



**North Carolina State Health Director's Standing Order for
Post Exposure Prophylaxis (PEP) for Human Immunodeficiency Virus (HIV)
March 28, 2022**

Pursuant to S.L. 2021-110, this standing order, signed by the North Carolina State Health Director, authorizes 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.

HIV PEP Dispensing Protocol							
Exposure Timeline	<ul style="list-style-type: none"> ▪ Communicate with the patient to identify when the exposure took place ▪ 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 & Risk Screening section <ul style="list-style-type: none"> - 72 hours or less: continue screening process - 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 ▪ Discuss with the patient the effectiveness of PEP based on time of initiation since exposure 						
	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 50%;">Time Since Exposure (Hours)</th> <th style="width: 50%;">CDC Guidelines Efficacy Evaluation</th> </tr> </thead> <tbody> <tr> <td align="center">0-72</td> <td align="center">Effective</td> </tr> <tr> <td align="center">More than 72</td> <td align="center">No Evidence Supporting Efficacy</td> </tr> </tbody> </table>	Time Since Exposure (Hours)	CDC Guidelines Efficacy Evaluation	0-72	Effective	More than 72	No Evidence Supporting Efficacy
Time Since Exposure (Hours)	CDC Guidelines Efficacy Evaluation						
0-72	Effective						
More than 72	No Evidence Supporting Efficacy						
Eligibility & Risk Screening	<p>For individuals age 13 years or older who voluntarily request Post-Exposure Prophylaxis and meet criteria for PEP initiation. https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf.</p> <p>This standing order may be used for persons < 18 years of age with a parent or legal guardian consent.</p> <ul style="list-style-type: none"> ▪ 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"> - High risk: PEP is recommended <ul style="list-style-type: none"> ▪ Intercourse (receptive or insertive) with a person known to be HIV positive ▪ Needle sharing with a person known to be HIV positive ▪ Injuries with exposure to potentially infectious fluids (through eye, mucous membrane, percutaneous, or non-intact skin) of a person known to be HIV positive - Lower risk: recommendation of PEP should be evaluated on a case-by-case basis <ul style="list-style-type: none"> ▪ Intercourse (receptive or insertive) with a person with an unknown HIV status ▪ Mouth to vagina, penis, or anus contact (insertive or receptive) with a person known to be HIV positive ▪ Injuries with exposure to potentially infectious fluids (through eye, mucous membrane, percutaneous, or non-intact skin) of a person with unknown HIV status - 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"> ▪ Non-intact oral mucosa (i.e., cuts, sores) ▪ The presence of blood ▪ If either party had a genital ulcer ▪ If either party had a sexually transmitted infection ▪ If the other person had a detectable HIV viral load (>200 copies/mL) ▪ Determination of HIV status <ul style="list-style-type: none"> - Patient should be provided the Pharmacist-Initiated HIV Post-Exposure Prophylaxis Patient Questionnaire to self-report if they have ever tested positive for HIV - 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. - 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 ▪ Sexual Assault 						



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

	<ul style="list-style-type: none"> - 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 - In these instances, PEP may be initiated without delay, if no other contraindication, with referral for specialty care 	
Contraindications	<ul style="list-style-type: none"> ▪ Patient self-reports, or if a point-of-care HIV test is positive ▪ > 72 hours since exposure ▪ Known or suspected reduced renal function 	
Precautions	<ul style="list-style-type: none"> ▪ Pregnancy (known or suspected) and breastfeeding ▪ Follow the guidance given in the sections below for each of these considerations 	
Safety Evaluation	<ul style="list-style-type: none"> ▪ 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"> - If no clinically-significant drug interactions, between current medications and PEP: <ul style="list-style-type: none"> ▪ Proceed to dispense PEP therapy - If clinically-significant drug interactions between current medications and PEP: <ul style="list-style-type: none"> Step 1: Contact patient-authorized medical provider for guidance If the authorized medical provider is not available: Step 2: Contact the National Clinician Consultation Center (NCCC) Post-Exposure Prophylaxis Hotline at (888) 448-4911 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 Step 3: Refer the individual seeking PEP therapy to the Emergency Department or other medical provider ▪ If individual seeking PEP therapy is breastfeeding, follow Step 1-3 as outlined in this section. 	
Medication Dispensing	28-Day Regimen (See 'How Supplied' Below)	Alternative 28-Day Regimen (See 'How Supplied' Below)
	Individuals 13 years and older (Including Pregnant Patients)	
	tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg once daily plus 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 plus darunavir 800 mg AND ritonavir 100 mg once daily
How Supplied	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 this standing order.	
Refills	None. No limit on how many courses per patient per year (see Patient Education section for addressing risk mitigation).	
Patient Education	<ul style="list-style-type: none"> ▪ Medication Education <ul style="list-style-type: none"> - When 30-day supply is dispensed, emphasize the minimum treatment duration is 28 days. - 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. - An offer to counsel should be made in accordance with standard North Carolina pharmacy practice ▪ Risk Mitigation <ul style="list-style-type: none"> - Educational material on PEP should be provided - Educational material on behaviors to avoid HIV exposure should be offered - Pre-exposure Prophylaxis (PrEP) Education <ul style="list-style-type: none"> ▪ This should be considered when: <ul style="list-style-type: none"> ● 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) ● More than 1 course of PEP therapy has been dispensed within a year ▪ If appropriate, written/verbal education on PrEP and the benefits to use should be provided ▪ HIV testing <ul style="list-style-type: none"> ▪ Each patient who receives PEP therapy shall be educated on the importance of having a test to determine their HIV infection status. ▪ Pharmacist shall educate the patient on self-test HIV kit and local HIV testing site options. 	



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

	<ul style="list-style-type: none">▪ 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.▪ Emphasize the importance of receiving follow-up care from a medical provider to allow for:<ul style="list-style-type: none">- Signs and symptoms of acute HIV infection- Full evaluation of the exposure- Receipt of HIV testing- Information on resources available for HIV exposure▪ Inform the patient of the importance of completing the full 28-day course of PEP therapy unless directed otherwise by a medical provider▪ 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.
Notification	Pharmacists choosing to dispense PEP, under the authority of this standing order, 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.

 CT. Tilson

Approved by: _____ Date signed: 3-28-22

Elizabeth Cuervo Tilson, MD, MPH
NPI: 1760540421

[\(Legal Authority Session Law 2021-110 HouseBill 96\)](#) This order is effective immediately upon signing and may be revised or revoked by the State Health Director according to his/her discretion. This order shall remain in effect until the later of the development of the protocols described in Section 4(a) Session Law 2021-110 HouseBill 96 or January 1, 2023.