SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

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

BILL: CS/CS/SB 2312

SPONSOR: Appropriations Subcommittee on Health and Human Services; Health, Aging, and Long-Term Care Committee and Senator Peaden

SUBJECT: Distribution of Prescription Drugs/Wholesalers

DATE: April 15, 2003 REVISED: _____ _____ _____ _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HC	Fav/CS
2.	Peters	Belcher	AHS	Fav/CS
3.			AP	Withdrawn: Fav/CS
4.				
5.				
6.				

I. Summary:

The bill revises the Florida Drug and Cosmetic Act to impose more stringent regulations on prescription drug wholesalers. The bill creates criminal offenses relating to illicit activities involving diversion from the wholesale distribution of prescription drugs. Additional prohibitions are created regarding label tampering with the intent to distribute a drug and the distribution of a drug previously dispensed by a Florida-licensed pharmacy. Effective January 1, 2004, the permitting requirements for drug wholesalers are overhauled to require extensive information upon application for a permit, including a criminal history background check, and to require that permits expire annually rather than biennially.

Reciprocity for out-of-state drug wholesalers who are already licensed in another jurisdiction is eliminated and such establishments must seek a Florida permit. The bill distinguishes "primary drug wholesalers" from "secondary drug wholesalers". The bill specifies factors that the Department of Health must consider in reviewing the qualifications of persons seeking a permit to engage in prescription drug wholesale activities in Florida. The department is authorized to adopt rules for the annual renewal of permits for prescription drug wholesalers.

The recordkeeping requirements for prescription drug wholesalers are revised for a wholesaler that is an authorized distributor of record (ADR) of a drug manufacturer. Each person who is engaged in wholesale drug distribution and who is not an ADR must provide to each wholesale drug distributor of such drug, before the sale is made, a written statement under oath *identifying each previous sale of the drug back to the last ADR*, the lot number of the drug, and the sales invoice number of the invoice evidencing the sale of the drug. The written statement must accompany the drug to the next wholesale drug distributor and *no longer needs to identify all sales of such drug* in the "pedigree papers."

Effective March 1, 2004, an ongoing relationship is defined to exist between a manufacturer and a wholesaler when:

- the wholesaler is on the manufacturer's list of ADRs; or
- the wholesaler buys at least 90 percent of all of the manufacturer's products handled by the wholesaler directly from the manufacturer and has total annual prescription drug sales of $100 million or more; or
- if the wholesaler has a verified account issued to the wholesaler by the manufacturer and makes twelve purchases from the manufacturer using the account and the wholesaler has more than $100 million in total annual prescription drug sales. The bill limits the definition of an authorized distributor to those wholesalers who have a verified account with a manufacturer, if the manufacturer fails to provide the department with a list of authorized distributors. The requirement for an ongoing relationship expires July 1, 2006.

Until July 1, 2006 wholesale prescription drug distributors of "specified drugs" must identify sales as required by the bill.

Each person who is engaged in the wholesale distribution of a "specified drug" (high-risk prescription drug) must provide to each wholesale drug distributor of such drug, before any sale of such high-risk drug is made to such wholesale distributor, a written statement under oath identifying each previous sale of the specified drug back to the manufacturer, the lot number of the high-risk prescription drug, and the sales invoice number of the invoice evidencing each previous sale of the high-risk prescription drug. The written statement must accompany the high-risk prescription drug at each subsequent wholesale distribution to a wholesale distributor. "High-risk prescription drug" is a specific drug on the list of drugs adopted by the department by rule, each of which is a specific drug seized by the department on at least five separate occasions because such drug was adulterated, counterfeited, or diverted from legal prescription drug distribution channels and the department has begun an administrative action to revoke the permits of two or more wholesale distributors that engaged in the illegal distribution of that specific drug.

Each wholesale distributor, must annually provide the department with a written list of all prescription drug wholesalers and out-of-state prescription drug wholesalers from whom the wholesale distributor purchases drugs. The term, "authorized distributor of record" is revised to mean those distributors with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's products, without regard to the whether the wholesale distributor acquired the products directly from the manufacturer. A wholesale distributor may not pay for any drug with cash.

The bill creates an eleven-member Drug Wholesaler Advisory Council within the Department of Health. The council must annually review rules adopted to enforce the Florida Drug and Cosmetic Act, provide input to the department, and make recommendations regarding all proposed rules and matters to improve coordination with other state regulatory agencies and the Federal government.

The bill increases the statutory fee caps: for a prescription manufacturer's permit from $600 to $750 annually; for a prescription drug wholesaler's permit from $400 to $800 annually; and for

an out-of-state prescription drug wholesaler's permit no less than $300 ($200) and no greater than $800 ($300) annually.
The Department of Health is authorized to inspect and copy financial documents or records related to the distribution of a drug in order to determine compliance with the Florida Drug and Cosmetic Act. A new cease and desist enforcement remedy is established, and the bill authorizes procedures for the department to issue an order to remove key personnel of a prescription drug wholesaler if she or he is engaged in specified prohibited acts.

The enforcement authority of the Statewide Grand Jury and the Office of the Statewide Prosecutor is expanded to investigate and prosecute criminal violations of the Florida Drug and Cosmetic Act. The criminal offenses relating to violations of the act which involve contraband or adulterated drugs may be prosecuted as racketeering. The Criminal Punishment Code is revised to include certain violations under the Florida Drug and Cosmetic Act.

This bill amends sections 499.003, 499.005, 499.006, 499.007, 499.01, 499.012, 499.0121, 499.013, 499.014, 499.041, 499.051, 499.055, 499.066, 499.067, 499.069, 921.0022, 16.56, 895.02, and 905.34, Florida Statutes.

This bill creates four undesignated sections and ss. 499.0051, 499.0052, 499.0053, 499.0054, 499.01211, 499.065, 499.0661, and 499.0691, F.S.

II. Present Situation:

OPPAGA Report No. 03-18

In February, 2003, the Office of Program Policy Analysis and Government Accountability issued Report No. 03-18 which highlights the problems with counterfeit and diverted drugs in Florida. The findings of the report indicate 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 drug cases involving counterfeit and diverted drugs in Florida's prescription drug industry. The report concludes that current Florida law does not provide adequate controls over wholesale drug market practices, and current administrative and criminal penalties fail to provide an adequate deterrent. The report recommends that the Legislature:

- Clarify state law requiring drug pedigree papers to track drugs back to manufacturers and direct the Department of Health to enforce provisions of Florida law;
- Strengthen the drug wholesale permitting process; and
- Increase administrative and criminal penalties for prescription drug violations.

Seventeenth Statewide Grand Jury

The Governor petitioned the Florida Supreme Court to impanel a grand jury to examine issues relating to the sale and resale of counterfeit drugs in the wholesale market in Florida. On February 27, 2003, the Seventeenth Statewide Grand Jury released a report that examined the sale and resale of counterfeit prescriptions drugs in the pharmaceutical wholesale market in Florida. The grand jury made the following recommendations to the Legislature:

- Mandate that DOH [Department of Health] create a standardized form for pedigree papers to be used in all transactions.
- Require that pedigree papers, at a minimum, contain amounts, dosage form, strength, and lot numbers of all drugs; name and address of each owner of the drug; shipping information; a signature and license number of the person certifying delivery or receipt of drugs; date of each transaction; phone number or e-mail contact of each wholesaler; signature certifying that the pedigree paper was verified.
- Require that pedigree papers be provided in sales transactions all the way from the manufacturer to the dispenser.
- Classify repackagers as wholesalers and require original manufacturer's lot number to be retained on new packaging.
- Require that wholesalers, repackagers and dispensers perform due diligence by verifying contents of pedigree papers, making it a third degree felony for failing to do so or for falsely swearing that they have done so.
- Grant DOH the authority to immediately shut down a permitted establishment operating in violation of 64F-12.013 and to keep an establishment closed until DOH is satisfied that the deficiencies have been corrected.
- Grant DOH the authority to immediately seize and destroy drugs which pose a danger to public health due to improper storage or adulteration wherever found.
- Increase the penalty for failure to provide pedigree papers to a third degree felony.
- Increase the penalty for forging pedigree papers to a second degree felony.
- Increase the penalty for knowingly purchasing from or selling to an unlicensed person or entity, to a second degree felony.
- Increase the penalty for forging a prescription label to a first degree felony.
- Create the offense of trafficking in adulterated prescription drugs, making it a first degree felony.
- Penalize the sale of adulterated drugs worth less than $1,000, making it a third degree felony.
- Penalize the manufacture, sale, delivery or distribution of an adulterated drug which results in great bodily harm as a result of ingesting that drug, as a first degree felony punishable by life in prison.
- Penalize the manufacture, sale, delivery, or distribution of an adulterated drug which results in the death of a person as a result of ingesting that drug, as a capital offense.
- Add these crimes to the list of racketeering predicates in section 895.02, F.S.
- We have reviewed the recommendations of the AD HOC Committee on Pedigree Papers and are in agreement with some of what they have to say. Specifically, we endorse the following recommendations:

    1. Require a $100,000 performance bond to be posted by wholesalers with DOH.
    2. Require a person in the wholesaler's business to be the designated representative responsible for all pharmaceutical receiving, shipping and warehousing activity, require that person to pass an examination of PDMA and Florida pharmaceutical wholesaling laws and rules, require that person to be employed full time and to be present during business hours.
    3. Require wholesalers to carry $2,000,000 in liability insurance.

The grand jury's recommendations to the Department of Health included:

- Deny licenses to applicants convicted of felonies or crimes involving moral turpitude.
- Prohibit licenses to be issued to out of state wholesalers that do not meet requirements of Rule 64F-012.013, F.A.C.
- Inspect out of state facilities and increase out of state license fees to cover the cost of inspections.
- Change the permit application to require disclosures of all convictions, including those that have been sealed.
- Require fingerprints and a national criminal background check on all applicants and designated representatives.
- Reduce the wholesale licensing period to one year.
- Increase the number of field inspectors statewide, increasing the amount of fees, if necessary, to pay for the inspectors.
- Promulgate a rule defining what DOH considers to be adequate facilities for pharmaceutical wholesalers.
- Strictly enforce the requirements of Rules 64F-12.012 and 64F-12.013, F.A.C.
- Impose fines daily for rules violations until the deficiency is corrected.
- Require licensees to secure and retain receipts for all cash transactions of pharmaceuticals.
- Strictly enforce section 499.0121(6)(d), F.S., as written including promulgating all rules necessary.
- Clarify the definition and responsibility of an authorized distributor of record.
- Track the proposed federal rule by requiring pedigree papers to be provided all the way to dispensers.
- Require all licensed wholesalers to have on-line access for verification of pedigree papers.
- Post names and business addresses of all current pharmaceutical wholesale licensees on the Department of Health website.
- Promulgate rules to allow for the waivers of pedigree papers during public emergencies.
- Promulgate rules to require wholesale licensees to report all instances of fraud, patterned after section 626.989(6), F.S., of the Florida Insurance Code.

The grand jury made the following recommendations to the wholesale prescription drug industry:

- Require pedigree papers from all vendors tracing the pharmaceuticals to the manufacturer whether or not required by law.
- Perform due diligence by authenticating all pedigree papers whether or not required by law.
- Refuse to do business with any wholesaler that does not provide a pedigree paper.
- Report all suspected fraud to DOH or law enforcement.

The grand jury made the following recommendations to pharmaceutical manufacturers:

- Improve anti-counterfeiting measures for labels and packaging.

- Provide complete access to all wholesalers and dispensers attempting to authenticate pedigree papers or products.

Florida Drug and Cosmetic Act

Pursuant to the Florida Drug and Cosmetic Act, pt. I, ch. 499, F.S., the Department of Health 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. Wholesalers, manufacturers, and distributors of drugs or devices must be permitted or otherwise exempt.[1]

Under the Florida Drug and Cosmetic Act (or the Act), any person who is at least 18 years of age or older and who can pay the permit fee, and after submission of specified information that all permit applicants must provide, with certain exceptions, may obtain a permit as a prescription drug wholesaler.[2] The applicant must not have been found guilty, regardless of adjudication, of a violation of a law that directly relates to a drug, device, or cosmetic. The applicant must submit information on contact persons for each facility used by the applicant for the storage, handling, and distribution of prescription drugs. The permit, once granted, may be renewed biennially.

An out-of-state prescription drug wholesaler is a wholesale distributor located outside Florida and which must be permitted by the Department of Health. The department is authorized to adopt rules that allow out-of-state drug wholesalers to obtain a drug wholesale permit on the basis of reciprocity in Florida to the extent that an out-of-state drug wholesaler possesses a valid permit from another state that has requirements that are comparable to those of Florida and can show that the other state from which the wholesaler holds a permit would extend reciprocal treatment under its laws to a Florida-permitted drug wholesaler. According to the Department of Health there are approximately 450 prescription drug wholesalers located in Florida and 900 out-of-state wholesalers, of which less than ten percent are one of the three large full-line wholesalers or their distribution centers, or are major full-line regional wholesalers. The remainder are secondary wholesalers that primarily buy and sell among other prescription drug wholesalers rather than to end-users such as hospitals or other health care entities, including physicians or pharmacies.

The Act specifies criminal penalties for violations relating to activities regulated by the department under the Act. Such criminal offenses are, with few exceptions, punishable as a second-degree misdemeanor (a maximum fine of $500 or 60 days in jail or both) or first degree misdemeanor (a maximum fine of $1,000 or 1 year imprisonment) if it is a second conviction for a violation of the Act.

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[1] Drug marketing is also subject to regulation under the Federal Prescription Drug Marketing Act of 1987 which establishes minimum standards for the prescription drug industry that include requirements for an audit trail of sales transactions.

[2] See ss. 499.01 and 499.012, F.S. The permitting requirements for a number of establishments licensed or permitted by the Department of Health to engage in activities regulated under the Florida Drug and Cosmetic Act are the same. Such establishments include: prescription drug manufacturer; over-the-counter drug manufacturer; compressed medical gas manufacturer; device manufacturer; cosmetic manufacturer; prescription drug wholesaler; compressed medical gas wholesaler; out-of-state prescription drug wholesaler; retail pharmacy drug wholesaler; veterinary legend drug retail establishment; medical oxygen retail establishment; complimentary drug distributor; or restricted prescription drug distributor.

In the drug wholesale market, the department has uncovered prescription drugs that have been sold or held for sale outside of permitted establishments. Within this market the department has found some of the manufacturer labeled drugs to be counterfeit, some of the actual medicine at less strength than indicated on the label and some of which has been saline.

The Act requires prescription drug wholesalers to maintain records that provide a complete audit trail of prescription drugs from purchase to sale or other disposition. Such records known as "pedigree papers" must include a written statement of all previous sales of the drug that is being sold in a wholesale market. Section 499.012(6)(d), F.S., requiring the pedigree papers, contains internal inconsistencies that have presented obstacles to its implementation according to the Department of Health. Section 499.012(6)(d), F.S., reads:

> (d)1. Each person who is engaged in the wholesale distribution of a prescription drug, and who is not an authorized distributor of record of such drug, must provide to each wholesale distributor of such drug, before the sale is made to such wholesale distributor, a written statement identifying each previous sale of the drug. The written statement identifying all sales of such drug must accompany the drug for each subsequent wholesale distribution of the drug to a wholesale distributor. The department shall adopt rules relating to the requirements of this written statement.
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> 2. Each wholesale distributor of prescription drugs must maintain separate and distinct from other required records all statements that are required under subparagraph 1.
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> 3. Each manufacturer of a prescription drug sold in this state must maintain at its corporate offices a current list of authorized distributors and must make such list available to the department upon request.

For the purposes of this subsection, the term "authorized distributors of record" means those distributors with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's products.[3]

The inconsistencies include an exception for a manufacturer's authorized distributor, while providing that, once created, the pedigree must accompany without exception each subsequent distribution of the drug to a wholesale distributor. The Department of Health has adopted an administrative rule which requires pedigree papers to include either the proprietary name or the generic name with the name of the manufacturer or distributor reflected on the label of the product, dosage form, strength, container size, quantity by lot number, the name and address of each owner of the prescription drug, the name and address of each location from which it was shipped if different from the owner's and the transaction dates.[4] Pursuant to the rule, a copy of the "pedigree paper" must be maintained by each recipient.[5] Furthermore, the term authorized distributor is defined with reference to the manufacturer's entire drug product line, whereas the

[3] The federal law defines authorized distributor of record (ADR) as a wholesaler who routinely purchases prescription drugs directly from manufacturers. It exempts an ADR wholesaler from providing pedigree papers when it sells drugs purchased from the manufacturer to another wholesaler.

[4] See Rule 64F-12.012, Florida Administrative Code

[5] The inconsistencies of the "pedigree requirements" have hampered implementation by the Department of Health. See also, a November, 2001 memorandum issued by the Dept. of Health regarding the pedigree paper requirements.

pedigree paper appears to be related to the specific unit of a drug subject to wholesale distribution.

III. Effect of Proposed Changes:

Section 1. Cites the act as the Prescription Drug Protection Act.

Section 2. Creates an undesignated section of law to provide legislative findings and intent regarding the Seventeenth Statewide Grand Jury's report on dangers and abuses due to illicit activity in the wholesale prescription drug industry. The grand jury found that the "lack of an effective pedigree paper requirement has resulted in the inability of prescription drug users to have confidence in the purity and efficacy of the drugs they use." Legislative intent is expressed that statutory changes and recommendations outlined in the Statewide Grand Jury's report be implemented.

Section 3. Amends s. 499.003, F.S., to define "affiliated party" to mean:

- A director, officer, trustee, partner, or committee member of a permitted establishment or an applicant or a subsidiary or service corporation of the permitted establishment or applicant;
- A person who, directly or indirectly, manages, controls, or oversees, the operation of a permitted establishment or applicant, regardless of whether such person is a partner, shareholder, manager, member, officer, director, independent contractor, or employee of the permitted establishment or applicant;
- A person who has filed or is required to file a personal information statement or is required to be identified in an application for a permit or to renew a permit as a wholesaler, manufacturer, or distributor of drugs, devices, or cosmetics; or
- The five largest natural shareholders that own at least 5 percent of the permitted establishment or applicant.

"Applicant" is defined to mean a person applying for a permit or certification as an establishment required under ss. 499.001-499.081, F.S., for wholesalers, manufacturers, and distributors of drugs, devices, and cosmetics.

"Authenticate" is defined to mean to affirmatively verify before any distribution of a legend drug occurs that each transaction listed on the pedigree paper has occurred.

"Contraband legend drug" is defined to mean any adulterated drug as defined in s. 499.006, F.S., any counterfeit drug, as defined in this section, and also means any legend drug for which a pedigree paper does not exist, or for which the pedigree paper in existence has been forged, counterfeited, falsely created, or contains any altered, false, or misrepresented matter.

"Diverted from the legal channels of distribution for prescription drugs" is defined to mean an adulterated drug pursuant to s. 499.006(10), F.S. Section 499.006(10), F.S., provides that a drug is adulterated if the drug is a legend drug for which the required pedigree paper is nonexistent, fraudulent, or incomplete under the requirements of the Florida Drug and Cosmetic Act or applicable rules, or that has been purchased, held, sold, or distributed at any time by a person not authorized under federal or state law to do so.

"Freight forwarder" is defined to mean a person who receives legend drugs which are owned by another person and designated by that person for export, and exports those legend drugs.

"Legend drug label" is defined to mean any display of written, printed, or graphic matter upon the immediate container of any legend drug prior to its dispensing to an individual patient pursuant to a prescription of a practitioner authorized by law to prescribe.

The definition of "manufacture" is revised to no longer include repackaging or otherwise changing the container, wrapper, or labeling to further the distribution of the drug, device, or cosmetic.

"Pedigree paper" is defined to mean a document required pursuant to s. 499.0121(6)(d) or (e), F.S., or effective July 1, 2006, a document in a form approved by the Department of Health and containing information that records each distribution of any given legend 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 information required to be included on a legend drug's pedigree paper must at least detail: the amount of the legend drug; its dosage form and strength; its lot numbers; the name and address of each owner of the legend drug and his or her signature; its shipping information, including the name and address of each person certifying delivery or receipt of the legend drug; and a certification that the recipient has authenticated the pedigree papers. It must also include the name, address, telephone number and, if available, the e-mail contact information of each wholesaler involved in the chain of the legend drug's custody. The Department of Health must adopt rules and a form relating to the requirements no later than 90 days after the effective date of this act.

"Prescription label" is defined to mean any display of written, printed, or graphic matter upon the immediate container of any legend drug dispensed pursuant to a prescription of a practitioner authorized by law to prescribe.

"Repackage" is defined to include repacking or otherwise changing the container, wrapper, or labeling to further the distribution of the drug, device, or cosmetic.

"Repackager" is defined to mean a person who repackages. The term excludes pharmacies that are operating in compliance with pharmacy practice standards as defined in ch. 465, F.S., relating to pharmacy and rules adopted thereunder.

Section 4. Amends s. 499.005, F.S., relating to prohibited acts, to revise or add additional acts which will make it unlawful for any person to:

- Purchase or sell prescription drugs for wholesale distribution in exchange for cash (deleting language which prohibited giving a false guaranty or false undertaking with respect to a drug, device, or cosmetic);
- Purchase or receive a legend drug from a person that is not authorized under ch. 499, F.S., to distribute drugs to the purchaser or recipient;

- Sell or transfer a legend drug to a person that is not authorized under the law of the jurisdiction in which the person receives the drug to purchase or possess legend drugs from the person selling or transferring the legend drug;
- Remove a pharmacy's dispensing label from a dispensed prescription drug with the intent to further distribute the prescription drug;
- Distribute a prescription drug that was previously dispensed by a licensed pharmacy, unless such distribution was authorized in ch. 465, F.S., or the rules adopted under ch. 465, F.S.;
- Fail to obtain or pass on a pedigree paper; and
- Receive a prescription drug under a wholesale distribution without first receiving a pedigree paper that was attested to as accurate and complete by the wholesale distributor.

Section 5. Creates s. 499.0051, F.S., relating to criminal acts involving contraband or adulterated drugs, to create criminal offenses relating to failure to maintain or deliver pedigree papers. A person, other than a manufacturer, engaged in the wholesale distribution of legend drugs who fails to deliver to another person complete and accurate pedigree papers concerning a legend drug or contraband legend drug prior to transferring the legend drug or contraband legend drug to another person commits a third degree felony punishable by imprisonment of up to 5 years and a $5,000 fine. A person engaged in the wholesale distribution of legend drugs who fails to acquire complete and accurate papers concerning a legend drug or contraband legend drug prior to obtaining the legend drug from another person commits a third degree felony punishable by imprisonment of up to 5 years and a $5,000 fine. Any person who knowingly destroys, alters, conceals, or fails to maintain complete and accurate pedigree papers concerning any legend drug or contraband legend drug in his or her possession commits a third degree felony punishable by imprisonment of up to 5 years and a $5,000 fine.

Until July 1, 2006, the bill creates a criminal offense punishable as a third degree felony for:

- A person engaged in the wholesale distribution of legend drugs who is in possession of documents required under s. 499.0121(6)(e), F.S., and who fails to authenticate the matters contained in the documents and who nevertheless attempts to further distribute legend drugs or contraband legend drugs; or

- A person in possession of documents required under s. 499.0121(6)(e), F.S., who falsely swears or certifies that he or she has authenticated the matters contained in the documents.

Effective July 1, 2006, to conform to changes in law requiring pedigree papers, the bill creates criminal offenses punishable as a third degree felony for:

- A person engaged in the wholesale distribution of legend drugs who is in possession of pedigree papers, and who fails to authenticate the matters contained in the documents and who nevertheless attempts to further distribute legend drugs or contraband legend drugs; or

- A person in possession of pedigree papers, who falsely swears or certifies that he or she has authenticated the matters contained in the pedigree papers.

The bill creates second degree felony criminal offenses which are punishable by jail up to 15 years and a fine of up to $10,000 for:

- A person who knowingly forges, counterfeits, or falsely creates any pedigree paper, who falsely represents any factual matter contained on a pedigree paper, or who knowingly omits to record material information required to be recorded in a pedigree paper;

- A person who knowingly purchases or receives from a person not authorized to distribute legend drugs under ch. 499, F.S., a legend drug in a wholesale distribution transaction;

- A person who knowingly sells or transfers to a person not authorized to purchase or possess legend drugs, under the law of the jurisdiction in which the person receives the drug, a legend drug in a wholesale distribution transaction; or

- A person who is knowingly in actual or constructive possession of any amount of contraband legend drugs, who knowingly sells or delivers, or who possess with intent to sell or deliver, any amount of contraband legend drugs.

The bill creates a first degree felony criminal offense punishable by imprisonment up to 30 years and a fine up to $10,000 for any person who knowingly forges, counterfeits, or falsely creates any prescription label or legend drug label, or who falsely represents any factual matter contained on any prescription label or legend drug label.

Section 6. Creates s. 499.0052, F.S., to create a criminal offense for trafficking in contraband legend drugs which is punishable as a first degree felony (imprisonment up to 30 years and a fine up to $10,000) for:

- A person who knowingly sells, purchases, manufactures, delivers, or brings into Florida, or who is knowingly in actual or constructive possession of any amount of contraband legend drugs valued at $25,000 or more. “Value” means the market value of the property at the time and place of the offense, or if such cannot be satisfactorily ascertained, the cost of replacement of the property within a reasonable time after the offense. Amounts of value of separate contraband legend drugs involved in distinct transactions pursuant to one scheme or course of conduct may be aggregated in determining the punishment of the offense. Upon conviction, each defendant shall be ordered to pay a mandatory fine according to a schedule specified in the bill.

Section 7. Creates s. 499.0053, F.S., to create a criminal offense for the sale or purchase of contraband legend drugs resulting in great bodily harm which is punishable as a first degree felony (imprisonment up to 30 years and a fine up to $10,000) for:

- A person who knowingly sells, purchases, manufactures, delivers, or brings into Florida, or who is knowingly in actual or constructive possession of any amount of contraband

legend drugs and whose acts in violation of this section result in great bodily harm to a person.

Section 8. Creates s. 499.0054, F.S., to create a criminal offense for the sale or purchase of contraband legend drugs resulting in death of a person which is punishable as a first degree felony (imprisonment up to 30 years and a fine up to $10,000) for:

- A person who knowingly sells, purchases, manufactures, delivers, or brings into Florida, or who is knowingly in actual or constructive possession of any amount of contraband legend drugs and whose acts in violation of this section result in the death of a person.

Section 9. Amends s. 499.006, F.S., relating to adulterated drugs or devices, to provide that a drug or device is adulterated if it is a legend drug for which the required pedigree paper is nonexistent, fraudulent, or incomplete under the requirements of ch. 499, F.S., or applicable rules, or that has been purchased, held, sold, or distributed at any time by a person not authorized under federal or state law to do so.

Section 10. Amends s. 499.007, F.S., relating to misbranded drugs or devices, to revise requirements for a drug or device to not be considered "misbranded" to additionally require the name and place of business of the repackager to be on the label of the drug in the finished dosage form of the drug. Currently, only the name and place of business of the manufacturer or distributor is required to be on the label of the finished dosage form of the drug. The bill deletes language requiring labels of medicinal drugs to contain the name and place of business of the manufacturer.

Section 11. Amends s. 499.01, F.S., relating to the permitting requirements for wholesalers, manufacturers, and distributors of drugs, devices, and cosmetics, to authorize the Department of Health to issue permits only to a natural person who is at least 18 years of age or to an applicant that is not a natural person if each person who, directly or indirectly, manages, controls, or oversees the operation of that applicant is at least 18 years of age.

A permit for a prescription drug manufacturer, prescription drug wholesaler, or retail pharmacy drug wholesaler may not be issued to a Florida-licensed pharmacy, except as provided in this section. The Department of Health may issue a prescription drug manufacturer permit to an applicant at the same address as a licensed nuclear pharmacy, which is a health care entity, for the purpose of manufacturing prescription drugs used in positron emission tomography or other radiopharmaceuticals, as listed in a rule adopted by the department pursuant to this section. The purpose of the exemption is to assure availability of state-of-the-art pharmaceuticals that would pose a significant danger to the public health if manufactured at a separate establishment address from the nuclear pharmacy from which the prescription drugs are dispensed. The department may also issue a retail pharmacy wholesaler permit to the address of a Florida-licensed community pharmacy which does not meet the definition of a closed pharmacy in s. 499.003, F.S.

A county or municipality is prohibited from issuing an occupational license for any licensing period beginning on or after October 1, 2003, for any establishment that requires a permit pursuant to the Florida Drug and Cosmetic Act, unless the establishment exhibits a current

permit issued by the Department of Health for the establishment. The department must furnish to local agencies responsible for issuing occupational licenses a current list of all establishments licensed under the Act.

A new permit expires on the expiration date of the original permit being changed, however, a new permit for a prescription drug wholesaler and out-of-state prescription drug wholesaler must expire on the expiration date of the original permit or 1 year after the date of issuance of the new permit, whichever is earlier. Permits expire and are subject to annual renewal rather than biennial renewal.

The bill provides that a new permit for a prescription drug wholesaler and out-of-state prescription drug wholesaler issued from July 1, 2003 through December 31, 2003, must expire 1 year after the last day of the anniversary month in which the permit was issued. Any valid prescription drug wholesaler or out-of-state prescription drug permit issued by the department on or before June 30, 2003, with an expiration date between January 1, 2005, and June 30, 2005, must automatically expire 1 year prior to the expiration date stated on the permit. A permittee that submits a renewal application for a permit with a state expiration date between January 1, 2005, and June 30, 2005, shall receive a credit of one-half of the permit fee paid when the application for the expiring permit was submitted. Any valid prescription drug wholesaler or out-of-state prescription drug permit issued by the department on or before June 30, 2003, with an expiration date between July 1, 2004, and December 31, 2004, must automatically expire 6 months prior to the expiration date stated on the permit. A permittee that submits a renewal application for a permit with a stated expiration date between July 1, 2004, and December 31, 2004, shall receive a credit of one-fourth of the permit fee paid when the application for the expiring permit was submitted. Permittees whose permit expiration date was accelerated may request a pro rata refund equivalent to the credit available for submission of a renewal application if the permittee does not submit a renewal application.

Section 12. Effective January 1, 2004, amends s. 499.01, F.S., as amended by this act, to reorganize the permitting provisions for the following entities: prescription drug manufacturer; over-the-counter drug manufacturer; compressed medical gas manufacturer; device manufacturer; cosmetic manufacturer; prescription drug wholesaler; compressed medical gas wholesaler; out-of-state prescription drug wholesaler; retail pharmacy drug wholesaler; veterinary legend drug retail establishment; medical oxygen retail establishment; complimentary drug distributor; or restricted prescription drug distributor. Any person intending to operate such establishments must obtain a permit, prior to operating that establishment.

In addition, permits will be required for prescription drug repackagers, nonresident prescription drug manufacturers, and freight forwarders.

The bill makes exceptions for the permitting requirements for prescription drug wholesalers to conform to changes in the bill that revise s. 499.012, F.S., with the licensing requirements for prescription drug wholesalers. Section 499.012, F.S., is revised to provide permitting requirements that are unique to permits for: a prescription drug wholesaler or out-of-state prescription drug wholesaler. A written application for a permit or to renew a permit must be filed with the Department of Health on forms furnished by the department. Information specified

in the section must be included for any applicant for an establishment other than for a permit for prescription drug wholesalers or out-of-state prescription drug wholesalers.

Section 13. Amends s. 499.012, F.S., to provide an exemption to the requirements for a permit to operate as a prescription drug wholesaler for the transfer of a prescription drug by a hospital or other health care entity to a person licensed under ch. 499, F.S., as a "repackager" of prescription drugs for the purpose of repackaging the prescription drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the prescription drug remains with the hospital or other health care entity at all times. In addition to the recordkeeping requirements of s. 499.0121(7), F.S., the hospital or health care entity that transfers prescription drugs under this exception must reconcile all drugs transferred and returned and resolve any discrepancies in a timely manner.

The bill increases the amount of the bond required for a permitted prescription drug wholesaler, after July 1, 2003, to require a prescription drug wholesaler to submit either a bond or other means of security equal to $100,000 payable to the Florida Drug, Device, and Cosmetic Trust Fund. The bill authorizes the Department of Health to collect a fine from the bond's surety in lieu of current requirements specifying complete forfeiture of the bond. The purpose of the bond is to secure payment of any administrative penalties imposed by the Department of Health and any fees and costs incurred by the department regarding that permit which are authorized under state law and which the permittee fails to pay 30 days after the fine or costs become final. The department may make a claim against such bond or security until 1 year after the permittee's license ceases to be valid or until 60 days after any administrative or legal proceeding under ch. 499, F.S., which involves the permittee is concluded, including any appeal, whichever occurs later.

Requirements for out-of-state prescription drug wholesalers involving intracompany sales or transfers of a prescription drug between a Florida-licensed establishment and an out-of-state establishment are revised to apply when both wholesalers conduct wholesale distributions of prescription drugs under the same business name, rather than being under common control.

The bill revises permitting requirements for *out-of-state* prescription drug wholesalers to eliminate reciprocity for such businesses based on possession of a valid permit granted by another state. The bill requires an out-of-state prescription drug wholesaler that applies to the Department of Health after July 1, 2003, to submit a bond or other means of security such as a letter of credit equal to $100,000 payable to the Florida Drug, Device, and Cosmetic Trust Fund.

Section 14. Effective January 1, 2004, amends s. 499.012, F.S., as amended by this act, to revise the application process for prescription drug wholesalers for any new permit or permit renewal after July 1, 2003.

The bill provides definitions of the following terms:

- "Primary wholesaler" means any wholesale distributor that purchased 90 percent or more of its prescription drugs directly from a manufacturer, in the previous year; and directly purchased prescription drugs from not fewer than 50 different prescription drug

manufacturers in the previous year; or has, or the affiliated group of which the wholesale distributor is a member has, not fewer than 250 employees.

- "Directly from the manufacturer" means purchases made by the wholesale distributor directly from the manufacturer of prescription drugs or transfers from a member of an affiliated group of which the wholesale distributor is a member, if the affiliated group purchases 90 percent or more of all of its prescription drugs from a manufacturer and the wholesale distributor discloses to the Department of Health the names of all members of the affiliated group and the affiliated group agrees in writing to provide records on such transfers not later than 48 hours after the Department of Health requests access to such records, regardless of the location where the records are stored; and
- "Secondary wholesaler" means a wholesale distributor that is not a primary wholesaler.

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, and located outside of Florida or that is an entity to whom an approved new drug application has been issued by the U.S. Food and Drug Administration, or the contracted manufacturer of the approved new drug application holder, and located outside the United States, which engages in the wholesale distribution in Florida of the prescription drugs it manufactures or is responsible for manufacturing. Each manufacturer must comply with all the requirements for a wholesale distributor except s. 499.0121(6)(d), (e), or (f), F.S.

A person that distributes prescription drugs that it did not manufacture must also obtain an out-of-state prescription drug wholesaler permit to engage in the wholesale distribution of the prescription drugs manufactured by another person and comply with the requirements of an out-of-state prescription drug wholesaler. Any person that distributes prescription drugs that it did not manufacture 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 Florida must comply with ch. 499, F.S. If a person intends to import prescription drugs from a foreign country into Florida, the nonresident prescription drug manufacturer must provide to the Department of Health a list identifying each prescription drug it intends to import and document approval by the U.S. Food and Drug Administration for such importation.

A freight forwarder permit is required for any person that engages in the distribution of a legend drug as a freight forwarder unless the person is a common carrier. The storage, handling, and recordkeeping of such distributions must comply with the requirements for wholesale distributors under s. 499.0121, F.S., except for the requirements of s. 499.0121(6)(d),(e) or (f), F.S.

The bill specifies information that the Department of Health must receive to issue a permit or to renew a permit for a prescription drug wholesaler or an out-of-state prescription drug wholesaler. Additional information that was not previously required includes:

- Specified information regarding corporate ownership;
- For new permits, the estimated annual dollar volume of prescription drug sales of the applicant;

- For renewed permits the total dollar volume of prescription drug sales in the previous year, 6 months, and the total volume of purchases made directly from manufacturers of prescription drugs;
- A copy of the deed of the establishment;
- A list of licenses and permits issued to the applicant by any other state that allows the applicant to purchase or possess prescription drugs; and
- The name of the manager of the establishment and the next four highest ranking employees responsible for prescription drug wholesale operations and a personal information statement for that manager and employees.

Each manager and employee that is required to provide a personal information statement must also submit under oath: a photograph taken within the previous 30 days, a self-reported criminal history, a set of fingerprints, and extensive personal and financial information. The personal information includes the names addresses, occupations, and date and place of birth for the members of the person's immediate family. "Immediate family" includes the person's spouse, children, parents, siblings, and the spouses of the person's children and siblings.

A criminal offense committed in another jurisdiction which would have been a felony in Florida must be reported. The department must submit the fingerprints of a person applying for initial licensure and for the initial renewal after July 1, 2004, to the Florida Department of Law Enforcement (FDLE) for a statewide criminal history check and FDLE must forward the fingerprints to the Federal Bureau of Investigation for a national criminal history check of the person. For any subsequent renewal of a permit, the department shall submit the required information for a statewide criminal history check only.

Secondary wholesalers must provide similar information but must additionally submit information regarding: any corporate shareholders; the name and address of all financial institutions in which the applicant has an account which is used for the operation of the establishment or to pay for drugs, and the signatories on such accounts; sources of all funds and amounts of such funds to purchase or finance purchases of prescription drugs or to finance the premises where the establishment is located; and other relevant information that the department requires.

The bill specifies factors that the Department of Health must consider, at a minimum, in reviewing the qualifications of persons seeking a permit to engage in prescription drug wholesale activities. Such factors include: the applicant's having been found guilty, regardless of adjudication, in a court of Florida or other jurisdiction of violating a law that directly relates to a drug, device, or cosmetic; the applicant's past experience in distributing drugs; the applicant's compliance with permitting requirements under previously granted permits; the applicant's compliance with requirements for access to records by the state permitting authority or to law enforcement; and whether the applicant or any affiliated party has been disciplined by a regulatory agency for an offense that would constitute a violation of the Florida Drug and Cosmetic Act.

The Department of Health may deny an application for a permit or refuse to renew a permit for a prescription drug wholesaler or an out-of-state prescription drug wholesaler if the department finds:

- The applicant has not met the requirements for the permit;
- The management, officers, or directors of the applicant or any affiliated party are incompetent or untrustworthy;
- The applicant is so lacking in experience in managing a wholesale distributor as to make the issuance of the proposed permit hazardous to the public health;
- The applicant is so lacking in experience in managing a wholesale distributor as to jeopardize the reasonable promise of successful operation of the wholesale distributor;
- The applicant is lacking in experience in the distribution of prescription drugs;
- The applicant's past experience in manufacturing or distributing prescription drugs indicates that the applicant poses a public health risk;
- The applicant is affiliated directly or indirectly with any person whose business operations are or have been detrimental to the public health;
- The applicant, or any affiliated party, has been found guilty of a felony or a crime punishable by imprisonment for 1 year or more;
- The applicant has furnished false or fraudulent material in any application made in connection with manufacturing or distributing drugs, devices, or cosmetics;
- A permit currently or previously held by the applicant, or any affiliated party for the manufacture or distribution of any drugs, devices, or cosmetics has been suspended or revoked and has not been reinstated
- The applicant or any affiliated party receives financial support and assistance from a person who was an affiliated party of a permittee whose permit was subject to discipline or was suspended or revoked;
- The applicant or any affiliated party receives financial support and assistance from a person who has been found guilty of specified violations;
- The applicant for renewal of a prescription drug wholesaler or out-of-state prescription drug wholesaler has not actively engaged in the wholesale distribution of prescription drugs;
- Information obtained by the department demonstrates that it would not be in the best interest of the public health, safety, and welfare to issue a permit;
- The applicant does not possess the financial standing and business experience for the successful operation of the applicant; or
- The applicant or any affiliated party has failed to comply with the requirements for manufacturing or distributing prescription drugs under the laws of this state, any other state, or the federal government.

The department must adopt rules for the annual renewal of permits for a prescription drug wholesaler or an out-of-state prescription drug wholesaler. The department must provide notice 90 days prior to expiration of the permit. Permits expire at 1 year after the last day of the anniversary month in which the permit was originally issued. If a renewal application and fee are submitted and postmarked after 45 days prior to the expiration date of the permit, the permit may be reinstated only upon payment of a delinquent fee of $100 plus the required renewal fee. If a permit has expired and the time for which it may be renewed has elapsed, before an establishment may continue in activities requiring a permit, an initial application must be submitted along with applicable fees and penalties.

Each establishment that is issued a permit as a prescription drug wholesaler or an out-of-state prescription drug wholesaler must designate in writing to the department at least one natural person to serve as the wholesaler's representative. The representative must be at least 18 years of age and meet specified experience requirements, and pass an examination given by the Department of Health regarding federal laws governing distribution of prescription drugs and the rules adopted by the department governing the wholesale distribution of prescription drugs, unless the person is a Florida-licensed pharmacist. The department must offer the examination at least four times each calendar year. The representative must provide the department with a personal information statement and fingerprints as required by this section. The duties of the representative are specified, which include notifying the department when leaving the employment of the wholesale distributor and the wholesale distributor may not operate for more than 10 business days after the wholesale representative leaves its employment, unless another representative is appointed.

Section 15. Amends s. 499.0121, F.S., relating to the storage, handling, and recordkeeping requirements for prescription drugs, to require wholesalers to review records required for the acquisition of prescription drugs for accuracy and completeness, considering the total facts and circumstances surrounding the transactions and the wholesale distributors involved. Prescription drug wholesalers must authenticate each transaction listed on a pedigree paper, as defined in s. 499.001(31), F.S. The recordkeeping requirements for prescription drug wholesalers are revised to include additional information for a complete audit trail from receipt to sale or other disposition: any financial documentation supporting the transaction; inventories and records must be made available for inspection and photocopying by authorized government officials for a period of 2 years following the disposition of the drugs or 3 years after the creation of the records, whichever period is longer.

Until July 1, 2006, s. 499.0121(6)(d), F.S., requires each person who is engaged in prescription drug wholesale distribution and who is not an "authorized distributor of record" (ADR) for the manufacturer's products, to provide a written statement under oath identifying:

- Each previous sale of the drug back to the last ADR;
- The lot number of the drug; and
- The sales invoice number of the invoice evidencing the sale of the drug.

This information must be provided to each wholesale distributor of such drug, before the sale is made to such wholesale distributor. The written statement must accompany the drug to the next wholesale distributor. "ADR" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's products. The requirements of this paragraph do not apply to a manufacturer unless the manufacturer is performing the manufacturing operation of repackaging prescription drugs.

Each manufacturer must file a written list of all of the manufacturer's authorized distributors of record with the department. A manufacturer must notify the department not later than 10 days after any change to the list. The department is required to publish a list of all authorized distributors of record on its website.

The "pedigree" recordkeeping requirements for wholesale drug distributors are revised for a wholesaler that is an authorized distributor of record (ADR) of a drug manufacturer. Effective

March 1, 2004, an ongoing relationship is deemed to exist when a wholesale distributor, including any affiliated group, as defined in s. 1504 of the Internal Revenue Code, of which the wholesale distributor is a member:

- Is listed on the manufacturer's current list of authorized distributors; or
- Annually purchases not less than 90 percent of all of its purchases of a manufacturer's prescription drug products, based on dollar volume, directly from that manufacturer and has total annual prescription drug sales of $100 million or more; or
- Has reported to the Department of Health pursuant to s. 499.012(2)(g) 2., F.S., that the wholesale distributor has a total annual prescription drug sales of $100 million or more, and has a verifiable account number issued by the manufacturer authorizing the wholesale distributor to purchase the manufacturer's drug products directly from that manufacturer and that wholesaler makes not fewer than twelve purchases of that manufacturer's drug products directly from the manufacturer annually using the verifiable account number in twelve months. These provisions apply with respect to a manufacturer that fails to file a copy of the manufacturer's list of authorized distributors of record with the department by July 1, 2003; that files a list of authorized distributors of record which contains fewer than five wholesale distributors permitted in this state, excluding the wholesale distributors described in the second bullet; or that, as a result of changes to the list of authorized distributors of record filed with the department, has fewer than five wholesale distributors permitted in this state as authorized distributors of record, excluding the wholesale distributors described in the second bullet.

A wholesale distributor that satisfies the requirements of the second bullet or third bullet must submit to the department documentation substantiating its qualification. The department shall add those wholesale distributors that the department has determined have met the requirements of the second or third bullet to the list of authorized distributors of record on the department's website. The requirement for an ongoing relationship expires July 1, 2006.

Until July 1, 2006, pursuant to s. 499.0121(6)(e), F.S., notwithstanding s. 499.0121(6)(d), each person who is engaged in the wholesale distribution of a specified drug must provide to each wholesale distributor of such specified drug:

- Upon any sale, a written statement that if the establishment is not a member of an affiliated group: "This establishment purchased the specific unit of the specified drug directly from the manufacturer"; or if the establishment is the member of an affiliated group: "This establishment or a member of the affiliated group purchased the specific unit of the specified drug directly from the manufacturer".

- Before the wholesale distribution, a written statement, under oath, that identifies each previous sale of the specific unit of the specified drug back to the manufacturer of the specified drug, the lot number of the specific unit of the specified prescription drug, and the sales invoice number of the invoice evidencing each previous sale of the specific unit of the specified drug. The written statement identifying all sales of such specific unit of the specified drug must accompany the specific unit of the specified drug for each subsequent wholesale distribution of the specific unit of the specified drug to a wholesale distributor. The Department of Health is authorized to adopt rules to administer the

requirements of these written statements. "Specified drug" means a specific prescription drug on the list of drugs adopted by the department by rule.

- The department may place any drug on the list of "specified drugs" if the department has seized or issued a stop sale notice on the prescription drug because of the adulteration, counterfeiting, or diversion of the prescription drug from the channels of distribution for prescription drugs, or the United States Food and Drug Administration, a manufacturer, a wholesale distributor, a law enforcement agency, or a government agency responsible for regulating the sale or distribution of prescription drugs in another state has notified the department in writing or through a website operated by such entities that the prescription drug has been adulterated, counterfeited, or diverted from the legal channel of distribution of prescription drugs and the drug meets one of the following criteria:
    - The prescription drug is included among the top 150 prescription drugs for which the state has incurred the highest amount of Medicaid claims in the most recently ended state fiscal year;
    - The prescription drug is available for normal prescription use in dosages or strengths that have a wholesale cost $200 or more;
    - The prescription drug is used extensively for patients with HIV, AIDS, cancer, or serious, life threatening conditions, where drug nonresponsiveness would not be considered to be medically unusual;
    - The prescription drug is an injectable drug;
    - The prescription drug is subject to a special, limited distribution process and is not generally sold to wholesale distributors by the manufacturer of the prescription drug;
    - The department has found not less than five instances where statements required by s. 499.0121(6)(d), F.S., for the prescription drug were not passed on other than because of unintentional oversight, or have been passed on by or to a wholesale distributor and such statements were fraudulent; or
    - A shipment of a prescription drug has been reported to a law enforcement agency as having been stolen or as missing.

A prescription drug may be placed on the list of "specified drugs" if the prescription drug satisfies any three of seven criteria above. A prescription drug may not be placed on the list of "specified drugs" if the drug is unlikely to be counterfeited or diverted from the legal channels of distribution for prescription drugs.

Except when the council and the department decide to remove a drug from the list, before the department begins rulemaking to place a drug on the list of "specified drugs," the Drug Wholesaler Advisory Council must consider whether a prescription drug should be included on or added to the list of specified drugs using the above criteria and provide a written recommendation adopted by majority vote to the Secretary of the Department of Health concerning each such drug. When a prescription drug is added to the list of "specified drugs," the requirements applicable to such drug shall be effective beginning 60 days after the effective date of the rule adding the prescription drug to the list, except when the department and the council decide to remove a drug from the list.

The bill authorizes the department to add a prescription drug to the list by emergency rule, notwithstanding any provision of ch. 120, F.S., if the Attorney General or Statewide Prosecutor certifies to the Secretary of Health that a prescription drug should be added to the list. The emergency rule is effective for one year and may not be renewed. The department must begin the rulemaking process to adopt a permanent rule to place the drug on the list not later than 90 days from the date on which the emergency rule is filed. A prescription drug may be placed on the list by emergency rule if the drug satisfies any two of the criteria in sub-subparagraphs (e)3.a. or b., or the drug has not yet become available for wholesale distribution or has been available for wholesale distribution for not more than sixty days.

Notwithstanding any provision of ch. 120, F.S., any emergency rule which places a prescription drug on the list may be challenged only as being an invalid exercise of the delegated legislative authority if the department lacks any substantial competent evidence that the prescription drug satisfied the criteria necessary for being placed on the list by emergency rule. The department must provide to any person, after request and within 7 days, the substantial competent evidence which justifies the adoption of the emergency rule adding a drug to the list.

The department is required to notify all prescription drug wholesalers and out-of-state prescription drug wholesalers when an emergency rule is adopted which places a prescription drug on the list. No later than 7 days after the department adopts an emergency rule placing a prescription drug on the list, wholesalers must provide the department with the lot numbers and quantities of such prescription drug which the wholesaler owns or has in transit on the date the emergency rule was adopted.

At least annually, the department and the council must evaluate whether each prescription drug included on the list of "specified drugs" should remain on the list. The bill specifies criteria for the council and department to consider when determining whether a prescription drug should remain on the list. The council must provide a written recommendation adopted by majority vote to the Secretary of the Department of Health concerning each drug that the council recommends to be removed from the list of "specified drugs." Repackagers must comply with the requirements of s. 499.0121(6)(e), F.S., and manufacturers are exempt.

Effective July 1, 2006, each person who is engaged in prescription drug wholesale distribution and who is not the manufacturer of that drug must, before each wholesale distribution of such drug, provide to the person who receives the drug a "pedigree paper" as defined in s. 499.003(31), F.S. Repackagers must comply with the "pedigree paper" requirements. Compressed medical gases and veterinary prescription drugs are exempt from the "pedigree paper" requirements.

Each prescription drug wholesale distributor must maintain separate and distinct from other required records all statements that are required for the "pedigree papers". In order to verify compliance with pedigree paper requirements, each manufacturer of a prescription drug sold in Florida must make available upon request distribution documentation related to its sales of prescription drugs, regardless of whether the prescription drug was sold directly by the manufacturer to a person in Florida. Each prescription drug wholesale distributor, except for the manufacturer, must annually provide the Department of Health with a written list of all wholesale distributors and manufacturers from whom the wholesale distributor purchases

prescription drugs. A wholesale distributor, except a manufacturer, must notify the department not later than 10 days after any change to either list. The bill provides that such portions of the required information which are a trade secret, as defined in s. 812.081, F.S., must be maintained by the Department of Health as trade secret information is required to be maintained pursuant to section 499.051, F.S.

Wholesale drug distributors must maintain a list of designated representatives in charge of wholesale drug distribution. The bill provides that the person responsible for shipment and transportation of a prescription drug in wholesale distribution may use: a common carrier, its own vehicle or employee acting in the scope of employment if authorized to possess prescription drugs in Florida under s. 499.03, F.S., or in the case of a prescription drug intended for domestic distribution, an independent contractor who must be the agent of the authorized seller or recipient responsible for shipping and transportation as specified in a written contract between the parties.

A person selling a prescription drug for export must obtain documentation, such as a valid airway bill, bill of lading, or other appropriate documentation that the prescription drug was exported. A person responsible for shipping or transporting prescription drugs is not required to maintain documentation from a common carrier that the designated recipient received the prescription drugs; however the person must obtain such documentation from the common carrier and make it available to the Department of Health upon the department's request.

Section 16. Effective January 1, 2004, amends s. 499.0121, F.S., relating to the storage and handling of prescription drugs, to revise requirements for due diligence that wholesale distributors must maintain in their purchasing activities with their suppliers. Due diligence requires wholesale drug distributors, prior to purchasing any prescription drugs from another wholesale drug distributor, to:

- Enter an agreement with the selling wholesale drug distributor by which the selling wholesale drug distributor will indemnify the purchasing wholesale drug distributor for any loss caused to the purchasing wholesale drug distributor related to the purchase of drugs from the selling wholesale drug distributor that are determined to be counterfeit or to have been distributed in violation of any federal or state law governing drug distribution;
- Determine that the selling wholesale drug distributor has insurance coverage of not less than the greater of 1 percent of the amount of total dollar volume of prescription drug sales reported to the department or $500,000 to $2 million;
- Obtain specified information about the selling wholesale drug distributor;
- Verify that the selling wholesale drug distributor's Florida permit is valid; and
- Inspect the selling wholesale drug distributor's licensed establishment to document compliance with matters relating to the distribution of drugs, and at least once each subsequent year, or before purchasing any drug from the distributor and each subsequent year obtain a complete copy of the most recent annual inspection report that was prepared by the department or other regulatory authority.

Section 17. Creates s. 499.01211, F.S., to create an eleven-member Drug Wholesaler Advisory Council within the Department of Health. The council includes the Secretary of the Department

of Health or his or her designee, and the Secretary of the Agency for Health Care Administration or his or her designee, and nine members appointed by the Secretary of Health. The council must meet each calendar quarter and shall be staffed by the Department of Health. The council must annually review rules adopted to enforce the Florida Drug and Cosmetic Act, provide input to the department and make written recommendations regarding the listing of "specified drugs", and provide input regarding all proposed rules and matters to improve coordination with other state regulatory agencies and the Federal government. Members of the council serve without compensation.

Section 18. Effective January 1, 2004, amends s. 499.013, F.S., relating to manufacturers of drugs, devices and cosmetics, to require any person that repackages a prescription drug in Florida to obtain a permit as a repackager from the Department of Health. Prescription drug repackagers must comply with all appropriate state or federal good manufacturing practices.

Section 19. Amends s. 499.014, F.S., relating to the distribution of legend drugs by hospitals, health care entities, charitable organizations, and return or destruction companies, to provide that storage and handling, and recordkeeping of these distributions must comply with the requirements for wholesale distributors under s. 499.0121, F.S., except for those set forth in s. 499.0121(6)(d), (e) or (f), F.S., relating to pedigree requirements.

Section 20. Amends s. 499.041, F.S., relating to fees, to increase the statutory fee caps: for a prescription drug manufacturer's permit from $600 to $750 annually; for a prescription drug wholesaler's permit from $400 to $800 annually; and for an out-of-state prescription drug wholesaler's permit no less than $300 ($200) and no greater than $800 ($300) annually. A fee is created: for a prescription drug repackager's permit to be not less than $500 or more than $750 annually; for a nonresident prescription drug manufacturer's permit to be not less than $300 or more than $500 annually; for a freight forwarder's permit to be not less than $200 or more than $300 annually; for out-of-state prescription drug wholesaler applicant's or permittee's on-site inspection fee to be no less than $1,000 or more than $3,000 annually, to be based on the actual cost of the inspection if an on-site inspection is performed by agents of the Department of Health; and for persons applying for certification as a designated representative a fee of $150, plus the cost of processing the criminal history record.

Section 21. Amends s. 499.051, F.S., relating to inspections, to provide that any application for a permit under the Florida Drug and Cosmetic Act and rules adopted under that act constitutes permission for agents of the Department of Health and the Florida Department of Law Enforcement, after presenting proper identification, to inspect, review, and copy financial documents or records related to the distribution of a drug in order to determine compliance with the Florida Drug and Cosmetic Act, and rules adopted by the Department of Health to administer that Act. The authority to inspect under this section includes the authority to access, review, and copy any and all financial documents related to the activity of manufacturing, repackaging, or distributing prescription drugs.

Section 22. Amends s. 499.055, F.S., relating to reports and the dissemination of information by the Department of Health, to require the department to publish on its website the following information regarding prescription drug wholesalers, out-of-state prescription drug wholesalers, and retail pharmacy drug wholesalers: a list of enforcement actions, including suspensions and

revocations; a list of permittees and the expiration date of each permit; and a list of permits that have been returned to the department, were suspended, were revoked, have expired, or were not renewed in the previous year.

Section 23. Creates s. 499.065, F.S., to require the Department of Health, notwithstanding s. 499.051, F.S., relating to inspections and investigations, to inspect each prescription drug wholesale establishment, prescription drug repackager establishment and retail pharmacy drug wholesaler establishment permitted under ch. 499, F.S., as often as necessary to ensure compliance with applicable laws and rules. The department must have the right of entry and access to these facilities at any reasonable time.

The department may examine, sample, seize, and stop the sale or use of prescription drugs to determine the condition of those drugs. The department may immediately seize and remove any prescription drugs if the Secretary of Health or his or her designee determines that such prescription drugs represent a threat to the public health. The owner of any property seized under this section may, within 10 days after the seizure, apply to a court of competent jurisdiction for whatever relief is appropriate. At any time after 10 days, the department may destroy the drugs as contraband.

The department may determine that a prescription drug wholesale establishment, prescription drug repackager establishment or retail pharmacy drug wholesaler establishment permitted under ch. 499, F.S., is an imminent danger to the public health and require its immediate closure if such establishment fails to comply with applicable laws and rules and, due to such failure, presents an imminent threat to the public health, safety or welfare. Any establishment so deemed and closed must remain closed until allowed by the department or by judicial order to reopen.

A refusal to allow entry to the Department of Health for inspection at reasonable times, or a failure or refusal to provide the department with required documentation for purposes of inspection, constitutes an imminent danger to the public health.

Section 24. Amend s. 499.066, F.S., relating to penalties under the Florida Drug and Cosmetic Act, to delete the Department of Health's cease and desist remedies and to authorize the department to institute such suits or other legal proceedings as are required to enforce any provision of the Act. If it appears that a person has violated any provision of the Act for which criminal prosecution is provided, the department may provide the appropriate state attorney or other prosecuting agency having jurisdiction with respect to such prosecution with the relevant information in the department's possession. Resignation or termination of an affiliated party does not affect the department's jurisdiction or discretion to proceed with action to suspend or revoke a permit or to impose other penalties or enforcement actions authorized by law.

Section 25. Creates s. 499.0661, F.S., to create new cease and desist remedies for the Department of Health to enforce its authority against permitted establishments under the Florida Drug and Cosmetic Act. In addition to other authority, the department is authorized to issue and serve a complaint stating charges upon any permittee or upon any affiliated party, whenever the department has reasonable cause to believe that the person or individual named therein is engaging in conduct that is:

- An act that demonstrates a lack of fitness or trustworthiness to engage in the business authorized under the permit, is hazardous to the public health, or constitutes business operations that are a detriment to the public health;
- A violation of the Act, any rule of the department, or any order of the department; or
- A breach of any written agreement with the department.

The complaint must contain a statement of facts and notice of an opportunity for an administrative hearing. If a hearing is not requested within the time required under the Administrative Procedure Act or if a hearing is held and the department finds that any of the charges are proven, the department may enter an order directing the permittee or the affiliated party named in the complaint to cease and desist from engaging in the conduct complained of and take corrective action to remedy the effects of past improper conduct and assure future compliance. A contested or default cease and desist order is effective when reduced to writing and served upon the permittee or affiliated party. An uncontested cease and desist order is effective as agreed.

The bill grants the department authority to issue an emergency cease and desist order if it finds conduct that is likely to cause an immediate threat to the public health. The emergency order is effective immediately upon service of a copy of the order upon the permittee or affiliated party named therein and remains effective for 90 days. If the department begins nonemergency cease and desist proceedings, the emergency order remains effective until the conclusion of the proceedings.

The bill specifies procedures for the department to remove, restrict or prohibit the participation by an affiliated party in the affairs of a permitted establishment. The chief executive officer, designated representative, or the person holding the equivalent office, of a permitted establishment must promptly notify the department if she or he has actual knowledge that any affiliated party is charged with a felony in a state or federal court. The department is authorized to enter an emergency order whenever an affiliated party is charged with a felony in a state or federal court or its equivalent in a country with which the United States maintains diplomatic relations, and the charge alleges violation of any law involving prescription drugs, pharmaceuticals, fraud, theft, or moral turpitude, to suspend the affiliated party or restrict or prohibit the affiliated party from participating in the affairs of the particular permitted establishment or any other permitted establishment upon service of the order.

The order must give notice of opportunity for a hearing for the affiliated party to contest the order. The emergency order remains in effect, unless otherwise modified by the department, until the criminal charge is disposed of. Acquittal of the person charged, or the final unappealed dismissal of all charges against the person dissolves the emergency order, but does not prohibit the department from instituting a complaint for removal or suspension. If the person charged is convicted or pleads guilty or nolo contendere, whether or not an adjudication of guilt is entered by the court, the emergency order becomes final. Any affiliated party removed by the department is ineligible for reemployment by the permittee or to be an affiliated party of any permitted establishment except upon written consent of the department.

Section 26. Effective January 1, 2004, amends s. 499.067, F.S., to authorize the Department of Health to deny an application for certification or to suspend or revoke a permit or certification

required under the Florida Drug and Cosmetic Act based on specified grounds, including: the applicant has not met the requirements for the permit or certification; the applicant is ineligible for a permit or certification; the applicant, permittee, or person certified under s. 499.012(11), F.S., demonstrates any of the conditions specified in s. 499.01 or s. 499.012(5), F.S.; or the applicant has committed any violation of the Act. The department must deny, suspend, or revoke the permit of any person or establishment if the assignment, sale, transfer, or lease of an establishment permitted under the Act will avoid an administrative penalty, civil action, or criminal prosecution.

If a permittee fails to comply with s. 499.01(7), F.S., which provides for the nontransferability of permits, the department may revoke the permit of the permittee and must provide notice of the intended agency action by posting a notice at the department's headquarters and by mailing a copy of the notice of intended agency action by certified mail to the most recent mailing address on record with the department and if the permittee is not a natural person, to the permittee's registered agent on file with the Department of State.

Section 27. Amends s. 499.069, F.S., relating to punishment for violations under s. 499.005, F.S., under the Florida Drug and Cosmetic Act, to limit the application of the section to permitted establishments involved with distribution or manufacture of a device or cosmetic. The bill deletes language that provides that no penalty attaches for a person who establishes a guaranty or undertaking if it is signed by and contains the name and address of the person residing in Florida, or the manufacturer, from whom he or she received the article in good faith, to the effect that such article is not adulterated or misbranded within the meaning of the Act.

Section 28. Creates s. 499.0691, F.S., to establish criminal offenses relating to violations under the Act regarding the distribution or manufacture of drugs.

Any person who violates any of the following provisions commits a second degree misdemeanor punishable by up to 60 days in jail and a fine up to $500, but if the violation is committed after a conviction of such person under this section has become final, such person commits a first degree misdemeanor punishable by up to 1 year imprisonment and a fine up to $1,000, or as otherwise provided in the Act. The enumerated offenses include:

- The manufacture, repackaging, sale, delivery, or holding or offering for sale of any drug that is adulterated or misbranded or has otherwise been rendered unfit for human or animal use;

- The adulteration or misbranding of any drug intended for further distribution;

- The receipt of any drug that is adulterated or misbranded, and the delivery or proffered delivery of such drug, for pay or otherwise;

- The dissemination of any false or misleading advertisement of a drug;

- The use, on the labeling of any drug or in any advertisement relating to such drug, of any representation or suggestion that an application of the drug is effective when it is not or that the drug complies with the Act when it does not;

- The purchase or receipt of a compressed medical gas from a person that is not authorized under ch. 499, F.S., to distribute compressed medical gases.

- Charging a dispensing fee for dispensing, administering, or distributing a prescription drug sample;

- The failure to maintain records related to a drug as required by the Act and rules, except for pedigree papers, invoices, or shipping documents related to legend drugs; or

- The possession of any drug in violation of the Act, except if the violation relates to a deficiency in pedigree papers.

Any person who violates any of the following provisions commits a third degree felony punishable by up to 5 years imprisonment and a fine up to $5,000, or as otherwise provided in the Act. The enumerated offenses include:

- The refusal or constructive refusal to allow the department to: enter or inspect an establishment in which drugs are manufactured, processed, repackaged, sold, brokered, or held; allow the department to inspect any record of that establishment; allow the department to enter and inspect any vehicle that is being used to transport drugs; or allow the department to take samples of any drug;

- The sale, purchase, or trade or the offer to sell, purchase, or trade, a drug sample as defined in s. 499.028, F.S.; the distribution of a drug sample in violation of s. 499.028, F.S.; or the failure to comply with s. 499.028, F.S.;

- Providing the department with false or fraudulent records, or making false or fraudulent statements, regarding any matter within the provisions of ch. 499, F.S., related to a drug;

- The failure to receive, maintain, or provided invoices and shipping documents, other than pedigree papers, if applicable, related to the distribution of a legend drug;

- The importation of a legend drug for wholesale distribution, except as provided by the Federal Food, Drug and Cosmetic Act;

- The wholesale distribution of any prescription drug that was purchased by a public or private hospital or other health care entity or donated or supplied at a reduced price to a charitable organization;

- The failure to obtain a permit as a prescription drug wholesaler when a permit is required by the Florida Drug and Cosmetic Act;

- Knowingly possessing any adulterated or misbranded legend drug outside of a designated quarantine area; or

- The purchase or sale of prescription drugs for wholesale distribution in exchange for cash.

Any person who violates any of the following provisions commits a second degree felony punishable by up to 15 years imprisonment and a fine up to $10,000, or as otherwise provided in the Act. The enumerated offenses include:

- Knowingly manufacturing, repackaging, selling, delivering, or holding or offering for sale any drug that is adulterated or misbranded or has otherwise been rendered unfit for human or animal use;

- Knowingly adulterating a drug that is intended for further distribution;

- Knowingly receiving a drug that is adulterated and delivering or proffering delivery of such drug for pay or otherwise;

- Committing any act that causes a drug to be a counterfeit drug, or selling dispensing, or knowingly holding for sale a counterfeit drug;

- Forging, counterfeiting, simulating, or falsely representing any drug, or, without the authority of the manufacturer, using any mark, stamp, tag, label, or other identification device authorized or required by rules adopted under the Act;

- Knowingly obtaining or attempting to obtain a prescription drug for wholesale distribution by fraud, deceit, misrepresentation, or subterfuge, or engaging in misrepresentation or fraud in the distribution of a drug;

- Removing a pharmacy's dispensing label from a dispensed prescription drug with the intent to further distribute the prescription drug; or

- Knowingly distributing a prescription drug that was previously dispensed by a licensed pharmacy unless such distribution was authorized by the Florida pharmacy practice act or rules adopt by the Florida Board of Pharmacy.

A publisher, radio broadcast licensee, or agency or medium for the dissemination of an advertisement, except the manufacturer, repackager, wholesaler, or seller of the article to which a false advertisement relates is not liable for a violation of this section by reason of the dissemination by him or her of such false advertisement, unless he or she has refused on the request of the Department of Health, to furnish the name and post office address of the manufacturer, repackager, wholesaler, seller, or advertising agency that requested him or her to disseminate such advertisement.

Section 29. Amends s. 921.0022, F.S., relating to the offense severity ranking chart of the Criminal Punishment Code, to include certain violations of ch. 499, F.S. The Code's offense severity ranking chart ranks most felony offenses from levels 1 to 10, and is the primary factor

which goes into the minimum sentence calculation. A level 10 offense scores highest and level 1 scores lowest.

The following third degree felony offenses relating to violations under the Florida Drug and Cosmetic Act are ranked as Level 4 offenses: failure to maintain or deliver pedigree papers; and failure to authenticate pedigree papers. The following second degree felony offense is ranked as a Level 4 offense: sale or delivery, or possession with intent to sell, contraband legend drugs.

The following second degree felony offenses relating to violations under the Florida Drug and Cosmetic Act are ranked as Level 6 offenses: forgery of pedigree papers; purchase or receipt of legend drug from an unauthorized person; and the sale of legend drug to unauthorized person.

The following first degree felony offenses relating to violations under the Florida Drug and Cosmetic Act are ranked as Level 8 offenses: forgery of prescription or legend drug labels; and trafficking in contraband legend drugs.

The following first degree felony offense relating to violations under the Florida Drug and Cosmetic Act is ranked as a Level 9 offense: sale or purchase of contraband legend drugs resulting in great bodily harm.

The following first degree felony offense relating to violations under the Florida Drug and Cosmetic Act is ranked as a Level 10 offense: sale or purchase of contraband legend drugs resulting in death.

Section 30. Amends s. 16.56, F.S., relating to the Office of Statewide Prosecution within the Department of Legal Affairs, to authorize the office to investigate and prosecute any criminal violation of part I, ch. 499, F.S., relating to Florida Drug and Cosmetic Act that involves multiple judicial circuits.

Section 31. Amends s. 895.02, F.S., to add the newly created criminal offenses relating to violations of the Florida Drug and Cosmetic Act which involve contraband and adulterated drugs to the racketeering provisions so that the offenses may be prosecuted as racketeering in appropriate cases, thereby allowing harsher sentencing for the criminal conduct and the further use of civil racketeering sanctions.

Section 32. Amends s. 905.34, F.S., relating to the statewide grand jury, to expand the jurisdiction of the statewide grand jury to investigate and prosecute any criminal offense under ch. 499, F.S., relating to the Florida Drug and Cosmetic Act that involves multiple judicial circuits.

Section 33. Provides a severability clause.

Section 34. Provides an appropriation of $453,851 from the Florida Drugs, Devices, and Cosmetic Trust Fund to the Department of Health and authorizes three additional positions to implement the requirements of the bill.

Section 35. Provides that, except as otherwise expressly provided in this act, the bill takes effect July 1, 2003.

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, s. 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 Art. I, s. 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.

D. Other Constitutional Issues:

Section 14 of the bill provides that the Department of Health may not approve a permit or renew a permit for a prescription drug wholesaler, an out-of-state prescription drug wholesaler, or retail pharmacy drug wholesaler if the department finds: the management, officers, or directors of the applicant or any affiliated party are found to be incompetent or untrustworthy; the applicant is so lacking in experience in managing a wholesale distributor as to make the issuance of the proposed permit hazardous to the public health; the applicant is so lacking in experience in managing a wholesale distributor as to jeopardize the reasonable promise of successful operation of the wholesale distributor; or the department has good reason to believe that the applicant is affiliated directly or indirectly with any person whose business operations are or have been marked to the detriment of the public health or by bad faith. It is unclear what conduct is being forbidden in terms so that persons of common understanding must necessarily guess at its meaning and differ as to its application. The bill provides that the department may not approve or renew any permit for a prescription drug wholesaler, an out-of-state prescription drug wholesaler, or a retail pharmacy drug wholesaler that does not possess the financial standing and business experience for the successful operation of the applicant.

It is not clear whether the criteria that the department is to consider are sufficiently explicit to inform persons subject to its provisions what conduct will render them liable to its penalties. See *Brock v. Hardie*, 154 So. 690 (Fla. 1934).

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

The bill increases the statutory fee caps: for a prescription drug manufacturer's permit from $600 to $750 annually; for a prescription drug wholesaler's permit from $400 to $800 annually; and for an out-of-state prescription drug wholesaler's permit no less than $300 ($200) and no greater than $800 ($300) annually. A fee is created: for a prescription drug repackager's permit to be not less than $500 or more than $750 annually; for a nonresident prescription drug manufacturer's permit to be not less than $300 or more than $500 annually; for a freight forwarder's permit to be not less than $200 or more than $300 annually; for out-of-state prescription drug wholesaler applicant's or permittee's on-site inspection fee to be no less than $1,000 or more than $3,000 annually, to be based on the actual cost of the inspection if an on-site inspection is performed by agents of the Department of Health; and for persons applying for certification as a designated representative a fee of $150, plus the cost of processing the criminal history record.

B. Private Sector Impact:

The persons or establishments seeking to engage in wholesale drug distribution in Florida will incur additional costs to comply with the bill's requirements for drug wholesale permits, recordkeeping, and due diligence as specified in the bill. Such requirements include a national and statewide criminal history check of key personnel of the establishment for the initial licensure by the Department of Health.

C. Government Sector Impact:

The Department of Health will incur additional costs to implement the bill's more stringent permitting requirements for the wholesale drug distribution industry in Florida. The department will incur costs to update its website with information regarding enforcement activities and lists of permitted drug wholesalers. The department estimates a need for an additional three positions and $453,851 in FY 2003-04 and $412,784 in FY 2004-05 to be funded from the Florida Drugs, Devices, and Cosmetic Trust Fund.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill imposes requirements on wholesalers to pass pedigree papers and imposes criminal penalties for a person engaged in the wholesale distribution of legend drugs and who fails to authenticate the matters contained in required documents and for a person who possesses required "pedigree documents" and who falsely swears or certifies that he or she has authenticated the matters in the documents. For the required documents referred to in these offenses, it is unclear if the statutory reference should be changed to "s 499.0121(6) (d) or (e), F.S."

It is unclear whether the statutory reference to pedigree papers in the existing public records law exemption for trade secrets maintained by the Department of Health should be revised to reflect the bill's requirements for "pedigree papers" under s. 499.0121(6)(d), (e), or (f), F.S.

The bill requires a statewide check for individuals representing pharmaceutical drug wholesalers who are subject to any subsequent permit renewals. Further if the individuals subject to the initial criminal background checks are not physically domiciled in Florida upon the subsequent renewal, it is unclear whether a national criminal history check of the individual is necessary for corroboration.

VIII. Amendments:

None.