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 18VAC10-20-120 of the Virginia Board of Pharmacy Regulations and must submit the required information with the application and fee. Pursuant to Virginia Code § 54.1-3321(I), a registered nurse ("RN") or licensed practical nurse ("LPN") practicing at an OTP may perform duties otherwise limited to a pharmacy technician under § 54.1-3321(A), provided that all take-home medication doses are verified for accuracy by a pharmacist. Additionally, 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 and retrieving pharmacist-verified take home doses of methadone and buprenorphine.

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, registered pharmacy technician under the supervision of a pharmacist, or an RN or LPN 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.
- 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 or retrieving pharmacist-verified take home doses of methadone and buprenorphine, 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 the ordering physician, the 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 the 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 or other opioid antagonists

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

Mobile Medication Unit

- To operate a mobile medication unit, an OTP may request waivers of applicable regulations associated with the pharmacy permit issued to the fixed location. These waivers may be in addition to other waivers approved for the fixed location. The following requirements may be waived to authorize the specific allowances listed:
    - 18VAC110-20-190 – To authorize a licensed nurse or prescriber to access the pharmacy to transfer methadone and take-home doses to and from the mobile medication unit on days that the mobile medication unit is being used for methadone dosing and delivery of take-home doses. Take-home doses must continue to be verified by a pharmacist.
    - 18VAC110-20-150(A) – To authorize the square footage of the mobile medication unit, if necessary.
    - 18VAC110-20-150(C) – To authorize the use of a mobile medication unit that is moveable.
    - 18VAC110-20-150(F) – To authorize a sink to be located outside of the dispensing area within the mobile medication unit, as long as it is readily accessible by staff.

Relevant statutes and regulations:

Va. Code § 54.1-3321
Va. Code § 54.1-3408
18VAC110-20-150
18VAC110-20-190
21 CFR § 290.5