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By the Appropriations Committee on Health and Human Services; the Committee on Health Policy; and Senator Calatayud

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A bill to be entitled An act relating to HIV infection prevention drugs; creating s. 465.1861, F.S.; defining terms; authorizing pharmacists to screen adults for HIV exposure and provide the results to such adults, with advice to seek consultation or treatment from a physician; authorizing pharmacists to dispense HIV preexposure prophylaxis drugs only pursuant to a prescription; authorizing pharmacists to order and dispense HIV postexposure prophylaxis drugs only pursuant to a written collaborative practice agreement with a physician; defining the term "geographic area"; specifying requirements for the practice agreements; requiring the supervising physician to review the pharmacist's actions in accordance with the practice agreement; requiring pharmacists who enter into such practice agreements to submit the agreements to the Board of Pharmacy; requiring pharmacists who enter into such practice agreements to provide evidence of certain certification to their supervising physician; requiring such pharmacists to provide certain written information when dispensing such drugs to patients; requiring pharmacists to comply with certain procedures under certain circumstances; requiring that pharmacists, before ordering and dispensing HIV postexposure prophylaxis drugs, be certified by the Board of Pharmacy in accordance with rules adopted by the board and approved by the Board of Medicine and the Board of Osteopathic Medicine; specifying minimum

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requirements for the certification; requiring the board to adopt by rule certain minimum standards to ensure that pharmacies providing adult screenings for HIV exposure submit to the Department of Health for approval an access-to-care plan (ACP) for a specified purpose; specifying requirements for ACPs; requiring that, beginning on a specified date, such ACPs be approved before a license may be issued or renewed; requiring such pharmacies to submit specified data to the department as part of the licensure renewal process and, or as directed by the department, before each licensure renewal; requiring the board to adopt rules; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 465.1861, Florida Statutes, is created to read:

465.1861 Ordering and dispensing HIV drugs.-

- (1) As used in this section, the term:
- (a) "HIV" means the human immunodeficiency virus.
- (b) "HIV infection prevention drug" means preexposure prophylaxis, postexposure prophylaxis, and any other drug approved by the United States Food and Drug Administration for the prevention of HIV infection as of March 8, 2024.
- (c) "HIV postexposure prophylaxis drug" means 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

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potential exposure to HIV issued as of March 8, 2024.

(d) "HIV preexposure prophylaxis drug" means 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 for the prevention of HIV transmission issued as of March 8, 2024.

- (2) A pharmacist may 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.
- (3) A pharmacist may dispense HIV preexposure prophylaxis drugs only pursuant to a valid prescription issued by a licensed health care practitioner authorized by the laws of this state to prescribe such drugs.
- (4) A pharmacist may order and dispense HIV postexposure prophylaxis drugs only pursuant to a written collaborative practice agreement between the pharmacist and a physician licensed under chapter 458 or chapter 459 who practices medicine or osteopathic medicine in the same geographic area as the pharmacist. As used in this subsection, the term "geographic area" means the county or counties, or any portion of the county or counties, within which the pharmacist and the physician provide health care services.
- (a) The written collaborative practice agreement must include particular terms and conditions imposed by the supervising physician relating to the screening for HIV and the ordering and dispensing of HIV postexposure prophylaxis drugs under this section. The terms and conditions of the practice agreement must be appropriate for the pharmacist's training, and

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the supervising physician is responsible for reviewing the pharmacist's actions in accordance with the practice agreement.

A pharmacist who enters into such a practice agreement with a supervising physician must submit the agreement to the board.

- (b) At a minimum, a written collaborative practice agreement must include all of the following:
- 1. 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.
- 2. 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.
- 3. A requirement that the pharmacist maintain records for any HIV postexposure prophylaxis drugs ordered and dispensed under the collaborative practice agreement.
- 4. A process and schedule for the physician to review the pharmacist's records and actions under the collaborative practice agreement.
- 5. Any other requirements as established by the board, with the approval of the Board of Medicine and the Board of Osteopathic Medicine.
- (c) A pharmacist authorized to screen for HIV and order and dispense HIV postexposure prophylaxis drugs pursuant to a written collaborative practice agreement must provide his or her supervising physician with evidence of current certification by the board as provided in subsection (6).
 - (5) A pharmacist who orders and dispenses HIV postexposure

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prophylaxis drugs pursuant to subsection (4) must provide the
patient with written information advising the patient to seek
follow-up care from his or her primary care physician. If the
patient indicates that he or she lacks regular access to primary
care, the pharmacist must comply with the procedures of the
pharmacy's approved access-to-care plan as provided in
subsection (7).

- (6) Before ordering or dispensing HIV postexposure prophylaxis drugs under this section, a pharmacist must be certified by the board, according to the rules adopted by the board and approved by the Board of Medicine and the Board of Osteopathic Medicine. To be certified, a pharmacist must, at a minimum, meet all of the following criteria:
- (a) Hold an active and unencumbered license to practice pharmacy under this chapter.
 - (b) Be engaged in the active practice of pharmacy.
- (c) Have earned a degree of doctor of pharmacy or have completed at least 3 years of experience as a licensed pharmacist.
- (d) Maintain at least \$250,000 of liability coverage. A pharmacist who maintains liability coverage pursuant to s. 465.1865 or s. 465.1895 satisfies this requirement.
- (e) 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:
 - 1. Performance of patient assessments.
 - 2. Point-of-care testing procedures.
 - 3. Safe and effective treatment of HIV exposure with HIV

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infection prevention drugs, including, but not limited to, consideration of the side effects of the drug dispensed and the patient's diet and activity levels.

- 4. Identification of contraindications.
- 5. Identification of patient comorbidities in individuals with HIV requiring further medical evaluation and treatment, including, but not limited to, cardiovascular disease, lung and liver cancer, chronic obstructive lung disease, and diabetes mellitus.
- (7) 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.
 - (a) An ACP must include:
- 1. 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.
- 2. A 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, 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 a federally qualified health center, county health

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develops a medical home at such setting for primary health care services. A pharmacy that establishes one or more collaborative partnerships under this subparagraph may not enter into an arrangement relating to such partnership which would prevent a federally qualified health center, county health department, or other primary care setting from establishing collaborative partnerships with other pharmacies.

- (b) Effective July 1, 2025, a pharmacy's ACP must be approved by the department 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 department regarding the implementation and results of its plan as part of the licensure renewal process, or as directed by the department, before each licensure renewal.
 - (8) The board shall adopt rules to implement this section. Section 2. This act shall take effect July 1, 2024.