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Proposed Committee Substitute by the Committee on Health Regulation

A bill to be entitled

An act relating to blood establishments; amending s. 381.06014, F.S.; defining the term "volunteer donor"; prohibiting local governments from restricting access to public facilities or infrastructure for certain activities based on whether a blood establishment is operating as a for-profit organization or not-for-profit organization; prohibiting a blood establishment from considering whether certain customers are operating as a for-profit organization or not-for-profit organization when determining service fees for selling blood or blood components; requiring that certain blood establishments disclose specified information on the Internet; amending s. 483.201, F.S.; providing for disciplinary action against clinical laboratories failing to disclose specified information on the Internet; providing a maximum annual administrative fine that may be imposed annually against certain clinical laboratories for failure to comply with such disclosure requirement; amending s. 499.003, F.S.; revising the definition of the term "health care entity" to clarify that a blood establishment may be a health care entity and engage in certain activities; amending s. 499.005, F.S.; clarifying provisions prohibiting the unauthorized wholesale distribution of a prescription drug that was purchased by a hospital or other health care entity,

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to conform to changes made by the act; amending s. 499.01, F.S.; exempting certain blood establishments from the requirements to be permitted as a prescription drug manufacturer and register products; requiring that certain blood establishments obtain a restricted prescription drug distributor permit under specified conditions; limiting the prescription drugs that a blood establishment may distribute with the restricted prescription drug distributor permit; authorizing the Department of Health to adopt rules; providing an effective date.

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

Section 1. Section 381.06014, Florida Statutes, is amended to read:

381.06014 Blood establishments.—

(1) As used in this section, the term:

(a) "Blood establishment" means any person, entity, or organization, operating within the state, which examines an individual for the purpose of blood donation or which collects, processes, stores, tests, or distributes blood or blood components collected from the human body for the purpose of transfusion, for any other medical purpose, or for the production of any biological product.

(b) "Volunteer donor" means a person who does not receive remuneration, other than an incentive, for a blood donation intended for transfusion, and the product container of the donation from the person qualifies for labeling with the


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statement "volunteer donor" under 21 C.F.R. 606.121.

(2) Any blood establishment operating in the state may not conduct any activity defined in subsection (1) unless that blood establishment is operated in a manner consistent with the provisions of Title 21 parts 211 and 600-640, Code of Federal Regulations.

(3) Any blood establishment determined to be operating in the state in a manner not consistent with the provisions of Title 21 parts 211 and 600-640, Code of Federal Regulations, and in a manner that constitutes a danger to the health or well-being of donors or recipients as evidenced by the federal Food and Drug Administration's inspection reports and the revocation of the blood establishment's license or registration shall be in violation of this chapter and shall immediately cease all operations in the state.

(4) The operation of a blood establishment in a manner not consistent with the provisions of Title 21 parts 211 and 600-640, Code of Federal Regulations, and in a manner that constitutes a danger to the health or well-being of blood donors or recipients as evidenced by the federal Food and Drug Administration's inspection process is declared a nuisance and inimical to the public health, welfare, and safety. The Agency for Health Care Administration or any state attorney may bring an action for an injunction to restrain such operations or enjoin the future operation of the blood establishment.

(5) A local government may not restrict the access to or use of any public facility or infrastructure for the collection of blood or blood components from volunteer donors based on whether the blood establishment is operating as a for-profit



organization or not-for-profit organization.

(6) In determining the service fee of blood or blood components received from volunteer donors and sold to hospitals or other health care providers, a blood establishment may not base the service fee of the blood or blood component solely on whether the purchasing entity is a for-profit organization or not-for-profit organization.

(7) A blood establishment that collects blood or blood components from volunteer donors must disclose on the Internet information to educate and inform donors and the public about the blood establishment's activities. A hospital that collects blood or blood components from volunteer donors for its own use or for health care providers that are part of its business entity is exempt from the disclosure requirements in this subsection. The information required to be disclosed under this subsection may be cumulative for all blood establishments within a business entity. Disciplinary action against the blood establishment's clinical laboratory license may be taken as provided in s. 483.201 for a blood establishment that is required to disclose but fails to disclose on its website all of the following information:

(a) A description of the steps involved in collecting, processing, and distributing volunteer donations, presented in a manner appropriate for the donating public.

(b) By March 1 of each year, the number of units of blood components, identified by component, that were:

1. Produced by the blood establishment during the preceding calendar year;

2. Obtained from other sources during the preceding

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calendar year;

3. Distributed during the preceding year to health care providers located outside this state. However, if the blood establishment collects donations in a county outside this state, distributions to health care providers in that county shall be excluded. Such information shall be aggregated by health care providers located within the United States and its territories or outside the United States and its territories; and

4. Distributed to entities that are not health care providers during the preceding year. Such information shall be aggregated by purchasers located within the United States and its territories or outside the United States and its territories;

For purposes of this paragraph, the components that must be reported include whole blood, red blood cells, leukoreduced red blood cells, fresh frozen plasma or the equivalent, recovered plasma, platelets, and cryoprecipitated antihemophilic factor.

(c) The blood establishment's conflict-of-interest policy, policy concerning related-party transactions, whistleblower policy, and policy for determining executive compensation. If a change to any of these documents occurs, the revised document must be available on the blood establishment's website by the following March 1.

(d)1. The most recent 3 years of the Return of Organization Exempt from Income Tax, Internal Revenue Service Form 990, if the business entity for the blood establishment is eligible to file such return. The Form 990 must be available on the blood establishment's website within 30 calendar days after filing it



with the Internal Revenue Service; or

2. If the business entity for the blood establishment is not eligible to file the Form 990 return, a balance sheet, income statement, statement of changes in cash flow, and the expression of an opinion thereon by an independent certified public accountant who audited or reviewed such financial statements. Such documents must be available on the blood establishment's website within 120 days after the end of the blood establishment's fiscal year and must remain on the blood establishment's website for at least 36 months.

Section 2. Subsection (11) is added to section 483.201, Florida Statutes, to read:

483.201 Grounds for disciplinary action against clinical laboratories.—In addition to the requirements of part II of chapter 408, the following acts constitute grounds for which a disciplinary action specified in s. 483.221 may be taken against a clinical laboratory:

(11) A blood establishment that collects blood or blood components from volunteer donors failing to disclose information concerning its activities as required by s. 381.06014. Each day of violation constitutes a separate violation and each separate violation is subject to a separate fine. If multiple licensed establishments operated by a single business entity fail to meet such disclosure requirements, the agency may assess fines against only one of the business entity's clinical laboratory licenses. The total administrative fine may not exceed $10,000 for each annual reporting period.

Section 3. Subsection (23) of section 499.003, Florida Statutes, is amended to read

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499.003 Definitions of terms used in this part.—As used in this part, the term:

(23) "Health care entity" means a closed pharmacy or any person, organization, or business entity that provides diagnostic, medical, surgical, or dental treatment or care, or chronic or rehabilitative care, but does not include any wholesale distributor or retail pharmacy licensed under state law to deal in prescription drugs. However, a blood establishment may be a health care entity and engage in the wholesale distribution of prescription drugs under s. 499.01(2)(g)1.c.

Section 4. Subsection (21) of section 499.005, Florida Statutes, is amended to read:

499.005 Prohibited acts.—It is unlawful for a person to perform or cause the performance of any of the following acts in this state:

(21) The wholesale distribution of any prescription drug that was:

(a) Purchased by a public or private hospital or other health care entity, except as authorized in s. 499.01(2)(g)1.c.; or

(b) Donated or supplied at a reduced price to a charitable organization.

Section 5. Paragraphs (a) and (g) of subsection (2) of section 499.01, Florida Statutes, are amended to read:

499.01 Permits.—

(2) The following permits are established:

(a) *Prescription drug manufacturer permit.*—A prescription drug manufacturer permit is required for any person that is a

manufacturer of a prescription drug and that manufactures or distributes such prescription drugs in this state.

1. A person that operates an establishment permitted as a prescription drug manufacturer may engage in wholesale distribution of prescription drugs manufactured at that establishment and must comply with all of the provisions of this part, except s. 499.01212, and the rules adopted under this part, except s. 499.01212, that apply to a wholesale distributor.

2. A prescription drug manufacturer must comply with all appropriate state and federal good manufacturing practices.

3. A blood establishment as defined in s. 381.06014, operating in a manner consistent with the provisions of Title 21 C.F.R. Parts 211 and 600-640, and manufacturing only the prescription drugs described in s. 499.003(53)(d) is not required to be permitted as a prescription drug manufacturer under this paragraph or register products under s. 499.015.

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

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

a. Any person that engages in the distribution of a prescription drug, which distribution is not considered "wholesale distribution" under s. 499.003(53)(a).

b.~~1.~~ Any ~~A~~ person who engages in the receipt or distribution of a prescription drug in this state for the purpose of processing its return or its destruction ~~must obtain a permit as a restricted prescription drug distributor~~ 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 that 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(53)(d) to a health care entity. 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; or

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

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.

2. Storage, handling, and recordkeeping of these distributions by a person permitted as a restricted prescription drug distributor must comply with the requirements for wholesale distributors under s. 499.0121, but not those set forth in s. 499.01212 if the distribution occurs pursuant to sub-subparagraph 1.a. or sub-subparagraph 1.b.

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, or other persons not involved in wholesale distribution, and blood establishments; which rules are necessary for the protection of the public health, safety, and welfare. The department may adopt rules related to the transportation, storage, and recordkeeping of prescription drugs which are essential to services performed or provided by a blood establishment, including requirements for the use of prescription drugs in mobile blood-collection vehicles.

Section 6. This act shall take effect July 1, 2010.