By the Committee on Health Regulation; and Senator Gaetz

588-00653-11 201194c1

A bill to be entitled

An act relating to blood establishments; amending s. 381.06014, F.S.; redefining the term "blood establishment" and 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 for-profit organizations or not-for-profit organizations when determining service fees for selling blood or blood components; requiring that certain blood establishments disclose specified information on the Internet; authorizing the Department of Legal Affairs to assess a civil penalty against a blood establishment that fails to disclose specified information on the Internet; providing that the civil penalty accrues to the state and requiring that it be deposited as received into the General Revenue Fund; amending s. 499.003, F.S.; redefining the term "health care entity" to clarify that a blood establishment is a health care entity that may engage in certain activities; amending s. 499.005, F.S.; clarifying provisions that prohibit the unauthorized wholesale distribution of a prescription drug that was purchased by a hospital or other health care entity or donated or supplied at a reduced price to a charitable

organization, 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 under a restricted prescription drug distributor permit; authorizing the Department of Health to adopt rules regarding the distribution of prescription drugs by blood establishments; 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. A person, entity, or organization that uses a mobile unit to conduct such activities within the state is also a blood establishment.

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

(2) Any blood establishment operating in the state may not conduct any activity defined in paragraph (1)(a) ~~subsection (1)~~ unless that blood establishment is operated in a manner consistent with the provisions of Title 21 C.F.R. 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 C.F.R. 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 is ~~shall be~~ in violation of this chapter and must ~~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 C.F.R. 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 the information required under this subsection to educate and inform donors and the public about the blood establishment's activities. A hospital that collects blood or blood components to be used only by that hospital's licensed facilities or by a health care provider that is a part of the hospital's 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. A blood establishment must disclose on its website all of the following information:

(a) A description of the steps involved in collecting, processing, and distributing volunteer donations.

(b) By March 1 of each year, the number of units of blood components which were:

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

2. Obtained from other sources during the preceding calendar year;

3. Distributed during the preceding calendar 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 reported in the aggregate for health care providers located within the United States and its territories or outside the United States and its territories; and

4. Distributed during the preceding calendar year to entities that are not health care providers. Such information shall be reported in the aggregate for purchasers located within the United States and its territories or outside the United States and its territories.

(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 occurs to any of these documents, the revised document must be available on the blood establishment's website by the following March 1.

(d) Except for a hospital that collects blood or blood components from volunteer donors:

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 60 calendar days after it is filed 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, and statement of changes in cash flow, along with 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.

(8) A blood establishment is liable for a civil penalty for failing to make the disclosures required under subsection (7). The Department of Legal Affairs may assess the civil penalty against the blood establishment for each day that it fails to make such required disclosures, but the penalty may not exceed $10,000 per year. If multiple blood establishments operated by a single business entity fail to meet such disclosure requirements, the civil penalty may be assessed against only one of the business entity's blood establishments. The Department of Legal Affairs may terminate an action if the blood establishment agrees to pay a stipulated civil penalty. A civil penalty so collected accrues to the state and shall be deposited as received into the General Revenue Fund unallocated. The Department of Legal Affairs may terminate the action and waive the civil penalty upon a showing of good cause by the blood establishment as to why the required disclosures were not made.

Section 2. Subsection (23) of section 499.003, Florida Statutes, is amended to read:

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 is a health care entity that may engage in the wholesale distribution of prescription drugs under s. 499.01(2)(g)1.c.

Section 3. 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; or

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

unless the wholesale distribution of the prescription drug is authorized in s. 499.01(2)(g)1.c.

Section 4. 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, which ~~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(54)(d) is not required to be permitted as a prescription drug manufacturer under this paragraph or to 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 located in this state that engages in the distribution of a prescription drug, which distribution is not considered "wholesale distribution" under s. 499.003(54)(a).

b.~~1.~~ Any ~~A~~ 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 ~~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 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(54)(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;

(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 either 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.

2. Storage, handling, and recordkeeping of these distributions by a person required to be 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.

Section 5. This act shall take effect July 1, 2011.