HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/HB 159 HIV Infection Prevention Drugs
SPONSOR(S): Health & Human Services Committee, Healthcare Regulation Subcommittee, Franklin
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthcare Regulation Subcommittee	14 Y, 0 N, As CS	Osborne	McElroy
2) Health & Human Services Committee	19 Y, 0 N, As CS	Osborne	Calamas

SUMMARY ANALYSIS

Pharmacy is the third largest health profession in the US, following only nursing and medicine. In Florida, the Board of Pharmacy (BOP), in conjunction with the Department of Health (DOH), regulates the practice of pharmacy. Pharmacist's scope of practice includes the compounding, dispensing, and consulting of patients concerning contents, therapeutic values, and uses of a medicinal drug.

Human Immunodeficiency Virus (HIV) is an immune system debilitating virus that affects specific cells of the immune system and over time the virus can destroy so many of these cells that the body cannot fight off infections and disease. If not properly treated, HIV can lead to fatal acquired immunodeficiency syndrome (AIDS). According to the Centers for Disease Control and Prevention (CDC), an estimated 1.2 million people in the United States currently living with HIV.

Pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) are two biomedical prevention strategies for people without HIV. PrEP is taken before HIV exposure and for people who do not have HIV but are at a high risk of exposure to HIV, PrEP can be used to significantly reduce risk of HIV infection. PrEP is available in two forms: a daily oral medication and a long-acting injectable delivered once every two months. PEP is taken after a person has been exposed to HIV. PEP is intended for use in emergency situations, and is not meant for frequent use by people who are at high risk of HIV exposure. When taken within 72 hours of HIV exposure, PEP significantly reduces risk of HIV infection.

CS/CS/HB 159 allows licensed pharmacists to screen adults for HIV exposure and provide the results of such screening. A pharmacist who has screened a patient for HIV must advise the patient to seek further medical consultation or treatment from a physician.

The bill also establishes a process by which a pharmacist may become certified to order and dispense postexposure prophylaxis under a collaborative practice agreement with a physician. The bill establishes minimum criteria for the certification which a pharmacist must obtain before they may order and dispense HIV infection prevention drugs. The bill outlines minimum requirements for the contents of the collaborative practice agreement, and requires pharmacies in which a pharmacist is providing services under such an agreement to submit an access-to-care plan to the BOP and DOH.

The bill directs the BOP to develop rules to implement the provisions of the bill.

The bill has an insignificant, negative fiscal impact on DOH, and no fiscal impact on local governments.

The bill provides an effective date of July 1, 2024.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Pharmacist Licensure and Regulation

Pharmacy is the third largest health profession in the US, following only nursing and medicine.[1] The Board of Pharmacy (BOP), in conjunction with the Department of Health (DOH), regulates the practice of pharmacists pursuant to ch. 465, F.S. To be licensed as a pharmacist, a person must:[2]

- Complete an application and remit an examination fee;
- Be at least 18 years of age;
- Hold a degree from an accredited and approved school or college of pharmacy;[3]
- Have completed a Board-approved internship; and
- Successfully complete the Board-approved examination.

A pharmacist must complete at least 30 hours of Board-approved continuing education during each biennial renewal period.[4] Pharmacists who are certified to administer vaccines or epinephrine auto-injections must complete a three-hour continuing education course on the safe and effective administration of vaccines and epinephrine injections as a part of the biennial licensure renewal.[5] Pharmacists who administer long-acting antipsychotic medications must complete an approved eight-hour continuing education course as a part of the continuing education for biennial licensure renewal.[6] All pharmacists are required to complete a one-hour continuing education course on HIV/AIDS as a part of their first licensure renewal.[7]

Pharmacist Scope of Practice

In Florida, the practice of the profession of pharmacy includes:[8]

- Compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of a medicinal drug;
- Consulting concerning therapeutic values and interactions of patent or proprietary preparations;
- Monitoring a patient's drug therapy and assisting the patient in the management of his or her drug therapy, including the review of the patient's drug therapy and communication with the patient's prescribing health care provider or other persons specifically authorized by the patient, regarding the drug therapy;
- Transmitting information from prescribers to their patients;
- Administering vaccines to adults;[9]
- Administering epinephrine injections;[10] and

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[1] American Association of Colleges of Pharmacy, *About AACP*. Available at https://www.aacp.org/about-aacp (last visited January 31, 2024).
[2] S. 465.007, F.S.
[3] *Id*. If the applicant has graduated from a 4-year undergraduate pharmacy program of a school or college of pharmacy located outside the United States, the applicant must demonstrate proficiency in English, pass the board-approved Foreign Pharmacy Graduate Equivalency Examination, and complete a minimum of 500 hours in a supervised work activity program within Florida under the supervision of a DOH-licensed pharmacist.
[4] S. 465.009, F.S.
[5] S. 465.009(6), F.S.
[6] S. 465.1893, F.S.
[7] *See*, Board of Pharmacy, *Pharmacist: Continuing Education Requirements*. Available at https://floridaspharmacy.gov/renewals/pharmacist/#tab-ce (last visited January 31, 2024).
[8] S. 465.003(13), F.S.
[9] *See* s. 465.189, F.S.
[10] *Id*.

- Administering antipsychotic medications by injection.[11]

A pharmacist may not alter a prescriber's directions, diagnose or treat any disease, initiate any drug therapy, or practice medicine or osteopathic medicine, unless permitted by law.[12]

Pharmacists may order and dispense drugs that are included in a formulary developed by a committee composed of members of the Board of Medicine, the Board of Osteopathic Medicine, and the BOP. The formulary may only include:[13]

- Any medicinal drug of single or multiple active ingredients in any strengths when such active ingredients have been approved individually or in combination for over-the-counter sale by the U.S. Food and Drug Administration (FDA);
- Any medicinal drug recommended by the FDA Advisory Panel for transfer to over-the-counter status pending approval by the FDA;
- Any medicinal drug containing any antihistamine or decongestant as a single active ingredient or in combination;
- Any medicinal drug containing fluoride in any strength;
- Any medicinal drug containing lindane in any strength;
- Any over-the-counter proprietary drug under federal law that has been approved for reimbursement by the Florida Medicaid Program; and
- Any topical anti-infectives, excluding eye and ear topical anti-infectives

A pharmacist may order the following, within his or her professional judgment and subject to the conditions established by rule:[14]

- Certain oral analgesics for mild to moderate pain. The prescription is limited to a six-day supply for one treatment of:
    - Magnesium salicylate/phenyltoloxamine citrate.
    - Acetylsalicylic acid (Zero order release, long acting tablets).
    - Choline salicylate and magnesium salicylate.
    - Naproxen sodium.
    - Naproxen.
    - Ibuprofen.
- Certain urinary analgesics, not exceeding a two (2) day supply;
- Otic analgesics. Antipyrine 5.4%, benzocaine 1.4%, glycerin, if clinical signs or symptoms of tympanic membrane perforation do not exist. The product shall be labeled for use in the ear only;
- Anti-nausea preparations;
- Certain antihistamines and decongestants;
- Certain topical antifungal;/antibacterial treatments;
- Topical anti-inflammatory treatments;
- Certain otic antifungal/antibacterial treatments.
- Keratolytics for the treatment of warts, except in patients under age two, or with diabetes or impaired circulation;
- Vitamins with fluoride, excluding vitamins with folic acid in excess of 0.9 mg;
- Medicinal shampoos containing lindane for the treatment of head lice;
- Certain ophthalmic solutions;
- Certain histamine H12 antagonists;
- Certain acne products; and
- Topical antiviral to treat herpes simplex infections of the lips.

[11] S. 465.1893, F.S.
[12] S. 465.003, F.S.
[13] S. 456.186, F.S.
[14] Rule 64B16-27.220, F.A.C.

Human Immunodeficiency Virus

Human Immunodeficiency Virus (HIV) is an immune system debilitating virus that affects specific cells of the immune system and over time the virus can destroy so many of these cells that the body cannot fight off infections and disease. If not properly treated, HIV can lead to acquired immunodeficiency syndrome (AIDS), the third and most severe stage of HIV infection. Without proper treatment, people with AIDS typically survive only three years.[15]

There is currently no effective cure for HIV. Once a person has HIV, they have it for life.[16] The symptoms and transmission of HIV can be mitigated through medication.[17] When HIV is controlled through medication, the risk of transmission is close to zero. People who have HIV and are not on medication and do not have consistent control of their HIV can transmit the virus through sex, sharing of needles used for IV drug use, pregnancy, and breastfeeding.[18]

A person can mitigate their risk of contracting HIV through various prevention strategies. Using condoms correctly during every sexual encounter, not using intravenous drugs, and if you do, using clean needles significantly reduce one's risk for contracting HIV. For pregnant women with HIV, taking the appropriate HIV medication reduces the change of transmitting HIV to the infant to less than one percent.[19]

According to the Centers for Disease Control and Prevention (CDC), an estimated 1.2 million people in the United States currently living with HIV.[20] HIV disproportionately impacts certain segments of the US population, particularly those who live in the Southern US, including Black and Hispanic Americans, men who have sex with men, transgender people, people who use drugs, and rural communities.[21]

PrEP and PEP

Pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) are two biomedical prevention strategies for people without HIV. "Prophylaxis" means to prevent or control the spread of an infection of disease, and pre- and post-exposure refers to when the treatment is taken in relation to HIV exposure.

PrEP is taken before HIV exposure and for people who do not have HIV but are at a high risk of exposure to HIV, PrEP can be used to significantly reduce risk of contracting HIV. A person may have a high risk of exposure to HIV through sex with a partner who is HIV-positive or through IV drug use. PrEP is available in two forms: a daily oral medication and a long-acting injectable delivered once every two months. Studies have shown that consistent use of PrEP reduces the risk of contracting HIV from sex by approximately 99 percent, and from IV drug use by at least 74 percent.[22]

PEP is a medication that is taken soon after exposure to HIV to prevent HIV infection in people who are HIV negative or do not know their HIV status. PEP must be taken within 72 hours of exposure, and should

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[15] Centers for Disease Control and Prevention, *About HIV*. Available at https://www.cdc.gov/hiv/basics/whatishiv.html (last visited January 31, 2024).
[16] *Id*.
[17] Medications for treating HIV help people with HIV live longer, healthier lives, and reduce the risk of HIV transmission. However, they can have significant side effects, and different people may react to the same medication very differently. For more information on HIV medications and their side effects. *See*, National Institutes of Health (NIH), *Side Effects of HIV Medicines* (2021). Available at https://hivinfo.nih.gov/understanding-hiv/fact-sheets/hiv-medicines-and-side-effects (last visited February 2, 2024).
[18] National Institutes of Health (NIH), *HIV and AIDS: The Basics* (2023). Available at https://hivinfo.nih.gov/understanding-hiv/fact-sheets/hiv-and-aids-basics (last visited January 31, 2024).
[19] National Institutes of Health (NIH), *The Basics of HIV Prevention* (2023). Available at https://hivinfo.nih.gov/understanding-hiv/fact-sheets/basics-hiv-prevention (last visited January 31, 2024).
[20] Centers for Disease Control and Prevention, *HIV Surveillance Report: Estimated HIV Incidence and Prevalence in the United States, 2015-2019* (2021). Available at https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-supplemental-report-vol-26-1.pdf (last visited January 31, 2024).
[21] Centers for Disease Control and Prevention, *HIV Surveillance Report: Diagnoses of HIV Infection in the United States and Dependent Areas, 2021* (2023). Available at https://www.cdc.gov/hiv/library/reports/hiv-surveillance/vol-34/index.html (last visited January 31, 2024). For more information on the growing prevalence of HIV in rural communities, *see*, Schafer, et al., *The Continuum of HIV Care in Rural Communities in the United States and Canada: What Is Known and Future Research Directions* (2019). Journal of Acquired Immune Deficiency Syndrome, 75(1): 35-44. doi: 10.1097/QAI.0000000000001329
[22] National Institutes of Health (NIH), *Pre-Exposure Prophylaxis (PrEP)* (2023). Available at https://hivinfo.nih.gov/understanding-hiv/fact-sheets/pre-exposure-prophylaxis-prep (last visited January 31, 2024).

be taken as soon after exposure as possible. PEP is intended for use in emergency situations, and is not meant for frequent use by people who are at high risk of HIV exposure. PEP is taken for 28 days following HIV exposure.[23]

PEP may be prescribed to someone who, in the last 72 hours:[24]

- May have been exposed to HIV during sex;
- Shared needles or other equipment to inject drugs;
- Were sexually assaulted; or
- May have been exposed to HIV at work.[25]

PEP is the only HIV prevention method that can be taken after exposure to HIV. When treatment is started within 72 hours of exposure, PEP is estimated to be more than 90 percent effective.[26]

At least 12 states have passed legislation allowing pharmacists to directly administer either PrEP or PEP to patients under certain circumstances.[27]

Effect of the Bill

CS/CS/HB 159 allows licensed pharmacists to screen adults for HIV exposure and provide the results of such screening. A pharmacist who has screened a patient for HIV must advise the patient to seek further medical consultation or treatment from a physician. The bill also establishes a process by which a pharmacist may become certified to order and dispense postexposure prophylaxis under a collaborative practice agreement with a physician. Postexposure prophylaxis (PEP) is a drug or drug combination that meets the clinical eligibility recommendations of the United States Centers for Disease Control and Prevention guidelines for antiretroviral treatment following potential exposure to HIV.

Certification

The bill requires a pharmacist to be certified by the BOP before they order and dispense PEP under a collaborative practice agreement with a physician. The BOP, in conjunction with the Board of Medicine and Board of Osteopathic Medicine, must adopt rules for the certification. To be certified, a pharmacist must, at a minimum:

- Hold an active and unencumbered license to practice pharmacy;
- Be engaged in the active practice of pharmacy;
- Have earned a doctorate of pharmacy degree or have completed at least 3 years of experience as a licensed pharmacist;
- Maintain at least $250,000 of liability coverage;[28] and
- Have completed a course approved by the board, in consultation with the Board of Medicine and the Board of Osteopathic Medicine, which includes, at a minimum, instruction on all of the following:
    - Performance of patient assessments;
    - Point-of-care testing procedures;
    - Safe and effective treatment of HIV exposure with HIV infection prevention drugs; and
    - Identification of contraindications and comorbidities.

Collaborative Practice Agreement

[23] National Institutes of Health (NIH), *Post-Exposure Prophylaxis (PEP)* (2021). Available at https://hivinfo.nih.gov/understanding-hiv/fact-sheets/post-exposure-prophylaxis-pep (last visited January 31, 2024).
[24] *Id*.
[25] Occupational exposure to HIV is very rare. For more information, *see*, Centers for Disease Control and Prevention, *HIV and Occupational Exposure* (2019). Available at https://www.cdc.gov/hiv/workplace/healthcareworkers.html (last visited January 31, 2024).
[26] Ayieko, J., Petersen, M. L., Kamya, M. R., & Havlir, D. V., *PEP for HIV prevention: are we missing opportunities to reduce new infections?* (2022). Journal of the International AIDS Society, 25(5), e25942. https://doi.org/10.1002/jia2.25942
[27] The states include Arkansas, California, Colorado, Illinois, Maine, Nevada, New Mexico, North Carolina, Oregon, Utah, and Virginia. *See*, NASTAD, *Pharmacist Authority to Initiate PrEP & PEP and Participate in Collaborative Practice Agreements*. (2023). Available at https://nastad.org/sites/default/files/2023-08/PDF-Pharmacist-Authority-Initiate-PrEP-PEP.pdf (last visited January 31, 2024).
[28] A pharmacist who maintains liability coverage pursuant to ss. 465.1865 or 465.1895, F.S. satisfies this requirement.

The bill allows a certified pharmacist to order and dispense PEP pursuant to a written collaborative practice agreement between the pharmacist and a licensed allopathic or osteopathic physician. The written collaborative practice agreement must include, at a minimum, the following:

- Terms and conditions relating to the screening for HIV and the ordering and dispensing of PEP by the pharmacist.;
- Specific categories of patients the pharmacist is authorized to screen for HIV and for whom the pharmacist may order and dispense PEP;
- The physician's instructions for obtaining relevant patient medical history for the purpose of identifying disqualifying health conditions, adverse reactions, and contraindications to the use of PEP;
- A process and schedule for the physician to review the pharmacist's actions under the practice agreement;
- Evidence of the pharmacists' current certification by the board; and
- Any other requirements as established by the BOP in consultation with the Board of Medicine and the Board of Osteopathic Medicine.

The physician partner is responsible for reviewing the pharmacist's actions to ensure compliance with the agreement. The bill requires that the pharmacist partner submit a copy of the written collaborative practice agreement to the BOP.

A pharmacist who orders and dispenses PEP under a collaborative practice agreement must provide the patient with written information advising the patient to seek follow-up care from the patient's primary care physician. If the patient indicates that they lack regular access to primary care, the bill requires the pharmacist to comply with the procedures of the pharmacy's access-to-care plan described below.

Access-to-Care Plan

The bill requires that a pharmacy wherein a pharmacist is providing services under such a collaborative practice agreement to submit an access-to-care plan (ACP) to the BOP and DOH annually. The ACP assists patients in gaining access to appropriate care settings when they present to a pharmacist for HIV screening and indicate that they lack regular access to primary care. The bill requires that an ACP include:

- Procedures to educate such patients about care that would be best provided in a primary care setting and the importance of receiving regular primary care; and
- The pharmacy's plan for collaborative partnership with one or more nearby federally qualified health centers, county health departments, or other primary care settings. The goals of such partnership must include, but need not be limited to, protocols for identifying and appropriately referring a patient who has presented to a pharmacist for HIV screening or access to HIV infection prevention drugs and indicates that he or she lacks regular access to primary care.

The bill directs the BOP to adopt rules to implement the provisions of the bill.

The bill provides an effective date of July 1, 2024.

B. SECTION DIRECTORY:

Section 1: Creates s. 465.1861, F.S., relating to ordering and dispensing HIV infection prevention drugs.
Section 2: Provides an effective date of July 1, 2024.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:
   None.

2. Expenditures:
   The bill has an insignificant, negative fiscal impact on DOH that can be absorbed within existing resources.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:
   None.

2. Expenditures:
   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:
   None.

D. FISCAL COMMENTS:
   None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:
   Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:
   None.

B. RULE-MAKING AUTHORITY:
   The bill provides sufficient rule-making authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:
   None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

On February 1, 2024, the Healthcare Regulation Subcommittee adopted an amendment to HB 159 and reported the bill favorably as a committee substitute. The amendment:

- Removed provisions of the bill that would allow pharmacists to order and dispense PrEP drugs.
- Removed provisions of the bill relating to a statewide drug therapy protocol.
- Allows a pharmacist to screen an adult for HIV exposure and advise the adult to seek medical consultation from a physician.
- Allows a certified pharmacist to order and dispense PEP drugs pursuant to a written collaborative practice agreement between the pharmacist and a licensed physician, and outlines specific requirements for such collaborative practice agreement.
- Requires certain pharmacies to submit an access-to-care plan to DOH and the Board of Pharmacy, and outlines the requirements for an access-to-care plan.

On February 15, 2024 the Health & Human Services Committee adopted an amendment and reported the bill favorably as a committee substitute. The amendment made a technical change correcting “pharmacy” to “pharmacist.”

The analysis is drafted to the bill as amended by the Health & Human Services Committee.