The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Health Regulation Committee

BILL:	CS/SB 1144
INTRODUCER:	Health Regulation Committee and Senator Peaden
SUBJECT:	Manufacturers and purchasers of prescription drugs
DATE:	March 31, 2009 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Wilson	HR	**Fav/CS**
2.	O'Callaghan	Cooper	CM	**Favorable**
3.			HA	
4.				
5.				
6.				

Please see Section VIII. for Additional Information:

A. COMMITTEE SUBSTITUTE.....	X	Statement of Substantial Changes
B. AMENDMENTS.....		Technical amendments were recommended
		Amendments were recommended
		Significant amendments were recommended

I. Summary:

This committee substitute (CS) allows a prescription drug manufacturer's subsidiaries and affiliated corporate entities to obtain title to the manufacturer's prescription drugs prior to distributing them externally, into the stream of commerce. These affiliated group members are treated like the manufacturer for purposes of pedigree papers. The CS recognizes situations when two manufacturers execute a written agreement to manufacture and distribute a prescription drug. Both manufacturers are treated as the manufacturer for purposes of permitting and pedigree papers. Finally, the CS expands the type of business entities that are eligible for a health care clinic establishment permit, so that medical practices are authorized to purchase and possess prescription drugs.

This CS substantially amends the following sections of the Florida Statutes: 409.9201; 465.0265; 499.003; 499.01; 499.012; 499.0121; 499.01211; 499.01212; 499.03; 499.041; 499.05; and 794.075. The CS also creates one undesignated section of law.

II. Present Situation:

Overview of the Florida Drug and Cosmetic Act

The Florida Drug and Cosmetic Act (Act) is found in part I of ch. 499, F.S. Its purpose is to safeguard the public health and promote the public welfare by protecting the public from injury by product use and by merchandising deceit involving drugs, devices, and cosmetics.[1] The Department of Health (department) is responsible for administering and enforcing efforts to prevent fraud, adulteration, misbranding, or false advertising in the preparation, manufacture, repackaging, or distribution of drugs, devices, and cosmetics.[2]

The department issues permits to "persons" (defined to also include business entities) who qualify to engage in activity regulated under the Act. Generally, each establishment (location) must be permitted. Prior to operating, a permit is required for each person and establishment that intends to operate as:

- A prescription drug manufacturer;
- A prescription drug repackager;
- A nonresident prescription drug manufacturer;
- A prescription drug wholesale distributor;
- An out-of-state prescription drug wholesale distributor;
- A retail pharmacy drug wholesale distributor;
- A restricted prescription drug distributor;
- A complimentary drug distributor;
- A freight forwarder;
- A veterinary prescription drug retail establishment;
- A veterinary prescription drug wholesale distributor;
- A limited prescription drug veterinary wholesale distributor;
- A medical oxygen retail establishment;
- A compressed medical gas wholesale distributor;
- A compressed medical gas manufacturer;
- An over-the-counter drug manufacturer;
- A device manufacturer;
- A cosmetic manufacturer;
- A third-party logistics provider; or
- A health care clinic establishment.

The Act identifies authorized and proscribed activities for each permitted entity, as well as particular storage, handling, and recordkeeping requirements for each. Administrative and criminal penalties may result for the failure to comply with requirements in the Act or administrative rules.[3] The Act also establishes the Cancer Drug Donation Program.

[1] The Federal Food, Drug and Cosmetic Act, 21 United States Code, beginning at section 301, forms the basis for the Act and also protects Floridians from dangerous drugs, devices, and cosmetics.
[2] Section 449.002, F.S.
[3] Chapter 64F-12, Florida Administrative Code, contains the rules adopted under the Act's authority.

The presence of adulterated, diverted, and counterfeit drugs in the United States has been a concern for years.[4] Some life saving or life sustaining drugs are very expensive. A drug's integrity may be compromised due to improper manufacturing, packaging, storage, or use beyond the expiration date. Generally, a compromised drug is undetectable to a medical practitioner and the consuming patient, which can lead to ineffective treatment or potentially fatal results. As a result, the laws addressing the manufacture, distribution, consumption, and disposal of drugs, especially prescription drugs, are very strict in this country.[5] A prescription drug is one that is not safe for use except under the supervision of a practitioner licensed by law to administer the drug and can only be dispensed pursuant to a prescription.[6]

Pedigree Paper

The Act requires persons engaged in the wholesale distribution[7] of prescription drugs to provide a pedigree paper to recipients (other than a patient) of a prescription drug. A pedigree paper is a written or electronic document which contains certain information regarding the sale and distribution of a given prescription drug.[8]

Although a manufacturer may engage in the wholesale distribution of prescription drugs it manufactures, a manufacturer is exempt from providing a pedigree paper.[9] The first prescription drug wholesale distributor that purchases or receives the prescription drug from the drug manufacturer initiates the pedigree paper to document that the prescription drug was obtained from the manufacturer. Thereafter, each person engaged in the wholesale distribution of the prescription drug, who owns or possesses it throughout the stream of commerce is added to the pedigree paper for that prescription drug until the drug is delivered to the hospital, pharmacy, or practitioner.

There are three types of pedigree papers, depending on the distribution scheme of the prescription drug through the stream of commerce, as follows:[10]

- *Normal Distribution Chain.* A prescription drug in the normal distribution chain means a wholesale distribution of a prescription drug in which the wholesale distributor or its wholly owned subsidiary purchases or receives the specific unit of the prescription drug directly from the manufacturer and distributes the prescription drug directly, or through up to two intracompany transfers, to a chain pharmacy warehouse or a person authorized by law to purchase prescription drugs for the purpose of administering or dispensing the drug. The term "intracompany" is defined as any transaction or transfer between any

[4] See U.S. Food and Drug Administration, *FDA's Counterfeit Drug Task Force Interim Report*, October, 2003, available at http://www.fda.gov/oc/initiatives/counterfeit/report/interim_report.html (Website last visited on March 28, 2009).
[5] See U.S. Food and Drug Administration, *Guidance for Industry; Container Closure Systems for Packaging Human Drugs and Biologics Chemistry, Manufacturing and Controls Documentation*, available at http://www.fda.gov/Cber/gdlns/cntanr.htm (Website last visited on March 28, 2009).
[6] See sec. 503(b) of the Federal Food, Drug and Cosmetic Act.
[7] Distribute or distribution means to sell; offer to sell; give away; transfer, whether by passage of title, physical movement, or both; deliver; or offer to deliver. The term does not mean to administer or dispense. See s. 499.003(17), F.S. Certain exemptions are provided in s. 499.003(53), F.S., for wholesale distribution.
[8] s. 499.003(36), F.S.
[9] s. 499.01212(3)(a), F.S.
[10] s. 499.01212, F.S.

parent, division, or subsidiary wholly owned by a corporate entity.[11] A pedigree for a prescription drug in the normal distribution chain must include the following statement: "This wholesale distributor purchased the specific unit of the prescription drug directly from the manufacturer."[12]

- *Drop Shipment.* A drop shipment means the sale of a prescription drug from a manufacturer to a wholesale distributor, where the wholesale distributor takes title to, but not possession of, the prescription drug, and the manufacturer of the prescription drug ships the prescription drug directly to a chain pharmacy warehouse or a person authorized by law to purchase prescription drugs for the purpose of administering or dispensing the drug.[13] A pedigree for a prescription drug that has been drop shipped must include the following statement: "This wholesale distributor purchased the specific unit of the prescription drug listed on the invoice directly from the manufacturer, and the specific unit of prescription drug was shipped by the manufacturer directly to a person authorized by law to administer or dispense the legend drug, as defined in s. 465.003, F.S., or a member of an affiliated group, with the exception of a repackager."[14]
- *All other distributions*. For all other distributions, a pedigree paper must disclose[15] the:
  - Quantity, dosage form, and strength of the prescription drug;
  - Lot number of the prescription drug;
  - Name and address of each owner of the prescription drug and his or her signature;
  - Shipping information, including the name and address of each person certifying delivery or receipt of the prescription drug;
  - Invoice number, shipping document number, or other number uniquely identifying the transaction;
  - Certification that the recipient wholesale distributor has authenticated the pedigree paper (verification that the prior transactions reflected on the pedigree paper occurred as represented);
  - Unique serialization of the prescription drug, if the manufacturer or repackager has uniquely serialized the individual prescription drug unit; and
  - 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.

2008 Legislation Affecting the Act

The Act was substantially reorganized during the 2008 Legislative Session.[16] Several new provisions were enacted related to the distribution of prescription drugs, pedigree papers, and the creation of the health care clinic establishment permit.

Third Party Logistics Provider Permit
A new permit was created for a third-party logistics provider (3PL). A 3PL permit is required for any person that contracts with a prescription drug wholesale distributor or prescription drug manufacturer to provide warehousing, distribution, or other logistics services on behalf of a

[11] s. 499.003(33), F.S.
[12] s. 499.01212(2)(a), F.S.
[13] s. 499.003(18), F.S.
[14] s. 499.01212(3)(f), F.S.
[15] s. 499.01212(2)(b), F.S.
[16] See s. 1, ch. 2008-207, L.O.F.

manufacturer or wholesale distributor, but who does not take title to the prescription drug or have responsibility to direct the sale or disposition of the prescription drug.[17] A 3PL that is performing a wholesale distribution of a prescription drug for a manufacturer is exempt from providing a pedigree paper to the recipient of the prescription drug, but is required to possess a permit, pursuant to s. 499.01, F.S.[18]

Revised Definition of "Manufacturer"
Prior to the amendments in 2008, the term "manufacturer" was defined to mean a person who prepares, derives, manufactures, or produces a drug, device, or cosmetic. The term excludes pharmacies that are operating in compliance with pharmacy practice standards as defined in ch. 465, F.S., and rules adopted under that chapter.[19] This definition was amended in 2008 to add provisions that had been adopted in rule by the department for consistency with persons and activities recognized under federal law as a manufacturer. Additional persons identified in the 2008 amendment included:

- 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, F.S.;
- 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.

Within the last couple years, manufacturers have reorganized and created subsidiaries or other separate legal entities to distribute prescription drugs into the stream of commerce. The department estimates that at least five manufacturers have reorganized in this manner. Since the prescription drug remains within the corporate umbrella of the manufacturer, the risk of introducing counterfeit or otherwise adulterated prescription drugs into the market is slight. The sponsors of the 2008 legislation intended the distribution point within the definition of manufacturer to extend throughout the corporate umbrella, including a manufacturer's wholly owned subsidiary or members of its affiliated group, so that the distribution point would be exempt from the requirement to provide a pedigree paper to the recipient of the prescription drug when the distribution point distributed prescription drugs manufactured by members within the corporate umbrella.[20] However, apparently when several provisions of the Act are read together, the objective to authorize subsidiaries or other corporate partners to act as a manufacturer for the distribution of prescription drugs was not achieved with the 2008 amendments.

Health Care Clinic Establishment Permit
The 2008 legislation also created a Health Care Clinic Establishment (HCCE) permit to enable a business entity (medical practice) to purchase prescription drugs. This provision took effect on

[17] s. 499.01(2)(s), F.S.
[18] s. 499.01212(3)(a), F.S.
[19] s. 499.003(28), F.S., (2007).
[20] Per correspondences from the House and Senate sponsors to the State Surgeon General of the Department of Health.

January 1, 2009. The HCCE permit is required for the purchase of prescription drugs by a place of business at one general location owned and operated by a:

- Professional corporation described in ch. 621, F.S., with a qualifying practitioner,
- Professional limited liability company described in ch. 621, F.S., with a qualifying practitioner, or
- Corporation that employs a veterinarian as a qualifying practitioner.

A qualifying practitioner is a licensed health care practitioner defined in s. 456.001, F.S., or a veterinarian licensed under ch. 474, F.S. The health care practitioners defined in s. 456.001, F.S., that are authorized to prescribe prescription drugs include a: medical physician, osteopathic physician, physician assistant, advanced registered nurse practitioner, optometrist, podiatric physician, dentist, or chiropractic physician. Both the qualifying practitioner and the HCCE must notify the department within 10 days of a change in the qualifying practitioner.

The biennial fee for the HCCE permit is $255 and the permit is valid for 2 years, unless suspended or revoked.

The HCCE permit is an optional permit that a medical practice may obtain in order to purchase and own prescription drugs in the business entity's name. The HCCE permit is not required if a practitioner in the clinic or practice wants to purchase and own prescription drugs in his or her own name using his or her professional license that authorizes that practitioner to prescribe prescription drugs.

The HCCE permit provisions in the Act do not adequately address the needs of the medical community because, among other reasons, many medical practices are not organized as a professional service corporation or professional limited liability company under ch. 621, F.S. Chapter 621, F.S., is available for business entities that provide professional services. It requires as a condition precedent to the rendering of the service, the obtaining of a license or other legal authorization; however, there is no requirement that a medical clinic must be organized under that chapter. Medical practices, health care clinics, and the like, may be organized, for example, as a: corporation under ch. 607, F.S., or ch. 617, F.S.; limited liability company under ch. 608, F.S.; or partnership under ch. 620, F.S.

Cooperative Agreements Between Manufacturers

Periodically, two manufacturers may enter into a collaborative agreement to develop, manufacture, and distribute a pharmaceutical or biologic. Frequently, this occurs when a smaller manufacturer, perhaps a start-up company, holds an NDA or BLA but does not have the resources and infrastructure to successfully bring the drug to market and accomplish widespread distribution of the product.

III. Effect of Proposed Changes:

Section 1 amends s. 409.9201, F.S., related to Medicaid fraud, to conform a cross-reference.

Section 2 amends s. 465.0265, F.S., related to centralized prescription filling, to conform a cross-reference.

Section 3 amends s. 499.003, F.S., to redefine "manufacturer" by deleting a distribution point for the manufacturer or private label distributor and including a manufacturer who has entered into a written agreement with another manufacturer to distribute a prescription drug as the manufacturer of that drug consistent with the federal act. "Federal act" means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. ss. 301, et seq.

This section defines the new term "manufacturer's distributor," and the definition of "normal distribution chain" is amended to recognize activities of a manufacturer's distributor and manufacturer's third-party logistics provider.

Section 4 amends s. 499.01, F.S., to create a new type of permit (a prescription drug manufacturer's distributor permit) and to modify provisions within certain existing permits related to the wholesale distribution of prescription drugs to conform to the new definitions and activities of a manufacturer's distributor and third-party logistics provider.

A prescription drug manufacturer's distributor permit is available for a member of a manufacturer's affiliated group to distribute only the prescription drugs manufactured by the affiliated group members. This permit requires the manufacturer's distributor to acquire title to the prescription drug from the manufacturer and allows the manufacturer's distributor to distribute the prescription drug without providing a pedigree paper to the recipient. As a part of the permit application process, the applicant must identify all members of the affiliated group and a state-licensed certified public accountant must certify that the members qualify as an affiliated group as defined in 26 U.S.C. s. 1504, which is part of the federal tax code.

The CS also expands the types of business entities that are eligible for a health care clinic establishment permit in order to purchase and possess prescription drugs as a business entity. The business entity must have a federal tax identification number and be an entity through which qualified practitioners[21] practice their profession. The CS clarifies that certain licensed practitioners may continue to purchase and possess prescription drugs under their practice license, the health care clinic establishment permit does not authorize the purchase or possession of controlled substances, and the prescription drugs that may purchased under the clinic permit are limited to the prescription drugs that the qualifying practitioner is lawfully authorized to prescribe.

Section 5 amends s. 499.012, F.S., to prohibit a prescription drug manufacturer's distributor permit from being issued to the address of a health care entity or pharmacy to mirror the prohibition associated with a prescription drug manufacturer's permit.

Section 6 amends s. 499.0121, F.S., to clarify that a wholesale distributor only needs to maintain pedigree papers separate and distinct from other records when a pedigree paper is required, and to remove a cross-reference to defined terms.

[21] Section. 499.01(2)(t), F.S., defines a qualifying practitioner as a licensed health care practitioner defined in s. 456.001, F.S., or a veterinarian licensed under ch. 474, F.S., who is authorized under the appropriate practice act to prescribe and administer a prescription drug.

Section 7 amends s. 499.01211, F.S., related to the Drug Wholesale Distributor Advisory Council, to remove cross-references to defined terms.

Section 8 amends s. 499.01212, F.S., to provide for the activities performed by a manufacturer's distributor or manufacturer's third-party logistics provider for purposes of pedigree papers. The statement that must be used for a pedigree paper for the wholesale distribution of a prescription drug within the normal distribution chain is modified. Additionally, the statement that must be used on a pedigree paper for a prescription drug that is the subject of a drop shipment from the manufacturer or manufacturer's distributor is modified.

A wholesale distributor that is required to provide a full pedigree for the wholesale distribution of a prescription drug to its customer is authorized to omit from the pedigree paper the invoice number, shipping document number, or other reference number related to the wholesale distribution of that drug between the manufacturer and manufacturer's distributor, if applicable.

This section also exempts a manufacturer's distributor from providing a pedigree paper to its customer upon the wholesale distribution of a prescription drug.

The failure of a manufacturer's distributor or manufacturer's third-party logistics provider to provide the requisite documentation related to a prescription drug that is the subject of a drop shipment, or forging the requisite documentation is a criminal act. The statement required on a pedigree paper for the distribution of certain prescription drugs from a repackager, solely for distribution to its affiliated group members for the exclusive distribution to and among retail pharmacies that are members of the repackager's affiliated group, is modified to accommodate the distribution of a prescription drug through a manufacturer's distributor.

Section 9 amends s. 499.03, F.S., related to possession of prescription drugs, to remove cross-references to defined terms.

Section 10 amends s. 499.041, F.S., to provide for a fee for a prescription drug manufacturer's distributor permit ranging from $500 to $750, annually, and to authorize the department to retain a portion of the application fee if the application is withdrawn or becomes void.

Section 11 amends s. 499.05, F.S., related to the department's rulemaking authority to conform a cross-reference.

Section 12 amends s. 794.075, F.S., related to sexual predators to conform a cross-reference.

Section 13 creates an undesignated section of law to provide for a one year period for system updates to reflect the revised pedigree paper statements contained in section 8 of this CS.

Section 14 provides an effective date of October 1, 2009.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The CS requires a $500 to $750 annual fee for a prescription drug manufacturer's distributor permit.

C. Government Sector Impact:

The department will have increased revenue due to the submission of new applications and renewal applications for a health care clinic establishment permit. Since this permit is optional, the amount of the increase can only be estimated. The department estimates 1,191 new applications will be received in year one of the two-year permitting cycle, generating revenue of $303,705. Two Regulatory Review Specialist II FTEs are needed to address this increased workload and the COMPASS system will need modification to accommodate affiliated group information. The department indicates that fee revenue will offset the increased costs to implement this bill.[22]

VI. Technical Deficiencies:

The definition of "drop shipment" needs to be amended to include the manufacturer's distributor to conform with the pedigree paper requirements related to the wholesale distribution of prescription drugs through drop shipment arrangements.

VII. Related Issues:

None.

[22] Department of Health Bill Analysis, Economic Statement and Fiscal Note for SB 1144, dated February 18, 2009.

VIII. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Regulation Committee on March 25, 2009:
The CS makes the following substantive changes:

- Removes the concept of a distribution point from the definition of "manufacturer;"
- Creates a new permit for a manufacturer's distributor to authorize a member of a manufacturer's affiliated group to acquire ownership of a prescription drug manufactured by its affiliated group member and to distribute the prescription drug without the requirement to provide a pedigree paper to the recipient;
- Modifies the definition of "normal distribution chain" to include the distribution of a prescription drug through a manufacturer's distributor;
- Modifies the pedigree paper requirements to accommodate the authority granted to a manufacturer's distributor within the distribution chain;
- Eliminates the term "co-licensee" from the definition of "manufacturer" and instead describes the contractual arrangement between manufacturers to enable either manufacturer to distribute a prescription drug as the manufacturer;
- Provides a one year period for computer system updates to reflect the revised pedigree paper statements; and
- Expands the types of business entities that are eligible to apply for a health care clinic establishment permit.

B. Amendments:

None.