NOTICE OF AGENCY PROPOSED RULEMAKING

AGENCY: 02-392 Department of Professional and Financial Regulation
Office of Professional and Occupational Regulation

Maine Board of Pharmacy

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)

BRIEF SUMMARY:

These proposed set of rules are in response to several laws enacted by the 131st Legislature:

1) Chapter 7 is amended in accordance with PL 2023 Chapter 245, by setting standards by which a pharmacy technician may qualify to be certified to administer vaccines;

2) Chapter 41 Sale of Nonprescription Drugs Through Vending Machines. Public Law 2023 Chapter 160 repeals the 12-item limit for drug outlet vending machines. Chapter 41 is amended to bring the rule in compliance with the amended law.

3) Chapter 43 is enacted 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;

4) Chapter 44 is enacted in accordance with Public Law 2023 Chapter 115 to implement requirements to increase access to birth control by making certain contraception accessible from a pharmacist. This rule sets training for pharmacists to prescribe, dispense and administer contraceptives that reflect evidence-based medical eligibility guidelines for contraceptive use and best practices to counsel patients.

PUBLIC HEARING DATE: August 1, 2024
TIME: 8:30 a.m.
TESTIMONY at the hearing: Testimony will be taken in the order prescribed by the Board President. Time limit on verbal testimony may be announced. If you wish to submit your testimony in writing, please follow instructions below for Deadline for Public Comments.

MEETING/HEARING LOCATION: Maine Board of Pharmacy, Gardner Annex, 76 Northern Ave., Gardiner ME -- You may attend the public hearing *in-person* at this location; **or** join virtually **Zoom link** https://mainestate.zoom.us/j/9733636344?pwd=ZHdIVnI5NWRvMlZrZkVjR0lkRFVsZz09&omn=82216714770

COPY OF THE PROPOSED RULES available at:
https://www.maine.gov/pfr/professionallicensing/professions/board-pharmacy/home/board-meeting-information
See Pharmacy Board Meeting Information and look for the August 1, 2024 board meeting block of information.

DEADLINE FOR PUBLIC COMMENTS: Monday, August 12, 2024, 5:00 p.m. (EST).
Written comments submitted by email should be addressed to: Geraldine.L.Betts@maine.gov
Please put the following in the *subject line of your email*: **PHarmacy Testimony on Rulemaking**

Public comments submitted by regular post mail, please send to:
Geraldine Betts, Regulatory Board Manager, 35 State House Station, Augusta, ME 04333-0035

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 7: LICENSURE AND EMPLOYMENT OF PHARMACY TECHNICIANS

Summary: This chapter sets forth the qualifications, permissible duties and supervision responsibilities of the pharmacist in charge or pharmacists on duty with respect to licensed pharmacy technicians.

1-A. License Requirement

No person other than a pharmacist or pharmacy intern may perform any of the following duties unless such other person holds a valid pharmacy technician license from the board:

1. Acceptance of an original or renewal prescription drug order;

2. Receipt of a transferred prescription for a noncontrolled drug pursuant to Chapter 19, Section 8(2) of the board's rules;

3. Prescription data entry;

4. Prescription drug selection from inventory; or

5. Counting, packaging and labeling of prescription drugs for delivery.

The assignment of any of the above duties to a pharmacy technician lies within the discretion of the pharmacist on duty.

1. Pharmacy Technician Licensure

1. Application

The pharmacy technician shall complete the application supplied by the board and provide such other information as the board may require, along with the fee required by Chapter 10 of the rules of the Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, entitled "Establishment of License Fees." Applications will not be considered for approval until they are complete. Applications that remain incomplete for more than 60 days will be discarded.

2. Qualifications

The applicant shall supply verification of licensure or registration for all states in which the applicant has at any time held any type of professional or occupational license. The board may refuse to register and may refuse to renew the registration of an applicant:

A. Whose pharmacy technician license or registration has been denied, revoked, suspended or restricted in any jurisdiction for disciplinary reasons; or

B. Who has been convicted of a crime involving alcohol or drugs. This restriction is subject to consideration and waiver by the board upon presentation of satisfactory evidence that the conviction does not impair the ability of the person to conduct, with safety to the public, the duties of a pharmacy technician.

[NOTE: The effect of a criminal conviction on an applicant's eligibility for licensure is governed generally by the Occupational License Disqualification on Basis of Criminal Record law, 5 MRSA §5301 *et seq*.]

3. [deleted]

4. Term of License

~~The~~ All pharmacy technician license~~s term is 1 year~~ expire on December 31. Licenses may be renewed annually upon completion of a renewal application form supplied by the board and payment of the prescribed fee. No applicant may commence training or employment as a pharmacy technician until the license has been issued by the board.

5. Notice of Change of Work Site or Contact Address

A pharmacy technician shall notify the board of a change in work site, cessation of employment as a pharmacy technician or a change of contact address via letter, fax or email within 10 days after the change.

2. Training

A pharmacy that employs a pharmacy technician shall develop or deploy a training program for pharmacy technicians employed at that pharmacy. The pharmacy shall keep a copy of the training program on site at all times and shall furnish the training program to the board upon inspection or upon request. The pharmacist in charge or other Maine-licensed pharmacist designated by the pharmacy shall train each pharmacy technician in accordance with the pharmacy's training program or shall ensure that each pharmacy technician.

satisfactorily completes the training program offered by the pharmacy. The training program shall accommodate the needs of the individual technician being trained.

The training program shall include specific instruction relating to the limited scope of practice of a pharmacy technician and shall clearly delineate functions that may only be performed by a pharmacist and may not be performed by a pharmacy technician.

3. [deleted]

3-A. Pharmacy Technician Certification to Administer Vaccines

Pursuant to the authorization to administer vaccines and requirements under 32 M.R.S. § 13831, sub-§6, the following also apply:

1. Application

A pharmacy technician shall complete the application supplied by the board and provide such other information as the board may require, along with the fee required by Chapter 10 of the rules of the Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, entitled "Establishment of License Fees." Applications will not be considered for approval until they are complete. Applications that remain incomplete for more than 60 days will be voided.

2. License Required. In order to qualify for certification from the board to administer vaccines, an individual must hold a valid, current and unrestricted pharmacy technician license issued by the board.

3. Certification Term. All certifications to administer vaccines expire on December 31. Certifications may be renewed annually upon completion of a renewal application form supplied by the board and payment of the prescribed fee. No applicant may commence administering vaccines as a pharmacy technician until the certification of administration has been issued by the board.

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).

5. Vaccine Administration Requirements. In addition to following the pharmacy's vaccine protocols, a pharmacy technician who engages in the administration of authorized vaccines shall, at a minimum, comply with the following:

A. Shall not administer any vaccine until the pharmacist has verified the vaccine is correct in all respects for administration to the patient;

B. Prior to administering the vaccine to the patient, the pharmacy technician shall give each patient or the patient's legal representative the

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;

D. Alert the pharmacist on duty immediately in the event of any of the following:

a. Potential adverse reactions;
b. Potential anaphylactic reactions; or
c. Accidental needle sticks.

E. Understand the proper procedures and course of action to handle and dispose of used or contaminated equipment and supplies; and

F. Following administration of a vaccine, the pharmacy technician shall provide the patient with complete and accurate documentation of the administered vaccination.

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.

7. **Delegation**. A pharmacy technician shall not delegate the administration of the vaccines to any person.

8. **Identification**. The pharmacy technician shall wear a name tag, identifying them as "Pharmacy Technician, Board-certified to Administer Vaccines" the wording may be adjusted to conform with tag size, but must easily be discernable to the general public.

4. Supervision by Pharmacist in Charge

1. Generally

The pharmacist in charge shall supervise pharmacy technicians employed at the pharmacy for which the pharmacist in charge is responsible. In the absence of the pharmacist in charge, a pharmacist on duty shall be the supervisor.

2. Direct Supervision

A pharmacy technician may engage in the practice of pharmacy at a pharmacy only under the direct supervision of a pharmacist as defined in Chapter 1, Section 14 of the board's rules. The pharmacist shall physically review each prescription drug order prepared by a pharmacy technician before the product is delivered to the patient or the authorized agent of the patient. The pharmacist is responsible for the work of each pharmacy technician working under the direct supervision of the pharmacist. The pharmacist is responsible for verification of every vaccine prior to administration.

3. Automated Pharmacy Systems At Remote Sites

[deleted]

5. Permissible Duties

1. Generally

The pharmacist in charge or the pharmacy shall determine the duties of pharmacy technicians based upon the needs of the pharmacy. At time of employment the pharmacist in charge shall provide the technician with a description of the tasks that the technician may perform.

Pharmacy technicians are limited to performing tasks in the dispensing of prescription legend drugs and nonjudgmental support services as set forth in Section 1-A above. Pharmacy technicians may also have access to a facsimile machine or computer used to receive original prescription drug orders via facsimile.

2. Automated Pharmacy Systems

A pharmacy technician on duty at an institutional pharmacy as described in Chapter 20, Subchapter 2, Section 1 of the board's rules may perform the duties relating to an automated pharmacy system described in Chapter 20, Subchapter 2, Section 4(2) of the board's rules only under the direct supervision of a pharmacist as defined in Chapter 1, Section 14(3) of the board's rules. The pharmacist in charge or pharmacist on duty at an automated pharmacy system is responsible for the work of each pharmacy technician at a point of care location served by the automated pharmacy system.

3. Limitations

A pharmacy technician may not perform any of the following tasks:

A. [deleted];

B. Clinically evaluate a patient profile relative to drugs that have or will be dispensed;

C. Perform patient counseling;

D. Make decisions that require the education and professional training of a pharmacist; or

E. Sign any federally-required controlled substance or inventory form.

4. Responsibility of Pharmacist

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. The pharmacist in charge, or a pharmacist on duty, is responsible for all actions performed by the pharmacy technician.

6. [deleted]

7. [deleted]

7-A. Limitation on Deployment of Pharmacy Technicians

A pharmacy and pharmacist in charge are responsible at all times for providing appropriate quality control over the work of pharmacy technicians employed at the pharmacy. A pharmacy is responsible for ensuring at all times that the number of pharmacy technicians on duty can be satisfactorily supervised by the pharmacist in charge and the pharmacists on duty.

7-B. Administrative Responsibilities

1. Verification of Status

The pharmacist in charge shall ensure that each pharmacy technician employed at the pharmacy for which the pharmacist in charge is responsible is licensed with the board. A pharmacy technician shall carry the wallet-sized license card issued by the board at all times the technician is on duty and shall produce the card upon request of the pharmacist in charge, a pharmacist on duty or an agent of the board. No pharmacist in charge or pharmacist on duty shall permit a person who is not licensed pursuant to the terms of this chapter to perform the duties of a pharmacy technician.

2. Notice of Employment and Non-Employment of Pharmacy Technicians

The pharmacist in charge shall notify the board via letter, fax, email or on line within 10 days after the commencement or cessation of employment of any pharmacy technician at a pharmacy for which the pharmacist in charge is responsible.

3. Notice of Termination of Employment For Drug-Related Reasons or Theft

The pharmacist in charge or a designee of the pharmacist in charge shall notify the board via letter, fax, email or on line of the termination of employment of a pharmacy technician for any of the following reasons and shall include in the notice the reason for the termination. Notice shall be provided within 7 days after the termination:

A. Any drug-related reason, including but not limited to adulteration, abuse, theft or diversion;

B. Theft of non-drug merchandise; or

C. Theft of cash or credit/debit card data.

8. Exemption

Nursing personnel with access to hospital pharmacy medications at times when the pharmacy is not open need not register as pharmacy technicians.

9. Discipline

Pharmacy technicians are subject to the disciplinary provisions of 10 MRSA §8003(5- A), 32 MRSA §§ 13742-A and 13743 and Chapters 30, 31 and 32 of the board's rules.

STATUTORY AUTHORITY: 32 MRSA §§13720, 13721(1)(H), 13723

EFFECTIVE DATE:
November 8, 2004 - filing 2004-509
March 11, 2012 – filing 2012-63

AMENDED:
December 11, 2013 – filing 2013-303

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 41: SALE OF NONPRESCRIPTION DRUGS THROUGH VENDING MACHINE OUTLETS

Summary: This chapter sets forth requirements for licensing, management and safe operation of vending machine outlets.

1. DEFINITIONS. As used in this chapter, the following terms are defined as follows:

1. Nonprescription drugs. "Nonprescription drugs" has the same meaning as set forth in 32 M.R.S. §13702-A(20).

2. Targeted methamphetamine precursor. "Targeted methamphetamine precursor" has the same meaning as set forth in 32 M.R.S. §13702-A(33).

3. Vending machine. "Vending machine" means any automated mechanical device operated by a vending machine outlet licensee from which nonprescription drugs are dispensed to a consumer after payment.

4. Vending machine outlet. "Vending machine outlet" means any location licensed by the ~~B~~board pursuant to 32 M.R.S. §13751(2)(F) to operate one or more vending machine(s) to sell non-prescription drugs.

2. LICENSURE

1. License Required. Only vending machine outlets may operate one or more vending machine(s) in accordance with the terms and conditions set forth in this chapter. A vending machine outlet is solely responsible for all vending machines the licensee operates.

2. Limited Authorization. A vending machine outlet license only authorizes operation of vending machines for one (1) physical location where one or more vending machines are located. Any person desiring to operate a vending machine outlet shall obtain from the board a vending machine outlet license for each physical location where one or more vending machines outlets are located.

3. Non-transferrable. A vending machine outlet license issued under this section is not transferable.

4. Application

A. A person seeking a vending machine outlet license shall submit an application on a form provided by the ~~B~~board and pay any fees as set forth in Chapter 10 of the rules of the Office of Professional and Occupational Regulation.

B. Any application shall include a detailed description, photograph(s) and drawing(s) of the intended location of each vending machine within the physical setting, as well as photograph(s) and drawings of the vending machine(s). Each vending machine shall be assigned a specific physical placement and orientation within a physical location that is:

1. weather-tight;
2. well-ventilated;
3. in a moisture-controlled environment;
4. well-lighted; and
5. protected from direct sunlight-

3. VENDING MACHINE REQUIREMENTS

1. Nonprescription Drugs Only; Limits. Only nonprescription drugs may be sold or dispensed from a vending machine. ~~Any single vending machine may sell or dispense no more than twelve (12) different nonprescription drugs.~~

2. No Targeted Methamphetamine Precursors. Under no circumstance may targeted methamphetamine precursors be sold from any vending machine.

3. Compliance with Manufacturer Recommendations. Nonprescription drugs dispensed by a vending machine shall be:

A. Stored in accordance with manufacturer recommendations, including those that require a stable temperature;

B. Sold only in the manufacturer's clearly labeled, original, unbroken, tamper-proof and expiration-dated packaging; and

C. No older than the manufacturer's expiration date.

4. Machine Labeling

1. Each vending machine outlet must have an obvious and legible statement or label on each machine that:

A. Identifies the owner of the machine, and, if different, the vending machine outlet licensee;

B. Identifies the vending machine's serial number;

C. Lists the Vending Machine License number issued by the Maine Board of Pharmacy and the license expiration date;

D. Provides a toll-free telephone number at which the consumer may contact the owner of the machine, and, if different, the vending machine outlet licensee;

E. Provides contact information for the Northern New England Poison Center; and

F. Advises the consumer to check the expiration date of the product before

using the product.

5. Expired Nonprescription Drugs

Under no circumstance may expired nonprescription drugs be sold or dispensed from a vending machine. It is the sole responsibility of each vending machine outlet licensee to ensure products are in date and that expired drugs are promptly removed upon expiration.

4. PROCEDURE FOR RELOCATING OR RETIRING A VENDING MACHINE

Before relocating or retiring any vending machine outlet previously covered by a vending machine outlet license, the vending machine outlet licensee shall notify the ~~B~~board in writing of that relocation or retirement. The notice shall include the following: license number; vending machine's serial number; action planned (relocation or retirement); if relocating, provide all information required above in subsection (2)(4)(B) for the new location; and if retiring a vending machine, the manner of disposition of the nonprescription drug contents of the vending machine.

5. INSPECTION

Each vending machine outlet is subject to inspection by a ~~B~~board designee. The vending machine outlet licensee or its agent shall provide access to the contents of the vending machine immediately upon request from the ~~B~~board's designee.

STATUTORY AUTHORITY:
32 M.R.S.A. §§ 13751, 13792(2)

EFFECTIVE DATE:
May 15, 2023 – filing 2023-069

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. **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:

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 (pp. 4-7)
- Utilize the standardized PEP Patient Informational Handout (p. 8)
- Utilize the standardized PEP Provider Notification (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 ≥ 325 mg □ 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>

<table>
<tr><td>If any boxes are checked, go to #7.</td><td></td><td></td></tr>
<tr><td colspan="2">5. Did the patient have receptive/insertive anal/vaginal intercourse without a condom with a partner of known or unknown HIV status?</td><td rowspan="2">Notes: This type of exposure puts the patient at a high risk for HIV acquisition.</td></tr>
<tr><td>☐ Yes: Go to #7</td><td>☐ No: Go to #6</td></tr>
<tr><td colspan="2">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?</td><td rowspan="2">Notes: Consider calling the HIV Warmline (888) 448-4911 for guidance.</td></tr>
<tr><td>☐ 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</td><td>☐ No: Use clinical judgement. Risk of acquiring HIV is low. Consider referral.
If clinical determination is to prescribe PEP then continue to #7.</td></tr>
<tr><td colspan="2">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?</td><td rowspan="2">Notes: Connection to care is critical for future recommended follow-up.</td></tr>
<tr><td>☐ Yes: Go to #8</td><td>☐ No: Do not prescribe PEP. Refer patient to local primary care provider, emergency department, urgent care, infectious disease specialist, or public health department.</td></tr>
<tr><td colspan="2">8. Does the patient have history of known Hepatitis B infection (latent or active)?</td><td rowspan="4">Notes: Tenofovir disoproxil fumarate treats Hepatitis B infection, therefore once stopped and/or completed, the patient could experience an acute Hepatitis B flare.</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 #9</td></tr>
<tr><td colspan="2">9. Has the patient received the full Hepatitis B vaccination series? ☐Yes ☐No
Verify vaccine records. Dates:_____</td></tr>
<tr><td>☐ Yes: Go to #11</td><td>☐ No: Go to #10</td></tr>
<tr><td colspan="2">10. Review the risks of hepatitis B exacerbation with PEP with the patient. Offer vaccine if appropriate and go to #11.</td><td></td></tr>
</table>

<table>
<tr><td colspan="2">☐ Vaccine administered
Lot:_____ Exp:_____ Signature:_____</td><td></td></tr>
<tr><td colspan="2">11. Does the patient have known chronic kidney disease or reduced renal function?</td><td rowspan="2">Notes: emtricitabine and tenofovir disoproxil fumarate requires renal dose adjustment when the CrCl <50 mL/min.</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: 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.</td></tr>
</table>

Regimen Selection (check one):

☐ **Option 1 (preferred)**:

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

PLUS

Raltegravir 400 mg twice daily for 28 days

☐ **Option 2:**

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

PLUS

Dolutegravir 50 mg 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

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____/____/_____

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

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

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

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 (pp. 4-7)
- Utilize the standardized PEP Patient Informational Handout (p. 8)
- Utilize the standardized PEP Provider Notification (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 ≥ 325 mg □ 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>
<tr><td>If any boxes are checked, go to #7.</td><td></td><td></td></tr>
<tr><td colspan="2">5. Did the patient have receptive/insertive anal/vaginal intercourse without a condom with a partner of known or unknown HIV status?</td><td>Notes: This type of exposure puts the patient at a</td></tr>
</table>

☐ Yes: Go to #7	☐ No: Go to #6	high risk for HIV acquisition.
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 200 mg/tenofovir disoproxil fumarate 300 mg (Truvada® or generic) once daily for 28 days

PLUS

Raltegravir 400 mg twice daily for 28 days

☐ **Option 2:**

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

PLUS

Dolutegravir 50 mg 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

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 44: PHARMACIST AUTHORIZATION TO MAKE CERTAIN CONTRACEPTION ACCESSIBLE

Summary: Pursuant to recently enacted 32 M.R.S. Section 13826, the Legislature authorized licensed pharmacists to expand their scope of practice to include the prescribing, dispensing and administering of statutorily defined injectable hormonal contraceptives or self-administered hormonal contraceptives, beyond the existing scope of practice allowing for dispensing of these contraceptives when prescribed by a patient's healthcare provider. This chapter sets forth the authorization requirements to engage in this expanded scope of practice for prescribing, dispensing and administering ~~of~~ the identified contraceptives.

1. Authorization Required.

1. 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.
2. A pharmacist who fails to follow the requirements of this chapter or the requirements of 32 M.R.S. § 13826 in prescribing, dispensing or administering permitted contraceptives engages in unprofessional conduct pursuant to 32 M.R.S. § 13742-A by violating the standards of professional behavior set forth in this chapter for the practice of pharmacy. Pursuant to 10 M.R.S. § 8003(5-A), the board may revoke, refuse to renew, or may impose discipline for such violations.

2. Contraceptive Authorization.

1. Application

The pharmacist shall complete the application supplied by the board and provide such other information as the board may require, along with the fee required by Chapter 10 of the rules of the Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, entitled "Establishment of License Fees." Applications will not be considered for approval until they are complete. Applications that remain incomplete for more than 60 days will be voided.

2. Qualification

The applicant shall have an active Maine pharmacy license and shall supply verification of the required training as set forth in Section 3.

3. Training

A. A pharmacist is eligible for authorization if they have completed appropriate training, consisting of either:

a) Within three (3) years immediately preceding application for contraceptive authorization, completion of an Accreditation Council for Pharmacy Education approved training program for hormonal contraceptives; or

b) Receipt of a Doctor of Pharmacy degree from a college of pharmacy accredited by the American Council on Pharmaceutical Education, or its successor organization, within the three (3) years immediately preceding application for contraceptive authorization that includes completion of training in the area of contraception.

B. On their application for authorization under this chapter, a pharmacist must attest to the board that they have completed the training required by this chapter. In addition, pharmacists authorized under this chapter must maintain documentation proving that they have completed the required training and must provide that documentation to the board upon request.

C. After a pharmacist obtains authorization under this Chapter, they shall remain current with best practices for the prescribing, dispensing and administering of hormonal contraceptive or injectable hormonal contraceptive. A pharmacist shall attest at the time of annual license renewal that they have complied with this provision.

3. Term of Authorization

The authorization expires annually at the same time as the pharmacist's license and is subject to renewal in the same manner.

4. Self-Screening Risk Assessment Tool

1. A pharmacist shall have the patient complete a self-screening risk assessment tool, in either hard copy or electronic form, based on evidence-based medical eligibility guidelines for contraceptive use. A self-screening risk assessment tool that substantially aligns with the most current United States Medical Eligibility Criteria for Contraceptive Use published by the federal Centers for Disease Control and Prevention satisfies the requirements of this subsection.

   Results of the self-screening risk assessment and patient assessment are records that must be maintained for a minimum of two (2) years and readily available to the board upon request.

5. A pharmacist shall review the self-screening risk assessment, and using evidence-based medical eligibility guidelines and best counseling practices shall, if medically appropriate, counsel the patient and issue an appropriate prescription for a permitted contraceptive as defined by 32 M.R.S. § 13862(1)(A)-(B).

6. Grounds for Discipline

A pharmacist who falsely attests that they have met any of the requirements of this chapter has engaged in the practice of fraud, deceit or misrepresentation pursuant to 10 M.R.S. § 8003(5-A)(A)(1), and on that basis the board may deny the pharmacist's license, refuse to renew that license, or impose disciplinary sanctions as authorized by 10 M.R.S. § 8003(5-A).

7. A pharmacist prescribing, dispensing or administering contraceptives pursuant to this chapter shall comply with the additional requirements of 32 M.R.S. § 13826(3)(D)-(F).