

Attachment A: Sample Standing Order and Protocol

**STANDING ORDER AND PROTOCOL FOR INITIATING HIV POST-EXPOSURE PROPHYLAXIS (PEP)
IN THE PHARMACY SETTING**

Issuing Licensed Health Care Provider	Insert the name of the licensed physician or certified nurse practitioner
Name of Participating Pharmacy or Name of Pharmacy and listing of pharmacists	Insert the name and address of the participating New York State licensed pharmacy <u>or</u> Insert the names and license numbers of each licensed pharmacist authorized to execute the non-patient specific order and protocol
Effective Time Period	From xx/xx/xxxx to xx/xx/xxxx

I. Signed and Dated Medical Directive/ Non-Patient Specific Standing Order

I, insert name of licensed physician or nurse practitioner, a licensed practitioner authorized to prescribe medication in the State of New York, authorize the pharmacy or pharmacists noted above to dispense HIV PEP medications to individuals who may benefit from this HIV prevention intervention in accordance with the attached protocol and Chapter 502 of the Laws of 2016 and relevant sections of the regulations of the Commissioner of Education.

Prescriber's Name Prescriber's Signature NYS License # Date

II. Authorized Pharmacy Manager

By signing this Non-Patient Specific Standing Order and Protocol for initiating HIV PEP in the Pharmacy Setting, I attest that the above noted registered pharmacists have read and understand this protocol and have received appropriate education to enable them to initiate HIV PEP in accordance with this protocol.

Pharmacy Manager Name Signature NYS License # Date

Pharmacy Name Pharmacy Address Phone number

STEP ONE: Screen the individual to determine whether an exposure occurred which would meet the criteria for PEP initiation.

A. Explain that PEP for HIV can prevent HIV infection if a person had a recent exposure with significant risk. Inquire why the person is interested in PEP and what specific behavior might have put the individual at risk for HIV infection. Another option would be to simply provide the person with a list of behaviors and then ask: “Based on this list of behaviors, are you interested in starting PEP?”

IMPORTANT CONSIDERATIONS:

- Demonstrate a nonjudgmental attitude in response to reported risk behavior.
- Adopt a low threshold for initiating PEP to individuals who express interest if there is any suspicion that the individual is uncomfortable disclosing the nature of the exposure.

High Risk Exposures for Which PEP Should be Recommended
Anal or vaginal intercourse (insertive or receptive) with a person known to be living with HIV or whose HIV status is unknown
Sharing needles with a person known to be living with HIV or unknown HIV status
Injuries with exposure to blood or other potentially infectious fluids such as needle sticks with hollow bore needles or human bite involving exposure to blood with a person living with HIV or unknown HIV status
Lower Risk Exposures Requiring Case by Case Evaluation
Mouth to vagina contact (insertive or receptive)
Mouth to anus contact (insertive or receptive)
Mouth to penis contact with or without ejaculation (insertive or receptive)

For lower risk exposures, inquire about the following factors that increase risk

- Do you know if the other person had a high HIV viral load?
- Was the oral mucosa not intact, i.e. sores, cuts or abrasions?
- Was blood present? Did you or your partner have a genital ulcer or sexually transmitted infection?

If any of these factors were present, it would weigh in favor of dispensing PEP.

IMPORTANT POINT: REFER VICTIMS OF SEXUAL ASSAULT TO THE EMERGENCY DEPARTMENT

- If it is learned that the individual was a victim of sexual assault with any risk of exposure, refer the person to the emergency room where specially trained staff are available and the person can access all needed services.
- In these instances, dispense one dose of PEP without delay and encourage the person to go to the Emergency Room without delay.

B. IF THE PERSON INDICATES SIGNIFICANT RISK, PROCEED TO STEP TWO.

C. If the person reports ONLY the following types of exposures, explain that these alone do not warrant PEP (no risk).

- Kissing: There is no risk associated with close-mouthed kissing. There is a remote risk associated with open-mouthed kissing if there are sores or bleeding gums and blood is exchanged.
- Oral-to-oral contact without mucosal damage (mouth-to-mouth resuscitation)
- Human bites not involving blood
- Exposure to solid-bore needles or sharps not in recent contact with blood: f.e.x solid-bore needles include tattoo needles and lancets used by people living with diabetes to measure blood-sugar levels.
- Mutual masturbation without skin breakdown or blood exposure.
- Exposure to saliva, including if spat on, in the absence of visible blood

IF NO SIGNIFICANT RISK WAS PRESENT, PROCEED TO END PROTOCOL

- If it is determined that there was no significant risk of HIV exposure, reassure the person and encourage the individual to talk with a health care provider or community-based program about HIV prevention.
- Provide the NYSDOH PEP 4 HIV Prevention Brochure and encourage the person to review the resources provided for more information.
- **END PROTOCOL, DO NOT PROCEED.**

STEP TWO: Assess the length of time since the exposure to determine if PEP can be initiated within the indicated timeframe.

A. Identify when the exposure took place and explain the timeline of effectiveness of PEP.

If the person is not sure about when the exposure took place, try to define the specific day it took place and a rough estimate of the time of day, for example morning, afternoon, evening or late night. Explain that PEP is most effective when initiated as soon as possible and, as time elapses, the effectiveness is diminished. Review the timeline for initiating PEP, including that the first dose of PEP should be initiated immediately, effectively before 36 hours, with diminished efficacy when 36 to 72 hours have elapsed and do not initiate if more than 72 hours has elapsed.

B. IF THE EXPOSURE TOOK PLACE WITHIN 72 HOURS, AND THE PERSON IS INTERESTED IN PEP, PROCEED TO STEP THREE.

IF MORE THAN 72 HOURS HAS ELAPSED FROM TIME OF EXPOSURE, PROCEED TO END PROTOCOL

- If the exposure took place more than 72 hours ago, refer the person to their health care provider or a local HIV prevention program for HIV testing and to learn about HIV prevention options including Pre-exposure Prophylaxis (PrEP). Explain that PrEP is an HIV prevention method for people who are known to be HIV negative where the person takes medication before any exposure to avoid HIV. Encourage individuals who may have ongoing risk, to consider PrEP.
- Provide the NYSDOH PEP 4 HIV Prevention brochure and encourage the person to review the resources provided for more information.
- **END PROTOCOL, DO NOT PROCEED.**

STEP THREE: If the individual reports significant risk and the exposure took place within the indicated timeframe, inquire about any other medications the person is currently taking.

- A. Ask the person for a list of health conditions and other medications the individual is currently taking. Review each item on the list of medications for drug to drug interactions with PEP medications.
- B. IF THE PERSON IS NOT TAKING OTHER MEDICATIONS OR IF THERE ARE NO INDICATED DRUG TO DRUG INTERACTIONS, PREPARE TO DISPENSE 7 DAYS OF PEP AS OUTLINED IN THE STANDING ORDER AND CONTINUE TO STEP FOUR.**

The PEP regimen recommended by the NYS Clinical Guidelines Program:

Tenofovir disoproxil fumarate 300 mg/ emtricitabine 200 mg (TDF/FTC; Truvada) once per day				
<i>or</i>				
TDF 300 mg/lamivudine (TDF/3TC; Cimduo) 300 mg once per day				
Plus one of the following				
Raltegravir (RAL; Isentress) 400 mg PO twice daily	OR	RAL HD 1200 mg once per day	OR	Dolutegravir (DTG; Tivicay) 50 mg PO once per day
Length of time: 28 days				

- C. If the person is taking a medication(s) with indicated drug to drug interaction, contact the authorizing medical provider or practice for guidance about how to proceed. If the provider is not available, contact one of the other health care providers listed in Section III for guidance or, if that is not possible, refer the individual to the Emergency Department for care. An additional resource is the HIV Clinical Education Initiative PEP hotline at 866-637-2342.

STEP FOUR: Provide counseling, coordination of follow-up care and dispense medication.

- A. Provide medication sheets for each medication prescribed and offer counseling on the medication and possible side effects in accordance with standard pharmacy procedures.
- B. Emphasize the importance of a follow-up appointment to allow a health care provider to:
 - 1. Fully evaluate the exposure;
 - 2. Conduct voluntary HIV testing;
 - 3. Decide about writing a prescription for the rest of the 28-day regimen;
 - 4. Offer counseling regarding protecting partners from possible exposure to HIV.
- C. The pharmacist shall assist the person in deciding whether to follow up with the individual's existing primary care provider or provide a health care provider from Section III of this protocol who is available to conduct follow-up care within 1-3 days of initiating PEP. Whenever possible, the pharmacist, or a designee, should call the health care provider to establish an appointment for the person. The pharmacist should provide the person with the date, time, address and name of provider who will provide follow-up care using the space provided on the NYS PEP 4 HIV Prevention Brochure.
- D. When it is not possible for the pharmacist or a designee to set up the appointment, the names of at least three health care providers from Section III shall be provided to the person.
- E. Request that the person sign an authorization for release of information so that the pharmacy may: 1) provide the follow-up health care provider with information regarding the patient's receipt of 7 days of PEP, 2) confirm a visit took place, and 3) determine whether the remaining 21 days of PEP were prescribed.
- F. Dispense the medication and provide the NYS PEP 4 HIV Prevention Brochure.
- G. **END PROTOCOL**

STEP FIVE: DOCUMENTATION

- A. Pharmacists should document provision of PEP medication and delivery of counseling and referral services in the same manner that they would document other similar services.
- B. Enter information into the patient's pharmacy record and the pharmacy's standard electronic record keeping system, in accordance with general pharmacy documentation practices.
- C. All documentation should be maintained in a retrievable format.