

The Licensed Pharmacist's Role in Initiating HIV Post-Exposure Prophylaxis: Overview and Frequently Asked Questions December 2017

Effective March 14, 2017, the New York State Board of Regents has amended scope of practice regulations to allow licensed pharmacists who are acting under a non-patient specific standing order from a licensed physician or nurse practitioner to dispense 7 days of HIV post-exposure prophylaxis (PEP) medication to individuals who present with a recent exposure to HIV. PEP is a highly effective biomedical intervention for preventing HIV infection, but it must be initiated as soon as possible following a potential exposure. Community pharmacists are trusted individuals who are in an excellent position to facilitate early initiation of PEP. Licensed pharmacists who dispense the initial 7 days of medication will coordinate a referral to a health care provider for a full evaluation of the exposure, HIV testing and to provide the individual with a prescription for the remaining days of the 28-day PEP medication regimen.

Specific Responsibilities of the Authorizing Licensed Medical Provider

The licensed medical provider who signs the non-patient specific standing order is expected to play an active role in partnering with the pharmacy and has several important responsibilities. It is expected that the licensed medical provider, and members of their practice, will be involved in providing timely follow-up care for patients who initiate PEP through pharmacists included in the standing order. Since a single medical provider may not be able to meet the potential demand for follow-up appointments, the issuing medical provider is also responsible for establishing agreements with other area medical providers to offer follow-up care within 1-3 days of initiating PEP in the pharmacy. The medical provider, and members of the practice, should be available to respond to calls from a pharmacist regarding medical management issues that may arise when preparing to dispense PEP medications. This may include on the spot decision-making regarding management of individuals with other health complications, addressing medical contraindications, potential drug-drug interactions and authorizing use of alternate PEP regimens when needed.

Comparison of Guidelines Regarding Timeline for Initiation of PEP

PEP is universally recognized as an effective prevention intervention but there are some differences in recommendations between New York State Clinical Guidelines and Centers for Disease Control and Prevention (CDC) guidelines. The following chart outlines the similarities and differences.

Length of Time from Exposure	NYS Clinical Guidelines	CDC Guidelines
0 – 2 hours	Ideal time for initiation	Effective
2 – 36 hours	Effective	Effective
36 – 72 hours	Diminishing efficacy as time elapses; evaluate on case by case basis	Effective
After 72 hours	No evidence to support effectiveness of PEP	

Requirement of a Non-Patient Specific Standing Order

Pharmacist involvement in initiation of HIV PEP is voluntary. Licensed pharmacists interested in initiating HIV PEP must partner with a licensed physician or nurse practitioner to establish a non-patient specific standing order and detailed protocol to dispense a designated medication regimen(s). According to amendments to Chapter 502 of the Laws of 2016 and pertinent sections of NYS Education Law, a non-patient specific standing order and protocol for PEP must outline the following details:

1. The name, license number, and signature of the licensed physician or nurse practitioner issuing the standing order;
2. The name and license number of each pharmacist authorized to execute the non-patient specific order and protocol **or** the name and address of the pharmacy that employs or contracts with the licensed pharmacist;
3. The period-of-time for which the standing order is effective;
4. The name and dose of the specific PEP medications to be dispensed;
5. A description of types of exposure for which PEP medication may be dispensed;
6. A review of the ideal and maximum length of elapsed time after exposure for which PEP medication may be dispensed;
7. A listing of the specific responsibilities of the pharmacist with regards to dispensing PEP including, at a minimum:
 - a. Screening each potential recipient to identify whether the exposure meets the clinical criteria and medication can be initiated within the designated timeframe;
 - b. Providing counseling and coordinating follow-up care with a medical provider. The counseling shall include an explanation of the importance of the follow-up care which will include: 1) a full evaluation of the exposure, 2) HIV testing, 3) obtaining a prescription for the rest of the 28-day regimen, and 4) learning strategies to protect partners;
 - c. Providing in writing the names and addresses of health care providers who will provide follow-up care.
8. The method by which pharmacist shall document services delivered, including counseling and referral information to be provided to the individual.

Specific Responsibilities of Pharmacists Initiating PEP

Pharmacists who are interested in including initiation of PEP in their scope of practice should seek to partner with a licensed medical provider to establish a non-patient specific standing order as outlined above. The order and protocol will define the scope of the pharmacist's responsibilities which should include the following:

I. Screening each potential recipient to identify whether the exposure meets the clinical criteria and whether medication can be initiated within the designated timeframe;

In conducting the screening, pharmacists should define a space where a confidential conversation can take place, out of the earshot of other pharmacy staff and customers. The pharmacist should demonstrate a non-judgmental attitude and engage in a conversation to accurately elicit information about the nature of the exposure(s). The pharmacist should be knowledgeable about the types of exposures that constitute significant risk, those with limited risk and those with no risk (see FAQ # 1 below). The pharmacist should be familiar with the timeline for initiating PEP, including that PEP should be initiated as soon as possible, ideally within two hours, effectively before 36 hours, with diminished efficacy when 36 to 72 hours have elapsed and not initiated if more than 72 hours has elapsed.

II. Providing counseling and coordinating follow-up care with a medical provider. The counseling shall include an explanation of the importance of the follow-up care which will include: 1) a full evaluation of the exposure, 2) HIV testing, 3) obtaining a prescription for the rest of the 28-day regimen, and 4) learning strategies to protect partners;

The NYSDOH will develop a consumer education brochure on PEP that pharmacists should provide to all individuals considering or initiating PEP in the pharmacy setting. The brochure is a resource that will assist the pharmacist in providing tailored counseling. The pharmacist should explain that the pharmacist is providing the individual with only 7 days of the medication but, to be effective, it must be taken for 28 days. The pharmacist should inform the individual of the importance of following-up with a medical provider within the next 1-3 days to: fully evaluate the exposure; conduct HIV testing; obtain the rest of the medication supply; and discuss strategies for protecting the person's sexual or needle sharing partners. The pharmacist should explain the signs of early HIV infection (see FAQ # 5 below) and emphasize the importance of seeing the health care provider as soon as possible if any of these symptoms develop.

III. Providing the names and addresses of health care providers who will provide follow-up care;

The non-patient specific standing order must include a list of health care providers with whom

formal agreements are in place to accept individuals for a health care appointment within 1-3 days of initiating PEP in the pharmacy setting. It is critical that pharmacists have a list of health care providers prepared to deliver care within 1-3 days because of the importance of follow-up care and the potential difficulty of obtaining an appointment on such short notice. Another important resource for follow-up care is the individual's regular primary care provider. In addition to wanting to see a familiar provider, it may be important to follow-up with the person's own provider, or a provider associated with the person's managed care plan or insurance company, to avoid out of network expenses for the appointment and the prescribed medication.

Regardless of whether follow-up care is provided by the person's own health care provider or one listed on the pharmacy's standing order, the pharmacist should request written authorization to facilitate follow-up between the pharmacist and that provider. Whenever possible, the pharmacist, or a designee, should call the medical care provider to establish an appointment for the individual. The pharmacist should provide the individual with the date, time, address and name of a medical care provider who will conduct follow-up care.

If an appointment cannot be made, for example, because the person comes to the pharmacy in the late evening or early morning, the pharmacist should provide the individual with the names of at least three medical care providers listed on the standing order to ensure the individual's success with obtaining follow-up care.

IV. Providing the medication along with directions for taking the medication, including emphasizing the importance of adherence.

Pharmacists should provide a 7-day supply of the medication along with directions for taking each medication. It is important to explain that, to be effective, the medication must be taken exactly as prescribed, preferably at the same time each day. If the pharmacist is not able to arrange a specific appointment for follow-up care, the pharmacist should emphasize to the individual the importance of obtaining the balance of the 28-day regimen in time to avoid missing any doses of the medication. Because prior authorizations and other barriers can slow the process of filling a prescription, pharmacists who do not provide the date of the medical appointment, should encourage individuals to make sure the appointment is within 1 to 3 days.

V. Documenting provision of services including counseling and referral information provided to the individual.

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. It is anticipated that pharmacists would enter information into the patient's pharmacy record and the pharmacy's standard electronic record keeping system, in accordance with general

pharmacy documentation practices. All documentation should be maintained in a retrievable format, meaning that it can be recovered and compiled from any database or record keeping system.

FREQUENTLY ASKED QUESTIONS

1. What constitutes an HIV exposure that would be appropriate for PEP?

When discussing the nature of the individual’s exposure to HIV, it is important to demonstrate openness and a non-judgmental attitude. Individuals may be reluctant to discuss the details of a sexual exposure or needle sharing event. It is important to explain to the individual that the nature of the exposure is essential for determining whether PEP is indicated. Pharmacists should 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. One option would be to simply provide the individual with a list of high risk exposures and then ask: “Based on this list, are you interested in starting PEP?”

High Risk Exposures for Which PEP Should be Recommended
Anal 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 whose HIV status is unknown
Injuries with exposure to blood or other potentially infected fluids such as needle sticks with hollow bore needles or human bite involving exposure to blood with a person living with HIV or unknown 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)
Factors that Increase Risk of HIV Transmission/Acquisition
<ul style="list-style-type: none">• High HIV viral load of source person• Oral mucosa not intact• Presence of blood; genital ulcer or STD

Types of exposures that 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 (e.g., tattoo needles and lancets used by a person with diabetes to measure blood-sugar levels) or sharps not in recent contact with blood.
- Mutual masturbation without skin breakdown or blood exposure.

For specific risk calculations for specific risk behaviors visit the NYS HIV Clinical Guidelines site: [Estimated Per-Act Probability of Acquiring HIV](#).

2. What is the current recommended PEP medication regimen?

The PEP regimen recommended by the NYS Clinical Guidelines Program is as follows:

Tenofovir 300 mg PO daily + emtricitabine 200 mg PO daily		
Note: a fixed-dose combination is available Truvada 1 PO qd.		
Plus one of the following		
Raltegravir 400 mg PO twice daily	OR	Dolutegravir 50 mg PO daily
Length of time: 28 days		

IMPORTANT POINT

The pharmacist should inquire about other health conditions and identify any medications the person is taking. If the person is taking a medication with a drug to drug interaction with a medication in PEP regimen, the pharmacist should contact the authorizing medical provider for guidance about how to proceed. If the provider is not available, the pharmacists should contact one of the other follow-up health care providers listed in the protocol for guidance. 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.

3. What are the expectations of the authorizing medical care provider and the pharmacist for arranging follow-up care for patients who initiate PEP in the pharmacy setting?

Establishing a strong network of health care providers who agree to provide timely follow-up care is critical to the success of initiating PEP in the pharmacy setting. It is expected that the authorizing health care provider, and other medical providers in the practice, will be available to provide follow-up care for patients who receive PEP from the pharmacy. In addition, the authorizing medical care provider is expected to establish agreements with a minimum of three other medical care providers in the area to provide appointments for follow-up care within 1-3 days of the initiation of PEP. In cases where an individual has an established primary care provider, the option of receiving follow-up care from that provider should be explored, including a discussion of the ability of the person to obtain the appointment within 1-3 days. It must be noted that, in many cases, individuals will need to receive follow-up care from their primary care providers or, providers associated with their managed care plan or insurance plan, to avoid out of network charges for the appointment and prescribed medication. Regardless of

the patient's choice of health care provider, the pharmacist or a designee should contact the health care provider who will provide follow-up care to establish an appointment for the individual before the person leaves the pharmacy. The name of the provider, address, date and time of the appointment should be provided to the patient in writing.

If an individual comes to the pharmacy late at night or early in the morning, it may not be possible to schedule the follow-up appointment before the person leaves the pharmacy. In these instances, the pharmacist should provide the name, address and contact information for at least three medical care providers who are listed in the Standing Order who have agreed to provide timely follow-up care. Providing three options should help ensure that the person will have success arranging an appointment for follow-up care within 1-3 days. When the person signs authorization for the pharmacist to communicate with the follow-up health care provider, the pharmacist can take steps to ensure the individual was successfully linked to care.

4. Can a pharmacy medical director serve as the licensed medical provider who issues the non-patient specific standing order for the pharmacy?

A pharmacy medical director would only be a candidate to serve as the authorizing medical provider only if able fulfill these responsibilities: 1) be available to provide follow-up appointments for care of patients who initiated PEP in the pharmacy; 2) establish agreements with other health care providers to accept referrals of patients within 1-3 days of the pharmacy initiating PEP; 3) respond to calls from pharmacists in cases when a patient has a contraindication to one of the medications in the standard PEP regimen or respond to other clinical issues that may arise when preparing to dispense PEP.

5. What are the signs of acute/early HIV infection?

The symptoms of acute/early HIV infection include: sore throat; swollen glands; fever; rash; joint and muscle aches; diarrhea; tired feeling and mouth sores. The symptoms of early HIV are similar to the symptoms of the flu with some important differences. Nasal congestion, sneezing and cough are not typically present with early HIV and can be used to help differentiate cases of the flu. The presence of rash or mouth sores may indicate early HIV, especially if the patient reports sexual or needle sharing behaviors or acquisition of a sexually transmitted infection. The signs and symptoms of early/acute HIV infection can begin 2 to 4 weeks after infection and symptoms can last for just a few days or weeks. For information about NYS Clinical Guidelines addressing Acute HIV Infection, visit <http://www.hivguidelines.org/adult-hiv/testing-diagnosis/acute/>.

6. How should a pharmacist respond if a person becomes argumentative after being denied PEP medication because the exposure took place more than 72 hours ago?

If a person is denied PEP and becomes argumentative, it is important to take steps to calm the

person. Important steps that can be taken include:

- Explain that, in this situation, there is no benefit to starting the medication;
- Refer the person to a community based organization for prevention information and HIV testing or to a health care provider for a full evaluation and HIV testing;
- Explain that if the exposure does lead to infection, HIV treatment is very effective, especially when started early;
- Explain that if an exposure results in infection there are often symptoms of early infection. These include: fever, rash, swollen glands, joint/ muscle aches, tired feeling. If the person has these symptoms, encourage him or her to seek medical care;
- Explain that if it is determined that this exposure did not result in HIV infection, the individual may consider talking to a health care provider about pre-exposure prophylaxis or (PrEP). PrEP involves taking a medication daily to prevent getting HIV.

7. Can PEP be initiated for minors?

Yes, PEP is an important HIV prevention intervention for minors who may be experimenting with sexual or needle sharing behaviors, as well as for minors who may have a long history of these behaviors. New York State Public Health law was amended in 2017 to allow minors to consent to their own HIV prevention and treatment decisions, just as they have long been allowed to consent for treatment of sexually transmitted infections. Pharmacists should emphasize to the minor the importance of follow-up care and consider additional steps to ensure the minor keeps that appointment. In complex cases, it may be beneficial to refer the young person to the emergency room. Pharmacists are prohibited from discussing any details related to the exposure or provision of PEP with the minor's parents or guardian without written permission of the minor.

8. How should a pharmacist respond to a person seeking HIV PEP who is a victim of sexual assault?

Care for victims of sexual assault is more complex than just initiating HIV PEP. Sexual assault victims should be referred to the emergency room where specially trained staff are available to provide the full range of needed services. If indicated in the protocol and standing order, the pharmacist may dispense one dose of the regimen to get the individual started on PEP before heading directly to the emergency room. Pharmacists should also provide the individual with the New York State Domestic and Sexual Violence Hotline at 1-800-942-6906 or 311 in NYC.

9. To what extent will private insurers, Medicaid or Medicare cover the cost of the medication?

Medicaid, Medicare and most private insurers cover the cost of medication for PEP. The patient may be responsible for a medication co-pay. In cases where an individual seeks PEP and does

not have insurance, it may be possible to connect the individual to the drug manufacturer to learn about availability of a reduced cost coupon or Patient Assistance Program. NYC residents, regardless of insurance status, can call the NYC PEP Hotline at 844-3-PEP NYC (844-373-7692) 24 hours a day, 7 days a week to initiate PEP right away. The Hotline can connect individuals to a clinic with expertise in providing PEP and staff to help them navigate payment options. If calling outside clinic hours, the Hotline will help individuals obtain a PEP starter pack through a pharmacy and connect the person to a clinic for follow-up care. Additionally, the NYC Health Department supports provision of PEP to uninsured individuals at NYC Sexual Health Clinics and at PEP Centers of Excellence, community-based clinical sites with expertise in providing PEP. For a list of such sites visit: <http://www1.nyc.gov/site/doh/health/health-topics/prep-pep-resources.page>.

10. To what extent can pharmacies bill for the additional counseling time required to initiate PEP in the pharmacy?

There is no specific new billing code or billing mechanism in place to provide reimbursement to pharmacists for the additional counseling time associated with initiation of PEP. Effective April 1, 2017, the state Medicaid program's dispensing fee of \$3.50 per prescription was updated to a professional dispensing fee with a new rate of \$10.00 per prescription. Managed care organizations and private insurance companies may have a range of different approaches and policies regarding pharmacist reimbursement for counseling services. Pharmacists may consult with other payors regarding these policies.

11. Truvada, one of the medications in the standard PEP regimen, is currently packaged in bottles of 30. To what extent is it allowable for a pharmacy to dispense 7 pills from the bottle of 30 and then dispense the rest of the medication at a later date?

Storage and stability information from the drug manufacturer, Gilead, indicates that the medication is stable at normal indoor temperatures in a bottle that has been previously opened (i.e. without an induction seal) for 6 weeks, as long as that time-period falls within the product's expiration date. This means that the pharmacist would have six weeks to use the remaining medication without having to dispose of the remaining medication as unused. If the medication is not sold within that 6-week period, the pharmacy can use standard practices to seek financial adjustments from the drug manufacturer for unused medication.

11. Must the standing order specifically list the names of all licensed pharmacists who may dispense PEP or may the standing order simply list the name of the pharmacy?

When developing the standing order, the pharmacy and authorizing health care provider may choose to list the names of all participating pharmacists or may simply list the name of the pharmacy. However, it is important is that all pharmacists clearly understand their

responsibilities with regards to dispensing PEP medication and that all those with this authority be fully versed in the protocol. Since the goal is to provide timely access to PEP, pharmacies will be in the best position to initiate PEP if there is always at least one pharmacist available that can dispense the medication during all hours of business. In many cases, individuals seeking PEP may present to the pharmacy late at night or early in the morning. This should be considered when deciding which and how many pharmacists will have the capacity to dispense PEP medications in accordance with the standing order and protocol.

12. What should a pharmacist do if an individual did not follow-up with a medical provider and returns to the pharmacy after completing 7 days of medication to request a refill?

If a person returns to the pharmacy after 6-7 days without having seen a medical provider, the pharmacist should attempt to arrange a follow-up appointment with a medical provider that same day. If an appointment cannot be made for that day, the pharmacist should explain the importance of seeking care immediately at the Emergency Department. HIV testing is a critical component of follow-up care. The PEP regimen should not be continued unless a baseline HIV test indicates that the person was not previously living with HIV. An individual who presents 6-7 days into the medication regimen needs follow-up care from a medical provider including immediate HIV testing and evaluation of appropriateness of continuing the PEP regimen.

13. What if an individual does not have any health coverage?

The NYC Health Department supports provision of PEP to uninsured individuals at NYC Sexual Health Clinics and at PEP Centers of Excellence, community-based clinical sites with expertise in providing PEP. For a list of such sites visit: <http://www1.nyc.gov/site/doh/health/health-topics/prep-pep-resources.page>.

For areas outside of New York City, refer people without health coverage to the nearest Emergency Department for care.

14. How will the public become aware of increased access to PEP through pharmacies?

The NYSDOH, NYC Health Department and other local health departments are taking steps to educate clinical and non-clinical providers who interact with the general public that PEP is an effective HIV prevention intervention that can be accessed in a variety of venues, including pharmacies. Consumer education materials about HIV prevention will inform the public about PEP and how to access it through participating community pharmacies. The NYSDOH is developing a logo or decal that can be displayed on the window of a participating pharmacy.

15. Is the NYSDOH involved in conducting a pilot study to identify best practices for implementing initiation of PEP in the pharmacy setting?

The NYSDOH, in conjunction with the NYC Health Department, is implementing a pilot program to identify best practices for initiating PEP in the pharmacy setting. Pharmacies participating in the pilot will receive a draft protocol, brief training, patient education materials and will be required to attend a monthly one hour phone conference and submit periodic data reports to the NYSDOH. The length of the pilot will be 6 months or provision of PEP to 50 patients, whichever comes first. The pilot is slated to begin in March of 2018. For more information about the status of the pilot and to indicate interest in participating, please email peppharmacy@health.ny.gov.

16. What resources will the NYSDOH make available to assist with implementing initiation of PEP in the pharmacy setting?

The NYSDOH is committed to providing a wide range of resources to assist with implementation.

- The NYSDOH Clinical Guidelines Program provides up to date clinical guidance on PEP through its on-line portal at www.hivguidelines.org;
- The HIV Clinical Education Initiative offers a PEP hotline at 866-637-2342;
- Sample non-patient specific standing orders and protocols can be obtained by emailing peppharmacy@health.ny.gov.
- Training programs for pharmacists with continuing education credits are available at www.ceitraining.org;
- A patient education brochure to be distributed along with PEP medication will soon be available in a variety of languages.

As the DOH becomes aware of additional needs, efforts will be made to address them. For more information, please email the AIDS Institute at peppharmacy@health.ny.gov.