

Virginia Board of Pharmacy Guidance for Pharmacies within Opioid Treatment Programs

Opioid treatment programs (OTP) that do not have a need for a full service pharmacy may apply for a special or limited-use permit as described in section 18 VAC 10-20-120 of the Virginia Board of Pharmacy Regulations and must submit the required information with the application and fee. While waivers are granted by the Board on an individual case basis after considering the merit of each such request, the Board will normally waive certain provisions of 18VAC110-20-190 to allow nurses access to an OTP pharmacy at a time when the pharmacist is not on-duty for the purpose of obtaining methadone doses for administration.

Pharmacies located within an OTP should comply with the following guidance to ensure drug security and protect against diversion:

Preparation of drugs for administration and dispensing

- A pharmacist or a registered pharmacy technician under the supervision of a pharmacist must prepare the methadone take-home doses or the dispensing of other drugs, to include performing the data entry of information into a computer system, if applicable, and the repackaging and labeling of the drugs. There is no authority for nurses to prepare or pre-label bottles for methadone take-home doses or other drugs for dispensing, as they may not perform duties restricted to a pharmacy technician in § 54.1-3321 unless they are registered as a pharmacy technician.
- If certain provisions of 18VAC110-20-190, such as the requirement that the pharmacy enclosure be locked and alarmed at all times when a pharmacist is not on duty, are waived by the Board to allow nurses access to the pharmacy at a time when the pharmacist is not on-duty for the purpose of obtaining methadone or buprenorphine doses for administration, then the nurse may access the key and alarm code for this specific purpose only. The pharmacy must remain locked and alarmed at all other times. The nurse must ensure a valid order for administration exists prior to preparing the drug for administration and must properly maintain a record of administration that contains minimally, the name of the patient, name of ordering physician, drug name, drug strength, quantity of drug administered, and date of administration. The pharmacy's inventory records must also accurately reflect the drug name, drug strength, quantity of drug removed from stock, date, and identification of person removing drug from inventory for patient administration.
- Only one drug and strength, as ordered for the patient, may be placed in the container, i.e., do not combine multiple strengths of a single drug or multiple types of drugs in one labeled container. Additionally, caution should be taken to not mix the same drug from multiple manufacturers in the same container.
- The National Drug Code (NDC) for the actual drug dispensed or administered should be accurately captured in the computer system, if applicable, and on all applicable records. If the computer defaults to a particular drug strength that is not consistent with the actual drug being dispensed, this must be corrected prior to dispensing or administering to accurately reflect the drug administered or dispensed.

- Per 2008 guidance from the Substance Abuse and Mental Health Services Administration, the label for a methadone take-home dose should include the opioid treatment program's name, address, telephone number, patient's name, medication name, physician's name, and dispensing date. In addition, labels for liquid methadone should include the dose and the directions of use such as "single dose".
- The label for dispensed drugs, other than methadone, shall include all required elements for a dispensed prescription drug. For example, the labels for Suboxone[®] or Subutex[®] should also include the strength, quantity dispensed, and the appropriate directions of use such as "Take [#] tablet(s) under the tongue once a day" or "Take [#] tablet(s) once a day," respectively.
- Appropriate cautionary statements should also appear on the take-home bottle. According to 21 C.F.R. 290.5, "[t]he label of any drug listed as a 'controlled substance' in schedule II, III, or IV of the Federal Controlled Substances Act shall, when dispensed to or for a patient, 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.'"
- A pharmacist must verify the accuracy of take-home doses and other dispensed drugs in all aspects, including verification that a valid order exists, prior to the patient receiving the drug.

Records

- The pharmacist must ensure records are properly maintained, to include all invoices, orders, and inventories, and should ensure that nurses are properly trained in recordkeeping requirements.
- Drug that is returned to stock must be inventoried. The pharmacist must print a reconciliation report and should routinely review the reconciliation report for accuracy and patterns of possible diversion.
- Overfill in manufacturer packages must be reconciled in the inventory record. The pharmacist may request a letter from the manufacturer regarding the amount of overfill in a bottle.
- The total amount, including overfill, may be accounted for when the bottle is initially added to inventory or the amount of overfill can be added as a separate entry.
- Spillage of drugs must be accurately documented.

Expired drugs

- Expired drugs must be segregated from the working stock and stored within the pharmacy.
- Expired drugs must be included in the inventory record until returned to a reverse distributor. Some software programs offer a "quarantine" feature to identify drugs removed from the working stock.
- Expired drugs should not be "stockpiled", but should be returned to a reverse distributor as soon as possible.

Naloxone

- Naloxone stored in the pharmacy may be dispensed by the pharmacist pursuant to §54.1-3408. Naloxone dispensed by persons other than a pharmacist should be stored outside of the pharmacy and may be dispensed in accordance with §54.1-3408.

18VAC110-20-190. Prescription department enclosures; access to prescription department.

A. The prescription department of each pharmacy shall be provided with enclosures subject to the following conditions:

- 1. The enclosure shall be constructed in such a manner that it protects the prescription drugs from unauthorized entry and from pilferage at all times whether or not a pharmacist is on duty.*
- 2. The enclosure shall be locked and alarmed at all times when a pharmacist is not on duty.*
- 3. The enclosure shall be capable of being locked in a secure manner at any time the pharmacist on duty is not present in the prescription department.*

B. The keys or other means of entry into a locked prescription department and the alarm access code shall be restricted to pharmacists practicing at the pharmacy and authorized by the PIC with the following exceptions:

1. The PIC or a pharmacist on duty, for emergency access, may place a key or other means of unlocking the prescription department and the alarm access code in a sealed envelope or other container with the pharmacist's signature across the seal in a safe or vault or other secured place within the pharmacy. This means of emergency access shall only be used to allow entrance to the prescription department by other pharmacists, or by a pharmacy technician in accordance with subsection D of this section. In lieu of the pharmacist's signature across a seal, the executive director for the board may approve other methods of securing the emergency access to the prescription department.

2. Pharmacy interns, pharmacy technicians, and other persons authorized by the PIC or pharmacist on duty may possess a key or other means of entry into a locked prescription department only when a pharmacist is on duty. Such key or other means of entry shall not allow entry when a pharmacist is not on duty.

C. The prescription department is restricted to pharmacists who are practicing at the pharmacy. Pharmacy interns, pharmacy technicians, and other persons designated by the pharmacist on duty may be allowed access by the pharmacist but only when the pharmacist is on duty. Each pharmacist while on duty shall be responsible for the security of the pharmacy, including provisions for effective control against theft or diversion of prescription drugs and devices.

D. A PIC or pharmacist on duty shall not permit access to the prescription department or controlled substances by a pharmacist, pharmacy intern, or pharmacy technician whose license or registration is currently suspended or revoked.

E. Upon a request by a patient to obtain an already-dispensed prescription, a pharmacy technician may enter the pharmacy for the sole purpose of retrieving filled prescriptions that have already been reviewed and certified for accuracy by a pharmacist and deemed ready for delivery to the patient if:

- 1. There is an unforeseen, unplanned absence of a pharmacist scheduled to work during regular prescription department hours;*
- 2. Alternate pharmacist coverage cannot immediately be obtained;*
- 3. The technician is accompanied by a member of the pharmacy's management or administration; and*

4. All requirements of subsection F of this section are met.

F. Requirements for entry into the prescription department in the absence of a pharmacist.

1. The requirements for prescriptions awaiting delivery in subsection A of 18VAC110-20-200 are followed.

2. Prior to entry into the prescription department, the pharmacy technician shall obtain verbal permission from the PIC or another pharmacist regularly employed by that pharmacy to obtain and use the emergency key or other access and alarm access code and enter the pharmacy.

3. A record shall be made by the pharmacy technician of the entry to include the date and time of entry; the name and signature of the pharmacy technician; the name, title, and signature of the person accompanying the pharmacy technician; the pharmacist's name granting permission to enter and telephone number where the pharmacist was reached; the name of the patient initially requesting needed medication and the nature of the emergency; a listing of all prescriptions retrieved during that entry; and the time of exit and re-securing of the prescription department.

4. The pharmacy technician shall reseal the key and alarm access code after the pharmacy is re-secured, and the PIC shall have the alarm access code changed within 48 hours of such an entry and shall document that this has been accomplished on the record of entry.

5. All records related to entry by a pharmacy technician shall be maintained for a period of one year on premises.