A bill to be entitled

An act relating to blood establishments; amending s. 381.06014, F.S.; prohibiting a local government from restricting access to or use of public facilities or infrastructure for the collection of blood or blood components from volunteer donors based on certain criteria; prohibiting blood establishments from determining the price of blood or blood components based on certain criteria; amending s. 499.003, F.S.; revising the definition of the term "wholesale distribution" to exclude certain drugs and products distributed by blood establishments; amending s. 499.01, F.S.; excluding certain blood establishments from the requirement to obtain a prescription drug manufacturer permit; providing an effective date.

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

Section 1. Subsections (5) and (6) are added to section 381.06014, Florida Statutes, to read:

381.06014 Blood establishments.—

(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 a not-for-profit organization.

(6) In determining the price of blood or blood components that are received from volunteer donors and sold to hospitals or

other health care providers, a blood establishment may not base the price of the blood or blood component solely on whether the purchasing entity is a for-profit organization or a not-for-profit organization.

Section 2. Paragraphs (e) and (f) of subsection (53) of section 499.003, Florida Statutes, are redesignated as paragraphs (f) and (g), respectively, and a new paragraph (e) is added to that subsection to read:

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

(53) "Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(e) The sale, purchase, or trade or the offer to sell, purchase, or trade, by a registered blood establishment that qualifies as a health care entity of any:

1. Drug indicated for a bleeding or clotting disorder or anemia;

2. Blood collection container approved under section 505 of the Prescription Drug Marketing Act;

3. Drug that is a blood derivative, or a recombinant or synthetic form of a blood derivative, as long as the health care services provided by the blood establishment are related to its activities as a registered blood establishment or the health care services provided by the blood establishment consist of collecting, processing, storing, or administering human hematopoietic stem or progenitor cells or performing diagnostic testing of specimens that are tested together with specimens

undergoing routine donor testing; or

4. Drug 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.

A blood establishment whose distribution of products is excluded under this paragraph must satisfy all other requirements of this part applicable to a wholesale distributor or retail pharmacy.

Section 3. Paragraph (a) of subsection (2) of section 499.01, Florida Statutes, is 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 21 C.F.R. parts 211 and 660—640 and manufacturing only the prescription drugs described in s. 499.003(53)(d) and (e) is not required to obtain a permit as a prescription drug manufacturer under this paragraph or register products under s. 499.015.

Section 4. This act shall take effect upon becoming a law.