**02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION**

**392 MAINE BOARD OF PHARMACY**

**Chapter 43: PRESCRIBING, DISPENSING AND ADMINISTERING HIV PREVENTION DRUGS**

**Summary:** This chapter sets forth the requirements to authorize, and the professional minimum standards required for, pharmacists to prescribe, dispense and administer HIV prevention drugs, including training requirements and protocols for when there is no prescription drug order, standing order or collaborative practice agreement.

1. **Generally.** A Maine-licensed pharmacist who completes the training set forth in Section 2 below may prescribe, dispense and administer HIV prevention drugs pursuant to the protocol developed by the board and as incorporated in section 3, when there is no prescription drug order, standing order or collaborative practice agreement, so long as the pharmacist meets all of the requirements of this rule and the requirements set forth in 32 M.R.S. § 13786-E.

##### Training.

* 1. **Content**. Prior to independently prescribing, dispensing, and administering HIV prevention drugs to a patient pursuant to 32 M.R.S. § 13786-E (2), the pharmacist shall successfully complete a training program by the Accreditation Council for Pharmacy Education (ACPE) or other board-approved provider accredited by an approved accreditation agency, or as part of an equivalent curriculum-based training program completed from a recognized school of pharmacy. At a minimum, the training shall consist of the criteria set forth in Section 2(1)(A), and the pharmacist must also complete training on the protocol adopted by the board as set forth in Section 2(1)(B).
     1. ​ **Training Program**. A pharmacist must complete a training program specific to the use of HIV preexposure and postexposure prophylaxis (PrEP/PEP), that includes instruction covering, at a minimum, the following areas:
        1. Screening for HIV and sexually transmitted infections (STIs), and laboratory testing to determine PrEP/PEP eligibility;
        2. Centers for Disease Control and Prevention (CDC) clinical practice guidelines for PrEP/PEP;
        3. Pharmacology, safety, efficacy, drug-drug interactions, and monitoring parameters for HIV medications used for PrEP/PEP;
        4. Related trauma-informed care; and
        5. Patient counseling information.
     2. ​ **Protocol Training**. A pharmacist must complete training on the protocol adopted by the board in section 3 of this chapter and verify completion as required by the board.
  2. Documentation.

1. A pharmacist shall maintain documentation of their successful completion of the required training as set forth in Section 2(1) for a period of at least five (5) years following any patient interactions involving prescribing, dispensing and administering HIV prevention drugs that is subject to this rule.
2. Training obtained as part of an equivalent curriculum-based training program can be documented by written certification from a member of the educational institution or program from which the licensee graduated stating that the training is included within the institution’s curriculum required for graduation at the time the pharmacist graduated, or within the coursework that was completed by the pharmacist. Documentation maintained pursuant to this subsection must be made available upon request of the board.
3. **Protocol**. The board hereby adopts the HIV Pre-Exposure Prophylaxis (PrEP) Statewide Protocol as incorporated in this Chapter as Appendix 1 and the HIV Post-Exposure Prophylaxis (PEP) Statewide Protocol as incorporated in this Chapter as Appendix 2.
4. **Limited Exercise of Clinical Judgment Permitted**. If a pharmacist certified under this chapter is aware, at the time of prescribing, dispensing and administering HIV prevention drugs to a patient, that best practices have changed since the adoption of the Board-approved protocol and it is not possible to follow both the applicable protocol and contemporary best practices, the pharmacist may exercise their clinical discretion and apply current best practices, so long as the pharmacist:
   1. Maintains complete documentation of the sources of new clinical practices;
   2. Maintains complete documentation of the clinical decision-making the pharmacist employed with the patient; and
   3. Can demonstrate that the pharmacist’s clinical decision-making was consistent with evidence-based practice standards that became effective after the adoption of the Board-approved protocol and was in the best interests of the patient.

If the pharmacist does not meet all three requirements for deviation from the adopted protocol, the pharmacist may be subject to discipline.

1. **Non-delegation**. A pharmacist may not delegate any of the tasks assigned specifically to the pharmacist pursuant to 32 M.R.S. § 13786-E.

STATUTORY AUTHORITY: 32 M.R.S. §§ 13720, 13786-E

EFFECTIVE DATE (NEW):

May 6, 2025 – filing 2025-105

**02-392**

**DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION**

**MAINE BOARD OF PHARMACY**

**Appendix 1 to Chapter 43**

**Prescribing, Dispensing, and Administering**

**HIV Prevention Drugs**

**For**

**Preventive Care**

**HIV Pre-Exposure Prophylaxis (PrEP)**

**Statewide Protocol**

**Adopted April 3, 2025**

**MAINE BOARD OF PHARMACY**

**Preventive Care**

**HIV Pre-Exposure Prophylaxis (PrEP) Statewide Protocol**

Consistent with the manufacturer’s instructions for use approved by the US Food and Drug Administration (FDA), a pharmacist may independently prescribe, dispense and administer HIV prevention drugs.

#### STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

* Utilize the standardized PrEP Patient Intake Form
* Utilize the standardized PrEP Assessment and Treatment Care Pathway Form
* Utilize the standardized PrEP Provider Notification Form

#### PHARMACIST EDUCATION AND TRAINING

* Prior to a pharmacist independently prescribing, dispensing, and administering HIV prevention drugs, the pharmacist shall be knowledgeable of the manufacturer’s instructions for use and shall have completed a comprehensive training program related to the prescribing, dispensing, and administering of HIV prevention drugs.

**\***Note: A pharmacy may create and use an electronic format for the PrEP Patient Intake Form, PrEP Assessment and Treatment Care Pathway, and PrEP Provider Notification if the information is identical to the forms included in this protocol.

### Pre-Exposure Prophylaxis (PrEP) Self-Screening Patient Intake Form (CONFIDENTIAL-Protected Health Information)

Date / / Date of Birth / / Age

Legal Name Preferred Name Sex Assigned at Birth (circle) M / F Gender Identification (circle) M / F / Other Preferred Pronouns (circle) She/Her/Hers, He/Him/His, They/Them/Their, Ze/Hir/Hirs, Other

Street Address Phone ( ) Email Address Healthcare Provider Name Phone ( ) Fax ( ) Do you have health insurance? Yes / No Insurance Provider Name

Any allergies to medications? Yes / No If yes, please list

**Background Information:** These questions are highly confidential and help the pharmacist to determine if PrEP is right for you and what Human Immunodeficiency Virus (HIV) and Sexually Transmitted Infection (STI) testing is recommended.

**Do you answer yes to any of the following? □ Yes □ No** (If any of the following apply to you, check Yes)

|  |
| --- |
| 1. Do you sexually partner with men, women, transgender, or non-binary people? |
| 2. Please estimate how often you use condoms for sex. Please estimate the date of the last time you had sex without a condom.  % of the time  / / last sex without a condom |
| 1. Do you have oral sex?    * Giving- you perform oral sex on someone else    * Receiving- someone performs oral sex on you |
| 1. Do you have vaginal sex?    * Receptive- you have a vagina and you use it for vaginal sex    * Insertive- you have a penis and you use it for vaginal sex |
| 1. Do you have anal sex?    * Receptive- someone uses their penis to perform anal sex on you    * Insertive- you use your penis to perform anal sex on someone else |
| 6. Do you inject drugs? |
| 7. Are you in a relationship with an HIV-positive partner? |
| 8. Do you exchange sex for money or goods? (includes paying for sex) |
| 9. Do you use poppers (inhaled nitrates) and/or methamphetamine for sex? |

**Medical History:** These questions are highly confidential and help the pharmacist to determine if PrEP is right for you.

|  |  |
| --- | --- |
| 1. Have you ever tested positive for Human Immunodeficiency Virus (HIV)? | □ Yes □ No |
| 2. Do you see a healthcare provider for management of Hepatitis B? | □ Yes □ No |
| 1. Have you ever received an immunization for Hepatitis B?    * If no, would you like a Hepatitis B immunization today? □ Yes □ No | □ Yes □ No  Date of vaccine / / |

|  |  |
| --- | --- |
| 4. Do you see a healthcare provider for problems with your kidneys? | □ Yes □ No |
| 1. Do you take non-steroidal anti-inflammatory drugs (NSAIDs)?    * Includes: aspirin, ibuprofen, naproxen | □ Yes □ No |
| 6. Are you currently pregnant, breastfeeding, or planning on becoming pregnant? | □ Yes □ No |
| 7. Do you have any other medical problems the pharmacist should know? If yes, list them here: | □ Yes □ No |

**Testing and Treatment:**

|  |  |
| --- | --- |
| 1. I understand that the pharmacist must document a negative HIV test to fill my PrEP   prescription. The pharmacist shall dispense a pre-exposure prophylaxis drug in at least a 30-day supply, and up to a 60-day supply as long as:   * + I can bring in my HIV test results, showing negative HIV testing, within the last 7 days     - I brought my labs in today □ Yes □ No   + If the patient does not provide evidence of a negative HIV test, the pharmacist shall order an HIV test | □ Yes □ No |
| 2. I understand that the effectiveness of PrEP is dependent on my taking all my doses. Missing doses increases the risk of getting HIV | □ Yes □ No |
| 3. I understand that the pharmacist may not dispense or administer more than a 60-day supply of a pre-exposure prophylaxis drug to a single patient once every 2 years; unless otherwise directed by a practitioner | □ Yes □ No |

**Please write down the names of any prescription or over the counter medications or supplements you take.**

**Please include herbal and nutritional products as well. This helps the pharmacist make sure you are not taking any contraindicated medications.**

* Evaluate for comorbid medications that can be nephrotoxic or decrease bone mineral density
* Concurrent tenofovir use in conjunction with NSAIDs may increase the risk of kidney damage

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| **Please list any questions you have for the pharmacy staff:** |

**Patient Signature:**  **Date:**

### Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway (CONFIDENTIAL-Protected Health Information)

Name Date of Birth Age Today’s Date

##### Background Information/ HIV and STI risk factors:

Document that a risk factor is present **(circle below)** and refer to the notes and considerations below to evaluate the risk factor(s). If a person has one or more risk factor, PrEP is recommended. The HIV Warmline offers consultations for providers from HIV specialists and is available every day at: (855) 448-7737. For information about PrEP, please visit the [CDC website.](https://www.cdc.gov/hiv/risk/prep/)

|  |  |
| --- | --- |
| **Risk Factor:** | **Notes and Considerations** |
| 1. Sexual partners | * Men who have sex with men activity is highest risk for HIV * Men who have insertive vaginal sex may not be at high risk of HIV unless other risk factors are present |
| 2. Estimated condom use  % of the time  / / last sex without a condom | * Condomless sex greatly increases risk of HIV and STIs * For patients with condomless sex within the last 72 hours, consider Post-Exposure Prophylaxis (PEP) * Condomless sex within last 14 days, repeat HIV test in one month |
| 3. Oral sex | * Oral sex is not considered high risk for HIV unless there is blood or ulcerations in the mouth or genitals * STIs such as gonorrhea and chlamydia can inhabit the mouth and should be screened for in   persons who have oral sex |
| 4. Vaginal sex | * Receptive vaginal sex can be high risk for HIV * Insertive vaginal sex is not considered high risk for HIV unless other risk factors are present |
| 5. Anal sex | * Receptive anal sex has the most risk of HIV of any sex act * Insertive anal sex has high risk for HIV * STIs such as gonorrhea and chlamydia can inhabit the rectum and should be screened in   persons who have anal sex |
| 6. Injection drug use | * Injection drug use is high risk for HIV. Consider referral for syringe exchange or sale of clean syringes |
| 7. HIV-positive partner | * People living with HIV who have undetectable viral loads will not transmit HIV * For partners of people living with HIV, consider partner’s HIV viral load when recommending PrEP |
| 8. Exchanging sex for money or goods | * People who buy or sell sex are at high risk for HIV |
| 9. Popper and/or  methamphetamine use | * Popper (inhaled nitrates) and/or methamphetamine use is associated with an increased risk of HIV |

##### Are one or more risk factors present: □ Yes □ No

* + If yes, HIV PrEP is recommended. Proceed to next section: Testing.
  + *If no, HIV PrEP is not recommended. Refer to a healthcare provider.*

##### Is HIV test complete? □ Yes/Non-reactive □ Yes/Reactive or Indeterminate □ No

* + If yes and non-reactive: Proceed
    - *If yes and reactive or indeterminate: Pharmacist may NOT prescribe PrEP. Patient should be referred to healthcare provider. NOTE: Sample language below*
  + *If no, obtain HIV test. Repeat question #2 once results are available*

*Sample language for reactive or indeterminate tests:*

*Your HIV test has tested reactive (or indeterminate). This is not a diagnosis of HIV or AIDS. We will need to confirm that this is the true result or confirm a result with a more specific test before a diagnosis can be made. We are going to refer you to your health care provider (or your public health department) so that they may perform the confirmatory test and clarify the result. Until you have had your confirmatory test, we are going to recommend you abstain from any condomless sexual activity. We will delay starting your PrEP until we have confirmation that you are HIV negative.*

##### Symptoms:

***Within the last 6 weeks have you experienced any of the following?***

|  |  |
| --- | --- |
| 1. Fever | □ Yes □ No |
| 2. Cough | □ Yes □ No |
| 3. Body aches | □ Yes □ No |
| 4. Headaches | □ Yes □ No |
| 5. Nasal congestion | □ Yes □ No |
| 6. Sore throat | □ Yes □ No |
| 7. Night sweats | □ Yes □ No |
| 8. Mouth ulcers | □ Yes □ No |
| 9. Chills | □ Yes □ No |
| 10. Fatigue | □ Yes □ No |
| 11. Rash | □ Yes □ No |

Medical history factor Notes and Considerations REFERRAL CONDITIONS

|  |  |
| --- | --- |
| 1. Positive HIV test  *Needs Referral:*  *□ Y*es □ No | * A positive or indeterminate HIV test either indicates HIV infection, a false positive, or a result requiring specialist interpretation * Confirmatory testing is beyond the testing capacity of the community pharmacist and the   patient should be referred for PrEP management |

CONSIDERATIONS

|  |  |
| --- | --- |
| 2. Impaired kidney function  □ Yes □ No | * Emtricitabine and tenofovir disoproxil fumarate is approved for patients with a CrCl   >60mL/min   * Consider Emtricitabine and tenofovir alafenamide in cis-gender men and male to female transgender women who have risk factors for kidney disease with a CrCl >30mL/min, but   <60mL/min   * Pharmacist prescribing of PrEP is contraindicated for patients who are under the care of a   specialist for chronic kidney disease |

|  |  |
| --- | --- |
| 3. NSAID use  Precaution- Counseled on limiting use:  □ Yes □ No | * Tenofovir use in conjunction with NSAIDs may increase the risk of kidney damage * Concurrent use is not contraindicated, but patient should be counseled on limiting NSAID use |
| 4. Hepatitis B vaccinated  □ Yes □ No | * Vaccination for Hepatitis B is preferred, but lack of vaccination is not a contraindication for PrEP * Counsel on risk factors for Hepatitis B and recommend vaccination |
| 5. Pregnant or breastfeeding  □ Yes □ No | * Pregnancy and breastfeeding are not contraindications for PrEP. * Women at risk of HIV who are also pregnant are at higher risk of intimate partner violence * Emtricitabine and tenofovir disoproxil fumarate is preferred due to better data in these   populations |

##### Regimen Selection:

|  |  |
| --- | --- |
| **Considerations** | **Preferred regimen** |
| Cis-gender male or male to female transgender woman.   * Both emtricitabine and tenofovir disoproxil fumarate and emtricitabine and tenofovir alafenamide are FDA-approved in these populations. May prescribe based on patient preference | May choose  emtricitabine and tenofovir disoproxil fumarate or  emtricitabine and  tenofovir alafenamide |
| Cis-gender female or female to male transgender man.   * Only emtricitabine and tenofovir disoproxil fumarate is FDA-approved in these populations * If patient has low bone mineral density or renal function that would preclude   emtricitabine and tenofovir disoproxil fumarate use, but has risk factors for HIV, refer the  patient to a specialist for PrEP management | Emtricitabine and tenofovir disoproxil fumarate |
| NSAID use   * If patient is male or a male to female transgender woman, consider emtricitabine and tenofovir alafenamide | Emtricitabine and tenofovir alafenamide |
| Patient has decreased bone mineral density or on medications that affect bone mineral density.   * If patient is male or male to female transgender woman, consider emtricitabine and tenofovir alafenamide | Emtricitabine and tenofovir alafenamide |
| Patient is pregnant or breastfeeding   * Emtricitabine and tenofovir disoproxil fumarate is approved and safe in these populations | Emtricitabine and tenofovir disoproxil fumarate |

**Counseling (at minimum):**

* + Proper use of medication. dosage, schedule, and potential common and serious side effects (and how to mitigate)
  + The importance of medication adherence with relation to efficacy of PrEP
  + Individualized strategies for optimum adherence
  + Behaviorally based adherence improvement strategies, such as pairing medication with established part of daily routine, pill boxes, reminder for daily dose
  + Signs/symptoms of acute HIV infection and recommended actions
  + Appropriate counseling regarding on-going risk for HIV and other STI acquisition
  + Consistent and correct use of condoms and prevention of STIs
  + The necessity of follow up care with a primary care provider for usual care
  + The importance and requirement of testing for HIV, renal function, Hepatitis B, Hepatitis C and STI’s

**Documentation:**

* + The pharmacist documents, to the extent possible, the services provided by the pharmacist in the patient’s record in the patient profile record system maintained by the pharmacy
  + The pharmacist shall maintain records of preexposure prophylaxis drugs dispensed to each patient

**Referrals to primary care provider:**

* + If a patient tests positive for HIV infection or has signs or symptoms of acute HIV infection, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care

### Provider Notification Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV)

Pharmacy Name:

Pharmacy Address: Pharmacy Phone: Pharmacy Fax:

Dear Provider (name) ( ) - (FAX) Your patient (name) / / (DOB)

Has been initiated treatment for HIV Pre-Exposure Prophylaxis (PrEP) by . This regimen was initiated on / / (Date) and follow-up HIV testing is recommended prior to receiving another HIV prevention drug prescription.

**This regimen consists of the following (check one):**

*□* Emtricitabine/tenofovir disoproxil fumarate *□* Emtricitabine/tenofovir alafenamide 200/300mg; One tablet by mouth daily for 200/25mg; tablets One tablet by mouth daily (circle one) 30 days/60 days for (circle one) 30 days/60 days

**Your patient has been tested for and/or indicated the following:**

|  |  |
| --- | --- |
| Test Name | Date of Test Result Needs referral |
| * HIV: | / / □ *reactive* □ *indeterminate* □ negative *□ yes* |

We recommend ordering the following labs as soon as possible: Follow-up HIV test

Hepatitis B surface antigen and surface antibody Hepatitis C antibody

Comprehensive metabolic panel

Treponema pallidum antibody as appropriate Pregnancy test as appropriate

STI screening as appropriate (chlamydia, gonorrhea at affected sites)

We recommend evaluating the patient, confirming the results, and treating as necessary. *Listed below are some key points to know about PrEP.*

**Provider pearls for HIV PrEP:**

* Emtricitabine and tenofovir disoproxil fumarate is not recommended for CrCl <60 mL/min.

Emtricitabine and tenofovir alfenamide is not recommended for CrCl <30 mL/min. Please contact

the pharmacy if this applies to your patient and/or there is a decline in renal function. Emtricitabine and tenofovir alafenamide may be a better option

* Emtricitabine and tenofovir disoproxil fumarate and emtricitabine and tenofovir alafenamide are both safe in pregnancy. If your patient is pregnant or becomes pregnant, they may continue PrEP
* NSAIDs should be avoided while patients are taking HIV PrEP to avoid drug-drug interactions with Emtricitabine and tenofovir disoproxil fumarate
* Emtricitabine and tenofovir disoproxil fumarate is a first-line option for Hepatitis B treatment. This is not a contraindication to PrEP use, but we recommended you refer Hepatitis B positive patients to an infectious disease or gastroenterology specialist
* A positive STI test is not a contraindication for PrEP

**Monitoring of HIV PrEP:**

* It is recommended that your office should take over management of this patient’s HIV PrEP from the

pharmacy as soon as possible

**If you have additional questions, please contact the prescribing pharmacy, or call the HIV Warmline. The HIV Warmline offers consultations for providers from HIV specialists and is available every day at (855) 448-7737. For information about PrEP, please visit th**[**e**](https://www.cdc.gov/hiv/clinicians/prevention/prep.html)[CDC website](https://www.cdc.gov/hiv/basics/prep.html)

**MAINE BOARD OF PHARMACY**

**Preventive Care**

**HIV Pre-Exposure Prophylaxis (PrEP) Statewide Protocol**

Consistent with the manufacturer’s instructions for use approved by the US Food and Drug Administration (FDA), a pharmacist may independently prescribe, dispense and administer HIV prevention drugs.

#### STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

* Utilize the standardized PrEP Patient Intake Form
* Utilize the standardized PrEP Assessment and Treatment Care Pathway Form
* Utilize the standardized PrEP Provider Notification Form

#### PHARMACIST EDUCATION AND TRAINING

* Prior to a pharmacist independently prescribing, dispensing, and administering HIV prevention drugs, the pharmacist shall be knowledgeable of the manufacturer’s instructions for use and shall have completed a comprehensive training program related to the prescribing, dispensing, and administering of HIV prevention drugs.

**\***Note: A pharmacy may create and use an electronic format for the PrEP Patient Intake Form, PrEP Assessment and Treatment Care Pathway, and PrEP Provider Notification if the information is identical to the forms included in this protocol.

### Pre‐Exposure Prophylaxis (PrEP) Self‐Screening Patient Intake Form

### (CONFIDENTIAL‐Protected Health Information)

Date / / Date of Birth / / Age

Legal Name Preferred Name

Sex Assigned at Birth (circle) M / F Gender Identification (circle) M / F / Other Preferred Pronouns (circle) She/Her/Hers, He/Him/His, They/Them/Their, Ze/Hir/Hirs, Other

Street Address Phone ( ) Email Address Healthcare Provider Name Phone ( ) Fax ( ) Do you have health insurance? Yes / No Insurance Provider Name

Any allergies to medications? Yes / No If yes, please list

**Background Information:** These questions are highly confidential and help the pharmacist to determine if PrEP is right for you and what Human Immunodeficiency Virus (HIV) and Sexually Transmitted Infection (STI) testing is recommended.

**Do you answer yes to any of the following? □ Yes □ No** (If any of the following apply to you, check Yes)

|  |
| --- |
| 1. Do you sexually partner with men, women, transgender, or non‐binary people? |
| 2. Please estimate how often you use condoms for sex. Please estimate the date of the last time you had sex without a condom.  % of the time  / / last sex without a condom |
| 1. Do you have oral sex?    * Giving‐ you perform oral sex on someone else    * Receiving‐ someone performs oral sex on you |
| 1. Do you have vaginal sex?    * Receptive‐ you have a vagina and you use it for vaginal sex    * Insertive‐ you have a penis and you use it for vaginal sex |
| 1. Do you have anal sex?    * Receptive‐ someone uses their penis to perform anal sex on you    * Insertive‐ you use your penis to perform anal sex on someone else |
| 6. Do you inject drugs? |
| 7. Are you in a relationship with an HIV‐positive partner? |
| 8. Do you exchange sex for money or goods? (includes paying for sex) |
| 9. Do you use poppers (inhaled nitrates) and/or methamphetamine for sex? |

**Medical History:** These questions are highly confidential and help the pharmacist to determine if PrEP is right for you.

|  |  |
| --- | --- |
| 1. Have you ever tested positive for Human Immunodeficiency Virus (HIV)? | □ Yes □ No |
| 2. Do you see a healthcare provider for management of Hepatitis B? | □ Yes □ No |
| 1. Have you ever received an immunization for Hepatitis B?    * If no, would you like a Hepatitis B immunization today? □ Yes □ No | □ Yes □ No  Date of vaccine / / |

|  |  |
| --- | --- |
| 4. Do you see a healthcare provider for problems with your kidneys? | □ Yes □ No |
| 1. Do you take non‐steroidal anti‐inflammatory drugs (NSAIDs)?    * Includes: aspirin, ibuprofen, naproxen | □ Yes □ No |
| 6. Are you currently pregnant, breastfeeding, or planning on becoming pregnant? | □ Yes □ No |
| 7. Do you have any other medical problems the pharmacist should know? If yes, list them here: | □ Yes □ No |

##### Testing and Treatment:

|  |  |
| --- | --- |
| 1. I understand that the pharmacist must document a negative HIV test to fill my PrEP prescription. The pharmacist shall dispense a pre‐exposure prophylaxis drug in at least a 30‐day supply, and up to a 60‐day supply as long as:   * I can bring in my HIV test results, showing negative HIV testing, within the last 7 days   + I brought my labs in today □ Yes □ No * If the patient does not provide evidence of a negative HIV test, the pharmacist shall order an HIV test | □ Yes □ No |
| 2. I understand that the eﬀectiveness of PrEP is dependent on my taking all my doses. Missing doses increases the risk of getting HIV | □ Yes □ No |
| 3. I understand that the pharmacist may not dispense or administer more than a 60‐day  supply of a pre‐exposure prophylaxis drug to a single patient once every 2 years; unless otherwise directed by a practitioner | □ Yes □ No |

**Please write down the names of any prescription or over the counter medications or supplements you take. Please include herbal and nutritional products as well. This helps the pharmacist make sure you are not taking any contraindicated medications.**

* Evaluate for comorbid medications that can be nephrotoxic or decrease bone mineral density
* Concurrent tenofovir use in conjunction with NSAIDs may increase the risk of kidney damage

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**Please list any questions you have for the pharmacy staﬀ:**

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**Patient Signature:**  **Date:**

### Pre‐Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway (CONFIDENTIAL‐Protected Health Information)

Name Date of Birth Age Today’s Date

##### Background Information/ HIV and STI risk factors:

Document that a risk factor is present **(circle below)** and refer to the notes and considerations below to evaluate the risk factor(s). If a person has one or more risk factor, PrEP is recommended. The HIV Warmline oﬀers consultations for providers from HIV specialists and is available every day at: (855) 448‐7737. For information about PrEP, please visit the CDC website.

|  |  |
| --- | --- |
| **Risk Factor:** | **Notes and Considerations** |
| 1. Sexual partners | * Men who have sex with men activity is highest risk for HIV * Men who have insertive vaginal sex may not be at high risk of HIV unless other risk factors are present |
| 2. Estimated condom use  % of the time  / / last sex  without a condom | * Condomless sex greatly increases risk of HIV and STIs * For patients with condomless sex within the last 72 hours, consider Post‐Exposure Prophylaxis (PEP) * Condomless sex within last 14 days, repeat HIV test in one month |
| 3. Oral sex | * Oral sex is not considered high risk for HIV unless there is blood or ulcerations in the mouth or genitals * STIs such as gonorrhea and chlamydia can inhabit the mouth and should be screened for in   persons who have oral sex |
| 4. Vaginal sex | * Receptive vaginal sex can be high risk for HIV * Insertive vaginal sex is not considered high risk for HIV unless other risk factors are present |
| 5. Anal sex | * Receptive anal sex has the most risk of HIV of any sex act * Insertive anal sex has high risk for HIV * STIs such as gonorrhea and chlamydia can inhabit the rectum and should be screened in persons who have anal sex |
| 6. Injection drug use | * Injection drug use is high risk for HIV. Consider referral for syringe exchange or sale of clean syringes |
| 7. HIV‐positive partner | * People living with HIV who have undetectable viral loads will not transmit HIV * For partners of people living with HIV, consider partner’s HIV viral load when recommending PrEP |
| 8. Exchanging sex for money or goods | * People who buy or sell sex are at high risk for HIV |
| 9. Popper and/or methamphetamine use | * Popper (inhaled nitrates) and/or methamphetamine use is associated with an increased risk of HIV |

##### Are one or more risk factors present: □ Yes □ No

* + If yes, HIV PrEP is recommended. Proceed to next section: Testing.
  + *If no, HIV PrEP is not recommended. Refer to a healthcare provider.*

##### Is HIV test complete? □ Yes/Non‐reactive □ Yes/Reactive or Indeterminate □ No

* + If yes and non‐reactive: Proceed
  + *If yes and reactive or indeterminate: Pharmacist may NOT prescribe PrEP. Patient should be referred to healthcare provider. NOTE: Sample language below*
  + *If no, obtain HIV test. Repeat question #2 once results are available*

*Sample language for reactive or indeterminate tests:*

*Your HIV test has tested reactive (or indeterminate). This is not a diagnosis of HIV or AIDS. We will need to confirm that this is the true result or confirm a result with a more specific test before a diagnosis can be made. We are going to refer you to your health care provider (or your public health department) so that they may perform the confirmatory test and clarify the result. Until you have had your confirmatory test, we are going to recommend you abstain from any condomless sexual activity. We will delay starting your PrEP until we have confirmation that you are HIV negative.*

##### Symptoms:

***Within the last 6 weeks have you experienced any of the following?***

|  |  |
| --- | --- |
| 1. Fever | □ Yes □ No |
| 2. Cough | □ Yes □ No |
| 3. Body aches | □ Yes □ No |
| 4. Headaches | □ Yes □ No |
| 5. Nasal congestion | □ Yes □ No |
| 6. Sore throat | □ Yes □ No |
| 7. Night sweats | □ Yes □ No |
| 8. Mouth ulcers | □ Yes □ No |
| 9. Chills | □ Yes □ No |
| 10. Fatigue | □ Yes □ No |
| 11. Rash | □ Yes □ No |

Medical history factor Notes and Considerations REFERRAL CONDITIONS

1. Positive HIV test

*Needs Referral:*

*□ Y*es □ No

1. Impaired kidney function

□ Yes □ No

* + A positive or indeterminate HIV test either indicates HIV infection, a false positive, or a result requiring specialist interpretation
  + Confirmatory testing is beyond the testing capacity of the community pharmacist and the patient should be referred for PrEP management

CONSIDERATIONS

* + Emtricitabine and tenofovir disoproxil fumarate is approved for patients with a CrCl

>60mL/min

* + Consider Emtricitabine and tenofovir alafenamide in cis‐gender men and male to female transgender women who have risk factors for kidney disease with a CrCl >30mL/min, but <60mL/min
  + Pharmacist prescribing of PrEP is contraindicated for patients who are under the care of a specialist for chronic kidney disease

1. NSAID use Precaution‐ Counseled on limiting use:

□ Yes □ No

1. Hepatitis B vaccinated

□ Yes □ No

* + Tenofovir use in conjunction with NSAIDs may increase the risk of kidney damage
  + Concurrent use is not contraindicated, but patient should be counseled on limiting NSAID use
  + Vaccination for Hepatitis B is preferred, but lack of vaccination is not a contraindication for PrEP
  + Counsel on risk factors for Hepatitis B and recommend vaccination

5. Pregnant or

breastfeeding

□ Yes □ No

•

•

•

Pregnancy and breastfeeding are not contraindications for PrEP.

Women at risk of HIV who are also pregnant are at higher risk of intimate partner violence Emtricitabine and tenofovir disoproxil fumarate is preferred due to better data in these

populations

##### Regimen Selection:

|  |  |
| --- | --- |
| **Considerations** | **Preferred regimen** |
| Cis‐gender male or male to female transgender woman.   * Both emtricitabine and tenofovir disoproxil fumarate and emtricitabine and tenofovir alafenamide are FDA‐approved in these populations. May prescribe based on patient preference | May choose emtricitabine and tenofovir disoproxil fumarate or emtricitabine and  tenofovir alafenamide |
| Cis‐gender female or female to male transgender man.   * Only emtricitabine and tenofovir disoproxil fumarate is FDA‐approved in these populations * If patient has low bone mineral density or renal function that would preclude   emtricitabine and tenofovir disoproxil fumarate use, but has risk factors for HIV, refer the patient to a specialist for PrEP management | Emtricitabine and tenofovir disoproxil fumarate |
| NSAID use   * If patient is male or a male to female transgender woman, consider emtricitabine and tenofovir alafenamide | Emtricitabine and tenofovir alafenamide |
| Patient has decreased bone mineral density or on medications that aﬀect bone mineral density.   * If patient is male or male to female transgender woman, consider emtricitabine and tenofovir alafenamide | Emtricitabine and tenofovir alafenamide |
| Patient is pregnant or breastfeeding   * Emtricitabine and tenofovir disoproxil fumarate is approved and safe in these populations | Emtricitabine and  tenofovir disoproxil fumarate |

**Counseling (at minimum):**

* + - Proper use of medication. dosage, schedule, and potential common and serious side eﬀects (and how to mitigate)
    - The importance of medication adherence with relation to eﬃcacy of PrEP
    - Individualized strategies for optimum adherence
    - Behaviorally based adherence improvement strategies, such as pairing medication with established part of daily routine, pill boxes, reminder for daily dose
    - Signs/symptoms of acute HIV infection and recommended actions
    - Appropriate counseling regarding on‐going risk for HIV and other STI acquisition
    - Consistent and correct use of condoms and prevention of STIs
    - The necessity of follow up care with a primary care provider for usual care
    - The importance and requirement of testing for HIV, renal function, Hepatitis B, Hepatitis C and STI’s

**Documentation:**

* + - The pharmacist documents, to the extent possible, the services provided by the pharmacist in the patient’s record in the patient profile record system maintained by the pharmacy
    - The pharmacist shall maintain records of preexposure prophylaxis drugs dispensed to each patient

**Referrals to primary care provider:**

* + - If a patient tests positive for HIV infection or has signs or symptoms of acute HIV infection, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care

### Provider Notification Pre‐Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV)

Pharmacy Name:

Pharmacy Address:

Pharmacy Phone: Pharmacy Fax:

Dear Provider (name) ( ) ‐ (FAX) Your patient (name) / / (DOB) has been initiated treatment for HIV Pre-Exposure Prophylaxis (PrEP) by .

This regimen was initiated on / / (Date) and follow‐up HIV testing is recommended prior to receiving another HIV prevention drug prescription

**This regimen consists of the following (check one):**

*□* Emtricitabine/tenofovir disoproxil fumarate *□* Emtricitabine/tenofovir alafenamide

200/300mg; One tablet by mouth daily for 200/25mg; tablet; One tablet by mouth daily

(circle one) 30 days/60 days for (circle one) 30 days/60 days

**Your patient has been tested for and/or indicated the following:**

Test Name Date of Test Result Needs referral

* + - * HIV: / / □ *reactive* □ *indeterminate* □ negative *□ yes*

We recommend ordering the following labs as soon as possible: Follow‐up HIV test

Hepatitis B surface antigen and surface antibody Hepatitis C antibody

Comprehensive metabolic panel

Treponema pallidum antibody as appropriate Pregnancy test as appropriate

STI screening as appropriate (chlamydia, gonorrhea at aﬀected sites)

We recommend evaluating the patient, confirming the results, and treating as necessary. *Listed below are some key points to know about PrEP.*

**Provider pearls for HIV PrEP:**

* Emtricitabine and tenofovir disoproxil fumarate is not recommended for CrCl <60 mL/min. Emtricitabine and tenofovir alfenamide is not recommended for CrCl <30 mL/min. Please contact the pharmacy if this applies to your patient and/or there is a decline in renal function. Emtricitabine and tenofovir alafenamide may be a better option
* Emtricitabine and tenofovir disoproxil fumarate and emtricitabine and tenofovir alafenamide are both safe in pregnancy. If your patient is pregnant or becomes pregnant, they may continue PrEP
* NSAIDs should be avoided while patients are taking HIV PrEP to avoid drug‐drug interactions with Emtricitabine and tenofovir disoproxil fumarate
* Emtricitabine and tenofovir disoproxil fumarate is a first‐line option for Hepatitis B treatment. This is not a contraindication to PrEP use, but we recommended you refer Hepatitis B positive patients to an infectious disease or gastroenterology specialist
* A positive STI test is not a contraindication for PrEP

**Monitoring of HIV PrEP:**

* It is recommended that your oﬃce should take over management of this patient’s HIV PrEP from the pharmacy as soon as possible

**If you have additional questions, please contact the prescribing pharmacy, or call the HIV Warmline. The HIV Warmline oﬀers consultations for providers from HIV specialists and is available every day at (855) 448-7737. For information about PrEP, please visit the CDC website.**

**02-392**

**DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION**

**MAINE BOARD OF PHARMACY**

**Appendix 2 to Chapter 43**

**Prescribing, Dispensing, and Administering**

**HIV Prevention Drugs**

**For**

**Preventive Care**

**HIV Post-Exposure Prophylaxis (PEP)**

**Statewide Protocol**

**Adopted April 3, 2025**

**MAINE BOARD OF PHARMACY**

**Preventive Care**

**HIV Post-Exposure Prophylaxis (PEP) Statewide Protocol**

Consistent with the manufacturer’s instructions for use approved by the US Food and Drug Administration (FDA), a pharmacist may independently prescribe, dispense and administer HIV prevention drugs.

#### STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

* Utilize the standardized PEP Patient Intake Form
* Utilize the standardized PEP Assessment and Treatment Care Pathway Form
* Utilize the standardized PEP Patient Informational Handout Form
* Utilize the standardized PEP Provider Notification Form

#### PHARMACIST EDUCATION AND TRAINING

* Prior to a pharmacist independently prescribing, dispensing, and administering HIV prevention drugs, the pharmacist shall be knowledgeable of the manufacturer’s instructions for use and shall have completed a comprehensive training program related to the prescribing, dispensing, and administering of HIV prevention drugs.

**\***Note: A pharmacy may create and use an electronic format for the PEP Patient Intake Form, PEP Assessment and Treatment Care Pathway, PEP Patient Informational Handout, and PEP Provider Notification if the information is identical to the forms included in this protocol.

### Post‐Exposure Prophylaxis (PEP) Self‐Screening Patient Intake Form

### (CONFIDENTIAL‐Protected Health Information)

Date / / Date of Birth / / Age Legal Name Preferred Name

Sex Assigned at Birth (circle) M / F Gender Identification (circle) M / F / Other Preferred Pronouns (circle) She/Her/Hers, He/Him/His, They/Them/Their, Ze/Hir/Hirs, Other

Street Address Phone ( ) Email Address Healthcare Provider Name Phone ( ) Fax ( )

Do you have health insurance? Yes / No Insurance Provider Name

Any allergies to medications? Yes / No If yes, please list

**Information:**

|  |  |  |
| --- | --- | --- |
| 1. | Do you think you were exposed to Human Immunodeficiency Virus (HIV)? | □ Yes □ No □ Not sure |
| 2. | What was the date of the exposure? | / / |
| 3. | What was the approximate time of the exposure? | : *AM/PM* |
| 4. | Was your exposure due to unwanted physical contact or a sexual assault? | □ Yes □ No □ Not sure |
| 5. | Was the exposure through contact with any of the following body fluids? Select any/all that apply:  □ Blood □ Tissue fluids □ Semen □ Vaginal secretions □ Saliva □ Tears □ Sweat □ Other  (please specify): | □ Yes □ No □ Not sure |
| 6. | Did you have vaginal or anal sexual intercourse without a condom? | □ Yes □ No □ Not sure |
| 7. | Did you have oral sex without a condom with visible blood in or on the genitals or mouth of your partner? | □ Yes □ No □ Not sure |
| 8. | Did you have oral sex without a condom with broken skin or mucous membrane of the genitals or oral cavity of your partner? | □ Yes □ No □ Not sure |
| 9. | Were you exposed to body fluids via injury to the skin, a needle, or another instrument or object that broke the skin? | □ Yes □ No □ Not sure |
| 10. | Did you come into contact with blood, semen, vaginal secretions, or other body fluids of one of the following individuals?  □persons with known HIV infection  □men who have sex with men with unknown HIV status  □persons who inject drugs  □sex workers | □ Yes □ No □ Not sure |
| 11. | Did you have another encounter that is not included above that could have exposed you to high risk body fluids? Please specify | Yes □ No □ Not sure |

**Medical History:**

|  |  |  |
| --- | --- | --- |
| 12. | Have you ever been diagnosed with Human Immunodeficiency Virus (HIV)? | □ Yes □ No □ Not sure |
| 13. | Are you seeing a provider for management of Hepatitis B? | □ Yes □ No □ Not sure |
| 14. | Have you ever received immunization for Hepatitis B? If yes, indicate when: If no, would you like a vaccine today? *Yes/No* | □ Yes □ No □ Not sure |
| 15. | Are you seeing a kidney specialist? | □ Yes □ No □ Not sure |
| 16. | Are you currently pregnant? | □ Yes □ No □ Not sure |
| 17. | Are you currently breast‐feeding? | □ Yes □ No □ Not sure |
| 18. | Do you take any of the following over‐the‐counter medications or herbal supplements?  □ Orlistat (Alli®) □ aspirin ≥ 325mg □ naproxen (Aleve®) □ ibuprofen (Advil®)  □ antacids (Tums® or Rolaids®), □ vitamins or multivitamins containing iron, calcium,  magnesium, zinc, or aluminum | □ Yes □ No □ Not sure |
| 19. | Do you have any other medical problems or take any medications, including herbs or supplements? If yes, list them here: | □ Yes □ No □ Not sure |

Signature

Date

### Post‐Exposure Prophylaxis (PEP) of Human Immunodeficiency Virus (HIV)

**Assessment and Treatment Care Pathway (CONFIDENTIAL‐Protected Health Information)**

Name: Date of Birth: / / Today’s Date: / /

|  |  |  |
| --- | --- | --- |
| 1. Is the patient known to be HIV‐positive? | | Notes: |
| * Yes: Do not prescribe PEP. Refer patient to local primary care provider, emergency department, urgent care, infectious disease specialist, or public health department. | * No: Go to #2. |
| 2. What time did the exposure occur? | | Notes: PEP is a time sensitive treatment with evidence supporting use  <72 hours from time of exposure. |
| * >72 hours ago: PEP not recommended. Do not prescribe PEP. Refer patient to local primary care provider, emergency department, urgent care, infectious disease specialist, or public   health department. | * ≤72 hours ago: go to #3 |
| 3. Was the exposure from a source person known to be HIV‐positive? | |  |
| * Yes: Go to #4 | * No: Go to #5 |
| 4. Was there exposure of the patient’s vagina, rectum, eye, mouth, other mucous membrane, or non‐intact skin, or percutaneous contact with the following body fluids: | | Notes: The fluids listed on the far left column are considered high risk while the fluids on the right column are only considered high risk if contaminated with blood. |
| Please check any/all that apply:   * Blood * Semen * Vaginal secretions * Rectal secretions * Breast milk * Any body fluid that is visibly contaminated with blood | Please check any/all that apply (*Note: only applicable if not visibly contaminated with blood*):   * Urine * Nasal Secretions * Saliva * Sweat * Tears * None of the above Go to #5 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| If any boxes are checked, go to #7. |  | | |  |
| 5. Did the patient have receptive/insertive anal/vaginal intercourse without a condom with a partner of known or unknown HIV status? | | | | Notes: This type of exposure puts the patient at a high risk for HIV  acquisition. |
| * Yes: Go to #7 | * No: Go to #6 | | |
| 6. Did the patient have receptive/insertive intercourse without a condom with mouth to vagina, anus, or penis (with or without ejaculation) contact with a partner of known or  unknown HIV status? | | | | Notes: Consider calling the HIV Warmline (888) 448‐ 4911 for guidance. |
| * Yes: Please check all that apply and go to #9: * Was the source person known to be HIV‐positive? * Were there cuts/openings/sores/ulcers on the oral mucosa? * Was blood present? * Has this happened more than once without PEP treatment? * None of the above | | | * No: Use clinical judgement. Risk of acquiring HIV is low. Consider referral.   If clinical  determination is to prescribe PEP then continue to #7. |
| 7. Does the patient have an established primary care provider for appropriate follow‐ up? –OR‐ Can the pharmacist directly refer to another local contracted provider or  public health department for appropriate follow‐up? | | | | Notes: Connection to care is critical for future recommended follow‐up. |
| * Yes: Go to #8 | | * No: Do not prescribe PEP. Refer patient to local primary care provider, emergency department, urgent care, infectious disease specialist, or public health   department. | |
| 8. Does the patient have history of known Hepatitis B infection (latent or active)? | | | | Notes: Tenofovir disoproxil fumarate treats Hepatitis B infection, therefore once stopped and/or completed, the patient could experience an acute Hepatitis B flare. |
| * Yes: Do not prescribe PEP. Refer patient to local primary care provider, emergency department, urgent care, infectious disease specialist, or public health   department. | | * No. Go to #9 | |
| 9. Has the patient received the full Hepatitis B vaccination series? ☐Yes ☐No Verify vaccine records. Dates: | | | |
| * Yes: Go to #11 | | * No: Go to #10 | |
| 10. Review the risks of hepatitis B exacerbation with PEP with the patient. Oﬀer vaccine if appropriate and go to #11. | | | |
| * Vaccine administered   Lot: Exp: Signature: | | | |

|  |  |  |
| --- | --- | --- |
| 11. Does the patient have known chronic kidney disease or reduced renal function? | | Notes: emtricitabine and tenofovir disoproxil fumarate requires renal dose adjustment when the CrCl <50 mL/min. |
| * Yes: Do not prescribe PEP. Refer patient to local primary care provider,   emergency department, urgent care, infectious disease specialist, or public  health department. | * No: PEP prescription recommended. See below for recommended regimen(s) and counseling points. Patient must be warm referred to appropriate provider following prescription of PEP for required baseline and follow‐up testing. Pharmacist must notify both the provider and patient. |

## Regimen Selection (check one):

* **Option 1** **(preferred)**:

Emtricitabine 200mg /tenofovir disoproxil fumarate 300mg (Truvada® or generic) once daily for 28 days PLUS

Raltegravir 400mg twice daily for 28 days

* **Option 2:**

Emtricitabine 200mg /tenofovir disoproxil fumarate 300mg (Truvada® or generic) once daily for 28 days PLUS

Dolutegravir 50mg once daily for 28 days

**Selection Notes:**

* + Dosing adjustments with renal dysfunction if CrCl <50 mL/min
  + If contraindications to raltegravir or dolutegravir exist, or for other reasons the preferred regimen cannot be given, then the “alternate regimens” per CDC guidelines should be referenced and used
  + Other FDA‐approved regimens can be used if they become available. Formulation cautions and dose adjustments for antiretroviral medications shall minimally follow the CDC guidelines and package insert information for all regimens
  + Although labeling is for a 28‐day supply, 30 days is recommended for prescribing due to the products being available only in 30‐day packaging and high cost of the medications which could provide a barrier to availability and care. If able, 28‐day regimens are appropriate if the pharmacist/pharmacy is willing to dispense as such
  + Pregnancy is not a contraindication to receive PEP treatment as Truvada® and Isentress® are preferred medications during pregnancy. If the patient is pregnant, please report their demographics to the Antiretroviral Pregnancy Registry: [http://www.apregistry.com](http://www.apregistry.com/)
  + If the patient is breastfeeding, the benefit of prescribing PEP outweigh the risk of the infant acquiring HIV. Package inserts recommend breastfeeding. “Pumping and dumping” may be considered. Consider consulting with an infectious disease provider, obstetrician, or pediatrician for further guidance
  + If using dolutegravir, monitor for drug-drug interactions and limit the dose of metformin to a maximum of 1,000mg per day

**COUNSELING POINTS (at minimum):**

* + - Proper use of medication, dosage, schedule, and potential common and serious side eﬀects (and how to mitigate)
    - The importance of medication adherence with relation to eﬃcacy of PEP
    - Signs/symptoms of acute HIV infection and recommended actions
    - The patient should be instructed on correct and consistent use of HIV exposure precautions including condoms and not sharing injection equipment
    - For women of reproductive potential with genital exposure to semen, emergency contraception should be discussed
    - The necessity of follow up care with a primary care provider for usual care
    - The importance and requirement of follow up testing for HIV, renal function, hepatic function, hepatitis B and C, and sexually transmitted infections
    - Inform the patient of the availability of pre‐exposure prophylaxis
    - Drug Interactions (such as polyvalent cations with raltegravir/dolutegravir)

PHARMACIST MANDATORY FOLLOW‐UP:

* + - The pharmacist will notify the patient’s primary care provider of the dispensing of the post‐exposure prophylaxis drugs. If the patient does not have a primary care provider, or refuses consent to notify their primary care provider, the pharmacist shall provide the patient a list of physicians, clinics, or other health care providers regarding follow‐up care.

Pharmacist Signature Date / /

**Patient Information**

**Post-Exposure Prophylaxis (PEP) for Human Immunodeficiency Virus (HIV)**

Pharmacy Name:

Pharmacy Address:

Pharmacy Phone Number:

# This page contains important information for you; please read it carefully.

You have been prescribed Post‐Exposure Prophylaxis (PEP) to help prevent Human Immunodeficiency Virus (HIV). Listed below are some key points to remember about these medications, and a list of next steps that will need to be done in order to confirm the PEP worked for you.

**Key Points**

* You must start the medications within 72 hours of your exposure
* Take every dose. If you miss a dose, take it as soon as you remember
  + If it is close to the time of your next dose, just take that dose. Do not double up on doses to make up for the missed dose
* Do not stop taking the medication without first asking your doctor or pharmacist
* The most common side eﬀect is stomach upset. Taking the medication with food can help with stomach upset. Over‐the‐counter nausea and diarrhea medications are okay to use with PEP if needed
* Avoid over‐the‐counter pain medications like ibuprofen or naproxen while taking PEP

**Follow‐up and Next Steps**

1. Contact your primary care provider to let them know you have been prescribed PEP because they will need to order lab tests and see you. The pharmacy cannot do these lab tests.
2. The tests we will be recommending to check at 6 weeks and at 3 months are listed below. The listed labs will involve a blood draw. Your provider may choose to do more tests as needed.

HIV test

Hepatitis B surface antigen and surface antibody Hepatitis C antibody

Treponema pallidum antibody Comprehensive metabolic panel

1. If you think that you might still be at risk of HIV infection after you finish the 28‐day PEP treatment, talk to your doctor about starting Pre‐Exposure Prophylaxis (PrEP) after finishing PEP

**Provider Notification**

**Post-Exposure Prophylaxis (PEP) for Human Immunodeficiency Virus (HIV)**

Pharmacy Name:

Pharmacy Address: Pharmacy Phone: Pharmacy Fax: Dear Provider (name), ( ) ‐ (FAX)

Your patient (name) / / (DOB) has been initiated treatment for HIV Post‐Exposure Prophylaxis (PEP) at Pharmacy.

**This regimen consists of:**

This regimen was initiated on (Date).

We recommend an in‐clinic oﬃce visit with you or another provider on your team within 1‐2 weeks of starting HIV PEP. Listed below are some key points to know about PEP and which labs are recommended to monitor.

**Provider pearls for HIV PEP:**

* Emtricitabine/tenofovir disoproxil fumarate needs renal dose adjustments for CrCl less than 50 mL/min. Please contact the pharmacy if this applies to your patient
* Emtricitabine/tenofovir disoproxil fumarate and raltegravir are both safe in pregnancy. If your patient is pregnant or becomes pregnant, they may continue PEP for the full 28 days
* NSAIDs should be avoided while patients are taking HIV PEP to avoid drug‐drug interactions with emtricitabine/tenofovir disoproxil fumarate
* Emtricitabine/tenofovir disoproxil fumarate is a first‐line option for Hepatitis B treatment. This is not a contraindication to PEP use, but we recommend you refer Hepatitis B positive patients to an infectious disease or gastroenterology specialist
* If your patient continues to have risk factors for HIV exposure, consider starting Pre‐Exposure Prophylaxis (PrEP) after the completion of the 28‐day PEP treatment course

We recommend ordering the following labs at **6 weeks** after the initiation date for HIV PEP: HIV test

Hepatitis B surface antigen and surface antibody Hepatitis C antibody

Comprehensive metabolic panel

Treponema pallidum antibody as appropriate Pregnancy test as appropriate

STI screening as appropriate (chlamydia, gonorrhea at aﬀected sites)

We recommend ordering the following labs at **12 weeks** after the initiation date for HIV PEP: HIV test

We recommend ordering the following labs at **6 months** after the initiation date for HIV PEP: HIV test

Hepatitis C antibody

If you have further questions, please contact the pharmacy or call the HIV Warmline. The HIV Warmline oﬀers consultations for providers from HIV specialists and is available every day at: (888) 448‐4911. For more information about PEP, please visit the CDC website at cdc.gov/hiv/basics/pep.html