An act relating to prescription drugs; amending s. 499.003, F.S.; revising the definition of the term "manufacturer" for purposes of the Florida Drug and Cosmetic Act; requiring certain manufacturers to disclose the names of affiliated group members to the Department of Health; amending s. 499.01, F.S.; revising requirements for a prescription drug manufacturer permit, nonresident prescription drug manufacturer permit, and health care clinic establishment permit; amending s. 499.0121, F.S.; clarifying that a wholesale distributor is required to maintain pedigree papers separately from other records of prescription drugs under certain circumstances; amending s. 499.01212, F.S.; revising requirements for a pedigree paper; providing an effective date.

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

Section 1. Subsection (31) 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:

(31) "Manufacturer" means:

(a) A person who prepares, derives, manufactures, or produces a drug, device, or cosmetic;~~.~~

(b) The holder or holders of a New Drug Application (NDA), an Abbreviated New Drug Application (ANDA), a Biologics License Application (BLA), or a New Animal Drug Application (NADA),

provided such application has become effective or is otherwise approved consistent with s. 499.023;

(c) A private label distributor for whom the private label distributor's prescription drugs are originally manufactured and labeled for the distributor and have not been repackaged; ~~or the distribution point for the manufacturer, contract manufacturer, or private label distributor whether the establishment is a member of the manufacturer's affiliated group or is a contract distribution site.~~

(d) A person registered under the federal act as a manufacturer of a prescription drug, who is described in paragraph (a), paragraph (b), or paragraph (c), who has entered into a written agreement with another prescription drug manufacturer that authorizes either manufacturer to distribute the prescription drug identified in the agreement as the manufacturer of that drug consistent with the federal act and its implementing regulations;

(e) A member of an affiliated group that includes, but is not limited to, persons described in paragraph (a), paragraph (b), paragraph (c), or paragraph (d), which member distributes prescription drugs, whether or not obtaining title to the drugs, only for the manufacturer of the drugs who is also a member of the affiliated group. As used in this paragraph, the term "affiliated group" means an affiliated group as defined in s. 1504 of the Internal Revenue Code of 1986, as amended. The manufacturer must disclose the names of all of its affiliated group members to the department; or

(f) A person permitted as a third party logistics provider, only while providing warehousing, distribution, or other

logistics services on behalf of a person described in paragraph (a), paragraph (b), paragraph (c), paragraph (d), or paragraph (e).

The term does not include a pharmacy ~~excludes pharmacies~~ that is ~~are~~ operating in compliance with pharmacy practice standards as defined in chapter 465 and rules adopted under that chapter.

Section 2. Paragraphs (a), (c), and (t) 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 ~~manufactures~~ 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.

(c) *Nonresident prescription drug manufacturer permit.*—A nonresident prescription drug manufacturer permit is required for any person that is a manufacturer of prescription drugs, ~~or the distribution point for a manufacturer of prescription drugs~~

unless permitted as a third party logistics provider, ~~and~~ located outside of this state~~,~~ or ~~that is an entity to whom an approved new drug application has been issued by the United States Food and Drug Administration, or the contracted manufacturer of the approved new drug application holder, and located~~ outside the United States and that~~, which~~ engages in the wholesale distribution in this state of such ~~the~~ prescription drugs ~~it manufactures or is responsible for manufacturing~~. Each such manufacturer ~~or entity~~ must be permitted by the department and comply with all of the provisions required of a wholesale distributor under this part, except s. 499.01212.

1. A person that distributes prescription drugs for which the person is not the manufacturer ~~that it did not manufacture~~ must also obtain an out-of-state prescription drug wholesale distributor permit or third party logistics provider permit pursuant to this section to engage in the wholesale distribution of such ~~the~~ prescription drugs ~~manufactured by another person and comply with the requirements of an out-of-state prescription drug wholesale distributor~~. This subparagraph does not apply to a manufacturer as defined in s. 499.003(31)(e).

2. Any such person must comply with the licensing or permitting requirements of the jurisdiction in which the establishment is located and the federal act, and any product wholesaled into this state must comply with this part. If a person intends to import prescription drugs from a foreign country into this state, the nonresident prescription drug manufacturer must provide to the department a list identifying each prescription drug it intends to import and document approval by the United States Food and Drug Administration for

such importation.

3. A nonresident prescription drug manufacturer permit is not required for a manufacturer to distribute a prescription drug active pharmaceutical ingredient that it manufactures to a prescription drug manufacturer permitted in this state in limited quantities intended for research and development and not for resale, or human use other than lawful clinical trials and biostudies authorized and regulated by federal law. A manufacturer claiming to be exempt from the permit requirements of this subparagraph and the prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall comply with the recordkeeping requirements of s. 499.0121(6), but not the requirements of s. 499.01212. The prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall maintain on file a record of the FDA registration number; the out-of-state license, permit, or registration number; and, if available, a copy of the most current FDA inspection report, for all manufacturers from whom they purchase active pharmaceutical ingredients under this section. The department shall specify by rule the allowable number of transactions within a given period of time and the amount of active pharmaceutical ingredients that qualify as limited quantities for purposes of this exemption. The failure to comply with the requirements of this subparagraph, or rules adopted by the department to administer this subparagraph, for the purchase of prescription drug active pharmaceutical ingredients is a violation of s. 499.005(14).

(t) *Health care clinic establishment permit.*—Effective January 1, 2009, a health care clinic establishment permit is

required for the purchase of a prescription drug by a place of business at one general physical location that provides health care or veterinary services, which is owned and operated by a business entity that has been issued a federal employer tax identification number ~~professional corporation or professional limited liability company described in chapter 621, or a corporation that employs a veterinarian as a qualifying practitioner~~. For the purpose of this paragraph, the term "qualifying practitioner" means a licensed health care practitioner defined in s. 456.001, or a veterinarian licensed under chapter 474, who is authorized under the appropriate practice act to prescribe and administer a prescription drug.

1. An establishment must provide, as part of the application required under s. 499.012, designation of a qualifying practitioner who will be responsible for complying with all legal and regulatory requirements related to the purchase, recordkeeping, storage, and handling of the prescription drugs. In addition, the designated qualifying practitioner shall be the practitioner whose name, establishment address, and license number is used on all distribution documents for prescription drugs purchased or returned by the health care clinic establishment. Upon initial appointment of a qualifying practitioner, the qualifying practitioner and the health care clinic establishment shall notify the department on a form furnished by the department within 10 days after such employment. In addition, the qualifying practitioner and health care clinic establishment shall notify the department within 10 days after any subsequent change.

2. The health care clinic establishment must employ a

qualifying practitioner at each establishment.

3. In addition to the remedies and penalties provided in this part, a violation of this chapter by the health care clinic establishment or qualifying practitioner constitutes grounds for discipline of the qualifying practitioner by the appropriate regulatory board.

4. The purchase of prescription drugs by the health care clinic establishment is prohibited during any period of time when the establishment does not comply with this paragraph.

5. A health care clinic establishment permit is not a pharmacy permit or otherwise subject to chapter 465. A health care clinic establishment that meets the criteria of a modified Class II institutional pharmacy under s. 465.019 is not eligible to be permitted under this paragraph.

6. This paragraph does not apply to the purchase of a prescription drug by ~~prohibit~~ a licensed ~~qualifying~~ practitioner under his or her license ~~from purchasing prescription drugs~~.

Section 3. Paragraph (e) of subsection (6) of section 499.0121, Florida Statutes, is amended to read:

499.0121 Storage and handling of prescription drugs; recordkeeping.—The department shall adopt rules to implement this section as necessary to protect the public health, safety, and welfare. Such rules shall include, but not be limited to, requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

(6) RECORDKEEPING.—The department shall adopt rules that require keeping such records of prescription drugs as are necessary for the protection of the public health.

(e) When pedigree papers are required by this part, a wholesale distributor must maintain the pedigree papers separate and distinct from other records required under this part ~~chapter~~.

Section 4. Paragraph (b) of subsection (2) of section 499.01212, Florida Statutes, is amended to read:

499.01212 Pedigree paper.—

(2) FORMAT.—A pedigree paper must contain the following information:

(b) For all other wholesale distributions of prescription drugs:

1. The quantity, dosage form, and strength of the prescription drugs.

2. The lot numbers of the prescription drugs.

3. The name and address of each owner of the prescription drug and his or her signature.

4. Shipping information, including the name and address of each person certifying delivery or receipt of the prescription drug.

5. An invoice number, a shipping document number, or another number uniquely identifying the transaction.

6. A certification that the recipient wholesale distributor has authenticated the pedigree papers.

7. The unique serialization of the prescription drug, if the manufacturer or repackager has uniquely serialized the individual prescription drug unit.

8. The name, address, telephone number, and, if available, e-mail contact information of each wholesale distributor involved in the chain of the prescription drug’s custody.

When an affiliated group member obtains title to a prescription drug before distributing the prescription drug as the manufacturer under s. 499.003(31)(e), information regarding the distribution between those affiliated group members may be omitted from a pedigree paper required under this paragraph for subsequent distributions of that prescription drug.

Section 5. This act shall take effect October 1, 2009.