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 Judiciary Committee

BILL:	CS/CS/SB 2756
INTRODUCER:	Judiciary Committee, Health Regulation Committee, and Senator Peaden
SUBJECT:	Drugs, Devices, and Cosmetics
DATE:	April 23, 2008 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Wilson	HR	**Fav/CS**
2.	Sumner	Maclure	JU	**Fav/CS**
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 bill reorganizes the Florida Drug and Cosmetic Act to consolidate regulatory provisions for all regulated permits and activity, and to use consistent terminology throughout the act. The bill also:

- modifies and provides additional definitions for terms used in the regulation of the wholesale distribution of prescription drugs;
- authorizes the normal distribution chain to include up to two intracompany transfers for purposes of a wholesale distributor providing a direct purchase pedigree;
- modifies the timing for authentication of pedigree papers;
- revises the administrative and criminal prohibitions to allow a pedigree paper to be received simultaneously with the receipt of the prescription drug;
- provides procedures for the authentication of prescription drugs included in medical convenience kits;
- modifies provisions related to a limited prescription drug veterinary wholesale distributor permit; and

- creates two new permit types, one for a third party logistics provider and one for a health care clinic establishment.

This bill substantially amends the following sections of the Florida Statutes: 409.9201, 460.403, 465.0265, 499.002, 499.003, 499.005, 499.0051, 499.0054, 499.006, 499.007, 499.008, 499.009, 499.01, 499.012, 499.01201, 499.0121, 499.01211, 499.015, 499.024, 499.028, 499.029, 499.03, 499.032, 499.033, 499.039, 499.04, 499.041, 499.05, 499.051, 499.052, 499.055, 499.06, 499.062, 499.065, 499.066, 499.0661, 499.067, 794.075, 895.02, and 921.0022.

This bill creates section 499.01212, Florida Statutes

This bill repeals the following sections of the Florida Statutes: 499.0122 and 499.013.

II. Present Situation:

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 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;
- An over-the-counter drug manufacturer;
- A compressed medical gas manufacturer;
- A device manufacturer;
- A cosmetic manufacturer;
- A prescription drug wholesaler;
- A veterinary prescription drug wholesaler;
- A compressed medical gas wholesaler;
- An out-of-state prescription drug wholesaler;
- A nonresident prescription drug manufacturer;
- A freight forwarder;
- A retail pharmacy drug wholesaler;
- A veterinary legend drug retail establishment;
- A medical oxygen retail establishment;
- A complimentary drug distributor;
- A restricted prescription drug distributor; or

[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 449.004, F.S.

- A limited prescription drug veterinary wholesaler.

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

The presence of adulterated, diverted, and counterfeit drugs in the United States has been a concern for years. Some life saving or life sustaining drugs are very expensive. Most drugs are subject to compromised integrity 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. 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.[4]

Wholesale Distribution of Prescription Drugs

Three national wholesalers, referred to as "The Big Three", dominate the prescription drug wholesale distribution market and account for 90 to 95 percent of the prescription drugs distributed in this county.[5] There are also a handful of regional wholesalers and a large group of wholesalers referred to as secondary wholesalers. The Big Three and the regional wholesalers buy most, if not all, of the prescription drugs they distribute directly from the manufacturer of the drug; although there is no requirement that they must do so. Several years ago, the Big Three and regional wholesalers were also purchasing prescription drugs from secondary wholesalers. Most secondary wholesalers are small businesses and primarily serve specialized markets and physicians' offices.

The Federal Prescription Drug Marketing Act of 1987 (PDMA)[6] and the accompanying regulations[7] mandated certain licensing requirements and minimum storage and recordkeeping requirements that each state must implement to help protect the prescription drug supply in this country. The PDMA was the result of Congressional hearings into adulterated and counterfeit drugs that were in the marketplace in the 1980s. Florida implemented those requirements in the Florida Drug and Cosmetic Act in 1992.

At that time, both the PDMA and Florida law required a document that traces the distributions of a prescription drug through the supply chain, referred to in Florida as a pedigree paper. To this day, the federal requirement has not been fully implemented. Because of the lack of uniformity

[3] Chapter 64F-12, F.A.C., contains the rules adopted under the Act's authority.
[4] See s, 503(b) of the Federal Food, Drug and Cosmetic Act.
[5] The Big Three include AmerisourceBergen Corporation, Cardinal Health Inc., and McKesson Corporation. See at - *Market Watch Special Report: Big drug wholesalers may get bigger, with FDA help*, March 31, 2007, at: http://marketwatch.com (Last visited on March 30, 2008).
[6] Public Law 100-293.
[7] 21 Code of Federal Regulations, Part 205.

throughout the county, initially the department did not aggressively enforce the pedigree paper requirement either.

Beginning in 2000, the department and federal officials from the Food and Drug Administration (FDA) began detecting a proliferation of diverted[8] and counterfeit prescription drugs in Florida. As a result, two significant reports were published which prompted additional legislation in Florida in 2003.

Seventeenth Statewide Grand Jury Report
In 2002, the Governor petitioned the Florida Supreme Court to impanel a grand jury to investigate the theft and diversion of high-end prescription drugs and the manufacture of counterfeit prescription drugs. The report, released early in 2003, concluded that drugs flowing through the wholesale market had been illegally acquired, diverted, or counterfeited, and posed a danger to the safety of Floridians. Some of the recommendations were to require all prescription drug wholesalers to prepare a pedigree paper that traces all distributions of a prescription drug from the manufacturer to the pharmacy or dispenser, require wholesalers to verify the distributions reflected on the pedigree paper it received, and provide that pedigree paper to the dispenser.[9]

Office of Program Policy Analysis and Government Accountability Report
In February 2003, the Office of Program Policy Analysis and Government Accountability issued a report that highlighted the problems with counterfeit and diverted drugs in Florida. The findings of the report indicated that millions of dollars are lost due to the counterfeit and diverted drugs in Florida's prescription drug wholesale industry. The report found a rise in cases involving counterfeit and diverted drugs in Florida's prescription drug industry. The report concluded that Florida law did not provide adequate controls over wholesale drug market practices, and that administrative and criminal penalties failed to provide an adequate deterrent.[10]

Pedigree Paper Requirements

The Prescription Drug Protection Act of 2003
In 2003, the Florida Legislature passed the Prescription Drug Protection Act[11] to enhance licensure requirements, pedigree paper requirements, and criminal enforcement for the wholesale distribution of prescription drugs in, into, and from Florida. The enhanced pedigree paper provisions were to be phased in, with full implementation to be effective in 2006.

Initially in 2003, all wholesalers were required to provide a pedigree paper that traced the distribution of the prescription drug back to the manufacturer for 31 prescription drugs on a specified list adopted by department rule to customers that were also wholesalers.[12] For all other

[8] A prescription drug is considered diverted if it has left the legal and regulated channels for a prescription drug.
[9] First Interim Report of the Seventeenth Statewide Grand Jury, Case No.: SC02-2645, *at*: http://myfloridalegal.com/grandjury17.pdf (last visited on March 30, 2008).
[10] *Justification Review: Counterfeit and Diverted Drugs Threaten Public Health and Waste State Dollars*, Report No. 03-18, February 2003, at http://www.oppaga.state.fl.us/reports/pdf/0318rpt.pdf (last visited on March 30, 2008).
[11] Chapter 2003-155, Laws of Florida (L.O.F.).
[12] Section. 499.0121(6)(e), F.S.

prescription drugs, if a wholesaler was not an authorized distributor of record,[13] a pedigree paper that started with the last authorized distributor of record must be provided to customers that were also wholesalers. If a wholesaler was an authorized distributor of record, no pedigree paper was required for the distribution of prescription drugs that were not on the specified list. All pedigree papers were to be provided under oath. Beginning on July 1, 2006, all prescription drug wholesalers were required to provide a pedigree paper, under oath, that traced all distributions of the prescription drug back to the manufacturer to all customers. Wholesalers were required to verify (referred to as authenticate) that the transactions listed on the pedigree paper occurred to prevent the introduction of counterfeit or adulterated drugs into the supply chain.

Amendments to the Prescription Drug Protection Act
The 2006 Legislature[14] amended the pedigree paper law that was to go into effect on July 1, 2006, by creating three types of pedigrees: a direct purchase pedigree, a full pedigree, and a procedure that satisfies the pedigree paper requirements related to the drop shipment[15] of a prescription drug. A pedigree paper may be provided in written or electronic form.

A direct purchase pedigree is a statement, under oath, included with the distribution of the prescription drug for those drugs that are purchased and received by a wholesaler directly from the manufacturer and provided to a chain pharmacy warehouse or a person authorized by law to administer or dispense that drug. The statement is, "This wholesale distributor purchased the specific unit of the prescription drug directly from the manufacturer." This statement may be used by a wholesaler that purchased and received the drug directly from the manufacturer or received the drug through *one* intracompany transfer. In addition, the document must include:

- The manufacturer's national drug code identifier;
- The name and address of the wholesaler and the purchaser;
- The name of the prescription drug as it appears on the label; and
- The quantity, dosage form, and strength of the prescription drug.

A wholesale distributor providing a direct purchase pedigree must also maintain and provide to the department upon request, the point of origin of the prescription drugs, including intacompany transfers; the date of shipment from the manufacturer to the wholesale distributor; the lot numbers; and the invoice numbers from the manufacturer.

The full pedigree records each distribution of a prescription drug, from sale by a pharmaceutical manufacturer, through acquisition and sale by any wholesaler or repackager, until final sale to a pharmacy or other person administering or dispensing the drug. The statutory provisions do not require the full pedigree to be issued under oath, although a prescription drug wholesale

[13] An authorized distributor of record is defined as a wholesaler with whom the manufacturer had established an ongoing relationship to distribute the manufacturer's products and that is listed on the manufacturer's list of authorized distributors of record. Section. 499.0121(6)(d)5., F.S. (2005).
[14] Chapter 2006-310, L.O.F.
[15] A drop shipment for purposes of this pedigree paper requirement occurs when a wholesale distributor takes title to, but not possession of, a prescription drug and the prescription drug's manufacturer ships the prescription drug directly to a person authorized by law to administer or dispense the drug or to a member of an affiliated group, except a repackager. An affiliated group must meet the definition in s. 1504 of the Internal Revenue Code and be composed of at least 50 retail pharmacies, warehouses, or repackagers.

distributor must certify that the pedigree paper received was authenticated; and, although it is implied, there is no specific requirement to identify the name of the prescription drug on a pedigree paper. The information required must at least include:

- The amount of the legend drug;
- The dosage form and strength;
- The lot numbers;
- The name and address of each owner of the legend drug and his or her signature;
- The shipping information, including the name and address of each person certifying delivery or receipt of the legend drug;
- An invoice number, a shipping document number, or another number uniquely identifying the transaction;
- A certification that the recipient wholesaler has authenticated the pedigree papers;
- The name, address, telephone number and, if available, e-mail contact information of each wholesaler involved in the chain of the legend drug's custody; and
- If the manufacturer or repackager has uniquely serialized the individual legend drug unit, that identifier must also be included.

The procedure related to the drop shipment of a prescription drug requires:

- The wholesale distributor to:
  - Deliver to the recipient of the prescription drug, within 14 days after the shipment notification from the manufacturer, an invoice with the following sworn 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, Florida Statutes, or a member of an affiliated group, as described in s. 499.0121(6)(f), Florida Statutes, with the exception of a repackager";
  - Provide to the recipient of the prescription drug an invoice containing a unique cross-reference to the shipping document sent by the manufacturer to the recipient; and
  - Maintain and make available to the department upon request, the lot number of the drug if not contained in the shipping document acquired by the recipient; and
- The manufacturer to provide to the recipient, within 14 days after receipt of the prescription drug, a shipping document that contains, at a minimum:
  - The name and address of the manufacturer, including the point of origin of the shipment, and the names and addresses of the wholesaler and the purchaser;
  - The name of the prescription drug as it appears on the label;
  - The quantity, dosage form, and strength of the prescription drug; and
  - The date of the shipment from the manufacturer.

Current Practices and Obstacles

The Act requires the pedigree paper to be sent and received prior to the receipt of the prescription drugs. This is not always practical. The prescription drug wholesale industry routinely sends the pedigree paper contemporaneously with the prescription drugs. The

prescription drug wholesale distributor will quarantine the product until the pedigree paper has been authenticated. Once the prescription drugs are determined acceptable, they are released from quarantine and processed through receiving and added to saleable inventory.

Some of the larger prescription drug wholesale distributors, especially the Big Three, have a central purchasing and receiving warehouse, regionally or nationally. The current pedigree paper provisions enable a prescription drug wholesaler to use the direct purchase pedigree with one intracompany transfer. This one intracompany transfer accommodates the distribution from the central warehouse to the prescription drug wholesale distributor. However, these wholesalers have indicated that, if for some reason a prescription drug is not accessible from the central warehouse, but another branch warehouse has the prescription drug, it requires the branch warehouse to prepare a full pedigree upon the distribution of the drug to the wholesale distributor needing the prescription drug. Then that prescription drug wholesaler is required to provide a full pedigree to the customer.

Prescription drugs are closely regulated so that every movement of the prescription drug is regulated. Also, each person purchasing and receiving the prescription drug must be authorized by law to do so. The type of authorization one has determines what the person may do with the prescription drugs. Under current law, a licensed physician is authorized to purchase and possess prescription drugs via his or her medical license. However, this medical license does not authorize that practitioner to distribute (share) those prescription drugs with other licensed physicians. This is cumbersome in a group medical practice or when an individual medical practitioner or group of medical practitioners has formed a business entity for the medical practice. A business entity can apply for an institutional pharmacy license under ch. 465, F.S., (generally the modified class II institutional pharmacy license) to purchase prescription drugs so that all practitioners are able to use that inventory of prescription drugs; but this license only authorizes those drugs to be administered to patients on site. An individual practitioner may dispense prescription drugs purchased under his or her medical license to patients to take home, but the practitioner cannot dispense the inventory of prescription drugs purchased by the business entity under the institutional pharmacy license. This is a regulatory ‘catch-22’ for practitioners and is problematic to a variety of medical practice settings, including veterinary clinics.

Medical Convenience Kits

Medical convenience kits contain medical devices and prescription drugs packaged together for easy availability in a medical setting. The contents are usually marketable individually but are sealed together and marketed as one unit. In many instances, the unit is sterilized. Because a prescription drug component of a convenience kit is separable, and in the same form as when distributed independently, it is subject to the same pedigree requirements as when it is independently distributed. The medical convenience kit may have its own lot number that is different from that on the prescription drug component. The FDA’s Guidance for Industry has indicated that the outer container of the kit should also list the lot or control number of the prescription drug component so that the integrity of the kit’s seal would not have to be

compromised to confirm that the drug's lot number is the same as that listed in the pedigree.[16] Florida's law requires authentication of the pedigree paper and lot number,[17] but is silent on how to accomplish this authentication of the prescription drug in a medical convenience kit.

Limited Veterinary Prescription Drug Wholesaler

Veterinarians administer to and dispense for animals prescription drugs that are labeled "for veterinary use only" as well as prescription drugs that are approved for human use. In 2006, the Legislature established a limited prescription drug veterinary wholesaler permit for a person that distributes in or into Florida veterinary prescription drugs and prescription drugs approved for human use under the following conditions:

- The person distributes the drugs to
  - Licensed veterinarians practicing on a full-time basis;
  - A person regularly and lawfully engaged in instruction in veterinary medicine;
  - A person regularly and lawfully engaged in law enforcement activities;
  - A person for use in research not involving clinical use; or
  - A person for use in chemical analysis or physical testing or for purposes of instruction in law enforcement activities, research, or testing;
- No more than 30 percent of total annual prescription drug sales may be prescription drugs approved for human use;
- The person is not permitted or otherwise authorized in any state to wholesale prescription drugs approved for human use to any person who is authorized to sell, distribute, purchase, trade, or use these drugs on or for humans; and
- The person must maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance with laws of the state in which it is a resident.

A prescription drug wholesale distributor in another state is authorized to distribute, through an intracompany sale or transfer, prescription drugs to a limited prescription drug veterinary wholesaler in Florida without obtaining any type of permit in Florida.[18]

However, since no other state has created a license that authorizes a wholesale distributor to distribute human drugs for animal use only, a person located outside of Florida is not eligible to obtain a limited prescription drug veterinary wholesaler permit. The wholesale distributor would need to obtain an out-of-state prescription drug wholesaler permit. The benefit of this permit is a reduced bond requirement,[19] no requirement for a designated representative, and an exemption from providing a pedigree paper for the wholesale distribution of prescription drugs approved for human use to a veterinarian.

[16] Food and Drug Administration, Guidance for Industry, PDMA Requirements, Questions and Answers (November 2006), at http://www.fda.gov/cder/regulatory/PDMA/PDMA_qa.pdf (last visited on March 30, 2008).
[17] See ss. 499.003(31) and 499.0121(4), F.S.
[18] Section 499.012(2)(h)8., F.S.
[19] A limited prescription drug veterinary wholesaler must only obtain a $20,000 bond, rather than a $100,000 bond.

III. Effect of Proposed Changes:

Section 1. Amends s. 499.002, F.S., to consolidate into this section the following sections of law that have been redesignated as parts of s. 499.002, F.S.:

- Section 499.004, F.S., related to the department's administration and enforcement of part I of ch. 499, F.S.;
- Section 499.0053, F.S., related to the department's authority to investigate and conduct proceedings by taking depositions, issuing subpoenas, etc.;
- Section. 499.07, F.S., related to state, county, or municipal attorneys instituting criminal prosecutions for violations of part I of ch. 499, F.S.;
- Section 499.071, F.S., related to authorizing the department to enforce minor violations with a written notice or warning; and
- Section 499.081, F.S., related to exempting carriers engaged in interstate commerce from part I of ch. 499, F.S., if engaged in the usual course of business as a carrier.

Section 2. Amends s. 499.003, F.S., related to the definitions in part I of ch. 499, F.S. Revisions include transferring definitions from other sections of law within this part, adding new terms, and substituting the terms "legend drug" and "medicinal drug" with "prescription drug." The following definitions have substantive changes:

- "Authenticate" is modified to change when the authentication of a pedigree paper and the prescription drug must occur. Authentication must occur upon receipt of the prescription drug as opposed to before any distribution. The definition also specifies that a wholesale distributor is not required to open a sealed medical convenience kit to authenticate a pedigree paper for a prescription drug contained within the kit and that authentication of a prescription drug included in a sealed, medical convenience kit is limited to verifying the transactions and pedigree information received;
- "Diverted from the legal channels of distribution for prescription drugs" is deleted;
- "Manufacturer" is amended to include 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 that 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;
- "Normal distribution chain" is changed to mean a wholesale distribution of a prescription drug where the wholesale distributor or its wholly owned subsidiary purchases and 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, as defined in s. 465.003, F.S. For purposes of this subsection, "intracompany transfer" means any transaction or transfer between any parent,

division, or subsidiary wholly owned by a corporate entity. Currently only one intracompany transfer is authorized; and

- "Pedigree paper" is revised the reflect of transfer of substantive provisions to a new section of law related to pedigree papers, which is in section 15 of this committee substitute.

Section 3. Amends s. 499.005, F.S., related to prohibited acts. These are technical and grammatical revisions. Section 499.005(29), F.S., changes the timing for receiving a pedigree paper in the prohibited acts for which an administrative penalty may be imposed to authorize receipt of the pedigree paper simultaneously with receipt of the prescription drug.

Section 4. Amends s. 499.0051, F.S., related to criminal acts, to change the timing for receiving a pedigree paper to authorize receipt of the pedigree paper simultaneously with receipt of the prescription drug. Other existing criminal provisions are transferred into this section of law from: ss. 499.0052, 499.00535, 499.00545, 499.069, and 499.0691, F.S.

Section 5. Amends s. 499.0054, F.S., related to advertising and labeling of drugs, devices, and cosmetics, by transferring s. 499.0055, F.S., into this section of the bill. (See the comments in Related Issues)

Section 6. Amends s. 499.006, F.S., related to adulterated drugs or devices, to make conforming changes.

Section 7. Amends s. 499.007, F.S., related to misbranded drugs or devices, to provide that an active pharmaceutical ingredient in bulk form is misbranded if it does not bear a label containing the name and place of business of the manufacturer, repackager, or distributor; and an accurate statement of the quantity of the contents. Technical and conforming changes are also made.

Section 8. Amends s. 499.008, F.S., related to adulterated cosmetics, to make a technical change.

Section 9. Amends s. 499.009, F.S., related to misbranded cosmetics, to make technical and grammatical changes.

Section 10. Amends s. 499.01, F.S., to consolidate and describe all the permits available under part I of ch. 499, F.S., in one place. Language related to permitting and application requirements is deleted for transfer into s. 499.012, F.S. A glitch in the eligibility criteria for a limited prescription drug veterinary wholesale distributor permit is corrected. It changes the focus of the criteria from a person being permitted to distribute to providing that a person may not distribute.

Two new permit types are created, a third party logistic provider and a health care clinic establishment. A third party logistic provider permit is required for a person under contract with a prescription drug wholesale distributor or a prescription drug manufacturer to warehouse, distribute, or provide other logistics services without taking title to the prescription drugs. A third party logistics provider performing contractual services for a prescription drug manufacturer is exempt from the pedigree paper requirement, but must comply with all of the provisions required of a wholesale distributor, such as obtaining a surety bond or equivalent means of security, having a designated representative, and complying with the other storage, handling, and recordkeeping requirements.

A health care clinic establishment permit is created for a professional corporation, professional limited liability company, or a corporation that employs a veterinarian as a qualifying practitioner to purchase prescription drugs. A qualifying practitioner is defined as a licensed health care practitioner or a veterinarian who is authorized under the appropriate practice act to prescribe and administer a prescription drug. The qualifying practitioner assumes all responsibility for the prescription drugs acquired, and changes in the qualifying practitioner must be communicated to the department. In addition to other penalties that may be imposed, the qualifying practitioner may be disciplined by his or her regulatory board for violations of requirements related to the health care clinic establishment permit. The committee substitute specifies that this permit is not a pharmacy permit or otherwise subject to the Pharmacy Practice Act, and a health care clinic establishment that meets the criteria of a modified class II institutional pharmacy under the Pharmacy Practice Act is not eligible for this permit.

A non-resident prescription drug manufacturer is exempt from the permitting requirement if it is distributing a prescription drug active pharmaceutical ingredient (API) that it manufactures to an in-state permitted prescription drug manufacturer in limited quantities intended for research and development. The prescription drug manufacturer in Florida that is purchasing and receiving the API must maintain documentation of the seller's FDA registration number, resident-state permit, and a copy of the most current FDA inspection report, if available. The department is responsible for specifying in rule the allowable number of transactions within a given period of time and the amount of APIs that qualify under this exemption. Although not required to be permitted, the non-resident manufacturer must comply with the wholesale distributor's recordkeeping requirements, except for pedigree papers.

Section 11. Amends s. 499.012, F.S., to consolidate all permitting and application requirements. Certain provisions from s. 499.01, F.S., are transferred to this section. Definitions in this section of law are transferred to Section 4 of the bill. The bill exempts a temporary transit storage facility from obtaining a prescription drug wholesale distributor permit, if the sole purpose of the establishment is for storage, not to exceed 12 hours, of prescription drugs when the wholesale distributor is temporarily unable to complete the delivery to the recipient.

Section 12. Amends s. 499.01201, F.S., to make conforming changes.

Section 13. Amends s. 499.0121, F.S., to make conforming changes and delete the provisions related to pedigree papers because s. 499.01212, F.S., is created to address pedigree paper requirements.

Section 14. Amends s. 499.01211, F.S., to conform cross references and terms.

Section 15. Creates s. 499.01212, F.S., to consolidate the requirements related to pedigree papers. Each person who is engaged in the wholesale distribution of a prescription drug, subject to certain exceptions, must, prior to or simultaneous with each wholesale distribution, provide a pedigree paper to the person who receives the drug.

A pedigree paper for the wholesale distribution of a prescription drug within the normal distribution chain, the direct purchase pedigree, must contain the following:

- The statement, "This wholesale distributor purchased the specific unit of the prescription drug directly from the manufacturer";
- The name of the prescription drug as it appears on the label; and
- The quantity, dosage form, and strength of the prescription drug.

The wholesale distributor must also maintain and make available to the department, upon request:

- The point of origin of the prescription drugs, including intracompany transfers;
- The date of the shipment from the manufacturer to the wholesale distributor;
- The lot numbers of the drug; and
- The invoice numbers from the manufacturer.

A pedigree paper for the wholesale distribution of a prescription drug that does not qualify as being within the normal distribution chain must contain the following:

- The quantity, dosage form, and strength of the prescription drug;
- The lot numbers of the prescription drug;
- The name and address of each owner of the prescription drug and his or her signature;
- The shipping information, including the name and address of each person certifying delivery or receipt of the prescription drug;
- An invoice number, a shipping document number, or another number uniquely identifying the transaction;
- A certification that the recipient wholesale distributor authenticated the pedigree papers;
- The unique serialization of the prescription drug, if the manufacturer or repackager has uniquely serialized the individual prescription drug unit; and
- The names, address, telephone number and, if available, e-mail contact information of each wholesale distributor involved in the chain of the prescription drug's custody.

There are seven exceptions to the requirement for a pedigree paper for the wholesale distribution of a prescription drug. These include:

- The wholesale distribution of a prescription drug by the manufacturer or the third party logistics provider performing a wholesale distribution of a prescription drug for a manufacturer;
- The wholesale distribution of a prescription drug by a freight forwarder;
- The wholesale distribution of a prescription drug by a limited prescription drug veterinary wholesale distributor to a veterinarian;
- The wholesale distribution of a compressed medical gas;
- The wholesale distribution of a veterinary prescription drug;
- A drop shipment[20] if the following conditions are met:

[20] A drop shipment is defined as 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

- The wholesale distributor delivers to the recipient of the prescription drug, within 14 days after the shipment notification from the manufacturer, an invoice that cross-references the manufacturer's shipping document and this sworn 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, Florida Statutes, or a member of an affiliated group, with the exception of a repackager";
- The manufacturer shipped the prescription drug directly to the recipient and the manufacturer provides within 14 days after receipt of the prescription drug a shipping document that identifies: the manufacturer, including the point of origin of the shipment; the wholesaler; the purchaser; the quantity, dosage form, and strength of the prescription drug; and the date of the shipment;
- The wholesale distributor makes available to the department, upon request, the lot number of the prescription drug if the lot number is not included on the shipping document; and
- The wholesale distributor participating in the drop shipment is not a member of the affiliated group that receives the prescription drug directly from the manufacturer. (Refer to the comment under Related Issues.)

- The wholesale distribution of a prescription drug by a warehouse within an affiliated group to a warehouse or retail pharmacy within its affiliated group under certain conditions; and
- The repackaging of prescription drugs by a repackager solely for distribution to its affiliated group member for the exclusive distribution to and among retail pharmacies that are members of the affiliated group to which the repackager is a member

Section 16. Repeals s. 499.0122, F.S. related to medical oxygen and veterinary legend drug retail establishment, since these provisions are picked up in other sections of this committee substitute.

Section 17. Repeals s. 499.013, F.S., related to manufacturers and repackagers, since these provisions are addressed in other sections of the committee substitute.

Section 18. Amends s. 499.015, F.S., related to the registration of drugs, devices, and cosmetics, to make conforming changes.

Section 19. Amends s. 499.024, F.S., related to drug product classification, to make conforming changes.

Section 20. Amends s. 499.028, F.S., related to prescription drug samples, to make conforming changes.

Section 21. Amends s. 499.029, F.S., related to the Cancer Drug Donation Program, to make technical corrections.

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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.

Section 22. Amends s. 499.03, F.S., related to the possession of certain drugs, to make conforming changes.

Section 23. Amends s. 499.032, F.S., related to phenylalanine, to make conforming changes.

Section 24. Amends s. 499.33, F.S., related to ephedrine, to make conforming revisions.

Section 25. Amends s. 499.039, F.S., related to harmful chemical substances, to make conforming changes.

Section 26. Amends s. 499.04, F.S., related to fee authority, to make conforming changes.

Section 27. Amends s. 499.041, F.S., related to the range of fees, to make conforming changes.

Section 28. Amends s. 499.05, F.S., to consolidate rulemaking authority that was scattered throughout other sections of part I of ch. 499, F.S., and to make conforming changes.

Section 29. Amends s. 499.051, F.S., related to inspections and investigations, to make conforming changes.

Section 30. Amends s. 499.052, F.S., related to records in interstate shipment, to make conforming changes. (See the comment in Technical Deficiencies.)

Section 31. Amends s. 499.055, F.S., related to reports and the dissemination of information by the department, to make conforming changes.

Section 32. Amends s. 499.06, F.S., related to embargoing, detaining, or destroying violative items, to make conforming changes.

Section 33. Amends s. 499.062, F.S., related to the seizure and condemnation of drugs, devices, and cosmetics, to make conforming changes.

Section 34. Amends s. 499.065, F.S., related to inspections and imminent danger, to make conforming changes.

Section 35. Amends s. 499.066, F.S., related to penalties and remedies, to make conforming changes.

Section 36. Amends s. 499.0661, F.S., related to cease and desist orders, to make conforming changes.

Section 37. Amends s. 499.067, F.S., related to the denials, suspensions, and revocations, to make conforming changes.

Section 38. Amends s. 409.9201, F.S., related to Medicaid fraud, to revise the definition of "legend drug" to use the term "prescription drug" instead and conforms cross-references to changes in this committee substitute.

Section 39. Amends s. 460.403, F.S., related to definitions used in the regulation of the practice of chiropractic medicine, to conform cross-references to changes in this committee substitute.

Section 40. Amends s. 465.0265, F.S., related to centralized prescription filling, to conform a cross-reference to changes in this committee substitute.

Section 41. Amends s. 794.075, F.S., related to sexual predators; erectile dysfunction drugs, to conform a cross-reference to changes in this committee substitute.

Section 42. Amends s. 895.02, F.S., related to definitions for offenses concerning racketeering and illegal debts, to make conforming revisions.

Section 43. Amends s. 921.0022, F.S., to make conforming revisions and republish the criminal punishment code.

Section 44. Provides that this act shall take effect on July 1, 2008.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The bill addresses the continued problem of counterfeit and diverted drugs in Florida by consolidating the requirements related to pedigree papers.

C. Government Sector Impact:

The Department of Health has indicated two additional positions are needed to implement the provisions of this bill and biennial fee collections will be affected. The annual effect on the trust fund for four years will be ($123,102), ($133,326), ($114,326), and ($133,326). Also, the department has indicated that it cannot implement the bill by July 1, 2008, but will need approximately six months to adopt rules, develop and modify forms, train staff, and educate stakeholders and interest parties.

VI. Technical Deficiencies:

Section 30. The phrase "in the manner set out below" at lines 3710-3711, which is current law, is an unnecessary provision since a manner for making the request is not provided.

VII. Related Issues:

Section 5. Beginning on line 1126, existing language prohibits the advertisement of drugs or devices represented to have any effect on certain conditions, disorders, diseases, or processes. This law was written many years ago before the FDA and the FTC authorized direct-to-consumer advertising. Lines 1126-1161 should probably be deleted and replaced with a prohibition on advertising any drug or device in violation of federal law. If this is done, the entire section needs to be reviewed because these are some other cross-references that need to be amended also.

Section 10. There is a dual permitting requirement, which is probably unintended. The third party logistics provider permit is required for a contract distributor for a prescription drug manufacturer. The non-resident prescription drug manufacturer permit is required for a manufacturer of prescription drugs. The definition of manufacturer includes a contract distributor, or the distribution point for a manufacturer of prescription drugs.

Section 15. The bill eliminates the requirement that the direct purchase pedigree paper be provided under oath (which is the requirement in current law). Since the direct purchase pedigree is not required to be issued under oath or certified, criminal prosecutions for falsely creating or falsely representing a factual matter contained on the pedigree paper may be more difficult. The other pedigree paper does not require that the name of the prescription drug or other identifying appear on the pedigree paper.

Section 15. The exemption for the freight forwarder is very broad. The Legislature may wish to limit it to a freight forwarder acting within the authorization granted under a freight forwarder permit.

VIII. Additional Information:

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

CS/CS by Judiciary on April 21, 2008:
The committee substitute makes the following changes to the prior version of the bill:

- Amends the definition of "authenticate" to provide that a wholesale distributor is not required to open a sealed, medical convenience kit to authenticate a pedigree paper for a prescription drug contained in the kit and authentication of a prescription drug included in a sealed, medical convenience kit shall be limited to verifying the transaction and pedigree information received;
- Adds a third party logistic provider and health care clinic establishment to the list of persons and establishments that must obtain a permit prior to operating from the Department of Health;
- Exempts a nonresident prescription drug manufacturer from having a permit if it is distributing a prescription drug active pharmaceutical ingredient that it manufactures to an in-state permitted prescription drug manufacturer in limited quantities intended for research and development. Clarifies that manufacturers claiming this exemption must comply with the recordkeeping requirements of s. 499.0121(6), F.S., but not the requirements of s. 499.01212, F.S.;
- Describes when a "third party logistics provider permit" and a "health care clinic establishment permit" are required;
- Provides that the fee for a third party logistics provider permit and a health care clinic establishment permit may not be less than $200 or more than $300 and $125 or more than $250 annually, respectively;
- A health care clinic establishment permit must be a corporation owned by professionals or a corporation that employs a veterinarian as a qualifying practitioner. The health care clinic establishment is prohibited from purchasing prescription drugs if a qualifying practitioner is not employed; and

CS by Health Regulation on April 1, 2008:
Deletes the definition of "authorized recipient," "co-licensed product," and "intracompany transfer."

Modifies the definition of:

- "Authenticate" to change when the authentication of a pedigree paper and the prescription drug must occur. Authentication must occur upon receipt of the prescription drug as opposed to before any distribution. The definition also specifies that a wholesale distributor is not required to open a sealed medical convenience kit to authenticate a pedigree paper for a prescription drug contained within the kit;
- "Distribute" or "distribution" to reinstate the definition to current law;
- "Manufacturer" to include language that is currently in rule and delete language that was added in the bill as originally filed;
- "Normal distribution chain" as follows:
- "Normal distribution chain" means a wholesale distribution of a prescription drug where the wholesale distributor or its wholly owned subsidiary purchases and 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, as defined in s. 465.003, F.S. For purposes of this subsection, "intracompany transfer" means

any transaction or transfer between any parent, division, or subsidiary wholly owned by a corporate entity; and
- "Wholesale distribution" to reinstate the definition to the current law.

A new definition is provided for "person authorized by law" to "purchase," "possess," "administer" or "receive" prescription or legend drug.

The administrative and criminal prohibitions change the timing for receiving a pedigree paper, to authorize receipt of the pedigree paper simultaneously with receipt of the prescription drug.

On the direct purchase pedigree, the committee substitute eliminates the:

- Requirement that it be provided under oath (which is the requirement in current law);
- Authorization for the direct purchase pedigree statement to be on the invoice;
- Requirement for the manufacturer's national drug code identifier; and
- Requirement for the name and address of the wholesale distributor and the purchaser of the prescription drug.

Additional sections of the Florida Statutes are added to conform statutory cross-references. These are s. 460.403, F.S., and s. 794.075, F.S.

B. Amendments:

None.