HOUSE OF REPRESENTATIVES STAFF FINAL BILL ANALYSIS

BILL #: CS/CS/HB 159 HIV Infection Prevention Drugs
SPONSOR(S): Health & Human Services Committee and Healthcare Regulation Subcommittee, Franklin and others
TIED BILLS: **IDEN./SIM. BILLS:** CS/CS/SB 1320

FINAL HOUSE FLOOR ACTION: 113 **Y's** 0 **N's** **GOVERNOR'S ACTION:** Approved

SUMMARY ANALYSIS

CS/CS/HB 159 passed the House on February 22, 2024. The bill was amended in the Senate on March 5, 2024, and returned to the House. The House concurred with the Senate amendments and subsequently passed the bill as amended on March 6, 2024.

Pharmacy is the third largest health profession in the US, following only nursing and medicine. In Florida, the Board of Pharmacy (BOP), within the Department of Health (DOH), regulates the practice of pharmacy. Pharmacist scope of practice includes compounding, dispensing, and consulting for patients concerning the 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). An estimated 1.2 million people in the United States currently live with HIV.

Pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) are two biomedical prevention strategies for HIV. PrEP is a daily oral medication which significantly reduces the risk of HIV infection in individuals who do not have HIV, but are known to be at a high risk of exposure. PEP is taken after a person has been exposed to HIV, and is intended for use in emergency situations; not 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 post-exposure prophylaxis (PEP) 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 PEP. 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 bill.

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

The bill was approved by the Governor on April 26, 2024, ch. 2024-121, L.O.F., and will become effective on July 1, 2024.

I. SUBSTANTIVE INFORMATION

A. EFFECT OF 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), within 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 a 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 March 14, 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 March 14, 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]

- Medicinal drugs 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);
- Medicinal drugs recommended by the FDA Advisory Panel for transfer to over-the-counter status pending approval by the FDA;
- Medicinal drugs containing any antihistamine or decongestant as a single active ingredient or in combination;
- Medicinal drugs containing fluoride in any strength;
- Medicinal drugs containing lindane in any strength;
- Over-the-counter drugs which under federal law have been approved for reimbursement by the Florida Medicaid Program; and
- 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 and 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

[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.

- Topical antiviral to treat herpes simplex infections of the lips.

Collaborative Pharmacy Practice Agreements

Under current law, a pharmacist may enter into a collaborative pharmacy practice agreement (CPPA) with a physician licensed under ch. 458, F.S., or ch. 459, F.S. A CPPA is a formal, written agreement in which a physician makes a diagnosis, supervises patient care, and refers specific patients to a pharmacist under a protocol that allows the pharmacist to provide specified patient care services for certain chronic medical conditions. A CPPA must indicate the functions beyond the pharmacist's typical scope of practice that may be delegated to the pharmacist by the collaborating physician. The terms and conditions of the CPPA must be appropriate to the pharmacist's training, and the services delegated to the pharmacist must be within the collaborating physician's scope of practice.[15] Common tasks under a CPPA include initiating, modifying, or discontinuing medication therapy, and ordering and evaluating tests.[16]

To provide services under a CPPA, a pharmacist must be certified by the BOP. To be certified, a pharmacist must complete a 20-hour course[17] which has been approved by the BOP, in consultation with the Board of Medicine (BOM) and Board of Osteopathic Medicine (BOOM), and:[18]

- Hold an active and unencumbered license to practice pharmacy;
- Have earned a doctorate of pharmacy degree or have completed at least five years of experience as a licensed pharmacist;
- Maintain at least $250,000 of liability coverage;[19] and
- Have established a system to maintain records of all patients receiving services under a CPPA for a period of five years from each patient's most recent provision of service.

A CPPA must specify each chronic health condition that may be collaboratively managed. A CPPA can allow a pharmacist to provide specific patient care services for the following chronic health conditions:[20]

- Anti-coagulation management;
- Arthritis;
- Asthma;
- Chronic obstructive pulmonary disease (COPD);
- HIV or acquired immune deficiency syndrome (AIDS);
- Hyperlipidemia;
- Hypertension;
- Nicotine dependence;
- Obesity;
- Opioid use disorder;
- Type 2 diabetes;
- Hepatitis C; and
- Any other chronic condition adopted in rule by the BOP, in consultation with the BOM and the BOOM.

A CPPA automatically terminates two years after execution if not renewed. A physician may not delegate the authority to initiate or prescribe a controlled substance[21] to a pharmacist.[22] A pharmacist who practices under a CPPA must complete a board-approved eight-hour continuing education course addressing CPPA-related issues for each biennial licensure renewal, in addition to the standard continuing education requirements for pharmacists.[23]

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[15] S. 465.1865, F.S.
[16] Centers for Disease Control and Prevention, *Advancing Team-Based Care Through Collaborative Practice Agreements* (2017). Available at https://www.cdc.gov/dhdsp/pubs/docs/CPA-Team-Based-Care.pdf (last visited March 14, 2024).
[17] At a minimum, the course must include instruction on the performance of patient assessments, ordering, performing, and interpreting clinical and laboratory tests, evaluating and managing diseases and health conditions, in addition to additional requirements set by the BOP. *See*, s. 465.1865, F.S.
[18] S. 465.1865, F.S.
[19] A pharmacist who maintains liability coverage pursuant to s. 465.1895, F.S. satisfies this requirement.
[20] S. 465.1865, F.S., and rule 64B-31.005, F.A.C.
[21] *See*, s. 893.03, F.S., and 21 U.S.C. s. 812 for the prohibited controlled substances.
[22] S. 465.1865(5), F.S.
[23] S. 465.1865(6), F.S.

Human Immunodeficiency Virus

Human Immunodeficiency Virus (HIV) is an immune system debilitating virus that affects specific cells of the immune system and over time can result in the destruction of 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.[24]

There is currently no effective cure for HIV. Once a person has HIV, they have it for life.[25] The symptoms and transmission of HIV can be mitigated through medication.[26] 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.[27] 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.[28]

According to the Centers for Disease Control and Prevention (CDC), an estimated 1.2 million people in the U.S. currently living with HIV.[29] HIV disproportionately impacts certain segments of the population; the Southern U.S. is especially impacted, particularly Black and Hispanic Americans, men who have sex with men, transgender people, people who use drugs, and rural communities.[30]

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 by people who do not have HIV, but are at a high risk of exposure to HIV. PrEP is a daily regimen of oral medication that, when taken consistently, significantly reduces the risk of contracting HIV upon exposure. 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.[31]

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[24] Centers for Disease Control and Prevention, *About HIV*. Available at https://www.cdc.gov/hiv/basics/whatishiv.html (last visited March 14, 2024).
[25] *Id*.
[26] 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 March 14, 2024).
[27] 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 March 14, 2024).
[28] 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 March 14, 2024).
[29] 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 March 14, 2024).
[30] 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 March 14, 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
[31] 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 March 14, 2024).

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 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.[32] PEP may be prescribed to someone who, in the last 72 hours:[33]

- May have been exposed to HIV during sex;
- Shared needles or other equipment to inject drugs;
- Was sexually assaulted; or
- May have been exposed to HIV at work.[34]

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 at preventing HIV infection.[35]

At least 12 states have passed legislation allowing pharmacists to directly administer either PrEP or PEP to patients under certain circumstances.[36]

Effect of the Bill

CS/CS/HB 159 creates the "John W. Rheay Act." The bill 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 post-exposure prophylaxis (PEP) under a collaborative practice agreement with a physician. PEP is a drug or drug combination that meets the clinical eligibility recommendations of the 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. 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;[37]
- 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; and

[32] 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 March 14, 2024).
[33] *Id*.
[34] 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 March 14, 2024).
[35] 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
[36] The states include Arkansas, California, Colorado, Illinois, Maine, Nevada, New Mexico, New York, 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 March 14, 2024).
[37] A pharmacist who maintains liability coverage pursuant to ss. 465.1865 or 465.1895, F.S. satisfies this requirement.

- Any additional criteria established by the BOP with the approval of the BOM and BOOM.

Collaborative Practice Agreement

The bill allows a certified pharmacist to order and dispense PEP pursuant to a written collaborative practice agreement between the pharmacist and a physician licensed under ch. 458, F.S., or ch. 459, F.S. 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;
- A requirement that the pharmacist maintain records for any PEP drugs ordered and dispensed under the agreement;
- 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 agreement;
- Evidence of the pharmacists' current certification by the board; and
- Any other requirements as established by the BOP in consultation with the BOM and the BOOM.

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, then the pharmacist must 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 annually submit an access-to-care plan (ACP) to the BOP and DOH. 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.

An ACP must include, at a minimum, procedures for educating 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.

If a pharmacy fails to comply with the ACP requirements, the BOP must notify the pharmacy of its noncompliance. The bill authorizes the BOP to fine a pharmacy that fails to comply with ACP requirements, or prohibit the pharmacy from allowing its pharmacists to screen for HIV exposure or order and dispense PEP under a collaborative practice agreement until the pharmacy complies with the ACP requirement.

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

The bill 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.