

Medication Access Site Requirements for Clinics
Pre-Exposure Prophylaxis (PrEP) Delivery Program
Virginia Medication Assistance Program (VA MAP)

- A. MOA (fully executed by both parties)
 - 1. Initiated by the Department (VDH Pharmacy Services)
 - 2. Sent to the Contractor (pick-up site)
 - 3. Final signature provided by the Department
 - 4. Copy kept on file by both parties

- B. Controlled Substance Registration (CSR) [**18VAC110-20-690 to 18VAC110-20-710**]
 - 1. Applies to an entity that intends to maintain a supply of Schedule II-VI controlled substances. VDH Pharmacy Services will only provide schedule VI substances.
 - 2. Registrants for a CSR may include alternative delivery sites, outpatient clinics and others listed in the BOP regulations. The site will be an alternative delivery site in this situation.
 - 3. Proposed location must be inspected by BOP agent prior to CSR issuance. The site must be secure and meet the storage recommendations of subsection A of 18VAC110-20-200 prior to inspection.
 - 4. Changes to a previously approved location or the security system requires filing an application with BOP and an inspection. Should the location change or the drug room move, an updated form with the change in address must be submitted to the Board of Pharmacy prior to moving the drugs, with a fee required.
 - 5. Drugs cannot be stocked in a proposed drug storage location or moved to a new location until approval granted by BOP.
 - 6. Application must be signed by person who will act as the Responsible Party (may be a prescriber, nurse, pharmacist or pharmacy technician) for the controlled substances; Responsible Party must be on site daily or at least once weekly on a typical work week.
 - 7. Designate a Supervising Practitioner (a prescriber or pharmacist who will have some supervisory authority over the Responsible Party).
 - 8. Any changes in Supervising Practitioner or Responsible Party for the site will require site to file an amended CSR with BOP 14 days prior to the change. There is no fee to make this change. VDH Pharmacy Services must be alerted via email of the change.
 - 9. Access to controlled substances limited to Supervising Practitioner or Responsible Party or those authorized by Supervising Practitioner and who are authorized by law to administer drugs in Virginia.
 - 10. In a facility not staffed 24 hours a day, the drugs must be stored in a fixed and secured room, cabinet or area which has a security device which meets BOP regulations.
 - 11. Renewed annually prior to expiration at the end of the month of February. VDH Pharmacy Services will need a confirmation that the CSR has been renewed.

- C. General Information Needed from Clinic & Process for Placing Medication Orders
 - 1. A contact name, phone number, and fax number
 - 2. Site shipping address
 - 3. Mutual understanding of how medication orders will be placed

- D. Policy & Procedures
 - Both entities to maintain a copy on site. VDH Pharmacy Services will provide to the site.

- E. Prescription Record
 - 1. VDH Pharmacy Services to maintain legal record for all prescriptions dispensed.

2. VDH Pharmacy Services to label all prescriptions in accordance to all state and federal requirements.
- F. Prescription Tracking & Accountability
1. VDH Pharmacy Services to keep a detailed log of all prescriptions shipped; tracking information will be available as needed.
 2. VDH Pharmacy Services will maintain a record of all prescriptions returned from pick-up site.
 3. Pick-up site will maintain a log for patients receiving a prescription from VDH Pharmacy Services; see attached sample log but site may opt to create a customized one.
- G. Patient Consent for Delivery
1. Pick-up site will be responsible for obtaining patient consent to allow VDH Pharmacy Services to fill prescriptions requested on their behalf in support of PrEP or VA MAP.
 2. Pick-up site's district director or designee to provide written authorization for receiving prescriptions on behalf of site's patients and storage and subsequent deliver of prescriptions to patient.
- H. Confidentiality of Patient Information
1. Both VDH Pharmacy Services and the pick-up site shall comply with existing policies of their respective organization for maintaining patient confidentiality and PHI integrity.
 2. VDH Pharmacy Services will comply with HIPPA regulations.
- I. Patient Prescription Drug Counseling
- Pick-up site to inform patients receiving new prescriptions from VDH Pharmacy Services that counseling is available from a pharmacist.
- J. Storage Requirements
- Pick-up site must store all prescriptions sent by VDH Pharmacy Services in accordance with subsection A of 18VAC110-20-200 of the BOP regulations.
- K. Security
1. Access to prescription storage area restricted to licensed staff at the pick-up site.
 2. Pick-up site must keep an up to date list of all licensed staff granted access to the prescription storage area.
 3. Only licensed staff granted access may possess keys to the prescription storage area.
- L. Emergency Access
1. Access to prescription storage area at site may be granted by Supervising Practitioner or Responsible Party to non-licensed staff in case of an emergency.
 2. Pick-up site to keep separate log of all incidents requiring emergency access.
 3. Key must be kept in a secure area in a sealed envelope.
 4. Responsible Party responsible for integrity of emergency access.