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.

2. **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).

        A. **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:

            i. Screening for HIV and sexually transmitted infections (STIs), and laboratory testing to determine PrEP/PEP eligibility;

            ii. Centers for Disease Control and Prevention (CDC) clinical practice guidelines for PrEP/PEP;

            iii. Pharmacology, safety, efficacy, drug-drug interactions, and monitoring parameters for HIV medications used for PrEP/PEP;

            iv. Related trauma-informed care; and

            v. Patient counseling information.

B. **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.
   i. 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.

   ii. 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.

5. **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:

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 XX, 2024 – filing 2024-XX

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 ~~(pp. 2-4)~~
- Utilize the standardized PrEP Assessment and Treatment Care Pathway Form ~~(pp. 5-8)~~
- Utilize the standardized PrEP Provider Notification Form ~~(pp. 9-10)~~

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
3. Do you have oral sex? • Giving- you perform oral sex on someone else • Receiving- someone performs oral sex on you
4. 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
5. 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
3. 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
5. 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

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.

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

1. 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.*

2. 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:* □ *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
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 200/300mg; One tablet by mouth daily for daily (circle one) 30 days/60 days for

□ Emtricitabine/tenofovir alafenamide 200/25mg; tablets One tablet by mouth (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

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.

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- Utilize the standardized PrEP Provider Notification Form ~~(pp. 9-10)~~

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
3. Do you have oral sex? • Giving- you perform oral sex on someone else • Receiving- someone performs oral sex on you
4. 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
5. 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
3. 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
5. 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 o 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

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.

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

1. **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.*

2. **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:* □ 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
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 200/300mg; One tablet by mouth daily for (circle one) 30 days/60 days

□ Emtricitabine/tenofovir alafenamide 200/25mg; tablet; One tablet by mouth daily 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 XX, 2024 – filing 2024-XX

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 ~~(pp. 2-3)~~
- Utilize the standardized PEP Assessment and Treatment Care Pathway Form ~~(pp. 4-7)~~
- Utilize the standardized PEP Patient Informational Handout Form ~~(p. 8)~~
- Utilize the standardized PEP Provider Notification Form ~~(pp. 9-10)~~

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:____/____/_____

<table>
<tr><td colspan="2">1. Is the patient known to be HIV-positive?</td><td rowspan="2">Notes:</td></tr>
<tr><td>☐ Yes: Do not prescribe PEP. Refer patient to local primary care provider, emergency department, urgent care, infectious disease specialist, or public health department.</td><td>☐ No: Go to #2.</td></tr>
<tr><td colspan="2">2. What time did the exposure occur?</td><td rowspan="2">Notes: PEP is a time sensitive treatment with evidence supporting use <72 hours from time of exposure.</td></tr>
<tr><td>☐ >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.</td><td>☐ ≤72 hours ago: go to #3</td></tr>
<tr><td colspan="2">3. Was the exposure from a source person known to be HIV-positive?</td><td rowspan="2"></td></tr>
<tr><td>☐ Yes: Go to #4</td><td>☐ No: Go to #5</td></tr>
<tr><td colspan="2">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:</td><td rowspan="2">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.</td></tr>
<tr><td>Please check any/all that apply:
☐ Blood
☐ Semen
☐ Vaginal secretions
☐ Rectal secretions
☐ Breast milk
☐ Any body fluid that is visibly contaminated with blood</td><td>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</td></tr>
</table>

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
- ~~Dolutegravir should not be used in pregnant women~~
- 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
- 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
3. 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

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.

2. **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).

        A. **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:

            i. Screening for HIV and sexually transmitted infections (STIs), and laboratory testing to determine PrEP/PEP eligibility;

            ii. Centers for Disease Control and Prevention (CDC) clinical practice guidelines for PrEP/PEP;

            iii. Pharmacology, safety, efficacy, drug-drug interactions, and monitoring parameters for HIV medications used for PrEP/PEP;

            iv. Related trauma-informed care; and

            v. Patient counseling information.

B. **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.
   i. 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.

   ii. 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.

5. **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:

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
3. Do you have oral sex? • Giving- you perform oral sex on someone else • Receiving- someone performs oral sex on you
4. 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
5. 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
3. 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
5. 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

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.

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

1. 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.*

2. 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:* □ 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
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 200/300mg; One tablet by mouth daily for daily (circle one) 30 days/60 days for

□ Emtricitabine/tenofovir alafenamide 200/25mg; tablets One tablet by mouth (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

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
3. Do you have oral sex? • Giving- you perform oral sex on someone else • Receiving- someone performs oral sex on you
4. 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
5. 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
3. 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
5. 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 o 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

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.

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

1. **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.*

2. **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:* □ 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
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 200/300mg; One tablet by mouth daily for (circle one) 30 days/60 days

□ Emtricitabine/tenofovir alafenamide 200/25mg; tablet; One tablet by mouth daily 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:____/____/_____

<table>
<tr><td colspan="2">1. Is the patient known to be HIV-positive?</td><td rowspan="2">Notes:</td></tr>
<tr><td>☐ Yes: Do not prescribe PEP. Refer patient to local primary care provider, emergency department, urgent care, infectious disease specialist, or public health department.</td><td>☐ No: Go to #2.</td></tr>
<tr><td colspan="2">2. What time did the exposure occur?</td><td rowspan="2">Notes: PEP is a time sensitive treatment with evidence supporting use <72 hours from time of exposure.</td></tr>
<tr><td>☐ >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.</td><td>☐ ≤72 hours ago: go to #3</td></tr>
<tr><td colspan="2">3. Was the exposure from a source person known to be HIV-positive?</td><td rowspan="2"></td></tr>
<tr><td>☐ Yes: Go to #4</td><td>☐ No: Go to #5</td></tr>
<tr><td colspan="2">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:</td><td rowspan="2">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.</td></tr>
<tr><td>Please check any/all that apply:
☐ Blood
☐ Semen
☐ Vaginal secretions
☐ Rectal secretions
☐ Breast milk
☐ Any body fluid that is visibly contaminated with blood</td><td>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</td></tr>
</table>

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
- 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
3. 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

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 BOARD OF PHARMACY

BASIS STATEMENT AND SUMMARY OF COMMENTS & RESPONSES

CHAPTER NUMBER AND TITLE OF RULE:

Chapter 43 Prescribing, Dispensing and Administering HIV Prevention Drugs (New) 32 M.R.S.A. §§ 13720, 13786-E

Basis Statement

The Notice of Proposed Rulemaking was published on July 10, 2024, and a public hearing was held on August 1, 2024 at 8:30 a.m. with option for the public to testify in-person or virtually. Written comments were also accepted with the public comment period ending on August 12, 2024 at 5:00 p.m. (EST).

Board Rule Chapter 43 is adopted as required by Public Law 2021 Chapter 265 (L.D. 1115 An Act to Improve Access to HIV Prevention Medications) to establish standards for authorizing pharmacists to prescribe, dispense and administer HIV prevention drugs, set adequate training requirements and protocols for when there is no prescription drug order, standing order or collaborative practice agreement. The Board also adopts Appendix 1 and Appendix 2 to this rule as its protocols.

The Board wishes to convey its sincere appreciation for the feedback, comments, suggestions and questions regarding the amendments to the proposed rule.

Comments

List of Commenters:

1) Michael Baxter, Vice President, Federal Government Affairs, American Pharmacist Association, 2215 Constitution Avenue NW, Washington D.C. 20037
2) Amelia Arnold, PharmD, Legislative Liaison, Maine Pharmacy Association (MPA), PO Box 5257, Augusta ME 04332
3) Audrey Wenworth, PharmD, Manager of Pharmacy Health Services, Wendy Boynton RPh, Director of Pharmacy Operations, Hannaford Brothers Co. LLC., 145 Pleasant Hill Road, Scarborough ME 04074
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   WRITTEN COMMENT: The MPA did not explicitly state their position as In Favor, Oppose, NFNA and therefore being listed under NFNA. The MPA stated that it, "has concerns regarding the board being responsible for maintaining and updating the protocol. We recognize it is important to have protocols in place for the prescribing of PREP and PEP medications, but caution if this were to be a board responsibility, would it be feasible for the protocol to be updated in a timely manner when new recommendations are released? MPA would urge to consider another mechanism for maintaining and updating treatment protocol such as employers or recognizing a standard protocol that may already be available through another body."

DRAFT BOARD RESPONSE: Comment not accepted. The Board is mandated by statute to adopt rules that establish these protocols. 32 M.R.S.A. § 13786-E (3).

2) American Pharmacist Association, Michael Baxter, Vice President, Federal Government Affairs

WRITTEN COMMENT: Overall, the APhA stated it is "supportive" of the proposed Chapter 43 rules.

DRAFT BOARD RESPONSE: No Board response required.

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WRITTEN COMMENT: "We are aware that the state of Virginia's protocols have been widely recommended across the country and were pleased to see Maine's protocols mirror those. Shortly before Maine's hearing, we learned that Virginia's BoP is working on enhancing their protocols similar to what the state of Oregon adopted in 2023. In the interest of providing a supportive reference, those protocols can be found here: https://www.oregon.gov/pharmacy/Documents/PHPFAC_Proposed_PrEP_Protocol_v.2023.pdf"

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4) Audrey Wenworth, PharmD, Manager of Pharmacy Health Services, Wendy Boynton RPh, Director of Pharmacy Operations, Hannaford Brothers Co. LLC.

- Section 2. Training, 1, A Training Program:
  Remove requirements of training defined in sub bullets iii and v. These are assumed requirements of a pharmacist professional license. Would expand to updating the current language to *A pharmacist must complete a training program specific to the use of HIV preexposure and postexposure prophylaxis (PrEP/PEP) and* remove reference to the minimum required areas of training.

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   Oral Comments and recommended revisions to the proposed protocols:

   a. Removal of raltegravir the preferred option over dolutegravir Post exposure prophylaxis. I understand that this came from a randomized controlled trial that had an interim analysis that came out in 2018 where there was a signal for the possibility of increased neural tube defect associated with the use of dolutegravir and that initial recommendation came out at that time to recommend use of dolutegravir in pregnancy or in anyone capable of pregnancy or may be newly pregnant. However that analysis was completed and it was determined that there was no difference between dolutegravir and the comparator drugs . That recommendation not to use dolutegravir in pregnancies has since been removed.

      The NIH HIV guidelines now recommend dolutegravir as a preferred treatment for patients who are pregnant or capable of becoming pregnant. Commenter's personal preference is for dolutegravir for post exposure prophylaxis and is safe and effective for pregnancy and is also once a day where adherence is likely to be higher and Shank would prefer not having a for raltegravir over dolutegravir or, even putting dolutegravir first.

   b. In addition, there is a drug interaction between dolutegravir and metformin. Metformin has a maximum dose of 1,000 milligrams. Commenter suggest that this less commonly known drug interaction be added in to the selection notes or the counseling points sections of the post exposure prophylaxis protocol.

   c. There is inconsistency throughout the protocols on the use of non-steroidal anti-inflammatories. While it is true that tenofovir can be nephron-toxic the use of NSAID is not prohibited or contraindicated while taking emtricitabine. The commenter suggests softening the recommendation and have the pharmacist counsel on conservative use of NSAIDs during the course of treatments and that applies to both post exposure prophylaxis and to the pre-exposure prophylaxis section. In the pre-exposure prophylaxis section there are places that say do not use NSAID and there are places that where it says conditional use is permitted. The commenter recommends consistency throughout the document on how pharmacists are asked to respond.

d. Commenter understands the protocol came from the State of Virginia Post exposure protocols and the State of Virginia is working on updating and adopting a different protocol that is more similar to the State of Oregon uses. Commenter indicated she is ok with what is proposed as a provider and clinician for pre-exposure prophylaxis and post exposure prophylaxis and state there were just a few things that could be better.

BOARD RESPONSE: ***Discussion and Response by the Board Required***. The board acknowledges that pharmacists using the adopted protocols that some updates may occur after adoption and to use good judgement. Pharmacists who wish to provide this care should maintain fluency with the best practices. The board concurred that moving forward it does not want to block the practitioner and acknowledges pharmacist using the current protocol. Pharmacists have flexibility of not using the recommended protocol, if a prescription, collaborative practice agreement or a standing order exists where the pharmacist would be following the directions therein. Only if a prescription, collaborative practice agreement or standing order is this protocol expected to be followed. The Legislature has mandated that the board adopt a specific protocol. The board agrees on the importance of reviewing the form regularly for updates.

Board Meeting 10-18-2024

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 BOARD OF PHARMACY

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   a. Removal of raltegravir the preferred option over dolutegravir Post exposure prophylaxis. I understand that this came from a randomized controlled trial that had an interim analysis that came out in 2018 where there was a signal for the possibility of increased neural tube defect associated with the use of dolutegravir and that initial recommendation came out at that time to recommend use of dolutegravir in pregnancy or in anyone capable of pregnancy or may be newly pregnant. However that analysis was completed and it was determined that there was no difference between dolutegravir and the comparator drugs . That recommendation not to use dolutegravir in pregnancies has since been removed.

      The NIH HIV guidelines now recommend dolutegravir as a preferred treatment for patients who are pregnant or capable of becoming pregnant. Commenter's personal preference is for dolutegravir for post exposure prophylaxis and is safe and effective for pregnancy and is also once a day where adherence is likely to be higher and Shank would prefer not having a for raltegravir over dolutegravir or, even putting dolutegravir first.

   b. In addition, there is a drug interaction between dolutegravir and metformin. Metformin has a maximum dose of 1,000 milligrams. Commenter suggest that this less commonly known drug interaction be added in to the selection notes or the counseling points sections of the post exposure prophylaxis protocol.

   c. There is inconsistency throughout the protocols on the use of non-steroidal anti-inflammatories. While it is true that tenofovir can be nephron-toxic the use of NSAID is not prohibited or contraindicated while taking emtricitabine. The commenter suggests softening the recommendation and have the pharmacist counsel on conservative use of NSAIDs during the course of treatments and that applies to both post exposure prophylaxis and to the pre-exposure prophylaxis section. In the pre-exposure prophylaxis section there are places that say do not use NSAID and there are places that where it says conditional use is permitted. The commenter recommends consistency throughout the document on how pharmacists are asked to respond.

d. Commenter understands the protocol came from the State of Virginia Post exposure protocols and the State of Virginia is working on updating and adopting a different protocol that is more similar to the State of Oregon uses. Commenter indicated she is ok with what is proposed as a provider and clinician for pre-exposure prophylaxis and post exposure prophylaxis and state there were just a few things that could be better.

BOARD RESPONSE: ***Discussion and Response by the Board Required.*** The board acknowledges that pharmacists using the adopted protocols that some updates may occur after adoption and to use good judgement. Pharmacists who wish to provide this care should maintain fluency with the best practices. The board concurred that moving forward it does not want to block the practitioner and acknowledges pharmacist using the current protocol. Pharmacists have flexibility of not using the recommended protocol, if a prescription, collaborative practice agreement or a standing order exists where the pharmacist would be following the directions therein. Only if a prescription, collaborative practice agreement or standing order does not exist is this protocol expected to be followed. The Legislature has mandated that the board adopt a specific protocol. The board agrees on the importance of reviewing the form regularly for updates.

Board Meeting 10-18-2024

Betts, Geraldine L

From: Krista Hein <Krista.Hein@albertsons.com>
Sent: Friday, January 10, 2025 4:58 PM
To: Betts, Geraldine L
Subject: PH Ch 43 – 2nd Public Comments
Attachments: ACI Comment Letter - Maine Board of Pharmacy HIV Prevention 1.10.25.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

EXTERNAL: This email originated from outside of the State of Maine Mail System. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Geraldine,

I hope you are doing well! Attached are comments from Albertsons Companies Inc. on PH Ch 43 - Prescribing, Dispensing, and Administering HIV Prevention Drugs. Please let me know if you have any questions.

Have a great weekend!

Thank you,
Krista

Krista Hein, PharmD
Manager, Patient Care Services
Pharmacist Prescribing & Point of Care Testing Services

Albertsons Companies

202-841-1825 cell
623-869-1307 fax
krista.hein@albertsons.com

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January 10, 2025

Jeri Betts
Regulatory Board Manager
35 State House Station
Augusta, ME 04333-0035
Phone: 207-441-1461
Geraldine.L.Betts@maine.gov

Re: PH Ch 43 – 2nd Public Comments: Prescribing, Dispensing, and Administering HIV Prevention Drugs

Dear Board of Pharmacy Members,

I am writing in response to the Maine Board of Pharmacy proposed rulemaking and second public comment period for Chapter 43 establishing standards to authorize pharmacists to prescribe, dispense, and administer HIV prevention drugs. Albertsons Companies Inc. ("ACI") family of pharmacies operates 13 locations in Maine under the Shaws banner. Nationwide, ACI operates 1726 pharmacies across 34 states and the District of Columbia.

ACI pharmacies provide critical support to Maine healthcare infrastructure by filling necessary prescriptions, encouraging vaccination to prevent disease and improve the health of our communities, and administering injectable medications in convenient locations to improve patient adherence. With advancing technology and growing patient demand for pharmacist services, the pharmacy profession should reconsider the regulatory constraints it places on individuals and businesses. ACI supports pharmacists' role as independent prescribers and believes improvements can be made to the proposed regulations to increase utilization and potential uptake of the service.

Protocols and patient algorithms can quickly become static in time and not clinically dynamic with changes in guidelines, requiring state rulemaking for updates. While we recognize there are statutory limitations set forth in the Main Pharmacy Act in Section §13786-E, we recommend the Board not create additional barriers within the protocol process – ensuring simplified attestation of training requirements, no further limitations on approved drugs including injectables, no additional limits on day supply or ordering laboratory testing. These restrictions are above and beyond the statutory requirements and will undoubtedly impact the uptake of the service as well as pharmacist liability when the protocol assessment and treatment pathway is not consistent with clinical guidelines and standard of care. Further, the ability to amend the intake form by combining symptoms will allow for a better patient experience and pharmacy workflow.

Albertsons is an active partner to many states in HIV public health initiatives and commends the Maine State Legislature and the Board in taking steps towards utilizing pharmacist to the full extent of their education, training, and experience. We hope to partner with the Board to learn from the experiences we've had in other state jurisdictions where prescriptive protocols, assessment pathways, and intake forms have created barriers to implementation and a direct loss in potential public health engagement and outcomes.

Thank you for the opportunity to provide public comment on the proposed regulations. If you have any questions as it relates to the impact of these rules, please reach out to me at krista.hein@albertsons.com or 202-841-1825.

Sincerely,

Albertsons Companies

Krista M. Hein

Krista Hein, PharmD
Manager, Patient Care Services
Albertsons Companies Inc.

BOARD OF PHARMACY
NOTICE OF AGENCY RULEMAKING

CHAPTER NUMBER AND TITLE – Routine Technical Rule Proposal

1) Chapter 7: Licensure and Employment of Pharmacy Technicians (Amend)
   32 M.R.S.A. §§13720, 13721(1)(H), 13723
2) Chapter 41: Sale of Nonprescription Drugs Through Vending Machine Outlets (Amend)
   32 M.R.S.A. §§ 13751, 13792(2)
3) Chapter 43: Prescribing, Dispensing and Administering HIV Prevention Drugs (New)
   32 M.R.S.A. §§ 13720, 13786-E
4) Chapter 44: Pharmacist Authorization to Make Certain Contraception Accessible (New)
   32 M.R.S.A. § 13826 (5)

PUBLIC COMMENTS RECEIVED

PUBLIC HEAIRNG HELD AUGUST 1, 2024 AND COMMENT PERIOD ENDED AUGUST 12, 2024 @ 5:00pm

- Amelia Arnold, PharmD, Legislative Liaison | Maine Pharmacy Association, PO Box 5257, Augusta ME 04332
- Michael Baxter, Vice President, Federal Government Affairs, American Pharmacist Association, 2215 Constitution Avenue NW, Washington D.C. 20037
- Katie Rutherford Executive Director, Frannie Peabody Center, Comprehensive HIV and AIDS Services, 30 Danforth St, Suite 309, Portland ME 04101
- Sierra Oliver, PharmD, MPH, BCACP, MaineHealth | Clinical Pharmacist - Primary Care, MaineHealth Primary Care - Family Medicine - *Portland* | *Peaks Island* | *Standish,* MaineHealth Primary Care - Internal Medicine and Pediatrics – *Windham,* Maine Medical Center PGY2 Ambulatory Care Pharmacy Residency Program Coordinator 340 County Road | Westbrook, ME 04092
- Audrey Wenworth, PharmD, Manager of Pharmacy Health Services, Wendy Boynton RPh, Director of Pharmacy Operations, Hannaford Brothers Co. LLC., 145 Pleasant Hill Road, Scarborough ME 04074
- Carly Schenk, Clinical Pharmacist and Board Certified in Infectious Diseases by the Board of Pharmacy Specialties Credentialed by the American Academy of HIV Medicine

MAINE PHARMACY
ASSOCIATION
PO Box 5257 | Augusta, ME | 04332

August 12, 2024

Geraldine Betts
Regulatory Board Manager
35 State House Station
Augusta, ME 04333-0035

Dear Ms. Betts:

The Maine Pharmacy Association would like to submit the following comments on the proposed rules on Chapter 7, Chapter 41, Chapter 43, and Chapter 44 of the Maine Board of Pharmacy Rules. The MPA is the state pharmacy organization that addresses the advocacy, continuing education, and professional needs of all licensed pharmacists, pharmacy technicians, and student pharmacists in Maine. Our mission is to promote public health by advocating for the profession of pharmacy. I submit these comments on behalf of MPA.

Chapter 7: Licensure and Employment of Pharmacy Technicians

- 3-A, 1-3: Clarify that pharmacy technicians will not need to obtain a separate license but may continue to have the authorization to administer vaccines listed as an authority under their Pharmacy Technician license. The MPA has heard from several pharmacies that when pharmacists and technicians need additional licenses instead of having the authority listed under their primary license, it can create issues with the space needed for display and additional barriers to successful license renewals.
- 3-A, 4: Clarify that the training course must be at least six (6) hours in ACPE-approved vaccine-related training. This is consistent with the current language in the law and clarifies that the 20-hour course would also be eligible.
- 4, 2: MPA would offer that where the pharmacist is responsible for the work of each pharmacy technician working under the direct supervision of the pharmacy, adding the last sentence of "the pharmacist is responsible for verification of every vaccine prior to administration" is not necessary. The rules already outline in Section 5, Permissible Duties, Number 4 Responsibility of the Pharmacist that "the pharmacist shall verify and confirm the correctness, exactness, accuracy, and completeness of the acts, tasks and functions undertaken by the pharmacy technician to assist the pharmacist in the practice of pharmacy."

Chapter 41: Sale of Nonprescription Drugs Through Vending Machine Outlets

- MPA has no issue removing the OTC 12-item limit for vending machines.

Chapter 43: Prescribing, Dispensing, and Administering HIV Prevention Drugs

- MPA has concerns regarding the board being responsible for maintaining and updating the protocol. We recognize it is important to have protocols in place for the prescribing of PREP and PEP medications, but caution if this were to be a board responsibility, would it be feasible for the protocol to be updated in a timely manner when new recommendations are released? MPA would urge to consider another mechanism for maintaining and updating treatment protocol such as employers or recognizing a standard protocol that may already be available through another body.

Chapter 44: Pharmacist Authorization to Make Certain Contraception Accessible

- MPA urges the board to authorize the prescribing of hormonal contraception as an authority granted under their primary pharmacist license and not require a separate license due to space issues and creating additional barriers or confusion for license renewals.

The Maine Pharmacy Association is happy to answer any questions from the Board of Pharmacy regarding these rules. Thank you for your time and consideration.

Most Sincerely,

Amelia Arnold, PharmD
Legislative Liaison | Maine Pharmacy Association

APhA
American Pharmacists Association

July 31, 2024

[submitted electronically via: Geraldine.L.Betts@maine.gov]

Geraldine Betts
Regulatory Board Manager 35 State House
Station Augusta, ME 04333-0035

Dear Ms. Betts:

The American Pharmacists Association (APhA) appreciates the opportunity to provide comments on the Maine Board of Pharmacy's proposed rules[1] that will be discussed during the August Board of Pharmacy Meeting. APhA thanks Governor Janet Mills and the Board of Pharmacy for the implementation of these important legislative changes that will increase patient access to services provided by pharmacists and pharmacy technicians.

Overall, APhA is supportive of the proposed rules to amend Chapter 7: Licensure and Employment of Pharmacy Technicians, and to create Chapters 43: Prescribing, Dispensing and Administering HIV Prevention Drugs and 44: Pharmacist Authorization to Make Certain Contraception Accessible.

In addition to our overall support, APhA provides the following minor recommendation to minimize any unintended consequences from the proposed changes. With the proposed new rule, Chapter 44: Pharmacist Authorization to Make Certain Contraception Accessible, APhA respectfully requests the following language be stricken (lined out below) from the well-intended "Authorization Required" section of the proposed rule:

> "No pharmacist shall prescribe, dispense and administer~~, including according to a standing order or a collaborative drug therapy management agreement,~~ a self-administered hormonal contraceptive or an injectable hormonal contraceptive before having been issued authorization as described in this chapter by the board."

The requirements outlined in subsection 3 of 32 M.R.S. § 13826 are specific to the prescriptive authority outlined in that section and does not mention standing orders or collaborative drug therapy management agreements or refer to their relevant sections of statute. Pharmacists that have been prescribing hormonal contraceptives for years via standing orders or collaborative drug therapy management agreements should not now have to complete the requirements of subsection 3 of 32 M.R.S. § 13826. Without any statutory

[1] https://www.maine.gov/pfr/professionallicensing/sites/maine.gov.pfr.professionallicensing/files/inline-files/PUBLIC_DISTRIBUTION_Rulemaking_Notice_Proposed_Rule_1.pdf

2215 Constitution Ave. NW
Washington, DC 20037
800 237 2742
pharmacist.com

mandate that pharmacists prescribing hormonal contraceptives via standing orders or collaborative drug therapy management agreements must complete the requirements outlined in 32 M.R.S. § 13826, APhA respectfully requests the above language be stricken from the well-intended proposed rule.

Thank you for the opportunity to provide these supportive comments and minor recommendations. If you have any questions or require additional information, please do not hesitate to contact E. Michael Murphy, PharmD, MBA, APhA Senior Advisor for State Government Affairs by email at mmurphy@aphanet.org.

Sincerely,

Michael Baxter

Michael Baxter
Vice President, Federal Government Affairs

About APhA: APhA is the largest association of pharmacists in the United States advancing the entire pharmacy profession, including 1,370 licensed pharmacists in Maine. APhA represents pharmacists in all practice settings, including community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care and enhance public health. APhA represents pharmacists and students who practice in numerous settings and provide care to many of your constituents. As the voice of pharmacy, APhA leads the profession and equips members for their role as the medication expert in team-based, patient-centered care. APhA inspires, innovates, and creates opportunities for members and pharmacists worldwide to optimize medication use and health for all.

FRANNIE PEABODY
CENTER
Comprehensive HIV & AIDS Services

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Katie Rutherford
Executive Director

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Client Services & Administration
Phone: (207) 774-6877
Fax: (207) 879-0761

HIV Prevention Services
HIV Testing: (207) 749-6818
Fax: (207)879-0761

info@peabodycenter.org

August 2, 2024

Maine Board of Pharmacy
Attn: Geraldine Betts, Regulatory Board Manager
35 State House Station
Augusta, ME 04333-0035

Members of the Board of Pharmacy;

Frannie Peabody Center is Maine's largest community-based HIV services organization, providing comprehensive care for people living with HIV/AIDS in Maine through case management, housing assistance, and peer support, as well as free rapid HIV and Hepatitis C testing services.

We appreciate the Board's hard work in proposing rules for Pharmacists' Prescribing, Dispensing, and Administering HIV Prevention Drugs. This is such an important step in expanding access to critical prevention services for people at risk for HIV. While we do not bring pharmacological expertise to this process, we frequently support members of our community with PrEP and PEP navigation, particularly in cases where people face significant barriers to accessing these resources from a medical provider.

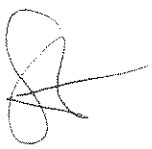
As mentioned at the Board of Pharmacy Public Hearing on August 1, 2024, we are supportive of the protocols as presented, and defer to our HIV specialty pharmacist partners with regard to the preferred medication regimen and selection notes in the protocols.

We are aware that the state of Virginia's protocols have been widely recommended across the country and were pleased to see Maine's protocols mirror those. Shortly before Maine's hearing, we learned that Virginia's BoP is working on enhancing their protocols similar to what the state of Oregon adopted in 2023. In the interest of providing a supportive reference, those protocols can be found here: https://www.oregon.gov/pharmacy/Documents/PHPFAC_Proposed_PrEP_Protocol_v.2023.pdf

Frannie Peabody Center recognizes the important role we can play in supporting individuals navigating these services as they are implemented, and contributing to the capacity needs of pharmacists to ensure individuals can access resources effectively. We will continue to advocate for policy pathways to ensure the services delivered by pharmacists in accordance with these protocols are covered by public and private health insurance.

Thank you again for your hard work and contributions toward ending the HIV epidemic.

Sincerely,



Katie Rutherford
Executive Director

58B8981A.msg

Pharmacist Testimony on Rulemaking

Oliver, Sierra N <Sierra.Oliver@mainehealth.org>
To Betts, Geraldine L
Cc Haas, Nicholas P
You replied to this message on 8/2/2024 12:51 PM.

Reply | Reply All | Forward | ...
Fri 8/2/2024 11:21 AM

EXTERNAL: This email originated from outside of the State of Maine Mail System. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hello Geradline,

I am sending comments regarding setting standards by which a pharmacy technician may qualify to be certified to administer vaccines as proposed amendment for Chapter 7 in accordance with PL 2023 Chapter 245.

The requirements in this proposal for a licensed pharmacy technician to administer vaccinations are much less stringent than a licensed pharmacist to provide vaccinations.

Currently, a licensed pharmacist must have either graduated pharmacy school within the previous 3 years OR completed a 20-hour training certificate within the previous 3 years OR have been licensed in a different state to administer vaccines within the previous 3 years to obtain their Administration of Drugs and Vaccines certification. Additionally, the pharmacist is required to have basic life support training.

This proposal for technicians states they are to complete six (6) hours in an ACPE-approved vaccine-related training. There is no time frame for when the individual has to complete this training; however, our pharmacists have to have completed 20 hours of training within the previous 3 years.

My comment about this proposal is to define a time frame for the technicians' training to obtain their vaccine license or perhaps (more favorably), remove the 3-year time frame for licensed pharmacists to obtain their Administration of Drugs and Vaccines certification. Pharmacists go through extensive college education, clinical experiences, and some even complete post-graduate training to learn about drugs and vaccines, so why would their requirements to administer these items be harder to obtain than it is for a pharmacy technician?

Additionally, please consider the appropriateness of technicians remaining up to date on basic life support training. This may be appropriate if they will be administering vaccines with potential for patients to have a reaction or serious life event.

Thanks,

Sierra Oliver, PharmD, MPH, BCACP *(she/her)*
MaineHealth | Clinical Pharmacist - Primary Care
MaineHealth Primary Care - Family Medicine - *Portland* | *Peaks Island* | *Standish*
MaineHealth Primary Care - Internal Medicine and Pediatrics - *Windham*
Maine Medical Center PGY2 Ambulatory Care Pharmacy Residency Program Coordinator
340 County Road | Westbrook, ME 04092
Office: 207-661-3466 | sierra.oliver@mainehealth.org

PATIENT CENTERED RESPECT INTEGRITY EXCELLENCE OWNERSHIP INNOVATION

Wendy Boynton RPh
Director of Pharmacy Operations
Hannaford Brothers Co. LLC.
t: 207-885-3738
e: wboynton@hannaford.com

From: Audrey Wentworth <Audrey.Wentworth@hannaford.com>
Sent: Tuesday, August 6, 2024 2:07 PM
To: Geraldine.L.Betts@maine.gov
Cc: Wendy Boynton <wboynton@hannaford.com>; Sara Lane <slane@hannaford.com>
Subject: PHarmacy Testimony on Rulemaking

Good Afternoon

Please see the attached document for public comment from Hannaford Pharmacy on the Routine Technical Rule Proposals that were discussed at the August 1st, 2024, Board of Pharmacy Meeting.

Thank you,

Audrey Wentworth, PharmD
Manager of Pharmacy Health Services
Hannaford Supermarket & Pharmacy

office: 207-885-2008
fax: 704-212-0053
email: audrey.wentworth@hannaford.com

145 Pleasant Hill Road
Scarborough, ME 04074
www.hannaford.com

NOTICE OF AGENCY PROPOSED RULEMAKING- Maine Board of Pharmacy

Routine Technical Rule Proposal Public Comment

Maine Board of Pharmacy Members,

This document is to serve as public comment on the proposed amended and new rules from Hannaford Pharmacy.

Chapter 7: Licensure and Employment of Pharmacy Technicians (Amend)

32 M.R.S.A. §§13720, 13721(1)(H), 13723

1-A License Requirement

- Remove this section from the rules. This is covered under Section 5 Permissible Duties already. To expand on this comment, it would be more effective to only list the Limitations of a Pharmacy Technicians in the rules and leave the Permissible Duties at the discretion of the licensed pharmacist on duty.

Pharmacy Technician Certification to Administer Vaccines

3-A, 1-3: Application, License Required and Certification Term

- Proposal to have one license for a technician be explored as part of this rule making. Hannaford is actively expanding the number of technicians that can vaccinate the community and with the requirement of two

licenses (Pharmacy Technician and Certification to Administer Vaccines) there is concern with limited space in the pharmacies to display these additional licenses. This would require multiple renewals and fees, which would create a barrier for successful license renewal.

3-A, 4: Training. An applicant must provide proof of completion of six (6) hours in an ACPE-approved vaccine-related training consistent with 32 M.R.S. § 13831(6)(D).

- This statement should match the current 32 M.R.S. § 13831(6)(D) rules which include the following language; *at least 6 hours of vaccine-related training.* This is to ensure those that completed the 20-hour course would also be eligible in these rules.

3-A,5 Vaccine Administration Requirements:

B and C refer to the pharmacist's responsibilities and counseling, should not apply to the technician responsibilities when administering a vaccine.

To remove from the rules:

B. Prior to administering the vaccine to the patient, the pharmacy technician shall give each patient or the patient's legal representative the 5 appropriate vaccine information for the vaccine to be administered. The pharmacy technician shall review with the patient or patient's legal representative the portions of the statement describing the risks of the vaccine and what to look for and what to do in the event of a severe reaction. Questions from the patient or patient's legal representative that are beyond a routine review of the statement describing the risks of the vaccine shall be directed to a licensed pharmacist for patient counseling.

C. After providing the vaccine information, but prior to administration, the pharmacy technician who holds a certificate of administration shall obtain in writing the informed consent of the patient or the patient's legal representative to administration of the vaccine and to emergency administration of epinephrine, diphenhydramine or both by the pharmacist if the patient has an adverse reaction to the vaccine administered. A pharmacy technician shall seek review of the informed consent by the pharmacist if the patient has indicated any reason they may be ineligible for the vaccine requested;

3-A, 6 Supervision: The pharmacy technician shall perform all functions associated with administration of vaccines under the direct supervision of a licensed pharmacist who has received from the board certification to administer vaccines.

- Expand the definition of direct supervision to include by electronic and virtual means. This request would apply to All Chapter rules and definitions.

3-A, 4, 2 Supervision by Pharmacist in Charge: See above comments.

3-A, 8 Identification:

- Looking for clarification on the requirement to identify technicians as, Board-certified to Administer Vaccines. It is not a requirement to identify any other professional who has completed the training to administer vaccines (i.e. Doctors, nurses, pharmacists, etc.). Hannaford would comment to remove this section from the rules.

Chapter 43: Prescribing, Dispensing and Administering HIV Prevention Drugs (New): 32 M.R.S.A. §§ 13720, 13786-E

2. Training

1, A Training Program:

- Remove requirements of training defined in sub bullets iii and v. These are assumed requirements of a pharmacist professional license. Would expand to updating the current language to *A pharmacist must*

complete a training program specific to the use of HIV preexposure and postexposure prophylaxis (PrEP/PEP) and remove reference to the minimum required areas of training.

1, B Protocol Training:

- Concern on the time to maintain and update the protocol for the board. What will the process look like? These group of medications require frequent updates, not limited to; therapeutic recommendations, side effects, medications that hit the market. Remove from the rules and create the requirements of a protocol to be developed and maintain by the pharmacy employers.

3. Protocol

- See above comments. Remove protocol pages 14-51 from rule making. Support and refer to Carly Schenk's public verbal comment from the meeting on Thursday August 1st. Similar language/requirements could be captured in these rules as they are in Chapter 44.

Chapter 44: Pharmacist Authorization to Make Certain Contraception Accessible (New): 32M.R.S.A. § 13826(5)

2 Contraceptive Authorization:

- Review the requirements to have a separate license for authorization under this chapter. There is concern with limited space in the pharmacies to display these additional licenses. This would require multiple renewals and fees, which would create a barrier for successful license renewal.

3, C:

- Remaining current with best practices for the prescribing, dispensing and administering of hormonal contraceptive or injectable hormonal contraceptive could be captured in a CE and is part of the pharmacist professional license. Who defines a best practice?

Thank you for your consideration,

Wendy Boynton, Director of Pharmacy Operations

Audrey Wentworth, Manager of Pharmacy Health Services

Sara Lane, Manager of Pharmacy Clinical Services

MAINE BOARD OF PHARMACY
PUBLIC HEARING ON PROPOSED RULES DATE: August 1, 2024 **TIME:** 8:30 a.m. (Virtual public comments)

Chapter 7 Licensure and Employment of Pharmacy Technicians (Amend)

Favor – No Comments

Opposition – No Comments

NFNA – No Comments

Chapter 41 Sale of Nonprescription Drugs Through Vending Machine Outlets (Amend)

Favor – No Comments

Opposition - No Comments

NFNA – No Comments

Chapter 43 Prescribing, Dispensing and Administering HIV Prevention Drugs (New)

Favor –

1) Katie Rutherford, Frannie Peabody HIV Center.

   Commenter is excited to see the rules adopted. The commenter is looking forward to working on other policy pathways to ensure that pharmacies will be reimbursed for the services for that these rules can be implemented effectively and grateful to the Board for working on this (rulemaking) and moving forward on this huge national effort in taking steps to end the national HIV epidemic.

Opposition – No comments

NFNA -

1) Carly Schenk, clinical pharmacist in the Portland area and board certified in infectious diseases by the board pharmacy specialties credentialed by the American Academy of HIV Medicine as an HIV pharmacist expert. Shank thanked the board for the hard work preparing the proposed rule to allow pharmacists to prescribe, dispense post exposure prophylaxis for HIV prevention. As the most accessible health care professions it is important that patients across the largely rural state of Maine have access to HIV preventative care which these rules provide.

   Oral Comments and recommended revisions to the proposed protocols:

   a. Removal of raltegravir the preferred option over dolutegravir Post exposure prophylaxis. I understand that this came from a randomized controlled trial that had an interim analysis that came out in 2018 where there was a signal for the possibility of increased neural tube defect associated with the use of dolutegravir and that initial recommendation came out at that time to recommend use of dolutegravir in pregnancy or in anyone capable of pregnancy or may be newly pregnant. However that analysis was completed and it was determined that there was no difference between dolutegravir and the comparator drugs . That recommendation not to use dolutegravir in pregnancies has since been removed.

      The NIH HIV guidelines now recommend dolutegravir as a preferred treatment for patients who are pregnant or capable of becoming pregnant. Commenter's personal preference is for dolutegravir for post exposure prophylaxis and is safe and effective for pregnancy and is also once a day where adherence is likely to be higher and Shank would prefer not having a for raltegravir over dolutegravir or, even putting dolutegravir first.

   b. In addition, there is a drug interaction between dolutegravir and metformin. Metformin has a maximum dose of 1,000 milligrams. Commenter suggest that this less commonly known drug interaction be added in to the selection notes or the counseling points sections of the post exposure prophylaxis protocol.

   c. There is inconsistency throughout the protocols on the use of non-steroidal anti-inflammatories. While it is true that tenofovir can be nephron-toxic the use of NSAID is not prohibited or contraindicated while taking emtricitabine. The commenter suggests softening the recommendation and have the pharmacist counsel on conservative use of NSAIDs during the course of treatments and that applies to both post exposure prophylaxis and to the pre-exposure prophylaxis section. In the pre-exposure prophylaxis section there are places that say do not use NSAID and there are places that where it says conditional use is permitted. The commenter recommends consistency throughout the document on how pharmacists are asked to respond.

d. Commenter understands the protocol came from the State of Virginia Post exposure protocols and the State of Virginia is working on updating and adopting a different protocol that is more similar to the State of Oregon uses. Commenter indicated she is ok with what is proposed as a provider and clinician for pre-exposure prophylaxis and post exposure prophylaxis and state there were just a few things that could be better. (At this point President Kane stated that the board would be happy to review her verbal and written comments.)

Chapter 44 Pharmacist Authorization to Make Certain Contraception Accessible (New)

Favor – No Comments

Opposition – No Comments

NFNA – No Comments

Hearing closed at 8:56 a.m.

Betts, Geraldine L

From: Aytay, Michelle <michelle.aytay@walgreens.com>
Sent: Friday, January 10, 2025 4:19 PM
To: Betts, Geraldine L
Cc: Cover, Nichole
Subject: PH Ch 43 – 2nd Public Comments
Attachments: Walgreens Comment Letter ME PH Ch 43 – 2nd Public Comments.pdf

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Hi Ms. Betts,

I have attached Walgreens comments on proposed rule number: 2024-P203 Chapter 43: Prescribing, Dispensing and Administering HIV Prevention Drugs. Please let me know if you have any questions.

Warm Regards,

Michelle

Michelle Aytay, RPh, CDE
Manager, Pharmacy Affairs

Walgreen Co.
Telephone 612-251-6508

Member of Walgreens Boots Alliance | MyWalgreens.com

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Walgreens

Nichole Cover, R.Ph.
Director, Pharmacy Affairs
Walgreen Co.
p: 224-507-9405
nichole.cover@walgreens.com

January 10, 2025

Maine Board of Pharmacy
Jeri Betts, Regulatory Board Member
35 State House Station
Augusta, ME 0433300035
Geraldine.L.Betts@maine.gov

Re: Comments on proposed rule number: 2024-P203 Chapter 43: Prescribing, Dispensing and Administering HIV Prevention Drugs

Dear Ms. Betts,

On behalf of all pharmacies owned and operated by Walgreen Co. in the state of Maine, we thank the Board for the opportunity to provide comments on your proposed rule number: 2024-P203 Chapter 43: Prescribing, Dispensing and Administering HIV Prevention Drugs. Walgreens appreciates the Board's time and effort related to enacting standards authorizing pharmacists to prescribe, dispense and administer HIV prevention drugs and considering public comments on these rules.

Walgreens respectfully requests the Board to consider the following recommendations and proposed amendments as outlined below during your review process.

Chapter 43: PRESCRIBING, DISPENSING AND ADMINISTERING HIV PREVENTION DRUGS Section 4.

Walgreens supports the Board's position to ensure that clinical practice changes and updates are not held back by the law. There can be a potential risk when pharmacists deviate from adopted protocols based solely on professional judgement without clear evidence based clinical guidelines. Walgreens therefore recommends the following amended language.

Section 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~~ evidence based clinical guidelines have changed since the adoption of the Board-approved protocol and it is not possible to follow both the applicable protocol and the updated guidelines, ~~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 evidence based clinical guidelines ~~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 clinical guidelines ~~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.

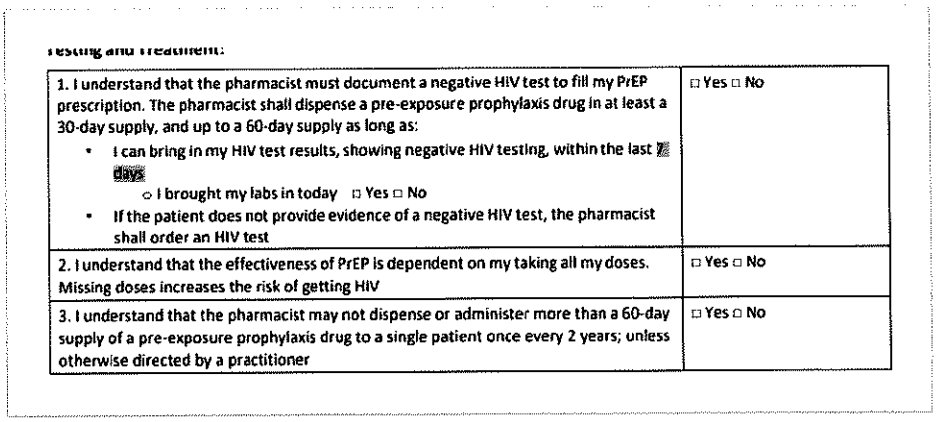
Preventative Care HIV Pre-Exposure Prophylaxis (PrEP) Statewide Protocol
Walgreens thanks the Board for their extensive and thorough work on developing the Statewide Protocol. We respectfully ask the Board to please consider the following during your review process.

- Maine allows a patient to bring a test or if not, the pharmacist can order one. Maine also allows pharmacists to order CLIA-waived tests. However, in the protocol, I do not see a specific test defined. Does the Board have a specific test they recommend or is it the intent all HIV tests are acceptable?

2. 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***

- The **Pre-Exposure Prophylaxis (PrEP) Self-Screening Patient intake Form** includes that a "test result must be within the last 7 days." Walgreens recommends updating this section to add language that the patient should abstain during this time frame.



Testing and Treatment:

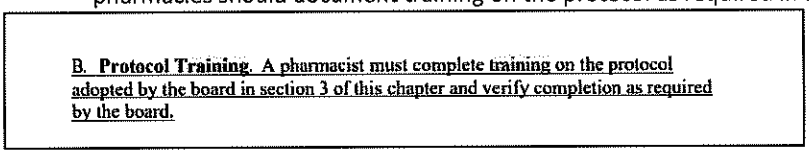
1. I understand that the pharmacist must document a negative HIV test to fill my PrEP prescription. The pharmacist shall dispense a pre-exposure prophylaxis drug in at least a 30-day supply, and up to a 60-day supply as long as: • I can bring in my HIV test results, showing negative HIV testing, within 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

- Walgreens recommends explicitly indicating that the pharmacist needs to complete the **Pre-Exposure Prophylaxis(PrEP) Assessment and Treatment Care Pathway form.**

- There are CDC guidelines around clinical follow up and monitoring for oral PrEP patients. Based on our review, these follow up and monitoring oral PREP guidelines are not addressed. Is there an expectation for Maine pharmacists to follow up and monitor oral PrEP patients, including kidney, liver and STI testing.

- The **Pre-Exposure Prophylaxis(PrEP) Assessment and Treatment Care Pathway** form includes a couple of patient disclosed questions regarding impaired kidney function. Most of these questions are in a yes or no format. Clinically, from a patient safety perspective, there could be risk and potential harm of prescribing oral PrEP simply based on a patient attestation.

- Section 2(1)(b) requires that a pharmacist must complete training on the protocol. Can the Board please clarify how pharmacies should document training on the protocol as required in Section 2(1)(B) Training?



B. **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.

Walgreens thanks the Board for the opportunity to comment on these proposed regulations. If the Board would like additional information, please feel free to contact me.

Sincerely,

Nichole Cover R.Ph.

Nichole Cover, RPh

MAINE DEPARTMENT OF PROFESSIONAL & FINANCIAL REGULATION
Office of Professional and Occupational Regulation
BOARD OF PHARMACY
35 State House Station, Augusta, ME 04333
Web Address: www.maine.gov/professionallicensing 207-624-8625

Janet T. Mills
Governor

To: Christopher J. Parr, Director of Rulemaking and APA Compliance, Maine Office of Secretary of State ~~#148~~ 101 SHS

From: Geraldine Betts, Administrator

RE: Notice of Rule Adoption – 02-392 Board of Pharmacy
Chapter 43 Prescribing, Dispensing and Administering HIV Prevention Drugs (New)
Appendix 1 Preventive Care HIV Pre-Exposure Prophylaxis (PrEP) Statewide Protocol and
Appendix 2 Preventive Care HIV Post-Exposure Prophylaxis (PEP) Statewide Protocol

Date: April 29, 2025

The following is a list of electronic documents that accompany this email today. The hardcopies will be sent by interoffice mail as quickly as possible.

- APA Checklist for Chapter 43 Prescribing, Dispensing and Administering HIV Prevention Drugs together with Appendix 1 & 2
- MAPA-4 Rulemaking Adoption Notice
- Signed MAPA-1 sheet (original with "wet" signatures of the Board President and the Assistant Attorney General assigned to review the final rule for form and legality (delivered with packet being mailed by interoffice)
- Fact Sheet
- Small Business and Economic Impact Statement
- Basis Statement and Response to Comments 2nd round and copy of 1st round
- **Chapter 43 Prescribing, Dispensing and Administering HIV Prevention Drugs together with Appendix 1 & 2**. This is an entirely new chapter and therefore there are no strikeouts.

The paper packet will be sent interoffice tomorrow as soon as the AAG delivers the ink signed Mapa-1 in the morning tomorrow, April 30. I am retiring, and my last day is tomorrow. This rulemaking has been a long haul and was important to me to get it completed and submitted to your office.

Thank you.

Small Business and Economic Impact Statement

(5 M.R.S. § 8052(5-A))

AGENCY: 02-392, Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, Maine Board of Pharmacy

NAME, ADDRESS, PHONE NUMBER, E-MAIL OF AGENCY CONTACT PERSON: Geraldine Betts, Regulatory Board Manager, 35 State House Station, Augusta, ME 04333-0035, 207-624-8625, TTY users call Maine Relay 711, Geraldine.L.Betts@maine.gov

CHAPTER NUMBER AND RULE TITLE:
Chapter 43: Prescribing, Dispensing and Administering HIV Prevention Drugs, including: Appendix 1 Preventive Care HIV Pre-Exposure Prophylaxis (PrEP) Statewide Protocol and Appendix 2 Preventive Care HIV Post-Exposure Prophylaxis (PEP) Statewide Protocol

TYPES AND NUMBER OF SMALL BUSINESSES SUBJECT TO THE RULE: The Board of Pharmacy licenses 9,939 individuals in various areas of practice and pharmaceutical entities, of which 3,131 are licensed pharmacists, 2,958 are licensed pharmacy technicians, 222 are licensed pharmacy interns, and 1 pending vending machine outlet. Title 5 M.R.S. § 8052 (5-A) defines "small business" as businesses that have 20 or fewer employees. The Board of Pharmacy does not collect sufficient information to reliably estimate the number of licensees that are small businesses as defined in 5 M.R.S. § 8052(5-A).

PROJECTED REPORTING, RECORD-KEEPING AND OTHER ADMINISTRATIVE COSTS REQUIRED FOR COMPLIANCE WITH THE PROPOSED RULE, INCLUDING THE TYPE OF PROFESSIONAL SKILLS NECESSARY FOR PREPARATION OF THE REPORT OR RECORD: Unknown.

PROBABLE IMPACT ON AFFECTED SMALL BUSINESSES: Unknown. The Board does not collect of have sufficient information to project probable impact, if any.

LESS INTRUSIVE OR LESS COSTLY, REASONABLE ALTERNATIVE METHODS OF ACHIEVING THE PURPOSES OF THE PROPOSED RULE: Unknown. The Board does collect of have sufficient information to project probable impact, if any.

Rulemaking Fact Sheet

(5 MRSA §8057-A)

AGENCY: 02-392, Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, 02-392 Maine Board of Pharmacy

NAME, ADDRESS, PHONE NUMBER, EMAIL OF AGENCY CONTACT PERSON:
Jeri Betts, Regulatory Board Manager, 35 State House Station, Augusta, ME 04333-0035, 207-624-8625, TTY users call Maine Relay 711, Geraldine.L.Betts@maine.gov

CHAPTER NUMBER AND RULE TITLE:
Chapter 43: Prescribing, Dispensing and Administering HIV Prevention Drugs, including:
Appendix 1 Preventive Care HIV Pre-Exposure Prophylaxis (PrEP) Statewide Protocol and
Appendix 2 Preventive Care HIV Post-Exposure Prophylaxis (PEP) Statewide Protocol

TYPE OF RULE *(check one)*: ☒ Routine Technical ☐ Major Substantive

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

DATE, TIME AND PLACE OF PUBLIC HEARING: Due to substantive changes to the proposed rules from public comments received during the first public comment period the substantive proposed rules were reopened for additional public comments. A public hearing was not held for the second public comment, only a 30-day written public comment period. The first public hearing was held on August 1, 2024, 8:30 a.m. (EST), Maine Department of Professional and Financial Regulation, Gardiner Annex, 76 Northern Ave., Gardiner ME and option for remote participation by Zoom Meeting link https://mainestate.zoom.us/j/9733636344?pwd=ZHdIVnI5NWRvMlZrZkVjR0lkRFVsZz09&omn=82216714770
Copy of the proposed rules were made available https://www.maine.gov/pfr/professionallicensing/professions/board-pharmacy/home/board-meeting-information,

COMMENT DEADLINE: Reopened public comment session closed January 10, 2025, 5:00 p.m. (EST)

PRINCIPAL REASON(S) OR PURPOSE FOR PROPOSING THIS RULE:
Chapter 43 is adopted in accordance with PL 2021 Chapter 265 to establish standards for authorizing pharmacists to prescribe, dispense and administer HIV prevention drugs, set adequate training requirements and protocols for when there is no prescription drug order, standing order or collaborative practice agreement;

IS MATERIAL INCORPORATED BY REFERENCE IN THE RULE? ___YES X NO

ANALYSIS AND EXPECTED OPERATION OF THE RULE:
The enactment of Public Law 2021 Chapter 265 authorizes a pharmacist to dispense HIV prevention drugs under certain conditions pursuant to a standing order or to protocols developed by the Maine Board of Pharmacy by authorizing a pharmacist to prescribe, dispense and administer HIV prevention drugs pursuant to a standing order or collaborative practice agreement or when there is no prescription drug order from a health care provider, subject to rules and protocols adopted by the board. Chapter 43 implements the newly enacted law.

BRIEF SUMMARY OF RELEVANT INFORMATION CONSIDERED DURING DEVELOPMENT OF THE RULE: Expertise of board members, assistant attorney general, and board staff.

ESTIMATED FISCAL IMPACT OF THE RULE: [*see* §8057-A(1)(C)]***FOR EXISTING RULES WITH FISCAL IMPACT OF $1 MILLION OR MORE, ALSO INCLUDE:***

ECONOMIC IMPACT, WHETHER OR NOT QUANTIFIABLE IN MONETARY TERMS: [*see* §8057-A(2)(A)]
Expected to be minimal, see attached "Small Business and Economic Impact Statement."
None known.

INDIVIDUALS, MAJOR INTEREST GROUPS AND TYPES OF BUSINESSES AFFECTED AND HOW THEY WILL BE AFFECTED: [*see* §8057-A(2)(B)] Pharmacists and pharmacies. The law was enacted to make HIV prevention drugs available to the public. There is no known information on impact to licensees or the public.

BENEFITS OF THE RULE: [*see* §8057-A(2)(C)] Making HIV prevention drugs available to the public.

Administrative Procedure Act
CHECKLIST

Agency: DPFR, Office of Professional and Occupational Regulation, **02-392 Board of Pharmacy**

Chapter Number and Title of Rule:
Chapter 43: Prescribing, Dispensing and Administering HIV Prevention Drugs, including:
Appendix 1 Preventive Care HIV Pre-Exposure Prophylaxis (PrEP) Statewide Protocol and
Appendix 2 Preventive Care HIV Post-Exposure Prophylaxis (PEP) Statewide Protocol

PROPOSED RULE:

1. Was this rule listed on the last regulatory agenda? Yes

2. Date of notification of:

   Anyone on mailing list: Anticipated on same date of SOS publication Wednesday, December 11, 2024 - Electronic GovDelivery Subscribers
   Any trade, industry or professional group

   Any trade publications _____

3. Date Notice of Rulemaking Proposal (MAPA-3) sent to Secretary of State: December 11, 2024, the proposed rule was noticed to open a second public comment period for purposes of collecting public comments on the substantial amended changes to the initially proposed rules.

4. Date Fact Sheet sent to Executive Director of Legislative Council: July 2, 2024, first public comment period and second public comment period on December 9, 2024.

5. Date of publication in Secretary of State's rule-making ad: Wednesday, July 10, 2024, for first public comment period and December 11, 2024, for second public comment period.

6. Date of hearing(s): August 1, 2024, at 8:30 a.m. Public hearing not held for the second collection of public comments on the substantially amended changes to the initial proposed rule.

7. Comment deadline: August 12, 2024, by 5:00 p.m. (EST) first Public Comment Collection; January 10, 2025 by 5:00 p.m. public comments to substantially amended proposed rule.

ADOPTED RULE:

8. Was comment deadline extended or comment period reopened? Comment period was reopened due to substantive changes to Chapter 43 based on the public comments received during the initial comment period. A second public comment period was advertised and opened to collect comments on the substantive changes to the proposed rule.

   If yes, date of second notice publication in Secretary of State's rule-making ad: December 11, 2024

9. Is adopted rule consistent with what was proposed? Yes
   (If not, please address the changes in the comments and responses section of your filing.)

10. Is the person signing the Certification Statement (MAPA-1, #9) authorized to do so as stated in your statutes or in 5 MRSA, c.71? Yes

11. Was the rule adopted within 120 days of the comment deadline? Yes, board voted to adopt Chapter 43 including Appendix 1 and 2 on April 3, 2025.

12. Was the rule approved and signed by the Office of the Attorney General within 150 days of the comment deadline?

13. Is a Basis Statement included? Yes Is a copy of the Fact Sheet included? Yes

    Are comments, with names and organizations, and your responses included? Yes

14. 5 M.R.S.A. § 8053, sub-§ 1, "Notice of rulemaking without hearing. At least 20 days prior to the comment deadline of any rule without hearing (emphasis), the agency shall delivery or mail written notice or, with written or electronic agreement of the party, provide electronic notice to:
    ¶ E, The primary sponsor of the legislation that was enacted and authorized the rulemaking, as long as the legislation was enacted within the previous 2 years."

    The primary sponsor of the legislation that was enacted and authorized the rulemaking was notified on September 11, 2024, of the initial rulemaking proposal.

Notice of Agency Rulemaking Adoption

AGENCY: 02-392 Department of Professional and Occupational Regulation (PFR)
Office of Professional and Occupational Regulation (OPOR)
Board of Pharmacy

CHAPTER NUMBER AND TITLE:

Chapter 43: Prescribing, Dispensing and Administering HIV Prevention Drugs, including:
Appendix 1 Preventive Care HIV Pre-Exposure Prophylaxis (PrEP) Statewide Protocol and
Appendix 2 Preventive Care HIV Post-Exposure Prophylaxis (PEP) Statewide Protocol

ADOPTED RULE NUMBER: **20xx.xxx**
(LEAVE BLANK - ASSIGNED BY SECRETARY OF STATE)

CONCISE SUMMARY:

Board Rule Chapter 43 establishes standards for authorizing pharmacists to prescribe, dispense and administer HIV prevention drugs, set adequate training requirements and protocols for when there is no prescription drug order, standing order or collaborative practice agreement pursuant to Public Law 2021 Chapter 265.

EFFECTIVE DATE: MAY 06 2025
(TO BE FILLED IN BY SECRETARY OF STATE)

AGENCY CONTACT PERSON: Geraldine L. Betts, Administrator
AGENCY NAME: Maine Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, Board of Pharmacy
ADDRESS: 35 State House Station, Augusta ME 04333
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TELEPHONE: 207-624-8625