

Pharmacist Prescribing Protocol
HIV Pre-Exposure and Post-Exposure Prophylaxis Medications

Background

Minn. Stats. §151.37, subd. 17, states the following:

“A pharmacist is authorized to prescribe and administer drugs to prevent the acquisition of human immunodeficiency virus (HIV) in accordance with this subdivision . . . the Board of Pharmacy shall develop a standardized protocol for a pharmacist to follow in prescribing the drugs described in (the above) paragraph. In developing the protocol, the board may consult with community health advocacy groups, the Board of Medical Practice, the Board of Nursing, the commissioner of health, professional pharmacy associations, and professional associations for physicians, physician assistants, and advanced practice registered nurses.”

This protocol was developed by Board staff after consulting with subject matter experts. It was approved at the December 4th, 2024 Board meeting. Pharmacists who *independently* prescribe medications for HIV prevention **must follow this** protocol. When prescribing per this protocol, the pharmacist is the prescriber-of-record.

Pharmacists can also issue legally valid prescriptions for HIV prevention medications through the use of other protocols that they enter into with a physician, advanced practice registered nurse (APRN), or physician assistant (PA) as allowed by Minn. Stats. §151.01, subd. 27(6) and Minn. Stats. §151.37, subd. 2. When working under those protocols, the practitioner, not the pharmacist, is the prescriber-of-record.

Definition

1. **HIV Prevention Medication.** HIV prevention medication (HPM) means a product approved by the United States Food and Drug Administration that is recommended by the CDC for use in HIV prevention. Only products approved by the FDA are included; compounded products are not included.

General Considerations

1. Pharmacists who use this protocol must keep a written copy of it at each location at which they issue prescriptions for an HPM. They must make a copy of the protocol available upon the request of a representative of the Board of Pharmacy. This protocol must list the names of each pharmacist who is issuing prescriptions for HPM at the location.
2. Before a pharmacist is authorized to prescribe HPM to a patient under this protocol, the pharmacist must successfully complete a training program on prescribing HPM that is offered by a college of pharmacy or by a continuing

education provider that is accredited by the Accreditation Council for Pharmacy Education, or a program approved by the board.

- a. Upon the request of a representative of the Board, pharmacists must provide proof that they have completed the training.
 - b. Pharmacists may request Board approval of a program by downloading the Continuing Education Program Approval Form for Non-ACPE Program Attendees, filling it out, and submitting it to the Board, along with information about the program. This form does not need to be submitted for a program offered by a college of pharmacy or by a continuing education provider that is accredited by ACPE.
 - c. Note that the program must be developed for the prescribing of HPMs. For example, a continuing education program that only provides education about the pharmacology of HPMs would not be sufficient.
3. Pharmacists may prescribe an HPM only as outlined in the protocol.
 4. Pharmacists and pharmacies are encouraged to post a notice or to otherwise alert customers that pharmacists may prescribe and dispense HPM
 5. Pharmacists should consider collaborating with local emergency departments/urgent care or local infectious disease providers/clinics for complex clinical situations and referral processes.

Procedure for Pre-Exposure Prophylaxis (PrEP)

1. When an individual requests an HPM for PrEP, or when a pharmacist (using sound professional judgment) decides to offer to prescribe an HPM for PrEP, the pharmacist shall complete the following steps:
 - a. Counsel on the benefits and risks of PrEP
 - b. Have the patient fill out the *Minnesota Board of Pharmacy HIV PrEP Intake Form*
 - c. Review the *Intake Form* with the patient and ask any necessary follow-up questions
 - d. **Prescribing and referral.** Once the above steps are completed, the pharmacist shall refer to the HIV PrEP Assessment & Treatment Care Algorithm to determine if prescribing an HPM is appropriate.
 - i. If it is appropriate, the pharmacist may prescribe an HPM per the Algorithm.
 - ii. When necessary, and as noted in the Algorithm, the pharmacist must refer the patient to a primary care provider or emergency department if the patient has a contraindication to HPM.
 - iii. The pharmacist must provide to the patient printed educational material regarding the safety and effectiveness of PrEP
 - e. When prescribing a HPM the pharmacist must ensure that the patient is appropriately trained in the administration of the requested or recommended medication.

- f. When a HPM medication is prescribed, the pharmacist must provide the patient with appropriate counseling and information for the product prescribed, as required by Minn. Rules 6800.0910. In addition to verbal counseling, the pharmacist must also supply a fact sheet to the patient that is specific to the drug prescribed. Pharmacists may refer the patient to an FDA-approved patient package insert. The information that must be provided includes the following:
 - i. the name and description of the drug;
 - ii. the dosage form, dose, route of administration, and duration of drug therapy
 - iii. intended use of the drug and expected action
 - iv. directions and precautions for preparation, administration, and appropriate use by the patient
 - v. common severe side effects, adverse effects, or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur
 - vi. techniques for self-monitoring of drug therapy
 - vii. proper storage; and
 - viii. any other information relevant to the patient's drug therapy.
- g. When a HPM medication is prescribed, the pharmacist must provide the patient with a written record of the medication prescribed. At a minimum, the record must include:
 - i. the patient's name and date-of-birth
 - ii. the name, practice address, and telephone number for the prescribing pharmacist
 - iii. the date on which the prescription was issued
 - iv. the name and strength of the HPM that was prescribed
 - v. the quantity prescribed and how many refills were authorized (if any)

Procedure for Post-Exposure Prophylaxis (PEP)

1. When an individual requests an HPM for PEP, or when a pharmacist (using sound professional judgment) decides to offer to prescribe an HPM for PEP, the pharmacist shall complete the following steps:
 - a. Counsel on the benefits and risks of PEP
 - b. Have the patient fill out the *Minnesota Board of Pharmacy HIV PEP Patient Intake Form*
 - c. Review the *Intake Form* with the patient and ask any necessary follow-up questions
 - d. **Prescribing and referral.** Once the above steps are completed, the pharmacist shall refer to the HIV PEP Assessment & Treatment Care Algorithm to determine if prescribing an HPM is appropriate.

- i. If it is appropriate, the pharmacist may prescribe an HPM per the Algorithm.
 - ii. When necessary, and as noted in the Algorithm, the pharmacist must refer the patient to a primary care provider or emergency department if the patient has a contraindication to HPM.
 - iii. The pharmacist must provide to the patient printed educational material regarding the safety and effectiveness of PrEP
- e. When prescribing a HPM the pharmacist must ensure that the patient is appropriately trained in the administration of the requested or recommended medication.
- f. When a HPM medication is prescribed, the pharmacist must provide the patient with appropriate counseling and information for the product prescribed, as required by Minn. Rules 6800.0910. In addition to verbal counseling, the pharmacist must also supply a fact sheet to the patient that is specific to the drug prescribed. Pharmacists may refer the patient to an FDA-approved patient package insert. The information that must be provided includes the following:
 - i. the name and description of the drug;
 - ii. the dosage form, dose, route of administration, and duration of drug therapy
 - iii. intended use of the drug and expected action
 - iv. directions and precautions for preparation, administration, and appropriate use by the patient
 - v. common severe side effects, adverse effects, or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur
 - vi. techniques for self-monitoring of drug therapy
 - vii. proper storage; and
 - viii. any other information relevant to the patient's drug therapy.
- g. When a HPM is prescribed, the pharmacist must provide the patient with a written record of the medication prescribed. At a minimum, the record must include:
 - i. the patient's name and date-of-birth
 - ii. the name, practice address, and telephone number for the prescribing pharmacist
 - iii. the date on which the prescription was issued
 - iv. the name and strength of the HPM that was prescribed
 - v. the quantity prescribed and how many refills were authorized (if any)

Delegation Prohibited

A pharmacist who is authorized to prescribe a HPM is prohibited from delegating the prescribing to any other person. A pharmacist intern registered pursuant to Minn. Stats.

§151.101 may prepare a prescription for a HPM, but before the prescription is processed or dispensed, a pharmacist authorized to prescribe under this subdivision must review, approve, and sign the prescription.

Records

The pharmacist must generate a written or electronic prescription for HPM that is prescribed and dispensed. The prescription must include all of the information required by Minn. Stats. §151.01, subd. 16a. The prescription must be processed in the same manner that any other prescription is processed, pursuant to the applicable statutes and rules for the dispensing of prescription drugs. The prescription shall be kept on file and maintained for a minimum of two years. Pharmacists are reminded that prescriptions paid for by Medicare and Medicaid must be kept on file for even longer periods of time.

Name of Pharmacists Who Will Be Prescribing Pursuant to this Protocol

Pharmacy or facility name:

Pharmacy or facility address:

Names of Prescribing Pharmacists:

- 1) _____
- 2) _____
- 3) _____
- 4) _____
- 5) _____
- 6) _____
- 7) _____
- 8) _____
- 9) _____
- 10) _____