

**North Carolina Medical Board and North Carolina Board of Pharmacy Protocols for  
Post Exposure Prophylaxis (PEP) for Human Immunodeficiency Virus (HIV)  
July 21, 2023**

Pursuant to S.L. 2021-110, these protocols adopted by the North Carolina Medical Board and the North Carolina Board of Pharmacy authorize immunizing pharmacists practicing pharmacy in the state of North Carolina and licensed by the North Carolina Board of Pharmacy to dispense, deliver, or administer PEP therapy products as directed below.

<b>HIV PEP Dispensing Protocol</b>	
<b>Exposure Timeline</b>	<ul style="list-style-type: none"> <li>▪ Communicate with the patient to identify when the exposure took place</li> <li>▪ Assess the length of time since the exposure took place to determine if initiation of PEP is recommended or if the patient should be referred to a medical care provider as outlined in the Eligibility &amp; Risk Screening section               <ul style="list-style-type: none"> <li>- 72 hours or less: continue screening process</li> <li>- Greater than 72 hours: screening process should stop, but provide education on the lack of evidence on effectiveness of PEP initiation after 72 hours and refer patient to a medical care provider for HIV screening</li> </ul> </li> <li>▪ Discuss with the patient the effectiveness of PEP based on time of initiation since exposure</li> </ul>
	<b>Time Since Exposure (Hours)</b>
	0-72
	More than 72
	<b>CDC Guidelines Efficacy Evaluation</b>
	Effective
	No Evidence Supporting Efficacy
<b>Eligibility &amp; Risk Screening</b>	<p>For individuals age 13 years or older who voluntarily request Post-Exposure Prophylaxis and meet criteria for PEP initiation. <a href="https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf">https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf</a>.</p> <p>These protocols may be used for persons &lt; 18 years of age with a parent or legal guardian consent.</p> <ul style="list-style-type: none"> <li>▪ The patient should be provided the Pharmacist-Initiated HIV Post-Exposure Prophylaxis Patient Questionnaire to screen the patient and to determine if an exposure occurred which would meet the criteria for PEP initiation               <ul style="list-style-type: none"> <li>- High risk: PEP is recommended                   <ul style="list-style-type: none"> <li>▪ Intercourse (receptive or insertive) with a person known to be HIV positive</li> <li>▪ Needle sharing with a person known to be HIV positive</li> <li>▪ Injuries with exposure to potentially infectious fluids (through eye, mucous membrane, percutaneous, or non-intact skin) of a person known to be HIV positive</li> </ul> </li> <li>- Lower risk: recommendation of PEP should be evaluated on a case-by-case basis                   <ul style="list-style-type: none"> <li>▪ Intercourse (receptive or insertive) with a person with an unknown HIV status</li> <li>▪ Mouth to vagina, penis, or anus contact (insertive or receptive) with a person known to be HIV positive</li> <li>▪ Injuries with exposure to potentially infectious fluids (through eye, mucous membrane, percutaneous, or non-intact skin) of a person with unknown HIV status</li> </ul> </li> <li>- For exposures determined to be lower risk, these additional risk factors should be assessed and the presence would weigh in favor of dispensing PEP therapy:                   <ul style="list-style-type: none"> <li>▪ Non-intact oral mucosa (i.e., cuts, sores)</li> <li>▪ The presence of blood</li> <li>▪ If either party had a genital ulcer</li> <li>▪ If either party had a sexually transmitted infection</li> <li>▪ If the other person had a detectable HIV viral load (&gt;200 copies/mL)</li> </ul> </li> </ul> </li> <li>▪ Determination of HIV status               <ul style="list-style-type: none"> <li>- Patient should be provided the Pharmacist-Initiated HIV Post-Exposure Prophylaxis Patient Questionnaire to self-report if they have ever tested positive for HIV</li> <li>- All persons considered for PEP who do not self-report they have tested positive in the past should have determination of their HIV infection status by HIV testing, preferably by using rapid combined Ag/Ab or antibody blood tests, including a rapid self-test.</li> <li>- If rapid HIV blood test results are unavailable, and PEP is otherwise indicated, it may be initiated without delay, but should be discontinued if the patient is later determined to have HIV infection</li> </ul> </li> <li>▪ Sexual Assault               <ul style="list-style-type: none"> <li>- If it is learned that the individual was a victim of sexual assault, refer to person to an emergency department or other medical facility specially trained for victims of sexual assault</li> <li>- In these instances, PEP may be initiated without delay, if no other contraindication, with referral for specialty care</li> </ul> </li> </ul>
<b>Contraindications</b>	<ul style="list-style-type: none"> <li>▪ Patient self-reports, or if a point-of-care HIV test is positive</li> <li>▪ &gt; 72 hours since exposure</li> <li>▪ Known or suspected reduced renal function</li> </ul>
<b>Precautions</b>	<ul style="list-style-type: none"> <li>▪ Pregnancy (known or suspected) and breastfeeding</li> <li>▪ Follow the guidance given in the sections below for each of these considerations</li> </ul>

<b>Safety Evaluation</b>	<ul style="list-style-type: none"> <li>▪ Obtain a list of all current medications the individual seeking PEP therapy is taking, and perform a drug-drug interaction review <ul style="list-style-type: none"> <li>- If no clinically-significant drug interactions, between current medications and PEP: <ul style="list-style-type: none"> <li>▪ Proceed to dispense PEP therapy</li> </ul> </li> <li>- If clinically-significant drug interactions between current medications and PEP: <ul style="list-style-type: none"> <li><b>Step 1:</b> Contact patient-authorized medical provider for guidance</li> <li>If the authorized medical provider is not available:</li> <li><b>Step 2:</b> Contact the National Clinician Consultation Center (NCCC) Post-Exposure Prophylaxis Hotline at (888) 448-4911</li> <li>If further guidance on dispensing PEP for this individual based on drug interactions is unavailable via the authorized provider or the NCCC PEP Hotline; then</li> <li><b>Step 3:</b> Refer the individual seeking PEP therapy to the Emergency Department or other medical provider</li> </ul> </li> </ul> </li> </ul> <li>▪ If individual seeking PEP therapy is breastfeeding, follow Step 1-3 as outlined in this section.</li>			
<b>Medication Dispensing</b>	<b>28-Day Regimen</b> (See 'How Supplied' Below)	<b>Alternative 28-Day Regimen</b> (See 'How Supplied' Below)		
Individuals 13 years and older (Including Pregnant Patients)				
<table border="0" style="width: 100%;"> <tr> <td style="width: 50%; text-align: center;"> tenofovir disoproxil fumarate 300 mg with emtricitabine  200 mg once daily  <b>plus</b>  raltegravir 400 mg twice daily OR dolutegravir* 50 mg daily  <i>(*Do not use dolutegravir in patients who are pregnant or have the potential to become pregnant)</i> </td> <td style="width: 50%; text-align: center;"> tenofovir disoproxil fumarate 300 mg with emtricitabine  200 mg once daily  <b>plus</b>  darunavir 800 mg AND ritonavir 100 mg once daily </td> </tr> </table>			tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg once daily <b>plus</b> raltegravir 400 mg twice daily OR dolutegravir* 50 mg daily <i>(*Do not use dolutegravir in patients who are pregnant or have the potential to become pregnant)</i>	tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg once daily <b>plus</b> darunavir 800 mg AND ritonavir 100 mg once daily
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<b>How Supplied</b>	Medications should be dispensed in accordance with manufacturer requirements. Some products require dispensing in unopened original containers, which may require the dispensing of a 30-day supply. A 30-day supply is allowed pursuant to these protocols.			
<b>Refills</b>	None. No limit on how many courses per patient per year (see Patient Education section for addressing risk mitigation).			
<b>Patient Education</b>	<ul style="list-style-type: none"> <li>▪ Medication Education <ul style="list-style-type: none"> <li>- When 30-day supply is dispensed, emphasize the minimum treatment duration is 28 days.</li> <li>- Drug information sheets that include side effects and adverse drug events for each medication dispensed should be given at the time medication is dispensed and patient should be counseled on what to do if they experience an adverse drug event.</li> <li>- An offer to counsel should be made in accordance with standard North Carolina pharmacy practice</li> </ul> </li> <li>▪ Risk Mitigation <ul style="list-style-type: none"> <li>- Educational material on PEP should be provided</li> <li>- Educational material on behaviors to avoid HIV exposure should be offered</li> <li>- Pre-exposure Prophylaxis (PrEP) Education <ul style="list-style-type: none"> <li>▪ This should be considered when: <ul style="list-style-type: none"> <li>● An individual who reports behaviors or situation that place them at risk for frequently occurring HIV exposure (e.g. injection drug use, sex without condoms or other high-risk sexual behavior)</li> <li>● More than 1 course of PEP therapy has been dispensed within a year</li> </ul> </li> <li>▪ If appropriate, written/verbal education on PrEP and the benefits to use should be provided</li> </ul> </li> </ul> </li> <li>▪ HIV testing <ul style="list-style-type: none"> <li>▪ Each patient who receives PEP therapy shall be educated on the importance of having a test to determine their HIV infection status.</li> <li>▪ Pharmacist shall educate the patient on self-test HIV kit and local HIV testing site options.</li> <li>▪ Pharmacist shall educate the patient that if their HIV test is positive, they should discontinue taking PEP and seek care from a medical provider for treatment.</li> </ul> </li> <li>▪ Emphasize the importance of receiving follow-up care from a medical provider to allow for: <ul style="list-style-type: none"> <li>- Signs and symptoms of acute HIV infection</li> <li>- Full evaluation of the exposure</li> <li>- Receipt of HIV testing</li> <li>- Information on resources available for HIV exposure</li> </ul> </li> <li>▪ Inform the patient of the importance of completing the full 28-day course of PEP therapy unless directed otherwise by a medical provider</li> <li>▪ Patients who report intravenous drug use should be assessed for their interest in substance use disorder treatment and information on services should be made available for those who desire treatment. Information on safer syringe use should be shared for those who continue to inject or who are at risk for relapse.</li> </ul>			

<b>Notification</b>	Pharmacists choosing to dispense PEP, under the authority of these protocols, shall notify the patient's primary care provider within 72 hours of providing therapy. Notification should include the pharmacist's name and NPI #, and the pharmacy/practice name and phone number, exposure history and medicines dispensed. If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary care provider, and provide information regarding primary care providers, including private practices federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.
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# Pharmacist-Initiated HIV Post-Exposure Prophylaxis

## Patient Questionnaire

### Part I: Patient Information

Patient Name \_\_\_\_\_ Birth Date: \_\_\_\_\_ Age: \_\_\_\_\_ Visit Date: \_\_\_\_\_  
First Last MM/DD/YY MM/DD/YY

Address: \_\_\_\_\_ City: \_\_\_\_\_ State: \_\_\_\_\_ Zip Code: \_\_\_\_\_

Phone: (\_\_\_\_) \_\_\_\_\_ Primary Care Provider: \_\_\_\_\_

### Part II: Patient History

Allergies: _____		
Please list all of your current medications, including nonprescription medications and dietary supplements: _____		
Have you ever tested positive for HIV?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
		If yes, when? _____ <small>Date</small>
Are you currently pregnant?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Are you able to become pregnant?	<input type="checkbox"/> Yes	<input type="checkbox"/> Not Applicable
Have you ever been diagnosed with kidney disease or told by a medical provider that you have decreased kidney function?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
		<input type="checkbox"/> Unsure
Have you ever taken PEP in the past?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
		If yes, when? _____ <small>Date</small>
If you answered yes to the previous question, did you have any side effects or serious problems?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
		If yes, please explain: _____ _____ _____

In the last 3 days (72 hours) have you experienced any of the following:

<i>High-Risk</i>		
<ul style="list-style-type: none"> <li>• Intercourse (receptive or insertive) with a person known to be HIV positive</li> <li>• Needle sharing with a person known to be HIV positive</li> <li>• Injuries with exposure to potentially infectious fluids (through eye, mucous membrane, percutaneous, or non-intact skin) of a person known to be HIV positive</li> </ul>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<i>Lower-Risk</i>		
<ul style="list-style-type: none"> <li>• Intercourse (receptive or insertive) with a person with an unknown HIV status</li> <li>• Mouth to vagina, penis, or anus contact (insertive or receptive) with a person known to be HIV positive</li> <li>• Injuries with exposure to potentially infectious fluids (through eye, mucous membrane, percutaneous, or non-intact skin) of a person with unknown HIV status</li> </ul>	<input type="checkbox"/> Yes	<input type="checkbox"/> No

Estimated time of potential exposure (XX:XX AM/PM, MM/DD/YY): \_\_\_\_\_

Estimated hours elapsed since exposure: \_\_\_\_\_

**Pharmacist-Initiated HIV Post-Exposure Prophylaxis  
Documentation & Communication Form**

**Part I: Patient Information**

Patient Name \_\_\_\_\_ Birth Date: \_\_\_\_\_ Age: \_\_\_\_\_ Visit Date: \_\_\_\_\_  
First Last MM/DD/YY MM/DD/YY  
 Address: \_\_\_\_\_ City: \_\_\_\_\_ State: \_\_\_\_\_ Zip Code: \_\_\_\_\_  
 Phone: (\_\_\_\_) \_\_\_\_\_ Primary Care Provider: \_\_\_\_\_

**Part II: PEP Dispensing**

At the time of dispensing did the patient have an HIV test performed?  <i>If yes, results were....</i>  <i>If no, was information provided on self-testing and local testing site options?</i>	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
	<input type="checkbox"/> Positive	<input type="checkbox"/> Negative	
	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Was a Drug-Drug Interaction Screening Performed?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not Applicable
Drug Therapy Dispensed: _____	Day-Supply Dispensed: _____		

**Part II: Education**

Education Provided:  Medication education for PEP regimen  Risk mitigation  
 Necessity for PCP or health dept follow-up  Importance of HIV testing

**Part III: Patient Consent to Release of Information**

**By signing this document, I agree to:**

- Seek HIV testing, if not already done
- Seek follow-up care with my primary provider, local health department or clinic; and
- Allow the pharmacist/pharmacy to release information about my care today to my primary provider or the medical provider of my choosing.

**Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_  
PATIENT SIGNATURE

\_\_\_\_\_  
Pharmacist Name Date  
 \_\_\_\_\_  
Pharmacist NPI# Pharmacy Name Pharmacy Phone #

Faxed to Primary Care Provider on \_\_\_\_\_ by \_\_\_\_\_  
Date Responsible Party

**For Pharmacy Use Only**  
 An attempt was made to follow-up with the patient to inquire as to whether the patient did schedule/keep an appointment for HIV testing and follow-up care with primary care or other medical provider.

Patient Reached  Yes  No

Date Follow-up Attempted \_\_\_\_\_ Method of Contact \_\_\_\_\_

Notes: \_\_\_\_\_