NOTICE OF INTENT

Department of Health
Office of Public Health

Administration and Treatment of
Human Immunodeficiency Virus
(LAC 48:I.Chapter 136)

Under the authority of R.S. 37:1218.2, and in accordance with R.S. 49:950 et seq., the Administrative Procedure Act, notice is hereby given that the Department of Health intends to promulgate Chapter 136 (Administration and Treatment of Human Immunodeficiency Virus) of Subpart 7 (Human Immunodeficiency Virus/AIDS) of Part I (General Administration) of Title 48 (Public Health—General) of the Louisiana Administrative Code (LAC).

The proposed Chapter is necessary to implement the procedures and statewide protocol by which a Louisiana-licensed pharmacist ("pharmacist") shall follow to dispense and/or administer pre-exposure and post-exposure prophylaxis medications for the prevention of Human Immunodeficiency Virus (HIV) infection pursuant to R.S. 37:1218.2.

Title 48
PUBLIC HEALTH—GENERAL
Part I. General Administration
Subpart 7. Human Immunodeficiency Virus/AIDS
Chapter 136. Administration and Treatment of Human Immunodeficiency Virus

§13601. Definitions

A. As used in this Chapter, the following terms shall, unless the context clearly requires otherwise, have the following meanings:

CDC—the Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

CDC Guidelines—with respect to PrEP, means the guidelines set forth in the CDC's "Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2021 Update Clinical Practice Guideline", and with respect to PEP, means the guidelines set forth in the CDC's "Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV—United States, 2016".

§13603. Scope

A. This statewide protocol establishes the rules a Louisiana-licensed pharmacist ("pharmacist") shall follow to dispense and/or administer pre-exposure and post-exposure prophylaxis medications for the prevention of HIV infection pursuant to Act 711 of 2024 (R.S. 37:1218.2).

B. Pharmacists may dispense and administer HIV pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) medication(s) approved by the U.S. Food and Drug Administration (FDA) to eligible patients according to the indications and recommendations in the current guidelines from the U.S. Centers for Disease Control and Prevention (CDC). Contraindications should be considered before the medication is dispensed and/or administered.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1218.2.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 51:

§13605. Pre-Requisites

A. Prior to dispensing and/or administering HIV prevention medication per this protocol, the pharmacist must:

1. hold a current pharmacy license that is in good standing to practice in the state of Louisiana;
2. be a current practicing pharmacist;
3. have earned a Doctor of Pharmacy (PharmD) degree or have at least five years of experience as a licensed registered pharmacist (RPh);
4. maintain professional liability insurance of at least $1,000,000 or participate in the Louisiana Patient's Compensation Fund, which allows a provider to have financial responsibility for the first $100,000 of exposure per claim whether through insurance or security deposit and enroll in the Fund for the excess coverage and be under an umbrella of the cap on damages;
5. review this statewide protocol and related standing order;
6. complete a training program as described in this protocol;

7. ensure that all pharmacy staff comply with patient privacy and confidentiality throughout appointment-setting, counseling, record-keeping, and dispensing and/or administration of PrEP/PEP therapies; and

8. obtain written patient consent for pharmacist-initiated HIV PrEP/PEP-related testing, counseling, administration, and referrals.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1218.2.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 51:

§13607. Records

A. Pharmacists shall maintain a patient record for all services and treatments dispensed and/or administered under this protocol.

B. If the patient provides written consent to do so, a process shall be in place for the pharmacist to communicate with the patient's primary care provider (PCP) for the PCP to document changes to the patient's medical record.

C. If the patient does not provide written consent to the release of information; does not have a PCP; or is unable to provide contact information for their PCP, the pharmacist shall provide the patient with a written record of the medications dispensed and/or administered; lab test(s) ordered; and all test results. If the patient's PCP is not notified, the pharmacist shall document the reason(s) no notification occurred.

D. Pharmacists shall maintain a signed attestation of review of this statewide protocol signed by the participating pharmacist with their training certifications. This attestation must be made available upon request of the LABP.

E. Pharmacists shall comply with all record-keeping requirements adopted by the Louisiana Board of Pharmacy (LABP) in LAC 46:LIII.Chapter11.Subchapter B.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1218.2.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 51:

§13609. Training

A. Training Content. Prior to independently dispensing and/or administering HIV prevention therapies to a patient pursuant to R.S. 37:1218.2, the pharmacist shall successfully complete a training program approved by the Accreditation Council for Pharmacy Education (ACPE). This training may take place as a stand-alone course or as part of an equivalent curriculum-based training program offered by an ACPE-accredited school of pharmacy. At a minimum, the training shall consist of the criteria set forth in Subsection A.1 of this Section, and the pharmacist must also complete the training required to administer medications in the state of Louisiana adopted by the LABP as set forth in Subsection A.2 of this Section.

1. Training Program. A pharmacist must complete a training program specific to the use of HIV pre-exposure and post-exposure prophylaxis (PrEP/PEP) that includes instruction covering, at a minimum, the following areas:

a. CDC Guidelines for PrEP/PEP;

b. screening for HIV and sexually transmitted infections (STIs) and laboratory testing to determine PrEP/PEP eligibility;

c. pharmacology, safety, efficacy, drug-drug interactions, and monitoring parameters for HIV medications used for PrEP/PEP;

d. strategies for serving historically marginalized patient populations and sexual assault survivors or related trauma-informed care;

e. culturally sensitive patient counseling information; and

f. strategies to access manufacturer and government financial assistance programs for HIV PrEP/PEP.

2. Administration of Medications Training. A pharmacist shall complete all training requirements required by the LABP and the State of Louisiana in LAC 46.LIII. prior to administering any medication.

3. Continuing Education Requirement. A pharmacist shall complete at least one hour of continuing education in the subject of HIV prevention every two years, to be reported to the LABP as per continuing education requirements.

B. Training Certification and Documentation

1. A pharmacist shall maintain documentation of their successful completion of the required training as set forth in Section 13609 of this Chapter for a period of at least two years following any patient interactions involving dispensing and/or administering HIV prevention medications that are subject to this rule per LAC 46.LIII.1121. Documentation maintained pursuant to this subsection must be made available upon request of the LABP.

2. Training obtained as part of an equivalent curriculum-based training program can be documented by written certification from a member of the educational institution or program from which the licensee graduated stating that the training is included within the institution's curriculum required for graduation at the time the pharmacist graduated, or within the coursework that the pharmacist completed. Documentation maintained pursuant to this subsection must be made available upon request of the LABP.

3. Sanctions

a. The failure of a pharmacist to obtain and maintain the education, training, and continuing competency described in this Section prior to administering medications to patients or supervising other pharmacy personnel administering medications to patients shall constitute a violation of R.S. 37:1218.2 and R.S. 37:1241(A)(3) and shall subject the pharmacist to disciplinary action by the LABP.

b. The failure of a pharmacist to provide documentation of their education, training, and continuing competency to administer medications when requested by the board shall constitute a violation of R.S. 37:1218.2 and R.S. 37:1241(A)(22) and shall subject the pharmacist to disciplinary action by the LABP.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1218.2.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 51:

§13611. HIV Pre-Exposure Prophylaxis (PrEP)

A. Under this protocol, pharmacists may assess for HIV status and high-risk behaviors in which pre-exposure prophylaxis against HIV would be warranted.

B. The pharmacist may dispense and/or administer the patient a 30-day supply of any antiretroviral agent that is a currently FDA-approved or CDC-recommended medication or regimen for HIV pre-exposure prophylaxis, according to the following criteria.

1. The patient is 17 years of age or older, is (or is planning to become) sexually active or is at risk for sharing injection or drug preparation equipment, and has a desire to start a PrEP regimen.

2. Evidence of baseline negative HIV status is obtained, as documented by a pharmacist either:

a. conducting a blood rapid test, which provides same-day results;

b. drawing blood (serum) and sending the specimen to a laboratory for an antigen/antibody test, with results being received within seven days before initially dispensing and/or administering PrEP; or

c. accepting patient's outside documentation of a non-reactive blood rapid test or laboratory test with the patient's name (matching their legal identification) dated within seven days before initially dispensing and/or administering PrEP.

3. Neither oral swab testing nor patient self-report of negative status are acceptable for evidence.

C. Pharmacists must ask the following screening question.

1. Do you have existing kidney disease, or do you know if your kidney function is decreased for any reason?

a. If the answer is yes, the pharmacist shall urgently order or refer the patient for a blood test to confirm creatinine clearance. The pharmacist may accept patient-provided creatinine clearance test results dated within 12 months from another lab or provider.

i. If the patient's creatinine values are acceptable for oral PrEP therapy, the pharmacist may proceed through the rest of the protocol.

ii. If the patient's creatinine values do not meet oral PrEP therapy minimums according to CDC Guidelines, and the pharmacist is able to administer injectable PrEP therapy, the pharmacist may proceed through the rest of the protocol for injectable PrEP therapy.

iii. If the patient's creatinine values do not meet oral PrEP therapy minimums according to CDC Guidelines and does not desire injectable PrEP or the pharmacist is unable to administer injectable PrEP, the pharmacist shall refer to an appropriate provider.

3. The following patients should NOT be provided PrEP under this protocol and should be referred to a primary care provider for further action:

a. patients younger than 17 years of age;

b. patients with reactive baseline HIV tests;

c. patients with symptoms which could indicate acute HIV infection; or

d. patients on medications contraindicated with PrEP therapy selected.

4. A pharmacist may administer injectable PrEP therapy, pursuant to R.S. 37:1164 and the LAC 46.LIII.521.

5. Other/Repeated Labs: Follow CDC Guidelines.

a. The pharmacist is authorized to order recommended labs and perform necessary FDA-approved and CLIA-waived point-of-care tests for the patient OR to refer the patient to another provider to order lab work and accept results.

b. At the patient's request, PrEP refills will be authorized past the initial 30-day supply for oral or injectable therapy if recommended baseline and follow-up testing are done according to CDC Guidelines as ordered by one of the above mechanisms.

6. Counseling shall include (at minimum):

a. instruction regarding proper medication use, adherence, schedule, and potential common and serious side effects (and how to mitigate them);

i. For injectable PrEP therapies: the long drug "tail" of gradually declining drug levels when discontinuing injections and the risk of developing a drug-resistant strain of HIV during this time;

b. description of signs/symptoms of acute HIV infection and recommended actions.

c. education on PrEP/PEP;

d. the necessity of follow up care with a primary care provider for usual care; and

e. the importance and requirement of testing for HIV, renal function, lipid profile, Hepatitis B, and other sexually transmitted infections, per CDC Guidelines.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1218.2.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 51:

§13613. HIV Post-Exposure Prophylaxis (PEP)

A. Post-Exposure Prophylaxis (PEP) is the use of antiretroviral drugs after a single high-risk event to decrease the risk of HIV seroconversion. PEP must be started as soon as possible to be effective and always within 72 hours of the possible exposure.

B. Under this protocol, pharmacists may assess patients 17 years of age and older for high-risk exposure to HIV and dispense an entire 28-day course of antiretroviral drugs if appropriate. PEP should only be provided for infrequent exposures.

C. Pharmacists must ask the following screening question:

1. Do you have existing kidney disease, or do you know if your kidney function is decreased for any reason?

2. If the patient has known kidney disease and can provide renal function test results within 12 months, the pharmacist may initiate a PEP regimen per CDC Guidelines.

3. If the patient has known kidney disease and cannot provide renal function test results within 12 months, the pharmacist shall urgently refer the patient to a provider who can see them to proceed with PEP initiation within 72 hours of possible exposure.

D. If the pharmacy is not able to provide care to the patient, or if the patient does not qualify for care at the pharmacy, the patient should be urgently referred to another provider.

E. Pharmacists shall follow CDC Guidelines. If the following criteria are met, HIV PEP is recommended:

1. the exposure has likely occurred within 72 hours of the patient's arrival at the pharmacy;

2. an FDA-approved blood rapid test has yielded a non-reactive result for HIV;

3. a blood rapid test is not available and PEP is otherwise indicated; or

4. the patient's vagina, rectum, eye, mouth or other mucous membrane, non-intact skin, or perforated skin (e.g., needle stick) came into contact with body fluids from a person with HIV within 72 hours before they sought care. If

the exposure source's HIV status is unknown, the pharmacist should make a case-by-case determination as to whether PEP should be initiated. Exposure types with the highest risk of transmission of HIV to be considered are:

a. needle sharing during injection drug use;

b. percutaneous needle stick; and

c. receptive anal intercourse.

F. The following patients should not be prescribed PEP under this protocol and should be referred to an appropriate care provider for further action:

1. patients younger than 17 years of age;

2. patients who seek care more than 72 hours after potential exposure;

3. patients taking any contraindicated medications per guidelines and package insert information;

4. patients with reactive or indeterminate baseline HIV tests;

5. patients who are taking PrEP who report consistent adherence to their medication regimen; or

6. patients who indicate a history of chronic kidney disease without providing renal function test results dated within 12 months.

G. Other Considerations:

1. If the case involves a sexually assaulted person (including potential victims of human trafficking), pharmacists shall provide the patient with the information necessary to pursue a Sexual Assault Nurse Examiner (SANE) exam locally (each parish's SANE program is run through the coroner's office), as well as the contact information for their closest rape crisis center.

2. If a child (under 17 years of age) presents to the pharmacy with a request for PEP and is potentially a victim of child abuse, child protective services must be contacted at 1-855-4LA-KIDS (1-855-452-5437).

H. Medication options include all FDA-approved or CDC-recommended medications or regimens for PEP. Formulations, cautions, and dose adjustments for antiretroviral medications shall minimally follow the CDC guidelines and package insert information for all regimens.

I. Labs: follow CDC Guidelines for PEP.

1. All efforts should be made to obtain a non-reactive HIV test at baseline. However, the sooner PEP is initiated, the more effective it is. If the patient refuses to undergo HIV testing but is otherwise eligible for PEP under this section, the pharmacist may dispense PEP.

2. For patients who request PEP, pharmacists shall offer testing for other sexually transmitted infections or refer them to another provider for testing.

3. The pharmacist is authorized to order recommended labs for the patient OR to refer the patient to another provider to order lab work and accept results.

4. The pharmacist shall make every reasonable effort to follow up with the patient post-treatment regimen at 4-6 weeks to test for confirmation of negative HIV status and inform the patient that repeat HIV testing is recommended at three and six months as well.

J. counseling shall include (at minimum):

1. instruction on proper medication use, adherence, schedule, and potential common and serious side effects (and how to mitigate them);

2. description of signs/symptoms of acute HIV infection and recommended actions;

3. emergency contraception, when appropriate;

4. the importance of engaging in routine primary care;

5. the importance and requirement of follow-up testing for HIV, renal function, hepatic function, Hepatitis B and C, and other sexually transmitted infections, per CDC Guidelines; and

6. education about pre-exposure prophylaxis (PrEP) and the potential for future need.

AUTHORITY NOTE: Promulgated in accordance and R.S. 37:1218.2.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 51:

§13615. HIV PrEP and PEP Documentation Requirements

A. Pharmacists shall document a focused assessment of the patient's eligibility for HIV PrEP/PEP following best practices and guidelines for preventing HIV according to CDC Guidelines.

B. Pharmacists shall document the patient's written consent for HIV PrEP/PEP-related testing, counseling, administration, recordkeeping, and referrals.

C. Pharmacists shall inform the patient's PCP of all test results and medications prescribed within 30 days of initiating HIV PrEP or PEP therapy with the patient's explicit written consent to do so.

D. If a patient does not consent to the release of their information or does not have a PCP, the pharmacist shall provide the patient with documentation of their test results and HIV PrEP or PEP medications and written information about providers and clinics from which they may seek ongoing care.

E. Pharmacists shall inform the Department of Health of any reactive HIV, Hepatitis B/C, or other sexually transmitted infection test results using the procedures adopted by the Louisiana Department of Health in LAC 51.II.Chapter 1.Section 107.

F. Pharmacists shall comply with all record-keeping requirements adopted by the Louisiana Board of Pharmacy in LAC 46.LIII.Chapter 11.Subchapter B. Sections 1119-1130.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1218.2.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 51:

§13617. Referral Requirements

A. Pharmacists shall refer patients with reactive HIV, STI, or Hepatitis B or C tests to an appropriate care provider for confirmatory testing and follow-up care as applicable and provide the patient with written information about appropriate providers and clinics in their desired geographical area.

B. Pharmacists who participate in this protocol shall immediately refer patients who display signs of acute HIV infection and designate such a referral as urgent with a linkage to and/or HIV care provider.

C. Pharmacists shall refer any female patients who become pregnant while on PrEP to an appropriate clinical care provider, including prenatal care.

D. For all patients who do not already have a PCP, pharmacists shall refer them to an appropriate provider, stressing the importance of routine primary care and health maintenance.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1218.2.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 51:

§13619. Reimbursement

A. All health coverage plans, third-party administrators, and pharmacy benefit managers operating within the state of Louisiana shall establish the process for pharmacists to enroll as providers for the purposes of dispensing and/or administering HIV PrEP and/or PEP, equivalent to the process established for other providers.

B. A pharmacist authorized to provide any service relative to HIV PrEP and/or PEP shall be reimbursed at the same rate as any other participating healthcare provider providing such service in accordance with the patient's health coverage plan.

C. This Section shall not be construed to require a health coverage plan or a third-party administrator or pharmacy benefit manager to reimburse a pharmacist or pharmacy as an in-network or preferred provider.

D. The provisions of this Section may apply to coverage under a group or individual health coverage plan provided to a resident of this state regardless of whether the health coverage plan policy, contract, or other agreement is delivered, issued for delivery, or renewed in this state.

E. No health coverage plan, third-party administrator, or pharmacy benefit manager operating within the state of Louisiana shall deny any pharmacy the opportunity to participate in the PrEP/PEP program offered in this state in any manner that will restrain the right of a consumer to select a pharmacy of their choosing.

F. Manufacturer and government financial assistance programs for HIV PrEP and PEP exist for patients who are uninsured, underinsured, or who meet financial criteria.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1218.2.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 51:

§13621. Standing Order

A. The Louisiana Department of Health will issue a standing order in compliance with and under the authority of R.S. 37:1218.2 which shall be deemed a medical order for any FDA-approved or CDC-recommended HIV PrEP or PEP therapy, as long as all conditions of the statewide protocol for R.S. 37:1218.2 are met. This standing order shall be valid for one year from the date of issue.

B. Pharmacists dispensing and/or administering HIV PrEP or PEP medications may use the standing order to prepare the prescription and/or refill as necessary, provided that all other requirements and qualifications necessary to do so are complete.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1218.2.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 51:

Family Impact Statement

The proposed Rule should not have any known or foreseeable impact on family formation, stability, and autonomy. In particular, the proposed Rule has no known or foreseeable impact on:

1. the stability of the family;
2. the authority and rights of persons regarding the education and supervision of their children;
3. the functioning of the family;
4. family earnings and family budget;
5. the behavior and personal responsibility of children;
6. the ability of the family or a local government to perform the function as contained in the proposed Rule.

Poverty Impact Statement

The proposed Rule should not have any known or foreseeable impact on any child, individual or family as defined by R.S. 49:973(B). In particular, there should be no known or foreseeable effect on:

1. the effect on household income, assets, and financial security;
2. the effect on early childhood development and preschool through postsecondary education development;
3. the effect on employment and workforce development;
4. the effect on taxes and tax credits;
5. the effect on child and dependent care, housing, health care, nutrition, transportation, and utilities assistance.

Small Business Analysis

In accordance with Sections 978.1 through 978.8 of the Small Business Protection Act of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a regulatory flexibility analysis/small business analysis on the Rule proposed for adoption, amendment or repeal. The impact of the proposed Rule on small businesses as defined in the Small Business Protection Act has been considered. Louisiana Department of Health does not expect that adoption of the proposed amendments will have an adverse economic impact on small businesses.

Provider Impact Statement

The proposed Rule should not have any known or foreseeable impact on providers as defined by HCR 170 of the 2014 Regular Legislative Session. In particular, there should be no known or foreseeable effect on:

1. the effect on the staffing level requirements or qualifications required to provide the same level of service;
2. the total direct and indirect effect on the cost to the providers to provide the same level of service; or
3. the overall effect on the ability of the provider to provide the same level of service.

Public Comments

Interested persons may submit written comments on the proposed Rule. Such comments must be received no later than Monday, February 10, 2025 at close of business, 4:30 p.m., and should be addressed to Dr. Samuel Burgess, Director, STD, HIV, and Hepatitis Program, Bureau of Infectious Disease, Louisiana Department of Health, 1450 Poydras St., Suite 2136, New Orleans, LA 70112 or emailed to Dr. Burgess at samuel.burgess@la.gov.

Public Hearing

Interested persons may submit a written request to conduct a public hearing either by U.S. mail to the Office of the Secretary ATTN: LDH Rulemaking Coordinator, Post Office Box 629, Baton Rouge, LA 70821-0629; however, such request must be received no later than 4:30 p.m. on Monday, February 10, 2025. If the criteria set forth in R.S. 49:953(A)(2)(a) are satisfied, LDH will conduct a public hearing at 10 am on Thursday, February 27, 2025, in Room 117 of the Bienville Building, which is located at 628 North Fourth Street, Baton Rouge, LA. To confirm whether or not

a public hearing will be held, interested persons should first call Allen Enger at (225) 342-1342 after Monday, February 10, 2025. If a public hearing is to be held, all interested persons are invited to attend and present data, views, comments, or arguments, orally or in writing. In the event of a hearing, parking is available to the public in the Galvez Parking Garage which is located between North Sixth and North Fifth/North and Main Streets (cater-corner from the Bienville Building). Validated parking for the Galvez Garage may be available to public hearing attendees when the parking ticket is presented to LDH staff at the hearing.

Bruce D. Greenstein
~~Michael Harrington, MBA, MA~~
Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES
RULE TITLE: Administration and Treatment of Human Immunodeficiency Virus

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)

There is an anticipated increased cost associated with this proposed rule to the Louisiana Medicaid Program for additional utilization of HIV PrEP and PEP medications to prevent HIV transmission, but the amount is indeterminable prior to implementation as there is insufficient peer-reviewed literature on which to base accurate projections. It is anticipated that HIV PrEP/PEP utilization will increase by an unknown amount due to the increased access points that this proposed rule affords in FYs 25, 26, and 27. If utilization increases, there may be a decrease in Medicaid participants becoming infected with HIV and a corresponding decrease in costs associated with HIV treatment medications and related medical problems that could offset the HIV PrEP and PEP costs in future fiscal years. There are no other anticipated implementation costs to other state or local governmental units.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

To the extent that the Louisiana Medicaid Program experiences increased HIV PrEP and PEP utilization among its members, the state would draw additional federal funds (revenue) to cover those costs. This proposed rule is not expected to affect the revenue collections of other state or local governmental units.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS, SMALL BUSINESSES, OR NONGOVERNMENTAL GROUPS (Summary)

The Pharmacist-Initiated HIV PrEP and PEP rules allow pharmacists to directly dispense or administer HIV PrEP and PEP medications to appropriate state residents. This could provide economic benefits to Pharmacies/Pharmacists.

Also, this proposed rule may result in cost savings for affected residents, as they would no longer need an additional provider visit and prescription to access HIV PrEP and PEP therapies. There are no other anticipated direct costs or economic benefits to small businesses or non-governmental groups associated with the Pharmacist-Initiated HIV PrEP and PEP rules.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule has no estimated effect on competition and employment.

Tonya Joiner
Assistant Secretary
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Patrice Thomas
Deputy Fiscal Officer
Legislative Fiscal Office