Guidance Document: 110-3 Revised: June 4, 2021 Effective: September 16, 2021

Virginia Board of Pharmacy

ALTERNATE DELIVERY OF PRESCRIPTIONS IN VIRGINIA

Pharmacy to Physician or Pharmacy to Controlled Substances Registration Type of Delivery

Reference: §54.1-3420.2 of the Code of Virginia, 18VAC 110-20-275 of the Regulations of the Virginia Board of Pharmacy

The following are examples of the Board's interpretation of 18VAC110-20-275 for delivery of dispensed prescriptions:

18 VAC 110-20-275. Delivery of dispensed prescriptions.

- 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 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 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;

> Example:

- The pharmacy will prepare a log of all the prescriptions. The employee delivering the prescriptions will sign this log. All of the prescriptions prepared for delivery and the signed log will be placed in a sealed tote/container prior to the employee leaving the pharmacy.
- The agent at the receiving location will sign for receipt of the sealed container, then open the sealed container and check the prescriptions against the delivery log to insure that all prescriptions have been received and sign the log as being complete. The delivered prescriptions shall be stored in accordance with law and regulations.
- Patients picking up their prescription(s) will sign the log indicating receipt of the prescription.

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b. Procedure for providing counseling;

Example: The prescriptions for a patient will be placed in a tamper-resistant bag with the Medi-Span Patient Information Leaflet for each prescription and a written offer for counseling by a pharmacist available by a toll free phone number to include the hours of operation for the pharmacy when counseling may be obtained. A label identifying the patient will be placed on the outside of the bag.

c. Procedure and recordkeeping for return of any prescription medications not delivered to the patient;

Example: Completed logs are to be returned to the originating pharmacy within 14 days, and maintained in chronological order for a period of 2 years. Any prescriptions not picked up within 14 days are to be returned to the originating pharmacy in a sealed tote/container.

d. The procedure for assuring confidentiality of patient information; and

Example: The only personnel handling the prescriptions will be employees of the pharmacy or employees of the permitted physician who already have access to these patients' medical records.

e. The procedure for informing the patient and obtaining consent for using such a delivery process.

Example: A form explaining the service and explicitly requesting the patient's consent to participate in the service.

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, or other device which cannot be easily moved and which 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.

Other notes:

- ➤ Copies of forms to be utilized should be included in the policy and procedure manual.
- ➤ Description of supplies used to deliver prescriptions should be included in the policy and procedure manual.
- ➤ Designation of other persons who may access the dispensed drugs shall be in writing and available for review by an agent of the board.
- Access by a designee shall occur at a time when a prescriber or pharmacist is present at all times with the exception of those qualifying facilities pursuant to 18VAC110-20-275 (E).

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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.

Example: A Virginia Department of Health department has been issued a controlled substances registration as an alternate delivery site without a prescriber or pharmacist present at all times the site is open because of the unique needs of the patients receiving services and the medical conditions being treated.

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:

Examples: A pharmacy is exempt from subsections B through E of this section when it needs to deliver a drug to a licensed alternate delivery site that does not routinely receive deliveries from the pharmacy and compliance with subsections B through E of this section would create a delay in delivery that may result in potential patient harm.

A pharmacy making regular deliveries of a standardized list of drugs to the same alternate delivery site over time would NOT be exempt from compliance with subsections B through E as this constitutes routine delivery from the pharmacy.

A pharmacy delivering a drug to an alternate delivery site when compliance with subsections B through E of this section would not create a delay that may result in patient harm is NOT exempt from subsections B through E of this section.

- 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.

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3. Prescriptions delivered to the alternate delivery site shall be stored in a lockable room or lockable cabinet, cart, 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.