the initials of all reviewers.

18VAC110-20-555. Use of automated dispensing devices and remote dispensing devices in nursing homes..

Nursing homes licensed pursuant to Chapter 5 (§ 32.1-123 et seq.) of Title 32.1 of the Code of Virginia may use automated drug dispensing systems and remote dispensing systems, as defined in § 54.1-3401 of the Code of Virginia, upon meeting the following conditions:

1. Drugs placed in an automated drug dispensing system or remote dispensing system in a nursing home shall be under the control of the pharmacy providing services to the nursing home, the pharmacy shall have online communication with and control of the automated drug dispensing system, and access to any drug for a patient shall be controlled by the pharmacy.

2. A pharmacy that is not located within the nursing home ~~without an in-house pharmacy it serves~~ shall obtain a controlled substances registration issued in the name of the pharmacy at the address of the nursing home and a registration from the Drug Enforcement Administration, if required, prior to using ~~an automated dispensing system~~ stocking drugs in Schedules II through VI, unless the automated drug dispensing system or remote dispensing system is exclusively stocked with drugs that would be kept in a stat-drug box pursuant to 18VAC110-20-550 or an emergency drug kit pursuant to 18VAC110-20-540 and are solely administered for stat or emergency administration.

3. ~~For facilities not required to obtain a controlled substance registration, access~~ Access to the automated drug dispensing device system or remote dispensing system shall be restricted to a licensed nurse, pharmacist, or prescriber or a registered pharmacy technician ~~for the purpose of stocking or reloading~~ pursuant to designation by the PIC or pharmacist on duty.

4. Removal of drugs from any automated drug dispensing system or remote dispensing system for administration to patients can only be made pursuant to a valid prescription or lawful order of a prescriber under the following conditions:

a. No drug may be administered to a patient from an automated drug dispensing device system or remote dispensing system until a pharmacist has reviewed the prescription order and electronically authorized the access of that drug for that particular patient in accordance with the order, except as provided in subdivision 4 c of this section.

b. The PIC of the provider pharmacy shall ensure that a pharmacist who has online access to the system is available at all times to review a prescription order as needed and authorize administering pursuant to the order reviewed.

c. Drugs that would be stocked in an emergency drug kit pursuant to 18VAC110-20-540 or a stat drug box pursuant to subsection B of 18VAC110-20-550 may be accessed pursuant to a valid prescription or lawful order of a prescriber and prior to receiving electronic authorization from the pharmacist, provided that the absence of the emergency drug would threaten the survival of the patient or that a delay in administration of the stat drug could result in harm to the patient.

d. Automated drug dispensing devices systems and remote dispensing systems shall be capable of producing a hard-copy record of distribution and dispensing, if applicable, that shall show patient name, drug name and strength, dose or quantity withdrawn, dose to be administered, if applicable, date and time of withdrawal from the device, and identity of person withdrawing the drug.

5. Drugs placed in automated drug dispensing devices systems shall be in the manufacturer's sealed original unit dose or unit-of-use packaging or in repackaged unit-dose containers in compliance with the requirements of 18VAC110-20-355 relating to repackaging, labeling, and records.

6. Drugs authorized pursuant to § 54.1-3404.02 of the Code of Virginia may be placed into and removed from automated drug dispensing systems or remote dispensing systems. Pharmacies servicing remote dispensing systems that package and label drugs for a specific patient may repackage drugs into bulk bins that are verified for accuracy by a pharmacist pursuant to 18VAC110-20-355. Drugs intended to be administered by the patient or a person not licensed to administer drugs must fully comply with the labeling requirements in §§ 54.1-3410 and 54.1-3463 of the Code of Virginia and board regulations. Directions for use may only be abbreviated when drugs are administered exclusively by persons licensed to administer drugs.

7. Prior to the removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in an automated drug dispensing device system and remote dispensing system, which shall include the date; drug name, dosage form, and strength; quantity; nursing home; a unique identifier for the specific device receiving drugs; and initials of the pharmacist checking the order of drugs to be removed from the pharmacy and the records of distribution for accuracy.

8. At the direction of the PIC, drugs may be loaded in the device by a pharmacist or a pharmacy technician adequately trained in the proper loading of the system.

9. At the time of loading, the delivery record for all Schedules II through VI drugs shall be signed by a nurse or other person authorized to administer drugs from that specific device, and the record returned to the pharmacy.

10. At the time of loading any Schedules II through V drug, the person loading will verify that the count of that drug in the automated drug dispensing device system or

remote dispensing system is correct. Any discrepancy noted shall be recorded on the delivery record and immediately reported to the PIC, who shall be responsible for reconciliation of the discrepancy or the proper reporting of a loss.

~~40~~ 11. Remote dispensing systems that dispense patient-specific drugs into an envelope shall satisfy compliance with 18VAC110-20-340 if the medication is assigned an expiration date of no more than 48 hours from the date of the packaging in an envelope and is not self-administered.

12. Remote dispensing systems that dispense multiple medications into a single container for a specific patient shall include a medication description as set forth in 18VAC110-20-340 on the label, medication envelope, or the medication run report.

13. Pharmacist verification of a patient-specific dispensed drug as required in 18VAC110-20-270 from a remote dispensing system is waived if a pharmacist verified the drug placed in the bulk bin that is placed in the device and the device incorporates sufficient technology assistance to ensure accuracy of the dispensed drug.

14. The PIC of the provider pharmacy or the PIC's designee shall conduct at least a monthly audit to review distribution ~~and~~, administration, and dispensing, if applicable, of Schedules II through V drugs from each automated drug dispensing device system and remote dispensing system as follows:

a. The audit shall reconcile records of all quantities of Schedules II through V drugs dispensed from the pharmacy with records of all quantities loaded into each device to detect whether any drugs recorded as removed from the pharmacy were diverted rather than being placed in the proper device.

b. A discrepancy report shall be generated for each discrepancy in the count of a drug on hand in the device. Each such report shall be resolved by the PIC or the PIC's designee within 72 hours of the time the discrepancy was discovered or, if determined to be a theft or an unusual loss of drugs, shall be immediately reported to the board in accordance with § 54.1-3404 E of the Drug Control Act.

c. The audit shall include a review of a sample of administration and dispensing records, if applicable, from each device per month for possible diversion by fraudulent charting. A sample shall include all Schedules II through V drugs administered and dispensed for a time period of not less than 24 consecutive hours during the audit period.

d. The audit shall include a check of medical records to ensure that a valid order exists for a random sample of doses recorded as administered or dispensed.

e. The audit shall also check for compliance with written procedures for security and use of the automated dispensing devices, accuracy of distribution from the device, and proper recordkeeping.

f. The hard copy distribution, dispensing, and administration records printed out and reviewed in the audit shall be initialed and dated by the person conducting the audit. If nonpharmacist personnel conduct the audit, a pharmacist shall review the record and shall initial and date the record.

~~44~~ 15. Automated drug dispensing devices systems and remote dispensing systems shall be inspected monthly by pharmacy personnel to verify proper storage, proper location of drugs within the device, expiration dates, the security of drugs and validity of access codes.

~~42~~ 16. Personnel allowed access to an automated drug dispensing device system or remote dispensing system shall have a specific access code that records the identity of the person accessing the device.

43 17. The PIC of the pharmacy providing services to the nursing home shall establish, maintain, and ensure compliance with written policy and procedure for the accurate stocking and proper storage of drugs in the automated drug dispensing system and remote dispensing system, accountability for and security of all drugs maintained in the ~~automated drug dispensing~~ system, preventing unauthorized access to the system, tracking access to the system, complying with federal and state regulations related to the storage and dispensing of controlled substances, maintaining patient confidentiality, maintaining required records, and ensuring compliance with the requirements of this chapter. The manual shall be accessible at both the pharmacy and the nursing home.

44 18. All records required by this section shall be filed in chronological order from date of issue and maintained for a period of not less than two years. Records shall be maintained at the address of the pharmacy providing services to the nursing home, except:

a. Manual Schedule VI distribution records may be maintained in offsite storage or electronically as an electronic image that provides an exact image of the document that is clearly legible, provided such offsite or electronic storage is retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

b. Distribution and delivery records and required signatures may be generated or maintained electronically, provided:

(1) The system being used has the capability of recording an electronic signature that is a unique identifier and restricted to the individual required to initial or sign the record.

(2) The records are maintained in a read-only format that cannot be altered after the information is recorded.

(3) The system used is capable of producing a hard-copy printout of the records upon request.

c. Schedules II through V distribution and delivery records may only be stored offsite off site or electronically as described in subdivisions 44 18 a and 44 18 b of this section if authorized by DEA or in federal law or regulation.

d. Hard-copy distribution ~~and~~, administration, and dispensing records that are printed and reviewed in conducting required audits may be maintained ~~offsite~~ off site or electronically, provided that (i) they can be readily retrieved upon request; (ii) they are maintained in a read-only format that does not allow alteration of the records; and (iii) a separate log is maintained for a period of two years showing dates of audit and review, the identity of the automated drug dispensing device system or remote dispensing system being audited, the time period covered by the audit and review, and the initials of all reviewers.

18VAC110-20-700. Requirements for supervision for controlled substances registrants.

A. A practitioner licensed in Virginia shall provide supervision for all aspects of practice related to the maintenance and use of controlled substances as follows:

1. In a hospital or nursing home without an in-house pharmacy, a pharmacist shall supervise.

2. In an emergency medical services agency, the operational medical director shall supervise.

3. For any other type of applicant or registrant, a pharmacist or a prescriber whose scope of practice is consistent with the practice of the applicant or registrant and who is approved by the board may provide the required supervision.

B. The supervising practitioner shall approve the list of drugs that may be ordered by the holder of the controlled substances registration; possession of controlled substances by the entity shall be limited to such approved drugs. The list of drugs approved by the supervising practitioner shall be maintained at the address listed on the controlled substances registration.

C. Access to the controlled substances shall be limited to (i) the supervising practitioner or to those persons who are authorized by the supervising practitioner and who are authorized by law to administer drugs in Virginia; (ii) such other persons who have successfully completed a training program for repackaging of prescription drug orders in a CSB, BHA, or PACE site as authorized in § 54.1-3420.2 of the Code of Virginia; (iii) other such persons as designated by the supervising practitioner or the responsible party to have access in an emergency situation; or (iv) persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and to dispense naloxone for opioid overdose reversal. If approved by the supervising practitioner, pharmacy technicians may have access for the purpose of delivering controlled substances to the registrant, stocking controlled substances in automated drug dispensing [~~devices~~ systems or remote dispensing systems], conducting inventories, audits and other recordkeeping requirements, overseeing delivery of dispensed prescriptions at an alternate delivery site, and repackaging of prescription drug orders retained by a CSB, BHA, or PACE site as authorized in § 54.1-3420.2 of the Code of Virginia. [~~Access to stock drugs in a crisis stabilization unit shall be limited to prescribers, nurses, or pharmacists.~~]

D. The supervising practitioner shall establish procedures for and provide training as necessary to ensure compliance with all requirements of law and regulation, including storage, security, and recordkeeping.

E. Within 14 days of a change in the responsible party or supervising practitioner assigned to the registration, either the responsible party or outgoing responsible party shall inform the board, and a new application shall be submitted indicating the name and license number, if applicable, of the new responsible party or supervising practitioner.

18VAC110-20-728. Drugs for immediate treatment in crisis stabilization units.

A. In accordance with § 54.1-3423 of the Code of Virginia, a crisis stabilization unit shall apply for and obtain a controlled substances registration in order to maintain a stock of ~~Schedule~~ Schedules II through VI controlled substances for immediate treatment of patients in crisis. ~~Schedule II through V controlled substances shall not be stocked.~~ The responsible party listed on the application shall be a nurse who regularly administers controlled substances at the crisis stabilization unit and the supervising practitioner shall be either the medical director for the unit or a pharmacist from a provider pharmacy.

B. In consultation with a provider pharmacist, the medical director for the unit shall determine the list of controlled substances to be stocked at the crisis stabilization unit. The list shall be limited to ~~Schedule VI controlled substances and only~~ those drugs routinely used for treatment of patients admitted for crisis stabilization. Only drugs on this drug list may be stocked.

C. A nurse administering a drug from this stock pursuant to an oral order of a prescriber in accordance with § 54.1-3423 of the Code of Virginia shall record such order in the patient's medical record.

D. Records.

1. A record shall be maintained of all drugs received as stock by the crisis stabilization unit.
2. A record shall be made documenting administration or other authorized disposition of stocked drugs that includes the following:
 - a. Name of patient;

- b. Date and time of administration;
 - c. Drug name, strength, and quantity administered;
 - d. Name or initials of person administering; and
 - e. Prescriber name.
3. Records shall be maintained at the same location listed on the controlled substances registration or, if maintained in an ~~off-site~~ offsite database, retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent. Any computerized system used to maintain records shall also provide retrieval via computer monitor display or printout of the history for drugs administered during the past two years. It shall also have the capacity of producing a printout of any data ~~which~~ that the registrant is responsible for maintaining.
4. Manual records may be maintained as an electronic image that provides an exact image of the document and is clearly legible.