By Senator Calatayud

38-01176-24 20241406__

A bill to be entitled

An act relating to restricted prescription drug distributors; amending s. 499.01, F.S.; exempting certain persons who engage in the receipt or distribution of prescription drugs for the sole purpose of processing the drugs' destruction from specified inventory and vehicle security requirements; amending s. 499.05, F.S.; requiring the Department of Business and Professional Regulation to adopt less stringent rules for certain persons who engage in the receipt or distribution of prescription drugs for the sole purpose of processing the drugs' destruction; providing requirements for such rules; providing an effective date.

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

Section 1. Paragraph (h) of subsection (2) of section 499.01, Florida Statutes, is amended to read:

499.01 Permits.—

(2) The following permits are established:

(h) *Restricted prescription drug distributor permit.*—

1. A restricted prescription drug distributor permit is required for:

a. Any person located in this state who engages in the distribution of a prescription drug, which distribution is not considered "wholesale distribution" under s. 499.003(48)(a).

b. Any person located in this state who engages in the receipt or distribution of a prescription drug in this state for

the purpose of processing its return or its destruction if such person is not the person initiating the return, the prescription drug wholesale supplier of the person initiating the return, or the manufacturer of the drug.

c. A blood establishment located in this state which collects blood and blood components only from volunteer donors as defined in s. 381.06014 or pursuant to an authorized practitioner's order for medical treatment or therapy and engages in the wholesale distribution of a prescription drug not described in s. 499.003(48)(j) to a health care entity. A mobile blood unit operated by a blood establishment permitted under this sub-subparagraph is not required to be separately permitted. The health care entity receiving a prescription drug distributed under this sub-subparagraph must be licensed as a closed pharmacy or provide health care services at that establishment. The blood establishment must operate in accordance with s. 381.06014 and may distribute only:

(I) Prescription drugs indicated for a bleeding or clotting disorder or anemia;

(II) Blood-collection containers approved under s. 505 of the federal act;

(III) Drugs that are blood derivatives, or a recombinant or synthetic form of a blood derivative;

(IV) Prescription drugs that are identified in rules adopted by the department and that are essential to services performed or provided by blood establishments and authorized for distribution by blood establishments under federal law; or

(V) To the extent authorized by federal law, drugs necessary to collect blood or blood components from volunteer

blood donors; for blood establishment personnel to perform therapeutic procedures under the direction and supervision of a licensed physician; and to diagnose, treat, manage, and prevent any reaction of a volunteer blood donor or a patient undergoing a therapeutic procedure performed under the direction and supervision of a licensed physician,

as long as all of the health care services provided by the blood establishment are related to its activities as a registered blood establishment or the health care services consist of collecting, processing, storing, or administering human hematopoietic stem cells or progenitor cells or performing diagnostic testing of specimens if such specimens are tested together with specimens undergoing routine donor testing. The blood establishment may purchase and possess the drugs described in this sub-subparagraph without a health care clinic establishment permit.

2.a. Except as provided in sub-subparagraph b., the storage, handling, and recordkeeping of these distributions by a person required to be permitted as a restricted prescription drug distributor must be in accordance with the requirements for wholesale distributors under s. 499.0121.

b. A person who is required to be permitted as a restricted prescription drug distributor and who engages in the receipt or distribution of a prescription drug in this state for the sole purpose of processing its destruction is not required to comply with the inventory requirements of s. 499.0121(6)(d) or (8) or the vehicle security requirements of s. 499.0121(2)(c).

3. A person who applies for a permit as a restricted

prescription drug distributor, or for the renewal of such a permit, must provide to the department the information required under s. 499.012.

4. The department may adopt rules regarding the distribution of prescription drugs by hospitals, health care entities, charitable organizations, other persons not involved in wholesale distribution, and blood establishments, which rules are necessary for the protection of the public health, safety, and welfare.

5. A restricted prescription drug distributor permit is not required for distributions between pharmacies that each hold an active permit under chapter 465, have a common ownership, and are operating in a freestanding end-stage renal dialysis clinic, if such distributions are made to meet the immediate emergency medical needs of specifically identified patients and do not occur with such frequency as to amount to the regular and systematic supplying of that drug between the pharmacies. The department shall adopt rules establishing when the distribution of a prescription drug under this subparagraph amounts to the regular and systematic supplying of that drug.

6. A restricted prescription drug distributor permit is not required for distributing medicinal drugs or prepackaged drug products between entities under common control that each hold either an active Class III institutional pharmacy permit under chapter 465 or an active health care clinic establishment permit under paragraph (r). For purposes of this subparagraph, the term "common control" has the same meaning as in s. 499.003(48)(a)3.

Section 2. Subsection (3) of section 499.05, Florida Statutes, is amended to read:

499.05 Rules.—

(3) The department shall adopt rules regulating recordkeeping for and the storage, handling, and distribution of medical devices and over-the-counter drugs to protect the public from adulterated products; however, rules regulating persons who engage in the receipt or distribution of a prescription drug in this state for the sole purpose of processing its destruction must be less stringent than the requirements for wholesale distributors under s. 499.0121 and may not include the inventory requirements in s. 499.0121(6)(d) or (8) or the vehicle security requirements in s. 499.0121(2)(c).

Section 3. This act shall take effect July 1, 2024.