Delaware Division of Public Health
Department of Health and Social Services

Guidelines for Delaware Pharmacists for HIV Pre-Exposure Prophylaxis (PrEP) and Post-Exposure Prophylaxis (PEP)

Effective dates:
12/1/2025-12/31/2027

Contents

Target Audience

1. This document applies to all pharmacists duly licensed under Chapter 25 of Title 24 of the Delaware Code
2. Supporting and regulatory agencies including the Delaware Board of Pharmacy & Delaware Division of Public Health

Background

Long-standing health provider shortages in Delaware were accentuated by the COVID-19 pandemic. This has happened against a backdrop of an ageing population with increasing health care needs. Expansion of traditional health care systems in the state has not been able to keep up with the increasing demand. Despite great ongoing efforts from multiple sectors (governmental and non-governmental), health disparities persist across multiple health conditions. These are driven, in no small part by problems around availability and accessibility to health services. It has thus become increasingly important to address the health needs of the population by leveraging all available health care resources including pharmacists (in particular community pharmacists)

Governing Legislation

1. SB 194 {152nd) - Signed 9/24/24 Covers HIV Pre-exposure Prophylaxis and HIV Post Exposure Prophylaxis
2. HB 399 (151st)- Signed 10/3/2022 Covers CUA waived laboratory testing

Purpose, Scope and Limitations

The purpose of this document is to provide treating Delaware licensed pharmacists with information regarding the management of conditions identified by the legislation noted under "governing legislation" above. Because of the rapidly changing nature of medical science, it is not the intention of this document to provide step-by-step or scenario specific recommendations for the management of these conditions. Rather this document will:

1. Provide users with information regarding those agencies and organizations that provide, maintain and update national guidelines for the management of the conditions specified
2. Direct users to the most current available guideline documents and webpages from the organizations mentioned in #1 above, as of the date of this document's publication.
3. Extract from these national guidelines and highlight, where relevant, certain elements that are noteworthy for the management of most (but not all) occurrences of the diseases or conditions covered
4. Because each patient is different, and each clinical scenario comes with several nuances, it is not possible for a document such as this to cover all possibilities.

5. Delaware licensed pharmacists (and where applicable, their employers) must ensure that pharmacists who will be treating patients under these guidelines do so in line with the "Pharmacist responsibilities" outlined below

Roles and Responsibilities

Pharmacist responsibilities

It is the responsibility of Delaware licensed pharmacists who will be providing care to patients in line with the legislation above to ensure that:

1. They remain familiar with the governing legislation regarding pharmacists' scope and what conditions are covered under the legislation noted in this document and elsewhere.
2. They remain familiar with the most current national guidelines for the conditions that they will be treating including those put forth by national governmental guideline providers (such as the Centers for Disease Control and Prevention- CDC) as well as specialist societies for the relevant conditions. For HIV prevention, this includes, but is not limited to ACOG (American College of Obstetricians and Gynecologists), IDSA (Infectious Diseases Society of America) among others.
3. At all times, they are practicing within the scope of practice appropriate for their license and within the limits of their training.
4. Similar to other medical providers, they at all times and in all cases apply sound clinical judgement when making clinical management decisions for the patient before them. This includes integrating elements from history-taking, physical examination, review of medical records, discussion of patient values/preferences and results of diagnostic testing.
5. They consider themselves as part of the patient's clinical team and share information with, consult with, and/or refer patients to other members of the clinical team as necessary for the patient's optimal care. This includes but is not limited to the patient's primary care providers, Division of Public Health providers, specialists, hospitals, emergency departments or other branches of the health care system as appropriate.
6. They become and remain familiar with the signs and symptoms of urgent, emergent or worsening health conditions that would necessitate referral to a different level of care or a different healthcare provider.

Employer responsibilities

It is the responsibility of all employers whose employed pharmacists will be working under these standing orders to:

1. Provide support, mentorship, community and practice-support resources to pharmacists
2. Provide clinical practice resources and as appropriate, training and clinical oversight for the practice of the employed pharmacists who will be working under this order.

Board of Pharmacy Responsibilities

It is the responsibility of the board of pharmacy to

1. Work with DPH to review and update these guidelines on (at the minimum) a biennial basis and/or as needs arise and changes are required due to expanding scientific knowledge or emerging health threats
2. Provide training to pharmacists where required by the governing legislation

DPH Responsibilities

DPH has responsibility to:

1. Review and update these guidelines on a biennial (every two years) basis in line with national guidelines from the other relevant organizations
2. Review and update these and other practice guidelines as needed during periods when there are emerging/evolving public health threats. This is to allow pharmacists' expertise to be leveraged as part of the state response to the emerging threat
3. Send a representative to appear before the board of pharmacy on a biennial basis, or whenever there are substantive changes to this document. The purpose of this is to inform and review the changes with the members of the board
4. Serve as a referral source where pharmacists can refer patients when needed (particularly for those patients who do not have a primary care provider)

HIV Pre-exposure Prophylaxis

"HIV Pre-exposure prophylaxis" (PrEP) for the purpose of this document, means the group of interventions (including history-taking, laboratory testing and use of antiretrovirals approved by the FDA) for the purpose of reducing the risk of acquiring HIV in persons at increased risk of HIV infection.

Pharmacists must complete and remain current with training in HIV Pre-exposure prophylaxis use as outlined by the DE Board of Pharmacy.

Relevant National Guidelines

Pharmacists must familiarize themselves with the most current guidelines on HIV Pre-Exposure prophylaxis from the US Department of Health and Human Services (DHHS), the United States Preventative Services Task force (USPSTF), the International Antiviral Society- US (IAS-US) and the Infectious Disease Society of America (IDSA). As of the date of publication of this document, these guidelines were available at:

- Centers for Disease Prevention and Control February 2025 Clinical Guidance for Pre-exposure Prophylaxis (See appendix 1)
- USPSTF Recommendation: Prevention of Acquisition of HIV: Preexposure Prophylaxis | United States Preventive Services Taskforce. Accessed 10/14/25

Procedures

Pharmacists initiating or continuing PrEP must:

1. **Review and become familiar with CDC's most recent "Clinical Guidance for PrEP" document** (Guidance document). As of the time of this document, the most recent clinical guidance was published in February of 2025. This guidance is available in Appendix 1 below and also on DPH's website.

2. **Identify persons at increased risk for HIV infection who may benefit from PrEP.** This is done by taking a comprehensive history covering sexual history and history of injection drug use. (See "Assessing Sexually Active Patients" flowchart in Guidance document). Additionally, in line with CDC recommendations, anyone requesting PrEP should be given PrEP.

3. **Rule out current HIV infection (acute or chronic HIV infection)**
   This is crucial to avoid inadvertently prescribing PrEP to a person already infected with HIV which would complicate future HIV treatment by creating drug-resistant HIV in the patient.

   Ruling out of current HIV infection is done by a combination of:
   a. Taking detailed history to identify symptoms of acute HIV and/or elicit recent use of antiretrovirals
   b. Selecting the appropriate HIV test based on history obtained in (a) above

   See PrEP guidance document in appendix 1 *"HIV testing for patients starting or restarting PrEP after a long stop"* flowchart and *"HIV testing for patients who are taking or have recently taken PrEP"* flowchart for guidance on selecting the appropriate HIV test by patient characteristics.

   Importantly:
   i. Tests used to guide decision on whether to prescribe PrEP must be at the minimum a combination antibody-antigen combination test. Lab-based 4th generation tests are preferred, but rapid antibody-antigen combination tests are acceptable.
   ii. In persons without symptoms of acute HIV, a review of the results of an HIV antibody-antigen test drawn in the 7 days prior to the PrEP initiation visit is acceptable as an alternative.
   iii. In some instances, an HIV viral load assay may be required prior to starting PrEP (see guidance document in Appendix 1 below).
   iv. Do not initiate PrEP in those who do not have a negative/non-reactive HIV antibody-antigen test.
   v. Do not use oral fluid tests or patient reported tests to guide PrEP decisions.
   vi. Note that HIV is a reportable disease. All positive HIV test results must be reported to the division of public health by emailing reportdisease@delaware.gov.
   vii. See Guidance Document (appendix 1) and PrEP laboratory testing guideline section of" Antiretroviral Drugs for Treatment and Prevention of HIV in Adults: 2024 Recommendations of the International Antiviral Society-USA Panel ."(Accessed 10/14/25)

4. **Complete baseline assessments** and order/review other laboratory testing as appropriate based on patient characteristics, medical history and PrEP medication to be used. This may include but is not limited to kidney function testing, Hepatitis B serology, lipid panel {See "Baseline Assessments" in Guidance document in Appendix 1.
5. **Select appropriate FDA-approved PrEP medication** taking into account patient's clinical profile {including concurrent medical diagnoses and results of laboratory testing), potential for drug-drug interactions, patient values and preferences as well as other factors including insurance coverage/ability to pay. {See "Treatment Options" in Guidance Document).
6. **Provide information to patients about the limitations of PrEP** including, but not limited to:
    a. Important of using condoms even while on PrEP {to reduce risk of HIV and other STIs)
    b. When Cabotegravir injections are discontinued, there is a risk of resistance if HIV is acquired in the months after during declining drug levels (Oral PrEP is recommended if ongoing HIV risk is anticipated)
7. **Ongoing monitoring** is crucial for persons who will be continuing PrEP. This may be done by the pharmacist or by referral of the patient to their primary care provider or other provider such as DPH. This includes ongoing HIV testing at least every 3 months, kidney function testing at least every 3 months {may be needed more frequently in certain patients), screening for sexually transmitted infections and lipid panel testing in patients on Tenofovir Alafenemide based PrEP.
8. **Provide patients with ongoing support for continuing or stopping PrEP** and with educational materials {See "Resources" in Guidance Document at the above link).

Referral

- Pharmacists should keep on-hand contact information for medical providers to which patients can be referred as needed. This includes primary care providers, specialist practices for HIV and/or the Division of Public Health {DPH).
- Pharmacists should encourage patients to seek care with a primary care provider in order to obtain preventative services and/or address other health care needs within the context of a medical home.
- Patients who do not have a medical home should be given contact information for Delawares Federally Qualified Health Centers or may be referred to the Division of Public Health either at:
    - DPH Telemedicine clinic
        - Receives referrals by phone to 302-661-9038 or via email dhss_dph_accessclinic@delaware.gov
    - DPH physical clinic locations in each county. See DPH website for contact details
- Patients presenting with significant known {or suspected) complications or adverse effects from medications prescribed should be referred as appropriate to primary care providers or the emergency department for evaluation and management.

HIV Post-exposure Prophylaxis **(PEP)**

Relevant National Guidelines

Centers for Disease Control and Prevention (CDC)'s February 2025 Clinical Guidance for Post-Exposure Prophylaxis (See appendix 3)

Procedures

Pharmacists who will be prescribing HIV post-exposure prophylaxis must:

1. Review and become familiar with CDC's Clinical Guidance for PEP (PEP Guidance). See Appendix 3 or CDC website
2. Assess timing and risk of HIV exposure following steps in "Algorithm for Evaluation and Treatment of Non-occupational HIV exposure" in PEP guidance (Appendix 3)
3. Consider HIV exposure a medical emergency which must be addressed in a timely manner (within 72 hrs of the potential exposure)
4. Perform baseline laboratory assessment if available (See "Evaluation" in guidance document). Most important of these is HIV testing to rule out pre-existing HIV infection
5. Not delay initiation of PEP while awaiting baseline laboratory assessment- Give first dose of PEP and immediately order or refer for baseline testing

Referral

Similar to referral guidance for PrEP above. Refer patients as needed to primary care providers, Federally qualified health centers or DPH clinics

Appendices

Appendix 1: CDC February 2025 Clinical Guidance for PrEP

(Downloaded 5/2/25}

Clinical Guidance for PrEP _ HIV Nexus

Also available at DPH HIV prevention website

Appendix 2: Miscellaneous Provider resources for PrEP

Also available at DPH HIV prevention website

a. Clinician's Quick Guide: PrEP for the Prevention of HIV in the US

(Downloaded 5/2/25}

cdc-hiv-together-brochure-prepguidelir

b. Clinician's Quick Guide: Injectable PrEP

(Downloaded 5/2/25}

cdc-lsht-prevention-brochure-dinicians

c. Clinician's Quick Guide: Oral PrEP

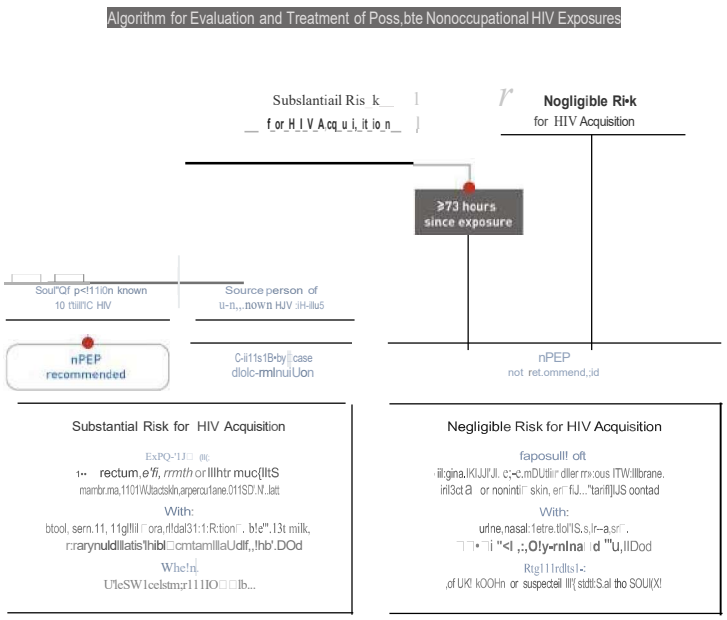
(Downloaded 5/2/25}

cdc-lsht-prevention-brochure-dinicians

Appendix 3: CDC February 2025, Clinical Guidelines for Post-Exposure Prophylaxis

(Downloaded 5/12/2025} also available on CDC website

Clinical Guidance
for PEP HIV Nexus



Signature page:

The preceding standing orders were authored by DPH. They were reviewed by the Board of Pharmacy on _11/19/25_____ and have been approved for use by Delaware licensed pharmacists for the period 12/1/25 to 12/31/27

Signed

For the Division of Public Health:

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