The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Rules

BILL:	CS/CS/SB 1320
INTRODUCER:	Appropriations Committee on Health and Human Services; Health Policy Committee; and Senator Calatayud
SUBJECT:	HIV Infection Prevention Drugs
DATE:	February 23, 2024 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Brown	HP	**Fav/CS**
2.	Gerbrandt	McKnight	AHS	**Fav/CS**
3.	Rossitto-Van Winkle	Twogood	RC	**Pre-meeting**

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/CS/SB 1320 creates s. 465.1861, F.S., to establish an additional process under which a pharmacist may order and dispense certain HIV drugs. The bill defines the following terms: HIV, HIV infection prevention drug, HIV postexposure prophylaxis drug, and HIV preexposure prophylaxis drug.

The bill authorizes a pharmacist to screen an adult for HIV exposure and provide the results to that adult, with the advice that the patient should seek further medical consultation or treatment from a physician, regardless of the test results.

The bill requires all pharmacies that provide adult HIV screenings have an access-to-care plan for assisting patients in gaining access to appropriate care settings when they present to the pharmacy for HIV screening and indicate that they lack regular access to primary care.

The bill does not have a fiscal impact on state expenditures.

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

II. Present Situation:

Pharmacist Licensure

Pharmacy is the third largest health profession behind nursing and medicine.[1] The Board of Pharmacy (BOP), in conjunction with the Department of Health (DOH), regulates the practice of pharmacists under ch. 465, F.S.[2] To be licensed as a pharmacist, a person must:[3]

- 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;[4]
- Have completed a BOP-approved internship; and
- Complete the BOP-approved examination.

A pharmacist must complete at least 30 hours of BOP-approved continuing education during each biennial renewal period.[5] 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 auto-injections as a part of the biennial licensure renewal.[6] Pharmacists who administer long-acting antipsychotic medications must complete an approved eight-hour continuing education course as a part of the continuing education.[7]

Pharmacist Scope of Practice

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

- Compounding, dispensing, and consulting concerning the contents, therapeutic values, and uses of any 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;
- Transmitting information from prescribers to their patients;

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[1] American Association of Colleges of Pharmacy, *About AACP*, *available at* https://www.aacp.org/about-aacp (last visited Jan. 24, 2024).
[2] Sections 465.004 and 465.005, F.S.
[3] Section 465.007, F.S. The DOH may also issue a license by endorsement to a pharmacist who is licensed in another state upon meeting the applicable requirements set forth in law and rule. *See* s. 465.0075, F.S.
[4] If the applicant has graduated from a 4-year undergraduate pharmacy program of a school or college of pharmacy located outside the U.S., 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.
[5] Section 465.009, F.S.
[6] Section 465.009(6), F.S.
[7] Section 465.1893, F.S.
[8] Section 465.003(13), F.S.

- Administering specified vaccines to adults and influenza vaccines to persons seven years of age or older;[9]
- Administering epinephrine autoinjections;[10] and
- 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 (BOM), the Board of Osteopathic Medicine (BOOM), and the BOP.[13] The formulary may only include:

- Any medicinal drug of single or multiple active ingredients in any strength 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-infective, excluding eye and ear topical anti-infective.[14]

A pharmacist may order the following, within his or her professional judgment and subject to the following conditions:

- Certain oral analgesics for mild to moderate pain. The pharmacist may order these drugs for minor pain and menstrual cramps for patients with no history of peptic ulcer disease. 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;
  - Phenazopyridine, for urinary pain; and
  - Antipyrine 5.4 percent, benzocaine 1.4 percent, glycerin, for ear pain if clinical signs or symptoms of tympanic membrane perforation are not present;
- Anti-nausea preparations;
- Certain antihistamines and decongestants;

[9] *See* s. 465.189, F.S.
[10] *Id.*
[11] Section 465.1893, F.S.
[12] Section 465.003(13), F.S.
[13] Section 465.186, F.S.
[14] *Id.*

- Certain topical antifungals/antibacterials;
- Topical anti-inflammatory preparations containing hydrocortisone not exceeding 2.5 percent;
- Certain otic antifungal/antibacterial;
- Salicylic acid 16.7 percent and lactic acid 16.7 percent in flexible collodion, to be applied to warts, except for patients under 2 years of age, and those with diabetes or impaired circulation;
- Vitamins with fluoride, excluding vitamins with folic acid over 0.9 mg.;
- Medicinal drug shampoos containing lindane for the treatment of head lice;
- Ophthalmic. Naphazoline 0.1 percent ophthalmic solution;
- Certain histamine H2 antagonists;
- Acne products; and
- Topical antiviral for herpes simplex infections of the lips.[15]

Collaborative Pharmacy Practice Agreements

Under s. 465.1865, F.S., a collaborative pharmacy practice agreement (CPPA) is a formal, written agreement in which a physician licensed under ch. 458, F.S., or ch. 459, F.S., 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 for the patients specified in the agreement. 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.[16] Common tasks include initiating, modifying, or discontinuing medication therapy and ordering and evaluating tests.[17]

Pharmacist Training for Collaborative Practice

To provide services under a CPPA, a pharmacist must be certified by the BOP. To obtain certification a pharmacist must complete a 20-hour course approved by the BOP, in consultation with the BOM and the BOOM, and:

- Hold an active and unencumbered license to practice pharmacy;
- Have a Ph.D. in pharmacy or have five years of experience as a licensed pharmacist;
- Have completed the BOP-approved, 20-hour course, eight hours of which must be live or live video conference that includes instruction in:
  - Performance of patient assessments;
  - Ordering, performing, and interpreting clinical and laboratory tests;
  - Evaluating and managing diseases and health conditions in collaboration with other health care practitioners; and
  - Writing and entering into a CPPA.
- Maintains at least $250,000 of professional liability insurance coverage; and
- Has established a system to maintain patient records of patients receiving services under a CPPA for five years from the patient's most recent service.[18]

[15] Fla. Admin. Code R. 64B16-27.220 (2023).
[16] U.S. Center for Disease Control and Prevention, *Advancing Team-Based Care Through Collaborative Practice Agreements: A Resource and Implementation Guide for Adding Pharmacists to the Care Team*, (2017), *available at* https://www.cdc.gov/dhdsp/pubs/docs/CPA-Team-Based-Care.pdf (last visited Jan. 25, 2024).
[17] *Id.*
[18] Section 465.1865(2), F.S. and Fla. Admin. Code R. 64B-31.007 (2023).

Required Contents of CPPA

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. A copy of the certification received from the BOP must be included as an attachment to the CPPA. A CPPA must include the following:

- The name of the collaborating physician's patient(s) for whom a pharmacist may provide services;
- Each chronic health condition to be collaboratively managed;
- The specific medicinal drug(s) to be managed for each patient;
- Material terms defined as those terms enumerated in s. 465.1865(3)(a), F.S.;
- Circumstances under which the pharmacist may order or perform and evaluate laboratory or clinical tests;
- Conditions and events in which the pharmacist must notify the collaborating physician and the manner and timeframe in which notification must occur;
- The start and end dates of the CPPA and termination procedures, including procedures for patient notification and medical records transfers;
- A statement that the CPPA may be terminated, in writing, by either party at any time; and
- In the event of an addendum to the material terms of an existing CPPA, a copy of the addendum and the initial agreement.

A CPPA will automatically terminate two years after execution if not renewed. The pharmacist, along with the collaborating physician, must maintain the CPPA on file at his or her practice location and must make the CPPA available to the DOH or BOP upon request or inspection. A pharmacist who enters into a CPPA must submit a copy of the signed agreement to the BOP before the agreement may be implemented.[19]

Allowable Chronic Health Conditions for Pharmacist CPPAs

CPPAs in Florida allow a pharmacist to provide specific patient care services for the following chronic health conditions:

- 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

[19] Section 465.1865(3), F.S. and Fla. Admin. Code R. 64B-31.003 (2023).

- Any other chronic condition adopted in rule by the BOP, in consultation with the BOM and the BOOM.[20]

Prohibited Acts Regarding a CPPA

A pharmacist may not:

- Modify or discontinue medicinal drugs prescribed by a health care practitioner with whom he or she does not have a CPPA; or
- Enter into a CPPA while acting as a pharmacy employee without the written approval of the owner of the pharmacy.

A physician may not delegate the authority to initiate or prescribe a controlled substance listed in s. 893.03, F.S. or 21 U.S.C. s. 812, to a pharmacist.

Continuing Education

A pharmacist who practices under a CPPA must complete an eight-hour continuing education (CE) course approved by the BOP that addresses CPPA-related issues each biennial licensure renewal, in addition to the CE requirements under s. 465.009, F.S. A pharmacist wishing to maintain CPPA certification must submit confirmation of having completed such course when applying for licensure renewal. A pharmacist who fails to complete this CE is prohibited from practicing under a CPPA.

CPPAs in Effect

According to the DOH 2022-2023 Annual Report there are 39,337 licensed pharmacists in Florida.[21] There are 120 pharmacists certified to provide care under a CPPA. There are 37 pharmacists and 37 physicians actively engaged in collaborative practice. The BOP has received 97 CPPAs, 47 of which contain more than one chronic health condition that can be collaboratively managed.[22] The list below illustrates the composition of chronic conditions treated by CPPA as of March 31, 2023.[23]

[20] Section 465.1865, F.S. and Fla. Admin. Code R. 64B-31.005 (2023). The statute provides for arthritis, asthma, COPD, Type 2 diabetes, HIV/AIDS, and obesity. The other items in the list (anti-coagulation management, hyperlipidemia, hypertension, nicotine dependence, opioid use disorder, and hepatitis C) were added under BOP rule.
[21] Florida Department of Health, Division of Medical Quality Assurance, *Annual Report and Long-Range Plan, Fiscal Year 2022-2023*, at pg. 4, available at https://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/annual-reports.html (last visited Jan. 26, 2024).
[22] Florida Department of Health, Division of Medical Quality Assurance, *Pharmacy Collaborative Practice Agreements*, Report to Senate Health Policy Committee, Aug, 1, 2023, (on file with the senate Committee on Health Policy). While the number of participating pharmacists and physicians are identical, this does not represent a one-to-one ratio; a pharmacist may have multiple agreements with more than one physician just as multiple physicians may have multiple agreements with more than one pharmacist.
[23] *Id.*

Condition	Count
Anti-Coagulation Management	48
Arthritis	46
Asthma	46
COPD	46
HIV/AIDS	85
Hyperlipidemia	45
Hypertension	50
Nicotine Dependence	44
Obesity	48
Opioid Use Disorder	1
Type 2 Diabetes	48

Human Immunodeficiency Virus (HIV)

HIV attacks and destroys the human body's infection-fighting CD4 cells (CD4 T lymphocyte) of the immune system. The loss of CD4 cells makes it difficult for the body to fight off infections, illnesses, and certain cancers. Without treatment, HIV can gradually destroy the immune system, causing health decline and the onset of AIDS. With treatment, the immune system can recover. [24]

If untreated, an HIV infection may cause acquired immunodeficiency syndrome (AIDS), the most advanced stage of HIV infection. People with HIV who are not on medication and do not have consistent control of their HIV can transmit HIV through bodily fluids exchanged via sex, sharing of needles, pregnancy, and/or breastfeeding. If HIV is controlled, the risk of transmission can be close to zero.[25]

For people without HIV, there are several ways to reduce the risk of becoming infected with HIV. Using condoms correctly with every sexual encounter, particularly with partners who are HIV positive with a detectable viral load or with partners whose HIV status is unknown, can reduce the risk of acquiring HIV. Reducing HIV risk also involves limiting and reducing sexual partners and avoiding sharing needles.[26]

Pre-exposure Prophylaxis (PrEP)

PrEP is an HIV prevention option for people who do not have HIV but who are at risk of becoming infected. PrEP involves taking a specific HIV medicine every day or a long-acting injection.[27]

Post-exposure Prophylaxis (PEP)

PEP means taking HIV medicines within 72 hours after a possible exposure to HIV to prevent HIV infection. PEP should be used only in emergencies. It is not meant for regular use by people

[24] U.S. National Institute of Health, *Understanding HIV*, available at https://hivinfo.nih.gov/understanding-hiv/fact-sheets/hiv-and-aids-basics (last visited Jan. 25, 2024).
[25] *Id.*
[26] *Id.*
[27] *Id.*

who may be exposed to HIV frequently. The sooner PEP is started after a possible HIV exposure, the better. Persons who are treated with PEP are directed to take the drug every day for 28 days.[28]

HIV Testing

Certain healthcare providers can give an HIV test. HIV testing is also available at many hospitals, medical clinics, substance abuse programs, and community health centers. Getting tested through a professional healthcare provider is recommended; however, there are HIV self-testing kits available.[29]

A rapid self-test is an oral fluid test done entirely at home or in private. A mail-in self-test requires a person to provide a blood sample from a finger-stick, which is then sent to a lab for testing.[30]

The federal Centers for Disease Control and Prevention (CDC) recommends that everyone age 13 to 64 get tested for HIV at least once as part of routine health care and that people at higher risk for HIV get tested more often. HIV testing can detect if a person has an HIV infection, but it cannot tell how long the person has had the infection or if the person has AIDS.[31]

There are three types of tests used to diagnose HIV infection: antibody tests, antigen/antibody tests, and nucleic acid tests:

- Antibody tests check for HIV antibodies in blood or oral fluid. HIV antibodies are disease-fighting proteins that the body produces in response to HIV infection. Most rapid tests and home-use tests are antibody tests;
- Antigen/antibody tests can detect both HIV antibodies and HIV antigens (a part of the virus) in the blood; and
- Nucleic acid tests look for HIV in the blood.

How soon each test can detect HIV infection differs, because each test has a different window period. The window period is the time between when a person may have been exposed to HIV and when a test can accurately detect HIV infection. A person's initial HIV test will usually be either an antibody test or an antigen/antibody test. Nucleic acid tests are very expensive and not routinely used for HIV screening unless the person had a high-risk exposure or a possible exposure with early symptoms of HIV infection.

When an HIV test is positive, a follow-up test will be conducted. Sometimes people will need to visit a health care provider to take a follow-up test. Other times, the follow-up test may be performed in a lab using the same blood sample that was provided for the first test. A positive follow-up test confirms that a person has HIV.

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[28] U.S. National Institute of Health, *HIV Prevention: Post-exposure Prophylaxis (PEP)*, available at https://hivinfo.nih.gov/understanding-hiv/fact-sheets/post-exposure-prophylaxis-pep (last visited Jan. 31, 2024).
[29] U.S. National Institute of Health, HIV Testing, *Where can someone get tested for HIV?*, https://hivinfo.nih.gov/understanding-hiv/fact-sheets/hiv-testing (last visited Jan. 25, 2024).
[30] *Id*.
[31] U.S. National Institute of Health, *HIV Testing*, available at https://hivinfo.nih.gov/understanding-hiv/fact-sheets/hiv-testing (last visited Jan. 25, 2024).

HIV Treatment

People with HIV should start taking HIV medicines as soon as possible after HIV is diagnosed. For people with HIV who have the following conditions, it is especially important to start taking HIV medicines right away:[32]

- Pregnancy;
- AIDS-defining conditions; and
- Early HIV infection.[33]

Antiretroviral therapy (ART) is the use of HIV medicines that reduce the level of HIV in the blood (called viral load). ART is recommended for everyone who has HIV. ART cannot cure HIV infection, but HIV medicines help people with HIV have about the same life expectancy as people without HIV. ART can eliminate the risk of HIV transmission. For mothers with HIV who want to breastfeed, the risk of transmitting HIV through breast milk is less than one percent with the consistent use of ART and an undetectable viral load. People on ART take a combination of medicines (called an HIV treatment regimen) every day (pills) or by schedule (injections). In many cases oral medicines may be combined into a single pill or capsule. There are newer long-acting medicines given by an injection every two months that may be used for some people.[34]

FDA Approved HIV Medications

The following is a list HIV medicines, by category, recommended for the treatment of HIV infection in the U.S., based on the U.S. Department of Health and Human Services (HHS) HIV/AIDS medical practice guidelines:[35]

- **Nucleoside Reverse Transcriptase Inhibitors (NRTIs):** These drugs block reverse-transcriptase, an enzyme HIV needs to make copies of itself.
  - Abacavir;
  - Emtricitabine;
  - Lamivudine;
  - Tenofovir disoproxil;
  - Fumarate; and
  - Zidovudine.
- **Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs):** These drugs bind to and later alter reverse-transcriptase.
  - Doravirine;
  - Efavirenz;
  - Etravirine;
  - Nevirapine; and
  - Rilpivirine.

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[32] U.S. National Institute of Health, *When to Start HIV Medicines* (rev, Aug. 16, 2021) available at https://hivinfo.nih.gov/understanding-hiv/fact-sheets/when-start-hiv-medicines (last visited Jan. 25, 2024).
[33] *Id.* Early HIV infection, also known as acute HIV infection, is the period up to six months after a person is infection with HIV.
[34] *Id.*
[35] U.S. National Institute of Health, FDA-*Approved HIV Medicines*, available at https://hivinfo.nih.gov/understanding-hiv/fact-sheets/fda-approved-hiv-medicines (last visited Jan. 25, 2024).

- **Protease Inhibitors (PIs):** These drugs block HIV protease, an enzyme HIV needs to make copies of itself.
  - Atazanavir;
  - Darunavir;
  - Tosamprenavir;
  - Ritonavir; and
  - Tipranavir.
- **Fusion Inhibitors:** These drugs block HIV from entering the CD4 T lymphocytes (CD4 cells) of the immune system.
  - Enfuvirtide.
- **CCR5 Antagonists:** These drugs block the CCR5 co-receptor on the surface of certain immune cells that HIV utilizes to enter the cells.
  - Maraviroc.
- **Integrase Strand Transfer Inhibitor (INSTIs):** These drugs block HIV integrase, an enzyme HIV needs to make copies of itself.
  - Cabotegravir;
  - Dolutegravir; and
  - Raltegravir.
- **Attachment Inhibitors:** These drugs bind to the gp120 protein on the outer surface of HIV, preventing HIV from entering CD4 cells.
  - Fostemsavir.
- **Post-attachment inhibitors:** These drugs block CD4 receptors on the surface of certain immune cells that HIV utilizes to enter the cells.
  - Ibalizumab-uiyk.
- **Capsid Inhibitors:** These drugs interfere with the HIV capsid, a protein shell that protects HIV's genetic material and enzymes needed for replication.
  - Lenacapavir.
- **Pharmacokinetic Enhancers:** These drugs are used in HIV treatment to increase the effectiveness of an HIV medicine included in an HIV treatment regimen.
  - Cobicistat.
- **Combination HIV Medicines:** These medicines contain two or more HIV medicines from one or more drug classes.

Side Effects of HIV Medication

Adverse effects have been reported with all ART antiretroviral (ARV) drugs. As ART is recommended for all patients regardless of CD4 T lymphocyte (CD4) cell count, and because therapy must be continued indefinitely, the focus of patient management has evolved from identifying and managing early ARV-related toxicities to individualizing therapy to avoid long-term adverse effects, including:

- Diabetes and other metabolic complications;
- Atherosclerotic cardiovascular disease;
- Kidney dysfunction;
- Bone loss; and
- Weight gain.

To achieve and sustain viral suppression over a lifetime, both long-term and short-term ART toxicities must be anticipated and managed. When selecting an ARV regimen, clinicians should consider potential adverse effects, as well as the patient's comorbidities, concomitant medications, and prior history of drug intolerances.[36]

HIV and Opportunistic Infections, Coinfections, and Conditions

Opportunistic infections (OIs) are infections that occur more often or are more severe in people with weakened immune systems than in people with healthy immune systems. People with weakened immune systems include people living with HIV, as HIV damages the immune system. A weakened immune system makes it harder for the body to fight off OIs. HIV-related OIs include:

- Pneumonia;
- Salmonella infection;
- Candidiasis;
- Toxoplasmosis; and
- Tuberculosis.

For people with HIV, the best protection against OIs is to take HIV medicines every day. HIV medicines prevent HIV from damaging the immune system. Because HIV medicines are now widely used in the United States, fewer people with HIV get OIs.[37]

III. Effect of Proposed Changes:

The bill creates s. 465.1861, F.S., to establish an additional process under which a pharmacist may order and dispense preexposure and postexposure HIV drugs.

The bill defines the following terms as follows:

- "HIV" means the human immunodeficiency virus.
- "HIV infection prevention drug" means preexposure prophylaxis, postexposure prophylaxis, and any other drug approved by the U.S. Food and Drug Administration for the prevention of HIV infection as of March 8, 2024.
- "HIV Postexposure prophylaxis drug" means a drug or drug combination that meets the clinical eligibility recommendations of Centers for Disease Control and Prevention (CDC) guidelines for antiretroviral treatment following potential exposure to HIV issued as of March 8, 2024.
- "HIV Preexposure prophylaxis drug" means a drug or drug combination that meets the clinical eligibility recommendations of CDC guidelines for antiretroviral treatment for the prevention of HIV transmission issued as of March 8, 2024.

[36] U.S. National Institute of Health, Do all HIV medicines cause the same side effects?, Limitations to Treatment Safety and Efficacy, *Adverse Effects of Antiretroviral Agents,* available at https://hivinfo.nih.gov/understanding-hiv/fact-sheets/hiv-medicines-and-side-effects (last visited Jan. 26, 2024).
[37] U.S. National Institute of Health, HIV and Opportunistic Infections, Coinfections and Conditions, *What is an Opportunistic Infection?* available at https://hivinfo.nih.gov/understanding-hiv/fact-sheets/what-opportunistic-infection (last visited Jan. 25, 2024).

The bill authorizes a pharmacist to screen an adult for HIV and provide the results to that adult, with the advice that the patient should seek further medical consultation or treatment from a physician.

The bill provides that a pharmacist may dispense HIV preexposure drugs only under a valid prescription issued by a licensed health care practitioner authorized by law to prescribe such drugs.

The bill authorizes a pharmacist to order and dispense HIV postexposure drugs only under a written collaborative practice agreement (CPA) with a medical or osteopathic physician in the same geographic area as the pharmacist. Under the bill, the term "geographic area" is the county or counties, or any portion of the county or counties, within which the pharmacist and the physician provide health care services.

The bill requires a CPA to contain particular terms and conditions imposed by the supervising physician relating to the screening for HIV and the ordering and dispensing of HIV postexposure drugs. The CPA must include:

- Specific categories of patients the pharmacist is authorized to screen for HIV and for whom the pharmacist may order and dispense HIV postexposure drugs;
- The physician's instructions for obtaining relevant patient medical history to identify disqualifying health conditions, adverse reactions, and contraindications to the use of HIV postexposure drugs;
- A requirement that the pharmacist maintain records for any HIV postexposure drugs ordered and dispensed under the CPA;
- A process and schedule for the physician to review the pharmacist's records and actions under the CPA; and
- Any additional requirements established by the Board of Pharmacy (BOP), and approved by the BOM and the BOOM.

A pharmacist who enters into a CPA with a supervising physician must submit the agreement to the BOP.

If a pharmacist orders and dispenses HIV postexposure drugs under the CPA, he or she must provide the patient with written information advising the patient to seek follow-up care from his or her primary care physician. If such patient indicates that he or she lacks regular access to primary care, the pharmacist must comply with the procedures set out in the pharmacy's approved access-to-care plan (ACP).[38]

A pharmacist must be certified by the BOP before ordering or dispensing HIV postexposure drugs. To be certified, a pharmacist must meet all of the following:

- Hold an active and unencumbered license to practice pharmacy;
- Be engaged in the active practice of pharmacy;

[38] Section 465.1861(7), F.S., as created by the bill, requires that all pharmacies that provide adult screening for HIV exposure must submit to the DOH an ACP for assisting patients to gain access to appropriate care settings when such patients present to the pharmacy for HIV screening and indicate that they lack regular access to primary care.

- Have a Ph.D. degree in pharmacy or have completed at least three years of experience as a licensed pharmacist;
- Maintain at least $250,000 of liability coverage;
- Complete a course approved by the BOP, in consultation with the Board of Medicine and the Board of Osteopathic Medicine, which includes, at a minimum, instruction on all of the following, but with no required number of hours:
  - Performance of patient assessments.
  - Point-of-care testing procedures.
  - Safe and effective treatment of HIV exposure with HIV infection prevention drugs, including, but not limited to:
    - Consideration of the side effects.
    - The patient's diet and activity levels.
  - Identification of contraindications;
  - Identification of comorbidities in individuals with HIV requiring further medical evaluation and treatment, including:
    - Cardiovascular disease;
    - Lung and liver cancer;
    - Chronic obstructive lung disease; and
    - Diabetes.

A pharmacist authorized to order and dispense HIV postexposure drugs under a CPA must provide his or her supervising physician with evidence of current certification.

The bill requires that all pharmacies that provide adult HIV screenings have an ACP for assisting patients gain access to appropriate care settings when they present to the pharmacy for HIV screening and indicate that they lack regular access to primary care. An ACP must include:

- Procedures to educate patients about care that would be best provided in a primary care setting and the importance of receiving regular primary care;
- A collaborative partnership with one or more nearby federally qualified health centers (FQHC), county health departments (CHD), or other primary care settings. The goals of such partnership must include, but need not be limited to:
  - Identifying patients who have presented to the pharmacy for HIV screening or access to HIV infection prevention drugs; and
  - If such a patient indicates that he or she lacks regular access to primary care, proactively seeking to establish a relationship between the patient and an FQHC, CHD, or other primary care setting so that the patient develops a medical home at such setting for primary health care services.

The bill provides that a pharmacy that establishes one or more collaborative partnerships may not enter into an arrangement relating to such partnership which would prevent an FQHC, CHD, or other primary care setting from establishing collaborative partnerships with other pharmacies.

Under the bill, as of July 1, 2025, a pharmacy's ACP must be approved by the DOH before the pharmacy may receive initial licensure or licensure renewal occurring after that date. A pharmacy with an approved ACP must submit data to the DOH regarding the implementation and results of its plan as part of the licensure renewal process, or as directed by the DOH, before each licensure renewal.

The bill requires the BOP to adopt rules to implement s. 465.1861, F.S.

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

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

The following language in the bill: "the board shall adopt by rule reasonable and fair minimum standards to ensure that all pharmacies that provide adult screening for HIV exposure submit to the department for approval an access-to-care plan (ACP) for assisting patients to gain access to appropriate care settings when they present to the pharmacy for HIV screening and indicate that they lack regular access to primary care" may present an unconstitutional delegation under Article II, Section 3 of the Florida Constitution. Askew v. Cross Key Waterways, 372 So. 2d 913, 925 (Fla. 1978); see also Avatar Dev. Corp. v. State; 723 So. 2d 199, 202 (Fla. 1998) (citing Askew with approval). "…fundamental and primary policy decisions must be made by members of the legislature who are elected to perform those tasks, and administration of legislative programs must be pursuant to some minimal standards and guidelines ascertainable by reference to the enactment establishing the program."

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

To the extent that pharmacists provide HIV testing or become certified and enter into collaborative practice agreements with physicians under the bill, HIV testing and treatment might become more accessible.

C. Government Sector Impact:

The bill does not have a fiscal impact on state expenditures.

VI. Technical Deficiencies:

None.

VII. Related Issues:

Unlike the current statutory provisions for a "collaborative pharmacy practice agreement" (CPPA) relating to treatment of chronic conditions found in s. 465.1865, F.S., the bill does not define a "collaborative practice agreement" nor provide the level of detail regarding requirements for what the agreement must contain or what form it must take as is required of a CPPA. Notable differences can be found between the two agreements in the following examples of requirements for a CPPA that are *not* required for a collaborative practice agreement (CPA) created under the bill:

- Must be signed by both practitioners.
- Pharmacist certification must be attached to CPPA;
- Applies only to the collaborating physician's patients who are named in the agreement.
- Specific drugs to be managed for each patient must be listed in the agreement;
- Triggers for the pharmacist to notify the collaborating physician and the manner and timeframe in which notification must occur must be included in the agreement;
- Duration limitations.
- Provisions for termination of the agreement.
- Certain actions prohibited.
- Employer permission (if applicable).
- Continuing education.

Lines 69-72 provide that a pharmacist may dispense HIV preexposure drugs *only* pursuant to a valid prescription issued by a licensed health care practitioner authorized by law to prescribe such drugs. Lines 73-78 provide that a pharmacist may order and dispense HIV postexposure drugs *only* pursuant to a written CPA with a physician who practices in the same geographic region as the pharmacist.

- These provisions appear to conflict with existing law in s. 465.1865, F.S., relating to authority for pharmacists to enter into a CPPA with a physician to treat chronic conditions, including HIV/AIDS.
- By use of the word "only" in the two instances cited above, the bill may conflict with a pharmacist's authority to order and dispense such drugs under current law's CPPA provisions, which are separate from the bill's CPA provisions.

Lines 183-186 require a pharmacy's ACP to be approved by the Department of Health (DOH)` before the pharmacy may receive *initial* licensure or licensure renewal after July 1, 2025. However, because a pharmacy may not establish an ACP until after it has been licensed, the bill's reference to "initial licensure" is not applicable and creates a "chicken or egg" situation. An amendment to remove the concept of initial licensure from this provision is advisable.

VIII. Statutes Affected:

This bill creates section 465.1861 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS/CS by Appropriations Committee on Health and Human Services on February 8, 2024:
The committee substitute:

- Revises the underlying bill's requirement that a collaborative practice agreement (CPA) must include any other requirements established by the Board of Pharmacy (BOP) ***in consultation with*** the Board of Medicine (BOM) and the Board of Osteopathic Medicine (BOOM), and instead requires that the CPA must include any other requirements established by the BOP, and ***approved by*** the BOM and BOOM.
- Revises the requirement that the CPA must include a process and schedule for the physician to review the pharmacist's actions under the CPA and instead requires the CPA to include a process and schedule to review the pharmacist's ***records*** and actions under the CPA.
- Revises the requirement that a pharmacist must be certified by the BOP, according to the rules adopted by the BOP, and ***in consultation with*** the BOM and BOOM, to order and dispense certain HIV drugs, and instead requires the rules adopted by the BOP to be ***approved by*** the BOM and BOOM.
- Requires a pharmacist to maintain records for any postexposure drugs ordered and dispensed under the CPA.

CS by Health Policy on January 30, 2024:
The committee substitute:

- Deletes the terms "postexposure prophylaxis" and "preexposure prophylaxis;" and replaces them with the terms, "HIV postexposure prophylaxis drug" and "HIV preexposure prophylaxis drug," but the language of the definitions does not change;
- Requires the CPA to require particular terms and conditions imposed by the supervising physician, and include:
  - Specific categories of patients the pharmacist is authorized to screen for HIV and for whom the pharmacist may order and dispense HIV postexposure prophylaxis drugs;
  - 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 HIV postexposure prophylaxis drugs;
  - A process and schedule for the physician to review the pharmacist's actions under the CPA; and
  - Any other requirements as established by the BOP in consultation with the BOM and the BOOM.

- Requires a pharmacist who screens an adult patient for HIV exposure to advise the patient to seek further medical consultation or treatment from a physician, regardless of the test results;
- Requires the BOP to adopt rules to create standards for pharmacies doing adult screening for HIV exposure to submit to the DOH for approval an ACP to assist patients to gain access to appropriate care settings when the patient indicate that they lack regular access to primary care;
- Requires a pharmacy's ACP to include patient educational procedures, a collaborative partnership with one or more FQHCs, CHDs, or other primary care settings, and have DOH approval of the ACP before the pharmacy may receive an initial license or renewal; and
- Requires a pharmacy that establishes one or more collaborative partnerships may not enter into an arrangement relating to these partnerships which would prevent an FQHC, CHD, or other primary care setting from establishing collaborative partnerships with other pharmacies.

B. Amendments:

None.