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 1 (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 1. 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.

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
2501#049

Patrice Thomas
Deputy Fiscal Officer
Legislative Fiscal Office

From: William Kirchain <wkirchai@xula.edu>
Sent: Monday, January 27, 2025 10:05 AM
To: Samuel Burgess <Samuel.Burgess@LA.GOV>; George Nawas <gnawas@xula.edu>
Cc: Murphy, Michael <mmurphy@aphanet.org>; office@lshp.org; Julie Fuselier <julie.fuselier@amstrategies.co>; Vincent Ekenga <vekenga@xula.edu>
Subject: Public Comment on Notices of Intent: LAC 48: I. Chapter 136

Dr. Burgess,

RE: Notices of Intent: Office of Public Health-Administration and Treatment of Human Immunodeficiency Virus (LAC 48: I. Chapter 136): 145-150. published in Louisiana Register, Vol. 51(1), January 20, 2025. IV. pages 145-150.

Thank you for your service to Louisiana. Your leadership in the struggle with HIV infections has made Louisiana a healthier place. Please accept the attached document with **my personal** suggestions for revisions to the significant work that you have led your staff and volunteer members of the working group to create.

The attached does not reflect the opinions of LSHP or LPA. Nor does it reflect any opinion or position held by Xaiver University of Louisiana, the Xavier University College of Pharmacy or any other associated entity. I have copied representatives at the American Pharmacists Association solely for their information as they are interested in this process.

All the Best,
Dr. Kirchain

William Kirchain, PharmD, CDCES

Director, Xavier Health & Wellness Service, Division of Clinical & Administrative Sciences

Xavier University of Louisiana
o: (504) 520-5053
a: 1 Drexel Drive,
New Orleans, LA 70125
w: *www.xula.edu/collegeofpharmacy/division-of-basic-and-pharmaceutical-sciences/division-of-clinical-and-administrative-sciences.html*
e: *wkirchai@xula.edu*

Louisiana Register, Vol. 51(1), January 20, 2025. IV. Notices of Intent: Office of Public Health-Administration and Treatment of Human Immunodeficiency Virus (LAC 48: I. Chapter 136): 145-150. ***Comments and Suggestions for Improving the Significant Accomplishments of the Working Group of Pharmacist Interventions in Preventing HIV+ Infections. just***

From: **William R. Kirchain, PharmD, CDCES**

Director, Xavier University Health and Wellness Service
Wilbur and Mildred Robichaux Endowed Professor
Public Policy Chair, Louisiana Society of Health-System Pharmacists
Past-President, Louisiana Pharmacist Association

With respect and appreciation for the significant amount of work accomplished by the staff and advisory group. Attached are several suggestions for improvement.

Importantly, the length and detail of the overall rule set will in my experience serve to suppress rather than allow pharmacists to pursue this area of practice.

Many of the regulations are overly detailed and are NOT written in a manner that respects the history, training and experience of the pharmacy profession.

	Suggested Changes	*Commentary and notes*	Clean Copy with Suggestions
Title 48. PUBLIC HEALTH—GENERAL. Part 1. General Administration. Subpart 7. Human Immunodeficiency Virus/AIDS Chapter 136. Administration and Treatment of Human Immunodeficiency Virus	Title 48. PUBLIC HEALTH—GENERAL. Part 1. General Administration. Subpart 7. Human Immunodeficiency Virus/AIDS Chapter 136. Administration and Treatment of Human Immunodeficiency Virus		Title 48. PUBLIC HEALTH—GENERAL. Part 1. General Administration. Subpart 7. Human Immunodeficiency Virus/AIDS Chapter 136. Administration and Treatment of Human Immunodeficiency Virus
§13601. Definitions	§ 13601. Definitions		§13601. Definitions
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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".

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".

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).

§13603. Scope

A. This statewide protocol establishes the rules a Louisiana-licensed pharmacist ("pharmacist") shall follow to **initiate**, 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).

This needs to be clear and unambiguous that it is the pharmacist, based on his skills and best assessment is the one starting this treatment.

A. This statewide protocol establishes the rules a Louisiana-licensed pharmacist ("pharmacist") shall follow to initiate, 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 preexposure 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.

B. Pharmacists may dispense and administer HIV preexposure 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~~

This is redundant. It is an essential element of a pharmacist's training and even our identity to always consider indications, contraindications, along with other issues of safety and efficacy for all drug-related assessments. *As outlined in LAC 46:LIII.5. §515. Prospective Drug Utilization Review*

A. A pharmacist shall review the patient record and each prescription presented for dispensing for purposes of enhancing pharmacy care and therapeutic outcomes by recognizing the following potential situations:

1. drug over-utilization or under-utilization;

2. therapeutic duplication;

3. drug-disease contraindications;

4. drug-drug interactions;

5. inappropriate drug dosage or treatment duration;

6. drug-allergy interactions; or

7. clinical abuse/misuse.

B. Pharmacists may dispense and administer HIV preexposure prophylaxis (PrEP) and post-exposure prophylaxis

	~~medication is dispensed and/or administered.~~		(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).
§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;*~~	§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~~;	*Redundant to 1.*	§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;
3. have earned a Doctor of Pharmacy (PharmD) degree or have at least five years of experience as a licensed registered pharmacist (RPh);	~~3. have earned a Doctor of Pharmacy (PharmD) degree or have at least five years of experience as a licensed registered pharmacist (RPh);~~	*There is NO other element of pharmacy practice in Louisiana, nor in any other U.S. State or Territory that requires a pharmacist with a bachelor's degree in pharmacy to have 5 years' experience prior to engaging in any type of practice. And if anything,* ***this is an issue for the profession, resolved by the Louisiana Board of Pharmacy*** *and not by an interdisciplinary group.*	
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	~~4.~~ 2. 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		2. maintain professional liability insurance of at least $1,000,000 or participate in the Louisiana Patient's

$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;	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~~. 4. complete a training program as described in this protocol;	*The training requirements dictate a review of the protocol and standing order.*	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;
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	~~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~~	*Because of these existing regulations and discussions this added regulation is redundant to established practices and professional norms.* *RS 36: 14.I.1164. Definitions (8) "Confidential information" means information accessed, maintained by, or transmitted to a pharmacist in the patient's records or which is communicated to the patient as part of patient counseling, which is privileged and may be released only to the patient or to those practitioners, other authorized healthcare professionals, and other pharmacists when, in a pharmacist's professional judgment, such release is necessary to protect the patient's health and well being; and to such other persons or agencies authorized by law to receive such confidential information regardless of whether such information is in the form of paper, preserved on microfilm, or is stored on electronic media.* *RS 36: 14.V.1241. Refusal, restriction, suspension, or revocation of license* *A. The board may, after due notice and hearing, assess a fine not to exceed the sum of five thousand dollars for each offense, refuse to license, register, certify, or permit any applicant, refuse to renew the license or permit of any person, or may revoke, summarily suspend, suspend, place on probation, reprimand, issue a warning against the person who was issued the license, registration, certificate, permit, or any other designation deemed necessary to engage in the practice of pharmacy upon proof that the person:* *(1) Practiced or assisted in the practice of pharmacy, or knowingly permitted or has permitted anyone in his employ or under his supervision to practice or assist in the practice of pharmacy, in violation of the provisions of this Chapter and any rules and regulations promulgated thereto in accordance with the Administrative Procedure Act.* *(10) Has departed from or failed to conform to the minimal*	

		standards of acceptable and prevailing pharmacy practice, whether or not actual injury to a patient has occurred. *Per Dept. Health and Human Services.Office for Civil Rights. December 28, 2022* *Does the **HIPAA Privacy Rule** require hospitals and doctors' offices to be retrofitted, to provide private rooms, and soundproof walls to avoid any possibility that a conversation is overheard?* *Answer: **No, the Privacy Rule does not require these types of structural changes be made to facilities.*** *Covered entities must have in place appropriate administrative, technical, and physical safeguards to protect the privacy of protected health information. This standard requires that covered entities make reasonable efforts to prevent uses and disclosures not permitted by the Rule. The Department does not consider facility restructuring to be a requirement under this standard. For example, the Privacy Rule does not require the following types of structural or systems changes: Private rooms. Soundproofing of rooms. Encryption of wireless or other emergency medical radio communications which can be intercepted by scanners. Encryption of telephone systems.* *Covered entities must implement reasonable safeguards to limit incidental, and avoid prohibited, uses and disclosures. The Privacy Rule does not require that all risk of protected health information disclosure be eliminated. Covered entities must review their own practices and determine what steps are reasonable to safeguard their patient information. In determining what is reasonable, covered entities should assess potential risks to patient privacy, as well as consider such issues as the potential effects on patient care, and any administrative or financial burden to be incurred from implementing particular safeguards. Covered entities also may take into consideration the steps that other prudent health care and health information professionals are taking to protect patient privacy.* *Examples of the types of adjustments or modifications to facilities or systems that may constitute reasonable safeguards are:* *> Pharmacies could ask waiting customers to stand a few feet back from a counter used for patient counseling.* *> In an area where multiple patient-staff communications routinely occur, use of cubicles, dividers, shields, curtains, or similar barriers may constitute a reasonable safeguard. For example, a large clinic intake area may reasonably use cubicles or shield-type dividers, rather than separate rooms, or providers could add curtains or screens to areas where discussions often occur between doctors and patients or among professionals treating the patient.*	
8. obtain written patient consent for pharmacist initiated HIV PrEP/PEP-related testing, counseling, administration, and referrals.	~~8~~ 7. obtain written patient consent for pharmacist initiated HIV PrEP/PEP-related testing, counseling, administration, and referrals.		7. obtain written patient consent for pharmacist initiated HIV PrEP/PEP-related testing, counseling, administration, and referrals.
§13607. Records	§13607. Records	*Pharmacists are already required to keep records of all patient care*	§13607. Records

A. Pharmacists shall maintain a patient record for all services and treatments dispensed and/or administered under this protocol.	~~A. Pharmacists shall maintain a patient record for all services and treatments dispensed and/or administered under this protocol~~.	*and patient care adjacent activities. Just like any other health care professional.*	
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.	~~B~~. A. 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.~~ about the initiation of PrEP/PEP.	*Simpler language that actually indicates what needs to be communicated.*	A. If the patient provides written consent to do so, a process shall be in place to communicate with the patient's primary care provider
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.	~~C~~. B. 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.~~ adequate information to allow the continuation of treatment. If the ~~patient's~~ PCP is not notified, the pharmacist shall document the reason(s) ~~no notification occurred~~.	*Some patients may be better served by simply having a phone number back to the pharmacist that a PCP may call for any needed additional information. The dispensed prescription will already have pharmacy's name, address, and telephone number; a prescription number; patient's name; date dispensed; drug name and strength; directions for use, as indicated; pharmacist's name or initials; and applicable cautionary auxiliary labels. And will be accompanied by any FDA required Med Guide as required by LAC 46:LIII.25.2527 and the Food Drug and Cosmetic Act.*	B. 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 adequate information to allow the continuation of treatment. If the PCP is not notified, the pharmacist shall document the reason(s).
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.	~~D~~. C. Participating 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.		C. Participating Pharmacists shall maintain a signed attestation of review of this statewide protocol 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.

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

Pharmacist MUST already comply with all record keeping requirements by the Board or face charges of unprofessional conduct, making this requirement redundant.

§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.

§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~~ a 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.~~

The last section is redundant to

LAC 46.LII.5.§521. Administration of Medications
A. Education and Training Required; Supervision
1. Pharmacists who intend to administer medications to their patients shall obtain the education and training described within this Section prior to engaging in such activity.
2. Pharmacists who intend to supervise other pharmacy personnel who administer medications to patients shall obtain the education and training described within this Section prior to engaging in such activity.

Including it and the entirety of A.2. is unneeded.

§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 a 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,

1. Training Program. A pharmacist must complete a training program specific to the use of HIV pre-exposure and post-exposure prophylaxis

1. Training Program. A pharmacist must complete a training program specific to the use of ~~HIV pre-exposure and post-exposure prophylaxis~~ PrEP

1. Training Program. A pharmacist must complete a training program

(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 information; and f. sensitive patient counseling strategies to access manufacturer and government financial assistance programs for HIV PrEP/PEP.	and 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~~ treatment 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 information; and f. sensitive patient counseling strategies to access manufacturer and government financial assistance programs for HIV PrEP/PEP.		specific to the use PrEP and 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 treatment 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 information; and f. sensitive patient counseling strategies to access manufacturer and government financial assistance programs for HIV PrEP/PEP.
2. Administration of Medications Training. A	~~2. Administration of Medications Training. A~~	*You are aware that pharmacists MUST take a 120 scenario-based*	

pharmacist shall complete all training requirements required by the LABP and the State of Louisiana in LAC 46.LIII. prior to administering any medication.	~~pharmacist shall complete all training requirements required by the LABP and the State of Louisiana in LAC 46.LIII. prior to administering any medication.~~	*question exam, SOLEY on the Laws and Regulations that govern the professional both Federal and State?*	
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.	~~3~~. 2. Continuing Education Requirement. A pharmacist shall complete at least one hour of ACPE approved continuing education in the subject of HIV prevention every two years~~, to be reported to the LABP as per continuing education requirements.~~	*All ACPE approved continuing education is automatically uploaded into a national database that any Board of Pharmacy may access to audit compliance.*	2. Continuing Education Requirement. A pharmacist shall complete at least one hour of ACPE approved continuing education in the subject of HIV prevention every two years.
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.	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.~~	*See above comment. The data in this database can be accessed for a period of 5 years without addition fees, with longer periods available for minimal fees.*	B. Training Certification and Documentation
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.	~~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~~	*If it's required, you cannot graduate. If it is within the curriculum, it is within the coursework.*	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

Documentation maintained pursuant to this subsection must be made available upon request of the LABP.	~~coursework that the pharmacist completed~~. Documentation maintained pursuant to this subsection must be made available upon request of the LABP.	graduated stating that the training is included within the institution's curriculum required for graduation. 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.	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.	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.
§13611. HIV Pre-Exposure Prophylaxis (PrEP)	§13611. HIV Pre-Exposure Prophylaxis (PrEP) Protocol		§13611. HIV Pre-Exposure Prophylaxis (PrEP) Protocol
A. Under this protocol, pharmacists may assess for HIV status and high-risk behaviors in which pre-exposure prophylaxis against HIV would be warranted.	A. Under this protocol, pharmacists may assess for HIV status and high-risk behaviors in which pre-exposure prophylaxis against HIV would be warranted.		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.	B. The pharmacist may initiate, dispense ~~and/~~or administer the patient a 30-day supply of any antiretroviral agent that is a currently FDA-approved medication via CDC-recommended ~~medication or~~ regimen for HIV pre-exposure prophylaxis, according to the following criteria.	*Important to have this word, not only for clarity but also to assure pharmacy liability coverage*. *FDA approves indications in the labelling* *CDC publishes guidelines for professionals*	B. The pharmacist may initiate, dispense and/or administer the patient a 30-day supply of any antiretroviral agent that is a currently FDA-approved medication via CDC recommended 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	1. The patient is 17 years of age or older, is ~~(or is planning to become) sexually active~~ at risk for sexually transmitted disease or is ~~at risk for~~	*We are assessing risks not behaviors per se.*	1. The patient is 17 years of age or older, is at risk for sexually transmitted disease or is

equipment, and has a desire to start a PrEP regimen.	sharing injection or drug preparation equipment and has a desire to start a PrEP regimen.		sharing injection or drug preparation equipment and has a desire to start a PrEP regimen.
[reformatted, Sections 2/3 are reversed] 3. The following patients should NOT be provided PrEP under this protocol and should be referred to a primary care provider for further action:	~~3~~. 2. The following patients should NOT be provided PrEP under this protocol and should be referred to a ~~primary care provider~~ PCP for further action:		2. The following patients should NOT be provided PrEP under this protocol and should be referred to a PCP 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.	~~a. patients younger than 17 years of age~~; ~~b. patients with reactive baseline HIV tests~~; ~~c~~. a. patients with symptoms which could indicate acute HIV infection; b. patients taking medications that would result in unresolvable drug-drug interactions; or c. patients with contraindications to PrEP. ~~d. patients on medications contraindicated with PrEP therapy selected.~~		a. patients with symptoms which could indicate acute HIV infection; b. patients taking medications that would result in unresolvable drug-drug interactions; or c. patients with contraindications to PrEP.
2. Evidence of baseline negative HIV status is obtained, as documented by a pharmacist either:	~~2~~. 3. Evidence of baseline negative HIV status, (a negative test within seven days) is obtained, as documented by a pharmacist either:		3. Evidence of baseline negative HIV status, (a negative test within seven days) 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. conducting a blood ~~rapid~~ test for HIV antigens or antibodies; ~~which provides same-day results;~~ b. drawing blood ~~(serum)~~ and sending the specimen to a laboratory for an antigen or antibody test; or ~~with results being received within seven days before initially dispensing~~	*Same day ≠ Rapid, Rapid ≤ 15 minutes.* *Please see… Insti-HIV1 HIV2 Fingerstick Blood Test…* *file:///C:/Users/44kir/Downloads/51-1080-I-INSTI-HIV1_HIV2-PI-US.pdf*	a. conducting a blood rapid test for HIV antigens or antibodies; b. drawing blood and sending the specimen to a laboratory for an antigen or

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.	~~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.~~	*It would be malpractice to accept a test that did not match at least two known patient identifiers.*	antibody test; or c. accepting patient's outside documentation of a non-reactive blood rapid test or laboratory test
3. Neither oral swab testing nor patient self-report of negative status are acceptable for evidence.	~~3~~. 4. ~~Neither~~ oral swab testing ~~nor~~ and patient self-report of negative status are not acceptable for evidence.		4. Oral swab testing and patient self-report of negative status are not acceptable for evidence.
C. Pharmacists must ask the following screening question.	C. Pharmacists ~~must ask the following screening question~~. must assess kidney function.		C. Pharmacists must assess kidney function.
1. Do you have existing kidney disease, or do you know if your kidney function is decreased for any reason?	~~1. Do you have existing kidney disease, or do you know if your kidney function is decreased for any reason?~~	*A trained pharmacist does not need to have his assessment approach micro-managed by the State.*	
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.	~~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 order urgent laboratories to directly assess the patient's kidney function or accept patient provided creatinine clearance test results dated within 12 months from another lab or provider.	*We required specific assessment and calculation skills (in our licensing exam) around kidney function.* *From National Associate of Board of Pharmacy, NAPLEX Competency Statements. Area 4 – Perform Calculations (Approximately 14% of Test) 4.1 – Patient parameters or laboratory measures; 4.9 – Pharmacokinetic parameters;*	The pharmacist may order urgent laboratories to directly assess the patient's kidney function or accept patient provided creatinine clearance or 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	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		i. If the patient's creatinine values are acceptable for oral PrEP therapy, the pharmacist may proceed

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.	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 the patient to an appropriate provider.		through the rest of the protocol. ii. If the patient's creatinine values do not meet oral PrEP therapy minimums according to CDC Guidelines, 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 and does not desire injectable PrEP the pharmacist shall refer the patient to an appropriate provider.
4. A pharmacist may administer injectable PrEP therapy, pursuant to R.S. 37:1164 and the LAC 46.LIII.521.	~~4. A pharmacist may administer injectable PrEP therapy, pursuant to R.S. 37:1164 and the LAC 46.LIII.521~~.	*Redundant, Chapter 136 has already stated this multiple times.*	
5. Other/Repeated Labs: Follow CDC Guidelines.	5. Other/Repeated Labs: Follow CDC Guidelines.		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.	~~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~~.	*Pharmacist can order or perform these tests now without this protocol.* *Pharmacists can refer patients for services he cannot directly provide without this protocol.*	
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	~~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		At the patient's request, PrEP refills will be authorized past the initial 30-day supply for oral or

done according to CDC Guidelines as ordered by one of the above mechanisms.	Guidelines. ~~as ordered by one of the above mechanisms.~~		injectable therapy if recommended baseline and follow-up testing are done according to CDC Guidelines.
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);	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);~~ comply with the standards established in LAC 46.LII.5. §517.	*Pharmacists already have extensive regulations on patient counseling as per LAC 46.LII.5. §517.* *Patient Counseling* *A. Patient counseling means the effective communication by a pharmacist of information to the patient or caregiver, in order to ensure proper use of drugs and devices.* *B. Minimum Requirements. At a minimum,* ***the pharmacist should be convinced that the patient*** *or caregiver is informed of the following: 1. name and description of the medication;* ***2. dosage form, dosage, route of administration, and duration of therapy; 3. special directions and precautions for preparation, administration, and use by the patient; 4. common severe side effects or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required in the event of their occurrence; 5. techniques for self-monitoring drug therapy;*** *6. proper storage of the medication; 7. prescription refill information, if any; and 8. the action to be taken in the event of a missed dose.* *C. The pharmacist may supplement oral information with written information, but shall not use written information alone to fulfill the counseling requirement.*	6. Counseling shall comply with the standards established in LAC 46.LII.5. §517.
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;	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;		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	b. description of signs and symptoms of acute HIV		b. description of signs and symptoms of

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.	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.		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.
§13613. HIV Post-Exposure Prophylaxis (PEP)	§13613. HIV Post-Exposure Prophylaxis (PEP) Protocol		§13613. HIV Post-Exposure Prophylaxis (PEP) Protocol
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.	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.		PEP is the use of antiretroviral drugs after a single high-risk event to decrease the risk of HIV seroconversion. PEP must be started within 72 hours of 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.	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~~.	*The last statement should be handled during the training.*	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.

[reformatted, Section F has been moved up] 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.

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.

~~F.~~ C.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 exposur~~e;
~~3. patients taking any contraindicated medications per guidelines and package insert information;~~
1. patients taking medications that would result in unresolvable drug-drug interactions; or
2. patients with contraindications to PEP.
~~4.~~ 3. patients with reactive or indeterminate baseline HIV tests;
~~5.~~ 4. patients who are consistently adherence taking PrEP ~~who report consistent adherence to their medication regimen~~; or
~~6.~~ 5. patients who indicate a history of chronic kidney disease without providing renal function test results dated within 12 months.

~~C~~. D. Pharmacists ~~must ask the following screening question~~. must assess kidney function.

~~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.~~

A trained pharmacist does not need to have his assessment approach micro-managed by the State.

We required specific assessment and calculation skills (in our licensing exam) around kidney function.

From National Associate of Board of Pharmacy, NAPLEX Competency Statements. Area 4 – Perform

C. 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 taking medications that would result in unresolvable drug-drug interactions; or
2. patients with contraindications to PEP.
3. patients with reactive or indeterminate baseline HIV tests;
4. patients who are consistently adherence taking PrEP; or
5. patients who indicate a history of chronic kidney disease without providing renal function test results dated within 12 months.

D. Pharmacists must assess kidney function.

The pharmacist may order urgent laboratories to directly assess the patient's kidney function

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.	~~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.~~ The pharmacist may order urgent laboratories to directly assess the patient's kidney function or accept patient provided creatinine clearance test results dated within 12 months from another lab or provider.	*Calculations (Approximately 14% of Test) 4.1 – Patient parameters or laboratory measures; 4.9 – Pharmacokinetic parameters;*	or accept patient provided creatinine clearance test results dated within 12 months from another lab or provider.
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.	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~~ an urgent~~ly referred to another provider~~ should be initiated.		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, an urgent referral should be initiated.
E. Pharmacists shall follow CDC Guidelines. If the following criteria are met, HIV PEP is recommended:	E. Pharmacists shall follow current CDC Guidelines~~.~~ If the following criteria are met, HIV PEP ~~is recommended:~~ for recommending HIV PEP:		E. Pharmacists shall follow current CDC Guidelines for recommending HIV PEP:
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;	1. the exposure has likely occurred within 72 hours of ~~the patient's arrival at the pharmacy~~; presentation for care; 2. an FDA-approved blood ~~rapid~~ test ~~has yielded a~~ is non-reactive ~~result~~ for HIV;		1. the exposure has likely occurred within 72 hours of the patient's presentation for care; 2. an FDA-approved blood test is non-reactive for HIV;
3. a blood rapid test is not available and PEP is otherwise indicated; or	3. If a blood ~~rapid~~ test is not available and PEP is otherwise indicated; or		If a blood 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	4. the patient's vagina, rectum, eye, mouth or other mucous membrane, non-intact skin, or		4. the patient's vagina, rectum, eye, mouth or other mucous

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.

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

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~~ and the exposure source's HIV status is unknown, the pharmacist ~~should~~ may ~~make a case-by-case~~ determin~~ation as to whether~~ if 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.

~~G.~~ D. Other Considerations:
1. If the case involves ~~a sexually assaulted person~~ sexual assault (including potential victims of human trafficking), pharmacists shall provide the patient ~~with the~~ information ~~necessary~~ needed 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

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; and the exposure source's HIV status is unknown, the pharmacist may determine if 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.
D. Other Considerations:
1. If the case involves sexual assault (including potential victims of human trafficking), pharmacists shall provide the patient information needed to pursue a Sexual Assault Nurse Examiner (SANE) exam locally, as well as the contact information for their closest

be contacted at 1-855-4LA-KIDS (1-855-452-5437).	potentially a victim of child abuse, child protective services must be contacted ~~at 1-855-4LA-KIDS (1-855-452-5437)~~.		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.
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.	~~H~~. G. 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.~~	*Redundantly redundant.*	G. Medication options include all FDA-approved or CDC-recommended medications or regimens for PEP.
I. Labs: follow CDC Guidelines for PEP.	~~I.~~ H. ~~Labs:~~ Laboratory Assessments shall follow current CDC Guidelines for PEP.		H. Laboratory Assessments shall follow current 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.	1. ~~All efforts should be made to obtain~~ a non-reactive HIV test should be obtained 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.		1. A non-reactive HIV test should be obtained 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.	2. For patients who request PEP, pharmacists ~~shall~~ may offer testing for other sexually transmitted infections or refer them to		2. For patients who request PEP, pharmacists may offer testing for other

	another provider for testing.		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	~~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.~~ 3. 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.	*Pharmacists do not need this protocol to perform these tasks.*	3. 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):	~~J.~~ I. counseling shall ~~include (at minimum):~~ comply with the standards established in LAC 46.LII.5. §517. And additionally include:		I. Counseling shall comply with the standards established in LAC 46.LII.5. §517. And additionally include:
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	~~1. instruction on proper medication use, adherence, schedule, and potential common and serious side effects (and how to mitigate them);~~ ~~2.~~ 1. description of signs/symptoms of acute HIV infection and recommended actions; ~~3.~~ 2. emergency contraception, when appropriate; ~~4.~~ 3. the importance of engaging in routine primary care; ~~5.~~ 4. the importance and requirement of follow-up testing for HIV, renal function, hepatic function, Hepatitis B and C, and other sexually transmitted	*as per LAC 46.LII.5. §517. Patient Counseling* *A. Patient counseling means the effective communication by a pharmacist of information to the patient or caregiver, in order to ensure proper use of drugs and devices.* *B. Minimum Requirements. At a minimum,* ***the pharmacist should be convinced that the patient*** *or caregiver is informed of the following: 1. name and description of the medication;* ***2. dosage form, dosage, route of administration, and duration of therapy; 3. special directions and precautions for preparation, administration, and use by the patient; 4. common severe side effects or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required in the event of their occurrence; 5. techniques for self-monitoring drug therapy;***	1. description of signs/symptoms of acute HIV infection and recommended actions; 2. emergency contraception, when appropriate; 3. the importance of engaging in routine primary care; 4. the importance and requirement of follow-up testing for HIV, renal function, hepatic

6. education about pre-exposure prophylaxis (PrEP) and the potential for future need.	infections, per CDC Guidelines; and ~~6.~~ 5. education about pre-exposure prophylaxis (PrEP) and the potential for future need.	*6. proper storage of the medication; 7. prescription refill information, if any; and 8. the action to be taken in the event of a missed dose.* *C. The pharmacist may supplement oral information with written information, but shall not use written information alone to fulfill the counseling requirement*	function, Hepatitis B and C, and other sexually transmitted infections, per CDC Guidelines; and 5. education about pre-exposure prophylaxis (PrEP) and the potential for future need.
§13615. HIV PrEP and PEP Documentation Requirements	§13615. HIV PrEP and PEP Communication and Documentation Requirements		§13615. HIV PrEP and PEP Communication and Documentation Requirements
[reformatted, Sections 2/3 are reversed] B. Pharmacists shall document the patient's written consent for HIV PrEP/PEP-related testing, counseling, administration, recordkeeping, and referrals.	~~B.~~ A. Pharmacists shall document the patient's written consent ~~for HIV PrEP/PEP-related testing, counseling, administration, recordkeeping, and referrals~~.	*The nature and extent of the consent has already been stated.*	A. Pharmacists shall document the patient's written consent.
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.	~~A.~~ B. Using the Patient-Centered Pharmacist Care Plan Approach (PCPCP), 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~~.	*The protocol already references best practices and guidelines.*	B. Using the Patient-Centered Pharmacist Care Plan Approach (PCPCP), pharmacists shall document a focused assessment of the patient's eligibility for HIV PrEP/PEP.
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.	C. With the patient's explicit written consent, 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~~. This notification shall be included in the Follow-up section of the PCPCP.		C. With the patient's explicit written consent, Pharmacists shall inform the patient's PCP of all test results and medications prescribed within 30 days of initiating HIV PrEP or PEP therapy.

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.

§13617. Referral Requirements

A. Pharmacists shall refer patients with reactive HIV,

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.

§13617. Referral Requirements

A. Pharmacists shall refer patients with any reactive

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.

§13617. Referral Requirements

A. Pharmacists shall refer

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.	~~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~~ to an HIV provider. C. Pharmacists shall refer ~~any female~~ patients who become pregnant while on PrEP to an appropriate ~~clinical care~~ provider, ~~including~~ who offers 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.		patients with any reactive tests to an appropriate care provider 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 to an HIV provider. C. Pharmacists shall refer patients who become pregnant while on PrEP to an appropriate provider, who offers 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.
§13619. Reimbursement	§13619. Reimbursement	*No Comments*	*No Comments*

From: Janese, David <david.janese@lsuhs.edu>
Sent: Tuesday, January 28, 2025 3:29 PM
To: Samuel Burgess <Samuel.Burgess@LA.GOV>
Subject: Act 711 open comment

Good afternoon,

My name is Dr. David Janese and I currently am practicing in primary care family medicine at Ochsner LSU Shreveport. I work closely with the Louisiana, Department of Health and Ochsner LSU infectious disease to provide care for those afflicted with HIV. We also provide a prep clinic to anyone who would like to start prep for HIV prophylaxis. We work with the Philadelphia Center to facilitate holistic care for these patients as well. I am writing to you in response to act 711 so that hopefully we can work together to improve healthcare and not possibly take a step back.

The proposal of Louisiana State Legislatures Act 711, which would allow pharmacists to initiate pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP), raises significant concerns, particularly from the perspective of overburdening an already overworked pharmacy workforce. While improving access to these critical HIV prevention medications is commendable, placing this responsibility on pharmacists could compromise both the quality of patient care and the well-being of the pharmacists themselves. Pharmacists are essential members of the healthcare system, but their current workload, especially in the retail setting, is already at a breaking point due to staffing shortages, increased administrative demands, and expanding responsibilities. Adding the initiation of PrEP and PEP to their duties could further strain their capacity to safely and effectively perform their core functions.

The administration of PrEP and PEP is not simply a matter of dispensing medication. It requires a thorough assessment of the patient's medical history, a detailed evaluation of potential risk factors, and, in the case of PrEP,

ongoing laboratory monitoring for renal function, HIV status, and adherence. These are tasks that require time, expertise, and access to patient records, which pharmacists in a retail setting often lack. Expecting pharmacists to take on this responsibility without additional training, infrastructure, or support could lead to suboptimal care, including missed contraindications, inadequate counseling, or improper follow-up. Such issues could not only jeopardize patient safety but also increase liability risks for pharmacists and the pharmacies employing them.

Moreover, this legislation does not address the systemic challenges pharmacists already face, such as high patient volumes and insufficient staffing. Adding a clinically complex task like initiating PrEP and PEP could exacerbate burnout and further erode the pharmacist workforce. This would be counterproductive to the goal of improving healthcare access, as an overstretched pharmacy system would ultimately struggle to meet the needs of patients across the board. A more effective approach would involve increasing collaboration between physicians and pharmacists, allowing pharmacists to support PrEP and PEP access within a shared care model rather than shouldering the entire burden of initiation and management.

While expanding access to PrEP and PEP is essential in addressing public health concerns related to HIV, Act 711 falls short in its understanding of the practical challenges faced by pharmacists. Policymakers should instead focus on bolstering the healthcare system as a whole by addressing provider shortages, enhancing interdisciplinary collaboration, and ensuring that any additional responsibilities placed on pharmacists are accompanied by the necessary resources and support to maintain safe and effective patient care.

Respectfully,

David Janese, MD, MS, NREMT-P
Associate Program Director
Emergency Medicine/Family Medicine
Shreveport Fire Department Chief Medical Director
(281) 851-2535

From: Tavell Kindall <tkindall@stthomaschc.org>
Sent: Monday, February 3, 2025 10:42 AM
To: Samuel Burgess <Samuel.Burgess@LA.GOV>
Subject: Public Comment, Act 711

Dear Dr. Burgess,

For you and the panel's consideration:

The current rules speak to creatine, creatinine values, and creatinine clearance. I recommend that the language be consistent with CREATININE CLEARANCE as it is the most sensitive measure to evaluate renal function in clients on PrEP.

- **Monitoring Renal Function**: Monitoring for renal function should be performed for all persons receiving oral PrEP. Renal function should be assessed every 6 months if the individual is 50 years of age and older, or they have a baseline estimated **creatinine clearance of less than 90 mL/min. Persons who are younger than 50 years of age and who have a baseline estimated creatinine clearance of at least 90 mL/min should have renal monitoring every 12 months.** Monitoring of renal function is not necessary for persons receiving injectable cabotegravir.

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ST THOMAS COMMUNITY HEALTH CENTER
Sincerely,
Tavell L. Kindall, Ph.D., DNP, APRN, AACRN, AAHIVS, FADLN, FAANP, FAAN (He/him)
Family Nurse Practitioner
Director, HIV Prevention and Treatment
1936 Magazine Street
New Orleans, LA 70130
Office: (504) 529-5558
Mobile: (504) 534-8748
Fax: (504) 529-8840

From: Ramon Gardenhire <ramon.c.gardenhire@viivhealthcare.com>
Sent: Thursday, February 6, 2025 10:31 AM
To: Samuel Burgess <Samuel.Burgess@LA.GOV>
Subject: ViiV Healthcare Comments on LA DOH Pharmacist PrEP Proposed Rules

Dear Dr. Burgess

ViiV is pleased to submit the attached comments on the proposed regulations implementing Louisiana pharmacist ability to dispense and/or administer PrEP.

Please let us know how we can partner with the Department of Health supporting development of training for long-acting injectable PrEP, and feel free to reach out with any questions.

Best,

Director Government Relations (South Region)
ViiV Healthcare
Email: ramon.c.gardenhire@viivhealthcare.com
Work Cell: 773-892-8848
Home: 301-379-3024

February 5, 2025

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

Submitted via email: Samuel.burgess@la.gov

RE: Regulations at Chapter 136, Subpart 7 of Part 1 of Title 48, implementing 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

Dr. Burgess:

ViiV Healthcare Company (ViiV) writes in support of the proposed regulations[1] from the Louisiana Department of Health ("Department") implementing procedures for a state protocol for pharmacists to dispense and/or administer pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) for the prevention of HIV. Specifically, ViiV supports:

- the proposed scope of the statewide protocol to allow pharmacists to dispense or administer PrEP;
- allowing pharmacists to maintain patient records and, in absence of a primary care provider (PCP), provide a written record of medications, lab tests, and results;
- the training requirements, which include long-acting injectable (LAI) PrEP in Administration of Medication training;
- the HIV PrEP protocol, including the scope of practice authority granted to pharmacists to dispense, administer, and provide for ancillary services related to oral and LAI PrEP;
- requirements for health coverage plans, third-party administrators, and pharmacy benefit managers to provide adequate and equitable reimbursement to pharmacists dispensing and/or administering PrEP; and
- the Department of Health's standing order to ease provision of care to people who could benefit from PrEP dispensation or administration by pharmacists.

ViiV is the only independent, global specialist company devoted exclusively to delivering advancements in human immunodeficiency virus (HIV) treatment and prevention to support the needs of people with HIV and those vulnerable to HIV. From its inception in 2009, ViiV has had a singular focus to improve the health and quality of life of people affected by this disease and has worked to address significant gaps and unmet needs in HIV care. In collaboration with the

HIV community, ViiV remains committed to developing meaningful treatment advances, improving access to its HIV medicines, and supporting the HIV community to facilitate enhanced care and treatment.

As a preliminary matter, ViiV applauds the Department for proposing regulations that recognize the critical role that pharmacists play in the Ending the HIV Epidemic initiative. Pharmacists are significantly more accessible than PCPs, particularly for individuals who could benefit from PrEP, with 90% of the US population living within 5 miles of a commercial pharmacy.[2] Reimbursing and authorizing pharmacists to dispense and administer PrEP in commercial pharmacy settings, where 85% of PrEP prescriptions are filled, can help address PrEP underutilization.[3]

ViiV supports the proposed scope of the statewide protocol to allow pharmacists to dispense or administer PrEP.

We support the Department's authorization of pharmacists to dispense and/or administer PrEP, including LAI PrEP. Additionally, we appreciate the Department's inclusion of all PrEP drugs approved by the U.S. Food and Drug Administration ("FDA") as well as the direction to follow the indications and recommendations of the U.S. Centers for Disease Control and Prevention ("CDC").[4]

In "§13603. Scope,"[5] ViiV also encourages the Department to reference the United States Preventive Services Task Force (USPSTF) Grade A Recommendation for PrEP as a highly effective intervention to prevent the acquisition of HIV.[6]

ViiV encourages the Department to finalize the proposed regulations outlining the training content, program, certification/documentation, and sanctions for the dispensing and/or administration of PrEP/PEP.[7]

We support the Department's proposed requirements for pharmacists to complete training in the Administration of Medications, as well as the six elements outlined as part of a mandatory training program specific to dispensing HIV PrEP/PEP. Part of effective and appropriate PrEP prescribing and administration requires screening for HIV and sexually transmitted infections to determine eligibility, which can include point-of-care rapid HIV testing.

Furthermore, ViiV applauds the Department's inclusion of proposed regulations that require training to support "serving historically marginalized patient populations[,] sexual assault survivors [, and] related trauma-informed care."[8] In 2022, Black and Hispanic Louisianans represented nearly 73% of new HIV diagnoses in the state, but only approximately 38% of PrEP users,[9] demonstrating the need for community pharmacists to understand and deploy strategies to reach these populations. Additionally, ViiV supports the proposal for training to include culturally sensitive patient counseling as a means to increase PrEP uptake.

Several studies have identified that costs associated with obtaining PrEP have been frequently cited as a barrier to PrEP access and reflect a need for patient support in navigating manufacturer and government assistance programs.[10] Finally, to ensure access to HIV PrEP is

not prevented by financial barriers, ViiV encourages the Department to finalize the training program requirement to educate pharmacists on "access manufacturer and government financial assistance programs for HIV PrEP/PEP."[11] We support the requirements for training certification, documentation, and sanctions as appropriate enforcement mechanisms to ensure the integrity of this vital authorization.

ViiV would like to extend our support to the Department in the development of both the training program for pharmacists and the Administration of Medication requirement, particularly as it relates to special considerations and practices for dispensing and/or administering LAI PrEP.

ViiV supports the proposed regulations outlining the protocol that pharmacists must follow to assess for HIV status, high-risk behaviors, and, if appropriate dispense and/or administer HIV PrEP.[12]

Screening for HIV status and lifestyle factors that increase the risk of an individual acquiring HIV are essential steps to determining the appropriateness of prescribing PrEP. ViiV therefore encourages the Department to finalize the proposed criteria for assessing risk factors and establishing a baseline negative HIV status. Additionally, we urge the Department to provide clear guidance and training materials for pharmacists through the proposed training program to help facilitate accurate, timely, and affordable assessment of these criteria.

ViiV also supports codification of the required screening questions, contingency tests, and required minimums for kidney function and repeated labs as outlined in the CDC Guidelines. However, ViiV suggests that the training program component for strategies serving historically marginalized patient populations, which are likely to include low-income and/or uninsured individuals, outlines low- or no-cost resources for such testing, which remains a barrier to PrEP access.[13] Existing federal law under the Affordable Care Act and coverage requirement guidance outlines that non-grandfathered group or individual health insurance plan and Medicaid Expansion plans are required to cover services associated with a USPSTF "Grade A" prevention service, which includes daily oral and LAI PrEP.

Finally, ViiV applauds the Department for incorporating LAI PrEP into its protocol for pharmacist-prescribed PrEP. This will support ongoing efforts to end the HIV epidemic in Louisiana and across the U.S.

ViiV supports finalization of the reimbursement rules as proposed.

Requiring that all health coverage plans, third-party administrators, and pharmacy benefit managers reimburse pharmacists at the same rates as other health providers for HIV PrEP and PEP services will help prevent new HIV cases and help make progress toward ending the HIV epidemic in Louisiana. One measure for identifying gaps in PrEP uptake is the PrEP-to-Need Ratio (PnR), which is a ratio of the number of people using PrEP compared to people newly diagnosed with HIV. In 2023, Louisiana had a PnR of 6.4, one of the lowest rates in the nation.[14] Adequate reimbursement rates will help incentivize pharmacists to provide PrEP and PEP services, expanding access for the community.

ViiV supports finalizing the standing order rule as proposed.

Establishing a standing order for pharmacists to provide access to HIV PrEP and PEP in the state aligns with a commitment to ending the HIV epidemic in Louisiana. This standing order will empower pharmacists to provide PrEP and PEP services to communities across the state and will facilitate faster and easier access for people who may benefit from PrEP or PEP. ViiV encourages the state to quickly implement this standing order and to renew it annually.

***

Thank you for your consideration of our comments. Please feel free to contact me at ramon.c.gardenhire@viivhealthcare.com with any questions or to discuss ViiV's support of the training requirements for pharmacists.

Sincerely,

Ramon Gardenhire
South Region Government Relations Director,
ViiV Healthcare

---

[1] Louisiana Register, Vol. 51, No.1, pp. 145-50, January 20, 2025. https://www.doa.la.gov/media/3jqhlpuq/2501.pdf. Accessed January 30, 2025.

[2] Strand MA, Bratberg J, Eukel H, Hardy M, Williams C. Community pharmacists' contributions to disease management during the COVID-19 pandemic. Prev Chronic Dis. 2020 Jul 23:17:E69. Accessible at: https://pubmed.ncbi.nlm.nih.gov/32701431/.

[3] Zhao A, Dangerfield DT 2nd, Nunn A, Patel R, Farley JE, Ugoji CC, Dean LT. Pharmacy-based interventions to increase use of HIV pre-exposure prophylaxis in the United States: a scoping review, 2022. AIDS Behav. 2022 May;26(5):1377-1392. Accessible at: https://pubmed.ncbi.nlm.nih.gov/34669062/.

[4] Centers for Disease Control and Prevention (CDC). Preexposure Prophylaxis for the Prevention of HIV Infection in the United States– 2021 Update: A Clinical Practice Guideline.https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf . Accessed January 30, 2025.

[5] Louisiana Register, Vol. 51, No.1, p. 145. January 20, 2025. https://www.doa.la.gov/media/3jqhlpuq/2501.pdf. Accessed January 30, 2025.

[6] US Preventive Services Task Force, Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis. August 22, 2023. https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis. Accessed January 30, 2025.

[7] Louisiana Register, Vol. 51, No.1, p. 146. January 20, 2025. https://www.doa.la.gov/media/3jqhlpuq/2501.pdf. Accessed January 30, 2025.

[8] Louisiana Register, Vol. 51, No.1, p. 147. January 20, 2025. https://www.doa.la.gov/media/3jqhlpuq/2501.pdf. Accessed January 30, 2025.

[9] AIDSVu. Louisiana. https://map.aidsvu.org/profiles/state/louisiana/prevention-and-testing#1-1-PrEP. Accessed January 30, 2025.

[10] Mayer KH, Agwu A, Malebranche D. Barriers to the Wider Use of Pre-exposure Prophylaxis in the United States: A Narrative Review. March 30, 2020. doi: 10.1007/s12325-020-01295-0

[11] Louisiana Register, Vol. 51, No.1, p. 147. January 20, 2025. https://www.doa.la.gov/media/3jqhlpuq/2501.pdf. Accessed January 30, 2025.

[12] Louisiana Register, Vol. 51, No.1, p. 147. January 20, 2025. https://www.doa.la.gov/media/3jqhlpuq/2501.pdf. Accessed January 30, 2025.

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[14] AIDSVu. Interactive Map: PnR. https://map.aidsvu.org/pnr/state/ratio/none/none/usa?geoContext=national. Accessed January 31, 2025.

From: Travis Manint <travis@tiicann.org>
Sent: Thursday, February 6, 2025 12:39 PM
To: Samuel Burgess <Samuel.Burgess@LA.GOV>
Cc: Jen Laws <jen@tiicann.org>
Subject: LDH Public Comment - CANN Letter re: HIV PrEP/PEP Pharmacist Rule

Dear Dr. Burgess,

Please find attached CANN's public comment letter regarding the Notice of Intent for LAC 48:I.Chapter 136 - Administration and Treatment of Human Immunodeficiency Virus.

Thank you for the opportunity to provide input on this important initiative to expand HIV prevention access in Louisiana. If LDH or any other arm of the rule making process would like to discuss our comments, we can be reached at this email address.

Thank you for your service to the great state of Louisiana.

Sincerely,

Travis Manint

Travis Manint
Communications Director
Community Access National Network (CANN)

985-960-4900
travis@tiicann.org
tiicann.org

COMMUNITY ACCESS NATIONAL NETWORK

Mailing Address:

Attn: Jen Laws
PO Box 3009
Slidell, LA 70459

Chief Executive Officer:

Jen Laws
Phone: (313) 333-8534
Fax: (646) 786-3825
Email: jen@tiicann.org

February 5, 2025

VIA Electronic Mail

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

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

Dear Dr. Burgess,

The **Community Access National Network (CANN)** is a 501(c)(3) national nonprofit organization focusing on public policy issues relating to HIV/AIDS and viral hepatitis. CANN's mission is to define, promote, and improve access to healthcare services and support for people living with HIV/AIDS and/or viral hepatitis through advocacy, education, and networking.

Access to PrEP, or pre-exposure prophylaxis, is of profound importance to our community.

Today, we write in strong **SUPPORT** of the proposed rule **AS WRITTEN** to enable pharmacist-initiated HIV prevention through PrEP and PEP services in Louisiana.

Louisiana's Critical Need for Expanded HIV Prevention
Louisiana ranks 4th nationally for HIV diagnosis rates (18.6 per 100,000), with 23,126 people living with HIV as of March 2024. Young people aged 13-34 account for 58% of new diagnoses, underscoring the urgent need for expanded access to prevention tools like PrEP and PEP.

Evidence from Other State Programs
Ten states have enacted similar legislation allowing pharmacists to prescribe PrEP/PEP. A Mississippi pilot program demonstrated success in reaching key populations, with 77% of prescriptions filled within one week. The program effectively served populations like Louisiana's most impacted communities, reaching predominantly Black (77%) and uninsured (65%) patients.

Building on Louisiana's Success
Louisiana's successful naloxone access program demonstrates pharmacists can effectively provide critical medications - expanding from 6,013 to 7,148 Medicaid recipients between 2016-2018. The proposed rule builds on this proven model while incorporating comprehensive training requirements and safety measures.

Strong Framework for Implementation
The proposed rule aligns with best practices identified from other state programs, including comprehensive pharmacist training requirements, HIV testing protocols, patient counseling requirements, and coordination with primary care providers. These elements mirror successful approaches in states like California, Colorado, and Virginia, where similar programs have been implemented.

Addressing Health System Capacity
With 90% of Americans living within five miles of a pharmacy, pharmacists are uniquely positioned to expand access to HIV prevention services. Recent studies of pharmacist-led programs have demonstrated reduced emergency department visits and improved healthcare access, particularly for underserved populations. This aligns perfectly with the goals outlined in Louisiana's "Get Loud" Ending the HIV Epidemic plan.

The evidence from other state programs, combined with Louisiana's own successful experience with pharmacy-based medication access, suggests this approach will effectively increase access to PrEP and PEP while maintaining high standards of care. The proposed rule represents a significant step forward in expanding HIV prevention services in Louisiana, particularly for communities most impacted by HIV.

We strongly encourage the adoption of this rule as written and appreciate the opportunity to provide these comments.

Respectfully submitted,

Travis Manint
Director of Communications
Community Access National Network (CANN)

On behalf of
Jen Laws
President & CEO
Community Access National Network

From: Philip, Jeenu <jeenu.philip@walgreens.com>
Sent: Monday, February 10, 2025 1:50 PM
To: Samuel Burgess <Samuel.Burgess@LA.GOV>
Cc: Joe Fontenot <JFontenot@pharmacy.la.gov>; Philip, Jeenu <jeenu.philip@walgreens.com>
Subject: Walgreens Comments: LAC 48:I.Chapter 136: Administration and Treatment of Human Immunodeficiency Virus

Dear Mr. Burgess,

Please find attached Walgreens comments on the proposed regulations for the administration and treatment of Human Immunodeficiency Virus (HIV) Pre-Exposure Prophylaxis (PrEP) and Post-Exposure Prophylaxis (PEP) as outlined in the Louisiana Register Vol. 51, No. 1, January 20, 2025.
If you would like additional information, please feel free to contact me.

Thank you!

Regards,
Jeenu

Jeenu Philip
Director, Pharmacy Affairs
Walgreen Co.
Telephone 904-386-6776
Member of Walgreens Boots Alliance | MyWalgreens.com

Jeenu Philip, R.Ph.
Director, Pharmacy Affairs
Walgreen Co.
p: 904-386-6776
jeenu.philip@walgreens.com

February 10th, 2025

Via Email

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
Email: samuel.burgess@la.gov
Cc: JFontenot@pharmacy.la.gov

Re: Request for Amendment to Rule:
LAC 48:I.Chapter 136: Administration and Treatment of Human Immunodeficiency Virus

Dear Mr. Burgess,

On behalf of all pharmacies owned and operated by Walgreen Co. in the state of Louisiana, we thank the department for the opportunity to provide comments on the proposed regulations for the administration and treatment of Human Immunodeficiency Virus (HIV) Pre-Exposure Prophylaxis (PrEP) and Post-Exposure Prophylaxis (PEP) as outlined in the Louisiana Register Vol. 51, No. 1, January 20, 2025.

While we fully support the Department's proposals in continued efforts to expand access for patients in Louisiana for pharmacists to dispense and/or administer pre-exposure and post-exposure prophylaxis medications for the prevention of HIV.

- CDC Guidelines Reference: The definition section references CDC clinical practice guidelines. Due to the current uncertainty about the potential status of CDC guidelines, we would recommend that it may be more prudent for the state to control and/or post its own guidelines to ensure consistency and accessibility.

- Training Requirements: We agree with the training requirements outlined. If training is received in pharmacy school, there may not be a formal certification. Therefore, the language should clarify that education received in school can be certified to meet the states requirements by a professor's signature on a *standardized form created by the state*. This approach ensures that both educational paths are recognized and standardized.

- Referral to Providers: While we agree in principle with referring patients to a provider if they do not have one, implementation will be challenging and likely inconsistent and potentially create issues of fairness. We believe it may be more practical to refer patients to the state department of health or a department website to ensure a consistent connection to care across all locations.

- Creatinine Clearance Test: The regulation allows pharmacists to order a creatinine clearance test. It is important to ensure this aligns with state guidelines on the types of tests pharmacists can order. Typically, creatinine clearance tests are not CLIA-waived, so clarification is needed to ensure a pharmacist ordering these tests is in compliance with state regulations.

- Follow-Up Tests: The regulation references follow-up tests per CDC guidelines, which likely include a panel of STI and hepatitis tests. This could complicate operations, as it would almost always necessitate referrals for testing beyond the standard point-of-care HIV tests. It is important to ensure all stakeholders are aware of these requirements.

- Documentation Requirements (Section 13615 (C)): It is unclear whether pharmacists are responsible for documenting all test results, including those referred to other providers, or only the tests they conduct. Clarification is needed to ensure proper documentation practices.

Walgreens thanks the Department for the opportunity to provide the request to amend this rule. If the Department would like additional information, please feel free to contact me.

Sincerely,

Jeenu Philip R.Ph.

From: Mary Staples <mstaples@NACDS.org>
Sent: Monday, February 10, 2025 9:36 PM
To: Samuel Burgess <Samuel.Burgess@LA.GOV>
Cc: Jessica Elliott <jessica@laretail.org>; Shelly Dupre <shelly@impactmanagement.com>
Subject: Comments Supporting Propose Rules Implementing HB 579

Dr. Burgess,

On behalf of the National Association of Chain Drug Stores (NACDS), we would like to express our support for the proposed rules to implement House Bill 579, which enables pharmacists to offer HIV prevention services. Please accept the attached comment letter for the record.

MARY STAPLES
Director, State Government Affairs
mstaples@nacds.org
P: (817) 442.1155
F: (817) 442.1140
C: (817) 308.2103
National Association of Chain Drug Stores (NACDS)
211 East Southlake Boulevard, Suite 108 Southlake, Texas 76092
Representing members in AK, AR, CO, IN, KS, LA, ME, MO, NH, NM, NV, OK, TX, WA
www.nacds.org
www.facebook.com/NACDS.org
www.twitter.com/@NACDS

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

February 10, 2025

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

Via email: samuel.burgess@la.gov

Re: Support Proposed Rule Enhancing Public Access to HIV Prevention Services via Pharmacies

Dear Dr. Burgess,

The National Association of Chain Drug Stores (NACDS) is writing to the Louisiana Department of Health in support of the proposed rules to implement HB579 which enables pharmacists to offer HIV prevention services – from providing HIV testing to dispensing and administering HIV pre-exposure and post-exposure prophylaxis medications. Louisiana has one of the highest rates of HIV in the United States, with reports of more than 23,000 people living with HIV as of March 2024 and 875 new diagnoses in 2023 alone.[1] Pre- and post-exposure prophylaxis (PrEP and PEP) are highly effective at preventing HIV, but need to be more readily available within communities. Pharmacists provide accessibility, trust, and clinical expertise in a destigmatizing environment to promote better health, including for HIV prevention. Research has also proven that pharmacist-led HIV prevention services are safe, effective, and beneficial to the public.[2,3,4]

Further, Louisiana residents support the role of pharmacists in HIV prevention. A recent poll commissioned by NACDS and conducted by Morning Consult indicates that 68% of Louisianians support pharmacists administering simple HIV tests at pharmacies; 63% of Louisianians support pharmacists prescribing HIV preventive medications to those who may not have been exposed to HIV (pre-exposure prophylaxis or PrEP); and 62% of Louisianians support pharmacists prescribing HIV preventive medications to those who have possibly been exposed (post-exposure prophylaxis or PEP). Importantly, 69% also support pharmacists being adequately paid for testing and initiating treatment.[5]

NACDS applauds the successful passage of HB579 and strongly urges the Louisiana Department of Health to follow suit in finalizing the proposed rules to secure broader access to essential care and improve the lives of Louisianians. If you have any questions or need additional information, please contact NACDS' Mary Staples, Director, State Government Affairs at MStaples@NACDS.org.

Sincerely,

Steven C. Anderson, FASAE, CAE, IOM
President and Chief Executive Officer
National Association of Chain Drug Stores

###

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate nearly 40,000 pharmacies, and NACDS' chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit NACDS.org.

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[1] https://ldh.la.gov/assets/oph/HIVSTD/2024-reports/First-Quarter-2024-HIV-and-Syphilis-Report.pdf

[2] Ryan K, Lewis J, Sanchez D, Anderson B, Mercier RC. 1293. The Next Step in PrEP: Evaluating Outcomes of a Pharmacist-Run HIV Pre-Exposure Prophylaxis (PrEP) Clinic. Open Forum Infect Dis. 2018 Nov 26;5(Suppl 1):S395. doi: 10.1093/ofid/ofy210.1126. PMCID: PMC6252683. https://pubmed.ncbi.nlm.nih.gov/30401342/

[3] Tung EL, Thomas A, Implementation of a community pharmacy-based pre-exposure prophylaxis service: a novel model for pre-exposure prophylaxis care. Nov 2018. https://www.ncbi.nlm.nih.gov/pubmed/30401342

[4] Pharmacist-Led, Same-Day, HIV Pre-Exposure Prophylaxis Initiation Program to Increase PrEP Uptake and Decrease Time to PrEP Initiation. AIDS Patient Care STDS. 2020;34(1):1-6. doi:10.1089/apc.2019.0235https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6983741/

[5] https://www.nacds.org/pdfs/Opinion-Research/NACDS-OpinionResearch-Louisiana.pdf

From: Jessica Elliott <jessica@laretail.org>
Sent: Tuesday, February 11, 2025 2:47 PM
To: Samuel Burgess <Samuel.Burgess@LA.GOV>
Cc: 'Shelly Dupre' <shelly@impactmanagement.com>
Subject: Act 711 Letter of Support

Dr. Burgess- Please see the attached letter on behalf of the Louisiana Alliance of Retail Pharmacies (LARP) in support of the proposed rule that will allow Louisiana pharmacists to dispense and/or administer PrEP and PEP medications.

Thank You,

Jessica Elliott
Louisiana Retailers Association
Louisiana Alliance of Retail Pharmacies
(225) 344-9481

LOUISIANA ALLIANCE
OF RETAIL PHARMACIES

February 10, 2025

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

Dear Dr. Burgess:

On behalf of the Louisiana Alliance of Retail Pharmacies (LARP), I am writing to express our strong support for the proposed rules to implement Act 711, which will allow pharmacists to play a greater role in HIV prevention. By providing HIV testing and dispensing pre-exposure and post-exposure prophylaxis (PrEP and PEP) medications, pharmacists play an important role in expanding accessibility to the communities most in need.

Louisiana faces significant challenges in the fight against HIV and expanding access to prevention measures is a critical step forward. Pharmacists are uniquely positioned to help—offering trusted, convenient, and confidential care to patients seeking preventive treatment. Across the state, residents recognize the value of pharmacist-led HIV prevention, and it's essential that these services are fully supported.

We applaud the enactment of Act 711 and urge the Louisiana Department of Health to move forward with finalizing these important rules. Doing so will ensure broader access to essential care and improve health outcomes for countless Louisianians. Please don't hesitate to reach out if we can provide any further information or support.

Sincerely,

Jessica Elliott

Jessica Elliott, Executive Director
jessica@laretail.org

From: Aliyah Ali <Aliyah@courageforwardstrategies.com>
Sent: Friday, February 21, 2025 11:14 AM
To: Samuel Burgess <Samuel.Burgess@LA.GOV>
Cc: Sara Zeigler <Sara@courageforwardstrategies.com>
Subject: Public Comment on Draft Rules for Pharmacist-Initiated HIV Prevention Services (HB 579 Implementation)

Dear Dr. Burgess,

I hope you're doing well. I realize the deadline has passed, but I still wanted to share the RxEACH Initiative's comments (below) on the draft rules for pharmacist-initiated HIV prevention services. RxEACH is a coalition of experts, organizations, and individuals who are deeply committed to expanding equitable access to HIV prevention services, and we appreciate the opportunity to contribute to this important effort.

While we regret missing the formal deadline, we remain eager to stay engaged and support implementation efforts moving forward. Please don't hesitate to reach out if there are ways we can be helpful. We appreciate your leadership on this issue and look forward to opportunities for future connections.

Best,
Aliyah

Dear Dr. Burgess,

On behalf of the [rxeach.org]RxEACH Initiative, a coalition dedicated to expanding equitable access to HIV prevention services in community pharmacies, I appreciate the opportunity to provide comments on the Louisiana Department of Health's draft rules implementing HB 579. These rules represent an important step in expanding access to pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) through pharmacy-based services.

We commend Louisiana for its leadership on this issue and ensuring that pharmacists are reimbursed at the same rate as other healthcare providers for comparable services. This provision is particularly notable for long-term sustainability. As implementation moves forward, we encourage continued attention to the following factors:

- **Clarity and Practicality in Pharmacist Reimbursement Pathways**

Ensuring that pharmacists can easily navigate reimbursement processes will be key to broad participation. Clear guidance on billing procedures and claim submission will help reduce administrative burden and improve access, particularly for pharmacies in rural or resource-limited settings.

- **Feasible Referral Pathways for Pharmacies Without Lab Capabilities**

Allowing pharmacists to conduct necessary HIV testing is an important step, but some pharmacies may not have on-site lab capabilities. Maintaining realistic and efficient referral pathways for these pharmacies will help ensure that patients can still access comprehensive care without unnecessary hurdles.

- **Flexibility in Training and Documentation Requirements**

While training is essential, making training requirements accessible and not overly burdensome will help ensure pharmacists can fully participate. Offering flexible formats for training could make it easier for pharmacies to integrate these services. Similarly, clear but streamlined documentation requirements will help ensure that administrative processes do not create barriers to service delivery.

- **Ongoing Support for Pharmacy-Based HIV Prevention**

Pharmacies are well-positioned to play a key role in expanding access to HIV prevention services, particularly in communities with limited healthcare options. Continued engagement with stakeholders, including pharmacists and community organizations, will be helpful in ensuring ongoing success of these efforts.

Thank you for the opportunity to provide feedback. We appreciate the steps Louisiana is taking to expand pharmacist-led HIV prevention services and look forward to continued discussions on implementation.

-Aliyah, on behalf of the RxEACH initiative

COURAGE FORWARD STRATEGIES

Aliyah A. Ali, MPH
Principal
Courage Forward Strategies
612.532.1717 aliyah@courageforwardstrategies.com

LOUISIANA DEPARTMENT OF HEALTH

Summary of Public Comments and Agency Response

Notice of Intent to promulgate Chapter 136 (Administration and Treatment of Human Immunodeficiency Virus) of Subpart 7 (Human Immunodeficiency Virus/AIDS) of Part 1 (General Administration) of Title 48 (Public Health—General) of the Louisiana Administrative Code (LAC)

Background

Effective August 1, 2024, Act 711 of 2024 adds R.S. 37:1218.2 to the Louisiana Revised Statutes and requires promulgation of administrative rules by the Louisiana Department of Health (LDH). In accordance with the legislation, LDH proceeded in the rulemaking process, beginning with an expert panel (as outlined in the legislation) to craft a statewide protocol for pharmacists to dispense and/or administer HIV pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP). The Notice of Intent (NOI) to promulgate Chapter 136 (Administration and Treatment of Human Immunodeficiency Virus) of Subpart 7 (Human Immunodeficiency Virus/AIDS) of Part 1 (General Administration) of Title 48 (Public Health—General) of the Louisiana Administrative Code (LAC) was published on pages 145-150 of the January 20, 2025 issue of the Louisiana Register. The deadline to submit written comment, via the U.S. Mail or via email, in response to the NOI was published as February 10, 2025 at 4:30 p.m. The Louisiana Department of Health continued to accept public comment until February 28, 2025 at 4:30 p.m.

Public Comments in Response to the NOI

LDH received nine (9) written submissions of public comment in response to the NOI.

Summary of Public comments in Response to the NOI

While it is highly uncommon to received public comments in support of an NOI, it is extraordinarily noteworthy that five (5) of the nine (9) public comment submissions received to this NOI were in support of proposed Chapter 136, as a "benefit" to public health and access to care, citing epidemiological data and research to support their agreement with the finalization of these rules as they are written in their entirety. One public comment submission offered implementation focus suggestions and another also offered support for specified provisions, detailed below.

Specified support within a particular comment included: Scope of the Rule, Training and Documentation of Training, Risk Assessment, Reimbursement, and Standing Order.

One (1) of the public comment submissions received expressed opposition to the legislation itself, rather than addressing the NOI for Chapter 136. Because LDH is not tasked or otherwise authorized to debate the merits of the legislation nor the Louisiana Legislature's choice to make laws, no changes are recommended based on this submission.

The final three (3) public comment submissions received expressed support for the NOI while also noting specific suggestions for edit. While there was no consensus on any specific suggestions, a summary of feedback received is as follows:

- Technical Edits: one submission provided line-by-line editing suggestions to reduce the length of the chapter, change grammar, or rearrange document flow, stating that the length and detail of the rule set will serve to stifle pharmacists in pursuing this area of practice and additionally noting that the level of detail does not respect the history, training, and experience of the pharmacy profession.
- Reference to the Center for Disease Control and Prevention's (CDC) materials: Concern about the rule set's reliance on reference materials from the Centers for Disease Control and Prevention's clinical guidelines for PrEP and PEP, and the accessibility of said documents in the future with the online presence of federal agencies currently in flux.
- Kidney function testing: feedback regarding consistency between the usage of terms "creatinine clearance", "creatinine", and "creatinine values" and their usage; request to remove detailed process information regarding such with the assertion that pharmacists are trained and do not need the guidance; concern about availability of CLIA-waived creatinine clearance tests.
- Training: requests to remove training requirements for pharmacists being enumerated in the rules to reduce burden on participating pharmacists; concern about how training via school curriculum will be provable and consistent; request to remove the five (5) year practice pre-requisite for pharmacists to participate.
- Referrals: concerns about implementation challenges and a request that LDH handle referrals rather than pharmacists.
- Documentation: request to remove documentation requirements to reduce burden on pharmacists; request for clarification on documentation requirements for test results.

No requests for a public hearing were received by the published hearing request deadline of February 10, 2025. As such, no public hearing on this NOI was scheduled, noticed, or occurred.

Response to Public Comments received in Response to the NOI

Scope of the Rule

LDH agrees with the sentiment that pharmacists have an extensive role in extending access to care, especially in rural geographies and among otherwise underserved populations. Extensive academic research and government-funded pilot projects have demonstrated that limited and well-managed scope of practice expansions, empowering cohesion among provider-types improve community health outcomes. LDH asserts that the extent of the proposed rule, with sufficient documentation and referral requirements facilitates appropriate collaboration between pharmacists and primary care providers, serving the legislative intent of Act 711.

Technical Edits
While LDH much appreciates a desire for brevity in any rule-making documents, the legislatively-described Expert Panel (comprised of doctors, pharmacists, the Louisiana State Medical Society, and the Louisiana Board of Pharmacy) reviewed these rules line-by-line in their creation, and deemed that the level of detail contained herein was appropriate to fill both the needs of pharmacists engaging in a new practice area as well as for the medical provider community's comfort in this expanded scope of practice. The Panel also ensured all requirements of the legislation were addressed, as the legislation outlined specific requirements for the rules set. While a request to remove references to specific regulations regarding the government of pharmacists was received, LDH, in agreement with the Panel, recognizes these references as appropriate to remain in these rules. In general, Rules, having regulatory impact, must sufficiently define and otherwise clarify provisions. The breadth of detail included in the proposed Rule serve this interest.

Reference to the Center for Disease Control and Prevention's (CDC) materials; Risk Assessments
One submission expressed concern about the future accessibility of the CDC clinical guidelines for the administration of PrEP and PEP, and this concern will be met by having copies of the applicable CDC documents available in full at the Office of the State Register. Also, LDH will maintain a webpage of resources to guide and assist pharmacists in this practice that will include copies of the applicable CDC guidelines. The rulemaking process created by the Louisiana Division of Administration (DOA) requires that *any* reference be static in nature to be incorporated into Louisiana's Administrative Code. If medical science developments necessitate an update to these guidelines (or a creation of an LDH set of similar guidelines), LDH will move to amend the Chapter and progress through the rulemaking process as necessary at that time.

Another comment submission stated support for use of the CDC's reference materials with regard to specified risk assessment tools. Herein LDH asserts the clinical practice guidelines provided by the Centers for Disease Control and Prevention (CDC) are sufficiently clear and accessible

LDH also agrees with the submission's concerns regarding lost- or no-cost screening resources in order to ensure access to PrEP is also available to historically underserved communities and patient populations; screenings should not become a barrier to accessing care and pharmacists administering PrEP under this Rule are encouraged to familiarize themselves with available resources. LDH believes the primary care referral requirement will help to address this worthy concern.

Reimbursement
One comment submission shared support for delineated reimbursement provisions of the Rule. LDH also recognizes that reimbursement, or lack thereof, has proven to be a barrier for provider engagement in HIV prevention. Specifying reimbursement both serves the practical nature of ensuring pharmacists are justly paid for their work and to encourage a more robust engagement

in HIV prevention efforts across the state. Additionally, Act 711 a requirement for reimbursement provision.

Standing Order
Support for the inclusion of a standing order was also expressed. Herein, LDH asserts an authority historically offered to the agency as a means of removing administrative and technical barriers to care, specifically addressing the needs of patients who may not already be engaged with a primary care provider. An example includes the agency's standing order for naloxone, prior to the Food and Drug Administration's approval of "over-the-counter" versions of the medication, in order to address the state's rate of opioid-induced fatal overdoses. Similarly, LDH recognizes the utility of the standing order here, creating a pathway to care for patients who would benefit from PrEP access but are otherwise not yet in the care of a primary care provider.

Kidney Function Testing
While the suggestion to standardize language related to kidney function is understood, the terms "creatinine", "creatinine values", and creatinine clearance" were carefully selected in each specific instance within the rules. LDH also recognizes that pharmacists are extensively trained regarding drug impacts on kidney function, and the level of detail provided in Chapter 136 on kidney function surveillance measures is necessary given the specific types of drugs being dispensed and/or administered in this program. Additionally, the legislatively described Expert Panel advising LDH in the rulemaking process verified that CLIA-waived creatinine clearance tests do exist. The expert panel also verified the existence of necessary point-of-care tests for the other sexually transmitted infections (STIs) recommended in the rules.

Training
With regard to specified training requirements, LDH received both a comment submission in criticism, with a concern of a lack of consistency in "certification" between curriculum-based versus specialized education programs, and a comment in support of the proposed training and training documentation requirements. All submissions that addressed training were in support of the content of the required training.

The pharmacy schools in Louisiana participated in the Expert Panel in creation of these rules and they are working to ensure all required training for this practice will be incorporated into their curriculum and that their schools are prepared to issue a certificate stating that a student has completed said training requirements. For pharmacists trained in other states at schools whose curriculum does not include the required training elements, there will be recommended online ACPE-accredited programs that meet all requirements, including certificate issuance. The availability of multiple routes towards competency is vital in maintaining accessibility of training to our independent pharmacists in rural areas. Proposed Chapter 136 states, "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." This description ensures that even pharmacists trained outside of Louisiana should have a clear method by which to document curriculum-based training they received in their respective schools of pharmacy.

With regards to pre-requisites for participation in this program, the Expert Panel extensively reviewed the statewide protocols/rules/regulations governing pharmacists in other states that have passed similar legislation, and LDH and the Panel established pre-requisite requirements consistent with the most common requirements of those other states.

Referrals
In response to the concern about implementation and the ability to maintain consistency with regards to referrals to other providers, proposed Chapter 136 provides specific resources for finding appropriate providers local to the patient's desired area. The administrative burden of the referral must remain with the pharmacy/pharmacist choosing to participate in the program, as they are the entity providing care and developing a patient relationship. Also, this administrative burden cannot be shifted to the State, as the legislation does not provide for the staff or funding to create the program with which to handle this work. However, LDH has established a resource webpage where referral, reporting, and training resources can be easily accessed.

Documentation
LDH recognizes the concern of additional burden on pharmacists with the increase in documentation inherent in this expanded practice. However, no documentation required in proposed Chapter 136 exceeds standard documentation requirements of clinicians providing similar services. Specific documentation requirements accompanying this practice are particularly important, as the patients in question may not be engaging with primary care practitioners in this aspect of their medical care.

As a point of clarification, documentation requirements in the proposed rules include documenting test results (either for a patient's PCP or to provide to the patient directly, in the absence of a PCP). As no tests are individually specified or excepted, this documentation will include ALL tests administered or ordered by the pharmacist in the initiation of PrEP/PEP with the patient.

Agency Response
In consideration of a piece of legislation intended to increase access to HIV prevention medications in Louisiana, LDH asserts that proposed Chapter 136 of Subpart 7 of Part 1 of Title 48 answers the legislative mandate and direction to the Department in Act 711 of 2024 (R.S. 37:1218.2).

LDH asserts that Chapter 136 meets all legislative requirements set forth for rulemaking in Act 711:

- ✓ The department shall promulgate rules in accordance with the Administrative Procedure Act to implement the provisions of this Section (Page 2, Lines 13-14).

- ✓ The department shall consult with an expert panel to advise it in promulgating administrative rules to implement the provisions of this Section (Page 2, Lines 15-16).
- ✓ The administrative rules shall be promulgated by March 2025 (Page 2, Lines 16-17).
- ✓ The expert panel shall integrate and coordinate expertise relative but not limited to testing, referrals, prescribing, and reimbursement for HIV pre-exposure prophylaxis and HIV post-exposure prophylaxis (Page 2, Lines 18-20).
- ✓ The expert panel shall be composed of the following members who shall serve without compensation (Page 2, Lines 21-30):
    - A representative from the Louisiana Department of Health, bureau of infectious diseases (Dr. Samuel Burgess)
    - An infectious disease physician to be selected by the department (Dr. Stacy Greene)
    - A primary care physician who has experience managing patients who utilize HIV medications to be selected by the department (Dr. Moses Braimoh)
    - Pharmacist selected by the department (Dr. George Nawas)
    - Pharmacist selected by the department (Dr. Glenn Green)
    - A representative from the Louisiana Board of Pharmacy (Dr. Alexis Horace)
    - A representative from the Louisiana State Board of Medical Examiners (Dr. Vince Culotta)
- ✓ The rules promulgated by the department shall include requirements relating to the testing, screening, and treatment of patients. At a minimum, the rules shall require the pharmacist to do all of the following (Page 3, Lines 1-20):
    - Complete a training program approved by the department on the use of HIV pre-exposure prophylaxis and HIV post-exposure prophylaxis prior to exercising the authority provided for in this Section. The training shall include but not be limited to all of the following:
        - Financial assistance programs for HIV pre-exposure prophylaxis and HIV post-exposure prophylaxis.
        - Strategies to access state and federal resources to provide the same level of care for patients regardless of insurance coverage status.
        - Document a focused assessment of the patient following best practices and guidelines for preventing HIV.
        - Document steps to obtain consent, order, process, evaluate, interpret, and discuss results with patients of any HIV laboratory tests authorized in the rules promulgated by the department.
        - Identify the nature and obligations for successful HIV pre-exposure prophylaxis or HIV post-exposure prophylaxis, as required by the patient, and the importance of timely testing for HIV and related complications and comorbid conditions.
- ✓ The rules promulgated by the department shall include procedures for the timely notification of the patient's primary care provider of the services provided, or when a patient does not have a primary care provider, documentation of a good faith effort to refer the patient to a primary care provider (Page 3, Lines 21-24).
- ✓ A pharmacist authorized to provide a service relative to HIV pre-exposure and post-exposure prophylaxis 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 (Page 3, Lines 25-28).

While thoroughly addressing each of the legislative requirements for rulemaking, LDH asaserts that proposed Chapter 136 remains as brief and clear as possible in the endeavor and accomplishes the Legislature's goal of increasing access to HIV prevention medications across the state of Louisiana. LDH strives to reduce as many barriers to implementation as possible in this process, while ensuring pharmacists maintain the highest Standard of Care all Louisianans deserve.

Agency Conclusion

The promulgation of Chapter 136 into LAC will place Louisiana in the forefront of the national HIV prevention landscape. While many states who have passed similar legislation have gotten mired in the rulemaking process or implementation phases, Louisiana stands uniquely positioned to become the national gold-standard for pharmacist-initiated PrEP and PEP.

LDH expects a significant increase in PrEP uptake and in PEP availability, which will result in decreased HIV transmissions in the state of Louisiana. LDH remains committed to working diligently toward ending the HIV epidemic in the State of Louisiana and believes proposed Chapter 136 as written is an important step in that quest.

With these considerations, in addition to the significant support expressed in public comments, LDH recommends moving forward with the promulgation and finalization of Chapter 136 (Administration and Treatment of Human Immunodeficiency Virus) of Subpart 7 (Human Immunodeficiency Virus/AIDS) of Part 1 (General Administration) of Title 48 (Public Health—General) of the Louisiana Administrative Code, regarding the authority of pharmacists to independently dispense and/or administer HIV PrEP and PEP.

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES

Person Preparing Statement:	Samuel Burgess, DHA	Dept.:	LDH/OPH/BID
Phone:	504-669-0565	Office:	STI/HIV/Hepatitis Program
Return Address:	1450 Poydras St., Rm 2114	Rule Title:	Pharmacist-Initiated HIV PrEP
	New Orleans, LA 70112		and PEP
		Date Rule Takes Effect:	4/1/2025

SUMMARY
(Use complete sentences)

In accordance with Section 961 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a fiscal and economic impact statement on the rule proposed for adoption, repeal or amendment. THE FOLLOWING STATEMENTS SUMMARIZE ATTACHED WORKSHEETS, I THROUGH IV AND WILL BE PUBLISHED IN THE LOUISIANA REGISTER WITH THE PROPOSED AGENCY RULE.

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL 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 NON-GOVERNMENTAL 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.

DocuSigned by:
Tonya Joiner
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Signature of Head or Designee

Patricia Thomas, Deputy Fiscal Officer
Legislative Fiscal Officer or Designee

Tonya Joiner, Assistant Secretary
Typed Name & Title of Agency Head or Designee

12/10/2024
Date of Signature

12/10/2024
Date of Signature

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES

The following information is required in order to assist the Legislative Fiscal Office in its review of the fiscal and economic impact statement and to assist the appropriate legislative oversight subcommittee in its deliberation on the proposed rule.

A. Provide a brief summary of the content of the rule (if proposed for adoption, or repeal) or a brief summary of the change in the rule (if proposed for amendment). Attach a copy of the notice of intent and a copy of the rule proposed for initial adoption or repeal (or, in the case of a rule change, copies of both the current and proposed rules with amended portions indicated).

Pursuant to Act 711 of 2024 (R.S. 37:1218.2), the proposed Pharmacist-Initiated HIV PrEP and PEP rule establishes the qualifications, record keeping, training, documentation, referral and reimbursement requirements that a Louisiana-licensed pharmacist shall follow to dispense and/or administer HIV pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) medications for the prevention of HIV infection. The proposed rule allows qualifying Pharmacists to dispense and administer HIV PrEP and 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 clinical guidelines from the U.S. Centers for Disease Control and Prevention (CDC).

B. Summarize the circumstances, which require this action. If the Action is required by federal regulation, attach a copy of the applicable regulation.

Act 711 of 2024 (R.S. 37:1218.2) requires LDH to promulgate this proposed Pharmacist-Initiated HIV PrEP and PEP rule.

C. Compliance with Act 11 of the 1986 First Extraordinary Session

(1) Will the proposed rule change result in any increase in the expenditure of funds? If so, specify amount and source of funding.

There is an anticipated increased expenditure of funds 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 medications for HIV treatment and other associated medical problems that may offset the HIV PrEP and PEP costs in future fiscal years. Federal funds would primarily cover any increased expenditures in the Medicaid program. There are no other anticipated implementation costs to state or local governmental units associated with this proposed Pharmacist-Initiated HIV PrEP and PEP rule.

(2) If the answer to (1) above is yes, has the Legislature specifically appropriated the funds necessary for the associated expenditure increase?

(a) ___X___ YES. If yes, attach documentation.

(b) _____ NO. If no, provide justification as to why this rule change should be published at this time

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

I. A. COSTS OR SAVINGS TO STATE AGENCIES RESULTING FROM THE ACTION PROPOSED

1. What is the anticipated increase (decrease) in costs to implement the proposed action?

COSTS	FY 25	FY 26	FY 27
PERSONAL SERVICES	$0	$0	$0
OPERATING EXPENSES	$0	$0	$0
PROFESSIONAL SERVICES	$0	$0	$0
OTHER CHARGES	Increase	See Below	See Below
EQUIPMENT	$0	$0	$0
MAJOR REPAIR & CONSTR.	$0	$0	$0
TOTAL	**Increase**	**See Below**	**See Below**
POSITIONS (#)	**0**	**0**	**0**

2. Provide a narrative explanation of the costs or savings shown in "A. 1.", including the increase or reduction in workload or additional paperwork (number of new forms, additional documentation, etc.) anticipated as a result of the implementation of the proposed action. Describe all data, assumptions, and methods used in calculating these costs.

   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 to guide 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 medications for HIV treatment and other associated medical problems that may offset the HIV PrEP and PEP costs in future fiscal years.

3. Sources of funding for implementing the proposed rule or rule change.

SOURCE	FY 25	FY 26	FY 27
STATE GENERAL FUND	Increase	See Below	See Below
AGENCY SELF-GENERATED	$0	$0	$0
DEDICATED	$0	$0	$0
FEDERAL FUNDS	Increase	See Below	See Below
OTHER (Ptax)	$0	$0	$0
TOTAL	**Increase**	**See Below**	**See Below**

4. Does your agency currently have sufficient funds to implement the proposed action? If not, how and when do you anticipate obtaining such funds?

   Yes, the Louisiana Medicaid Program has sufficient funds to implement this proposed rule.

B. COST OR SAVINGS TO LOCAL GOVERNMENTAL UNITS RESULTING FROM THE ACTION PROPOSED.

1. Provide an estimate of the anticipated impact of the proposed action on local governmental units, including adjustments in workload and paperwork requirements. Describe all data, assumptions and methods used in calculating this impact.

   The proposed rule will have no anticipated impact on local governmental units.

2. Indicate the sources of funding of the local governmental unit, which will be affected by these costs or savings.

   Not applicable.

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

II. EFFECT ON REVENUE COLLECTIONS OF STATE AND LOCAL GOVERNMENTAL UNITS

A. What increase (decrease) in revenues can be anticipated from the proposed action?

REVENUE INCREASE/DECREASE	FY 25	FY 26	FY 27
STATE GENERAL FUND	Increase	See Below	See Below
AGENCY SELF-GENERATED	$0	$0	$0
DEDICATED	$0	$0	$0
FEDERAL FUNDS	Increase	See Below	See Below
Other (Ptax)	$0	$0	$0
LOCAL FUNDS	$0	$0	$0
TOTAL	Increase	See Below	See Below

*Specify the particular fund being impacted.

B. Provide a narrative explanation of each increase or decrease in revenues shown in "A." Describe all data, assumptions, and methods used in calculating these increases or decreases.

The increase in revenues is indeterminable prior to implementation as there is insufficient peer-reviewed literature to guide projections. However, related revenues may increase by an indeterminable amount due to increased access points that this proposed rule may afford. If utilization increases, there may be a decrease in Medicaid participants becoming infected with HIV, and the corresponding costs associated with their HIV treatment would decrease if that occurs.

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

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

A. What persons, small businesses, or non-governmental groups would be directly affected by the proposed action? For each, provide an estimate and a narrative description of any effect on costs, including workload adjustments and additional paperwork (number of new forms, additional documentation, etc.), they may have to incur as a result of the proposed action.

The proposed Pharmacist-Initiated HIV PrEP and PEP rule allows pharmacists to directly dispense or administer HIV PrEP and PEP medications to appropriate state residents and this could provide economic benefit to Pharmacies/Pharmacists that would be accompanied by some additional workload and related recordkeeping should they chose to provide this service, but these rules do not require them to do so.

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 should they choose to seek PrEP or PEP directly from a pharmacy.

B. Also provide an estimate and a narrative description of any impact on receipts and/or income resulting from this rule or rule change to these groups.

While the proposed rule may increase business and revenues for Pharmacies choosing to participate, it is not expected that the rule would have any impact on receipts and/or income for impacted individuals or groups.

IV. EFFECTS ON COMPETITION AND EMPLOYMENT

Identify and provide estimates of the impact of the proposed action on competition and employment in the public and private sectors. Include a summary of any data, assumptions and methods used in making these estimates.

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