HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1481 w/CS Pharmaceutical Wholesalers
SPONSOR(S): Homan
TIED BILLS: None. **IDEN./SIM. BILLS:** SB 2312 (s), SB 2698 (s)

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Standards (Sub)	8 Y, 0 N	Mitchell	Collins
2) Health Care	17 Y, 0 N w/CS	Mitchell	Collins
3) Appropriations			
4)			
5)			

SUMMARY ANALYSIS

A statewide grand jury report released by the Office of the Attorney General, February 28, 2003, found that "an alarming percentage of drugs flowing through the wholesale market have been illegally acquired." Drugs are acquired via theft from pharmacies and hospitals; purchases on the black market by individuals defrauding insurance companies and Medicaid; or illegal importation. The report found that state law requiring drugs to have documentation showing all the hands they passed through on the way to the patient has never been fully enforced, in part due to industry objections. (Interim Report of the Seventeenth Statewide Grand Jury.)

The Office of Program Policy Analysis and Government Accountability (OPPAGA) found in a report released in February, 2003, that counterfeit and diverted drugs are a growing problem in Florida that threatens public health and wastes government resources (Report No. 03-18). OPPAGA found:

- Regulators estimate that the problem costs Florida millions of dollars annually;
- Current state law does not provide adequate controls over wholesale drug market practices; and
- Current administrative and criminal penalties fail to provide an adequate deterrent.

HB 1481 addresses these issues by providing additional permit requirements for prescription drug wholesalers, out-of-state prescription drug wholesalers, and retail pharmacy drug wholesalers. It provides for annual renewal and increases permit fees to support improved enforcement.

The bill requires reporting of previous sales of prescription drugs, including high-risk prescription drugs. It requires wholesale distributors to submit an annual list of the wholesalers from whom they purchase drugs and it prohibits a wholesale drug distributor from paying for any drug with currency. The bill prohibits acts relating to previously dispensed drugs. Effective July 1, 2006, a “pedigree paper” system of tracking the wholesale distribution of every prescription drug is established. The pedigree papers contain detailed information about the identity and control of the drug for each step in its distribution.

The bill provides penalties and expands the authority of the Department of Health and the Department of Law Enforcement to inspect financial records and investigate complaints and violations. The bill’s enforcement provisions include cease and desist orders, and removal of affiliated parties. It creates the Drug Wholesaler Advisory Council to oversee rules and make recommendations to the Department of Health.

The effective date of the bill is July 1, 2003.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. DOES THE BILL:

1. Reduce government?	Yes[]	No[X]	N/A[]
2. Lower taxes?	Yes[]	No[]	N/A[X]
3. Expand individual freedom?	Yes[]	No[]	N/A[X]
4. Increase personal responsibility?	Yes[]	No[]	N/A[X]
5. Empower families?	Yes[]	No[]	N/AX]

For any principle that received a “no” above, please explain:

The bill establishes more stringent permitting requirements for the wholesale drug distribution industry in Florida. It increases the statutory fee caps for prescription drug wholesaler permits and its requirements for drug wholesale permits, recordkeeping, and due diligence will increase the costs of wholesale drug distribution in Florida.

B. EFFECT OF PROPOSED CHANGES:

HB 1481 revises the Florida Drug and Cosmetic Act (Part I. ch. 499, F.S.) to impose more stringent regulations on prescription drug wholesalers. The bill creates criminal offenses relating to illicit activities involving diversion of prescription drugs from wholesale distribution. The bill creates additional prohibitions against label tampering 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 (DOH) 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 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;
- The wholesaler buys at least 90 percent of all of the manufacturer’s products handled by the wholesaler directly from the manufacturer and has a total annual drug sales of $100 million or more;
- 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;

- Meets other criteria for an ongoing relationship that the Department of Health has determined by rule. (The requirement for an ongoing relationship expires July 1, 2006 when pedigree papers become effective.)

“Specified drug” (high-risk prescription drug) provisions are in effect 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 must provide to each wholesale distributor of the drug, a written statement under oath that identifies each previous sale of the high-risk prescription drug back to the manufacturer, including the drug lot number and invoice number of each previous sale, before any sale of such high-risk drug is made to the wholesale distributor. The written statement must accompany the high-risk prescription drug for each subsequent wholesale distribution to a wholesale distributor. "High-risk prescription drug" is defined as a specific drug on the list of drugs adopted by rule by the Department of Health. The list is of drugs is to include specific drugs seized by the department on at least five separate occasions because such drug was adulterated, counterfeited, or diverted from legal prescription drug distribution channels, for which 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.

“Pedigree paper” provisions become effective July 1, 2006. At that date, each person who is engaged in wholesale distribution of any prescription drug and who is not the manufacturer of the drug must, before each wholesale distribution provide to the person who receives the drug a “pedigree paper” of that drug. The “pedigree paper” maintains the history of the distribution of the drug with detailed required information. Each prescription drug wholesale distributor must maintain all statements that are required for the “pedigree papers” separate from other required records, and must make documentation available to establish compliance. Repackagers must comply with the “pedigree paper” requirements.

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 bill revises the term, "authorized distributor of record" 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 a nine-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 statutory fee caps for:

- A prescription drug manufacturer’s permit from $600 to $750 annually;
- A prescription drug wholesaler’s permit from $400 to $800 annually; and
- An out-of-state prescription drug wholesaler’s permit no less than $300 and no greater than $800 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.

The effective date of the bill is July 1, 2003.

CURRENT SITUTATION/ISSUES IDENTIFIED:

Statewide Grand Jury Interim Report
A statewide grand jury report released by the Office of the Attorney General, February 28, 2003, found "an alarming percentage of drugs flowing through the wholesale market have been illegally acquired" via theft from pharmacies and hospitals; purchases on the black market by individuals defrauding insurance companies and Medicaid; or illegal importation. Despite a 1993 state law that requires drugs to have documentation showing all the hands they passed through on the way to the patient, the investigative panel found that neither this law nor an updated version in 1996 has ever been fully enforced, in part due to industry objections. (Interim Report of the Seventeenth Statewide Grand Jury.)

The grand jury heard testimony in Fort Lauderdale of a case in which counterfeiters relabeled drugs to overstate their strength by as much as 2,000 percent. The grand jury recommended making it a felony to accept a shipment without verifying its legitimacy, and giving Florida the power to shut down firms that break the law as well as confiscate questionable drugs. The panel also said the state should improve background checks for wholesale licenses and inspect facilities more often.

Office of Program Policy Analysis and Government Accountability (OPPAGA) Report
In a report released in February, 2003, the Office of Program Policy Analysis and Government Accountability (OPPAGA) found that counterfeit and diverted drugs are a growing problem in Florida and threaten public health and waste government resources (Report No. 03-18). OPPAGA found:

- Regulators estimate that the problem costs Florida millions of dollars annually;
- Current state law does not provide adequate controls over wholesale drug market practices; and
- Current administrative and criminal penalties fail to provide an adequate deterrent.

CURRENT STATUTORY AND REGULATORY FRAMEWORK:

Current State and Federal Law
Drug marketing is regulated by both federal and state law. The federal Prescription Drug Marketing Act (PDMA) of 1987 establishes minimum standards for the prescription drug wholesale industry. The Florida Drug and Cosmetic Act, Ch. 499, Florida Statutes, incorporates the standards set forth in the federal PDMA, and requires the Department of Health to provide regulatory oversight of wholesalers.

Pedigree Papers
The key standard for control of the wholesale drug industry requires wholesalers to provide purchasers with a written sales history tracing each drug back to its initial manufacturer that is designed to prevent drug diversion and counterfeiting. These written histories, commonly referred to as pedigree papers, provide an audit trail and should contain specific information about each sales transaction, such as the name and address of each previous purchaser of the drug.

Exemption for wholesalers who routinely purchase prescription drugs directly from manufacturers.
A related provision of the federal act establishes the designation of authorized distributor of record (ADR) and defines ADRs as wholesalers who routinely purchase prescription drugs directly from manufacturers. It exempts ADR wholesalers from providing pedigree papers when they sell drugs purchased from the manufacturer to another wholesaler. This exemption assumes that ADR wholesalers purchase legitimate and safe drugs directly from the manufacturer, making a chain of

custody unnecessary. To become an ADR wholesaler, the law requires a minimum number of transactions during a specified time period between a wholesaler and manufacturer.

Bureau of Statewide Pharmaceutical Services
The Bureau of Statewide Pharmaceutical Services of the Department of Health regulates the wholesale market by permitting, inspecting, and investigating drug wholesalers. Drug wholesalers must obtain a permit from the bureau to legally sell drugs in Florida. Bureau inspectors inspect in-state wholesaler facilities as part of the initial application process and annually thereafter. If inspections reveal infractions, the bureau investigates and may impose administrative fines and penalties.

The bureau also investigates wholesalers suspected of misconduct such as counterfeiting or diverting drugs. To combat illegal activities in the wholesale market, the bureau works closely with local, state, and federal law enforcement officials, the Agency for Health Care Administration, the Medicaid Fraud Control Unit, the Statewide Prosecutor's Office, and the Food and Drug Administration.

The 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, who can pay the permit fee and who submits required information may, with certain exceptions, obtain a permit as a prescription drug wholesaler.[2] The applicant must not have been found guilty of a violation of a law directly related 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 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 based on reciprocity, if the out-of-state drug wholesaler possesses a valid permit from another state that has requirements comparable to those of Florida.

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 major full-line regional wholesalers. The rest of the out-of-state wholesalers 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.

[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.

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.

According to the department, s. 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. 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 from pedigree papers for a manufacturer's authorized distributor, while also providing that once created, the pedigree must accompany each subsequent distribution of the drug to a wholesale distributor without exception.
- The term authorized distributor is defined with reference to the manufacturer's entire drug product line, whereas the pedigree paper appears to be related to the specific unit of a drug subject to wholesale distribution.
- 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, plus the dosage form, strength, container size, quantity by lot number, and the name and address of each owner of the prescription drug, and 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]

PROBLEMS IDENTIFIED IN THE OPPAGA REPORT:

OPPAGA found that counterfeit and diverted prescription drugs pose a substantial public health risk to patients and cost Florida millions of dollars annually. According to the OPPAGA report, in recent years, state regulatory and law enforcement agencies have observed a significant increase in the incidence of counterfeit and diverted drugs. DOH Bureau of Statewide Pharmacy Services officials reported that between 50 and 55 of the 1,458 Florida permitted wholesalers are under suspicion for counterfeiting or diversion activities. [6] In addition, criminal prescription drug counterfeiting and diversion cases have increased from almost none in the 1990's to more than 50 since 1999.[7]

Counterfeit drugs pose major health risks. In its report, OPPAGA found that criminals create counterfeit drugs by either producing substances that have no active ingredients but are labeled as genuine drugs or by relabeling genuine drugs as a higher strength version of the same drug or as an entirely different drug. These offenders duplicate manufacturer packaging and labels and falsify pedigree papers to sell the counterfeit drugs into the wholesale market as legitimate products. Counterfeit products are difficult to distinguish from authentic drugs, making it unlikely that health care professionals will detect them.

[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.
[6] These wholesalers have suspicious pedigree papers, have bought or sold drugs without pedigree papers, or have permits but no records of conducting legitimate business.
[7] These cases involve both permitted wholesalers and individuals who are not permitted for wholesale drug distribution.

Diverters fraudulently obtain prescription drugs and sell them back into the wholesale market for substantial profits. OPPAGA found that diversion occurs when individuals buy drugs from end-users such as patients, nursing homes, practitioners, and pharmacies and resell these drugs to wholesalers. Offenders obtain drugs for prices substantially below the market value, often from closed pharmacies, such as those in hospitals and clinics. [8] Diversion is a major problem in the Medicaid program, because criminals can obtain these drugs at low cost.

To facilitate diversion, dishonest wholesalers seek to own or have business interests in pharmacies and clinics. In one case, two individuals with interests in seven corporations obtained $1.3 million in drugs through fake Medicaid HIV/AIDS prescriptions then sold the drugs back into the wholesale market for $2.3 million. Medicaid drugs comprise the single largest source of diverted prescription drugs.

OPPAGA found that regulation of Florida's prescription drug wholesale market needs to be strengthened to control drug counterfeiting and diversion. OPPAGA found that current laws and procedures in Florida for regulating the prescription drug wholesale market have three major weaknesses that need to be addressed in order to reduce drug counterfeiting and diversion.

- Lack of clarity in the law allows counterfeiters and diverters to introduce illicit drugs into the prescription drug wholesale market.
- Inadequate safeguards for current drug wholesaler permit requirements make it easy for unscrupulous individuals to invade Florida's wholesale market.
- Inadequate administrative and criminal penalties for drug counterfeiting and diversion do not deter criminal behavior.

OPPAGA found that current laws regulating Florida's prescription drug wholesale market do not clearly define when authorized distributors of record (ADRs) are exempt from providing pedigree papers. As a result, ADR wholesalers do not provide pedigree papers for drugs that they purchased from other wholesalers, resulting in concealed counterfeit and diverted drugs that can reach end-users.

According to OPPAGA actual industry practice departs sharply from assumptions of the law, and a prescription drug can change hands or 'churn' through many wholesalers. Prescription drug wholesalers gain profits by purchasing drugs at lower than market value from manufacturers or other wholesalers that they then resell at a markup to other wholesalers. Because Florida law currently defines authorized distributors of record as wholesalers having an "ongoing relationship" with the manufacturer, large wholesalers typically claim the ADR exemption from pedigree papers for any purchase they make, even those purchased from another wholesaler and not from a manufacturer.

OPPAGA found that under current permitting procedures some individuals who the Bureau might otherwise deny a permit to are able to gain access to the wholesale market by using another person, usually a relative, as a front. Bureau officials have concerns about some wholesalers that maintain warehouses but do not appear to be actively doing business. Bureau officials suspect these premises may be used for illegal transactions. However, the bureau has no authority to deny or revoke permits for such businesses.

Moreover, the bureau extends reciprocity to wholesalers that are permitted in other states, even though Florida law provides that reciprocity should be granted only to wholesalers from states with comparable permitting procedures. Bureau officials interpret comparable permitting procedures to mean that the other states follow federal requirements. The federal requirements are less stringent than Florida's.

OPPAGA concluded that current administrative and criminal penalties may not deter criminal behavior. According to OPPAGA, criminals who counterfeit and divert drugs put the public at risk, make huge illicit profits, and waste government resources, yet current administrative and criminal penalties for counterfeiting and diverting prescription drugs may not be severe enough to deter their activities.

[8] Closed pharmacies are not open to the general public, but fill prescriptions for patients in these facilities.

Currently, the least severe penalty the bureau can impose on wholesalers is a fine ranging from $250 to $1,000. For violations it considers most severe, the bureau can impose fines ranging from $1,000 to a maximum $5,000 and suspend or revoke a wholesaler's permit. For investigations closed in calendar year 2001, the bureau assessed permitted wholesalers fines totaling $116,600 of which it collected $65,352 and revoked 13 wholesaler permits.

Under current criminal code, some prohibited acts involving counterfeit or diverted drugs are classified as third degree felonies, while others are first or second-degree misdemeanors. For example, first-time offenders diverting drugs from a hospital or a charity could be prosecuted only as a second-degree misdemeanor with a maximum sentence of 60 days incarceration and a $500 fine. The maximum sentence for first-degree misdemeanors is one-year incarceration and a $1,000 fine, while third-degree felonies carry a maximum sentence of five years incarceration and a $5,000 fine.

RECOMMENDATIONS MADE BY THE STATEWIDE GRAND JURY

Grand jury recommendations to the Legislature include:

- Mandate that Department of Health (DOH) 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.
- Require a $100,000 performance bond to be posted by wholesalers and require wholesalers to carry $2,000,000 in liability insurance.

Grand jury recommendations to the Department of Health include:

- 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.

Grand jury recommendations to the wholesale prescription drug industry include:

- 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.
- Report all suspected fraud to DOH or law enforcement.

Grand jury recommendations to pharmaceutical manufacturers include:

- Improve anti-counterfeiting measures for labels and packaging.
- Provide complete access to all wholesalers and dispensers attempting to authenticate pedigree papers or products.

SPECIFIC PROVISIONS OF THE BILL

Name of the Act:
Section 1 of the bill cites the act as the Prescription Drug Protection Act.

Findings and Intent:
Section 2 of the bill creates an undesignated section of law to provide legislative findings and intent. Based on the Seventeenth Statewide Grand Jury's report on dangers and abuses due to illicit activity in the wholesale prescription drug industry, the Legislature finds that "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.

Definitions:
Section 3 of the bill amends s. 499.003, F.S., to define:

- "**Affiliated party**" is defined 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;
  - A person who has filed or is required to file a personal information statement or be identified in an application; or
  - The five largest natural shareholders that own at least 5 percent of the permitted establishment or applicant.
- "**Authenticate**" is defined to mean to affirmatively verify that each transaction listed on the pedigree paper has occurred, before any distribution of a legend drug occurs.
- "**Contraband legend drug**" is defined to mean: any adulterated drug; any counterfeit drug; and any legend drug for which a pedigree paper does not exist or has been forged, counterfeited, falsely created, or contains false information.
- "**Diverted from the legal channels of distribution for prescription drugs**" is defined to mean an adulterated drug if the drug is a legend drug for which the required pedigree paper is nonexistent, fraudulent, or incomplete, 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 who exports those legend drugs.
- "**Legend drug label**" is defined to mean any display of written, printed or graphic matter on the immediate container of any legend drug, prior to its dispensing to an individual patient by prescription.
- 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), F.S. **Effective July 1, 2006**, a pedigree paper is defined as 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. Detailed information is required to be included on a legend drug's pedigree paper.
- "**Prescription label**" is defined to mean any display of written, printed or graphic matter on the immediate container of any legend drug dispensed through a prescription of a legally authorized practitioner.
- "**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., and rules, relating to pharmacy.

Prohibited Acts:
Section 4 of the bill amends s. 499.005, F.S., relating to prohibited acts, to revise or add additional acts which 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.

Criminal Acts Relating to Failure to Maintain or Deliver Pedigree Papers:
Section 5 of the bill creates s. 499.0051, F.S., relating to criminal acts involving contraband or adulterated drugs.

Failure to Maintain or Deliver--The bill creates criminal offenses relating to failure to maintain or deliver pedigree papers. The bill provides that:

- A person engaged in the wholesale distribution of legend drugs, other than a manufacturer, who fails to deliver complete and accurate pedigree papers concerning a legend drug or contraband legend drug to another person prior to transferring the drug to them, 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 drug 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.

Failure to Authenticate—
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:

Forgery of Pedigree Papers--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;

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

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

Sale or Delivery of Contraband Legend Drugs--A person who is knowingly in actual or constructive possession of any amount of contraband legend drugs, who knowingly sells or delivers, or who possesses 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:

Forgery of Labels--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.

Trafficking in Contraband Legend Drugs:
Section 6 of the bill creates s. 499.0052, F.S., to create a criminal offense of a first degree felony 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. Trafficking in contraband legend drugs is punishable by imprisonment up to 30 years and a fine up to $10,000.

Sale or Purchase of Contraband Legend Drugs Resulting in Great Bodily Harm:
Section 7 of the bill creates s. 499.00523, F.S., to create a criminal offense of a first degree felony 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. (Punishable by imprisonment up to 30 years and a fine up to $10,000.)

Sale or Purchase of Contraband Legend Drugs Resulting in Death:
Section 8 of the bill creates s. 499.00525, F.S., to create a criminal offense of a first degree felony 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. (Punishable by imprisonment up to 30 years and a fine up to $10,000.)

Adulterated Drugs:
Section 9 of the bill 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.

Misbranded Drugs:
Section 10 of the bill 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. The bill deletes language requiring labels of medicinal drugs to contain the name and place of business of the manufacturer.

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.

General Permitting Requirements in Section 499.01, F.S., Effective July 1, 2003:
Section 11 of the bill amends s. 499.01, F.S., relating to the permitting requirements for wholesalers, manufacturers, and distributors of drugs, devices, and cosmetics to make the following changes:

A permit for a prescription drug manufacturer, prescription drug wholesaler, or retail pharmacy drug wholesaler may only be issued to a natural person. A permit may not be issued to a Florida-licensed pharmacy.

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 of Health may issue a prescription drug manufacturer permit to an applicant at the same address as a licensed nuclear pharmacy for the purpose of manufacturing prescription drugs used in positron emission tomography or other radiopharmaceuticals.

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.

Permits expire and are subject to annual renewal rather than biennial renewal. 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.

The bill continues the provision for a phase in of licensing requirements. The bill provides that for prescription drug wholesaler and out-of-state prescription drug wholesaler permits:

- A new permit 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 permit issued 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.

- Any permit issued 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.

Credits are provided for unexpired permits that must be renewed.

General Permitting Requirements in Section 499.01, F.S., Effective January 1, 2004:
Section 12 of the bill, effective January 1, 2004, amends s. 499.01, F.S., as amended.

The bill reorganizes 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.

Permits are also required for prescription drug repackagers, nonresident prescription drug manufacturers, and freight forwarders.

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.

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., that provide licensing requirements for prescription drug wholesalers. The bill provides for permitting requirements that are unique to permits for a prescription drug wholesaler or out-of-state prescription drug wholesaler.

Wholesale Distribution Permit Requirements in Section 499.012, F.S., Effective July 1, 2003:
Section 13 of the bill amends s. 499.012, F.S., to make the following changes:

Exemption for Hospitals--The bill provides 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” 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.

Definitions--The bill provides definitions of the following terms:

- “**Primary wholesaler**” means any wholesale distributor that purchased 90 percent or more of its prescription drugs in the previous year directly from a manufacturer; 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.
- "**Secondary wholesaler**" means a wholesale distributor that is not a primary wholesaler.

Required Bond--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 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.

Intra-company Sales or Transfers--Requirements for out-of-state prescription drug wholesalers involving intra-company 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.

Elimination of Reciprocity Permits--The bill revises eliminate reciprocity permitting requirements for out-of-state prescription drug wholesalers 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.

Wholesale Distribution Permit Requirements in Section 499.012, F.S., Effective January 1, 2004: Section 14 of the bill, 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.

A Nonresident Prescription Drug Manufacturer Permit is required for any person who engages in the wholesale distribution in Florida of the prescription drugs it manufactures and 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 which 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.

An Out-of-State Prescription Drug Wholesaler Permit is required for any person who distributes wholesale prescription drugs that it did not manufacture.
- 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 who 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.

Information Required for a Permit--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.

Person Information Required--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 that 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.

Submission of Fingerprints--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 Wholesaler Information—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.

Factors that the department must consider in reviewing the qualifications of persons seeking a permit to engage in prescription drug wholesale activities 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.

Reasons for which the department 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 are specified, including whether 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.

Department Rules--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.

Designation of a Natural Person--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 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.

Storage, Handling and Recordkeeping Requirements and Effective Dates:
Section 15 of the bill amends s. 499.0121, F.S., relating to the storage, handling, and recordkeeping requirements for prescription drugs

Examination of Materials and Records--
Wholesalers are required 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. (Effective July 1, 2006, prescription drug wholesalers must authenticate each transaction listed on a pedigree paper.)

Record Keeping--
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.

Record Keeping Provisions in Effect Until July 1, 2006--
Section 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.

"Authorized Distributor of Record" (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.

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.

Each manufacturer must file a written list of all of the manufacturer's authorized distributors with the department and must notify the department no later than 10 days after any change to the list. The department must publish the list on its website.

An ongoing relationship **(effective March 1, 2004)** is deemed to exist for purposes of s. 499.0121(6)(d), F.S., when a wholesale distributor:

- Is listed on the manufacturer's current list of authorized distributors.
- Annually purchases not less than 90 percent of the dollar volume of its purchases of a manufacturer's prescription drug products directly from that manufacturer, and has annual prescription sales of $100 million or more.
- 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.

Specified Drug Provisions in Effect Until July 1, 2006—
"**Specified drug**" means a specific prescription drug on the list of drugs adopted by the department by rule. Pursuant to s. 499.0121(6)(e), F.S., 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 Department of Health is authorized to adopt rules to administer the requirements of these written statements.

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 non-responsiveness 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;
    - The department has found not less than five instances where statements required for the prescription drug were not passed on or have been passed on and 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.

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.

Pedigree Papers Provisions Effective July 1, 2006—
Effective July 1, 2006, pursuant to s. 499.0121(6)(f), F.S., 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. The department may by rule, exempt compressed medical gases and veterinary prescription drugs from the "pedigree paper" requirements.

Each prescription drug wholesale distributor must maintain all statements that are required for the "pedigree papers" separate and distinct from other required records, and must, upon request, make documentation available to document compliance.

Pursuant to s. 499.0121(6)(g), F.S., each wholesale distributor 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.

Written Policies and Procedures--
Pursuant to s. 499.0121(7), F.S., 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.

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.

Due Diligence of Suppliers:
Section 16 of the bill, **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 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.

Drug Wholesaler Advisory Council:
Section 17 of the bill 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.

Conforms Cross References:
Section 18 of the bill, effective January 1, 2004, amends s. 499.0122(2)(b), F.S., relating to medical oxygen and veterinary legend drug retail establishments to conform cross references to changes in the bill.

Section 19 of the bill, which is effective July 1, 2003, amends s. 499.0122(2)(c), F.S., to conform cross references.

Repackager Permits:
Section 20 of the bill **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.

Hospital Distribution Exemption:
Section 21 of the bill 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 relating to pedigree requirements.

Conforms Cross References:
Section 22 of the bill amends s. 499.015(1)(a), F.S., relating to registration, to conform cross references to changes in the bill.

Section 23 of the bill amends s. 499.024(3), F.S., relating to drug product classification, to conform cross references.

Section 24 of the bill amends s. 499.03(1), F.S., relating to exemptions to possession of new drugs without prescriptions, to conform cross references.

Increased Fees:
Section 25 of the bill 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;
- A prescription drug wholesaler's permit from $400 to $800 annually; and
- An out-of-state prescription drug wholesaler's permit no less than $300 and no greater than $800 annually.

The bill creates new fees for:

- A prescription drug repackager's permit to be not less than $500 or more than $750 annually;
- A nonresident prescription drug manufacturer's permit to be not less than $300 or more than $500 annually;
- A freight forwarder's permit to be not less than $200 or more than $300 annually;
- An 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
- Persons applying for certification as a designated representative a fee of $150, plus the cost of processing the criminal history record.

Conforms Cross References:
Section 26 of the bill amends s. 499.05(1)(g), F.S., relating to rules, to conform cross references to changes in the bill.

Inspections:
Section 27 of the bill 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 to inspect, review, and copy financial documents or records related to the distribution of a drug to determine compliance with the Florida Drug and Cosmetic 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.

Public Reporting:
Section 28 of the bill 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.

Imminent Danger Inspections:
Section 29 of the bill creates s. 499.065, F.S., relating to imminent danger, to require the Department of Health 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 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.

The department must have the right of entry and access to these facilities at any reasonable time. 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.

Civil, Criminal and Cease and Desist Actions:
Section 30 of the bill 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.

Section 31 of the bill 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.

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 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 non-emergency 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 order must give notice of opportunity for a hearing for the affiliated party to contest the order.

Authority to Deny, Suspend or Revoke a Permit:
Section 32 of the bill, 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.

Specific grounds to deny, suspend or revoke a permit include:

- 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.

Punishment for Violations:
Section 33 of the bill 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.

Criminal Offenses:
Section 34 of the bill creates s. 499.0691, F.S., to establish criminal offenses relating to violations under the Act regarding the distribution or manufacture of drugs.

Second Degree Misdemeanors/First Degree Misdemeanors for Second Offense-- 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. If the violation is committed after a conviction under this section has become final, the 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.

Third Degree Felonies--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.

Second Degree Felonies--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.

Criminal Punishment Code Severity Rankings:
Section 35 of the bill amends s. 921.0022, F.S., relating to the offense severity ranking chart of the Criminal Punishment Code, to include certain violations of the Florida Drug and Cosmetic Act, 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 ranking of offenses established by the bill are:

Third degree felony offenses, ranked as Level 4 offenses:

- Failure to maintain or deliver pedigree papers; and
- Failure to authenticate pedigree papers.

Second degree felony offense, ranked as a Level 4 offense:

- Sale or delivery, or possession with intent to sell, contraband legend drugs.

Second degree felony offenses, 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.

First degree felony offenses, ranked as Level 8 offenses:

- Forgery of prescription or legend drug labels; and
- Trafficking in contraband legend drugs.

First degree felony offense, ranked as a Level 9 offense:

- Sale or purchase of contraband legend drugs resulting in great bodily harm.

First degree felony offense, ranked as a Level 10 offense:

- Sale or purchase of contraband legend drugs resulting in death.

Office of Statewide Prosecution:
Section 36 of the bill 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.

Racketeering Provisions:
Section 37 of the bill 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.

Statewide Grand Jury:
Section 38 of the bill 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.

Severability Clause:
Section 39 of the bill provides a severability clause.

Section 40 of the bill provides that, except as otherwise expressly provided in this act, the bill takes effect July 1, 2003.

C. SECTION DIRECTORY:

Section 1. Names the act the Prescription Drug Protection Act.

Section 2. Provides Legislative findings and intent.

Section 3. Amends s. 499.003, F.S., to provide definitions.

Section 4. Amends s. 499.005, F.S., relating to prohibited acts.

Section 5. Creates s.499.0051, F.S., relating to criminal acts involving contraband or adulterated drugs.

Section 6. Creates s. 499.0052, F.S., to create a criminal offense for trafficking.

Section 7. Creates s. 499.00523, F.S., to create a criminal offense for sale or purchase resulting in great bodily harm.

Section 8. Creates s. 499.00525, F.S., to create a criminal offense for sale or purchase resulting in death.

Section 9. Amends s. 499.006, F.S., relating to adulterated drugs.

Section 10. Amends s. 499.007, F.S., relating to misbranded drugs.

Section 11. Amends s. 499.01, F.S., relating to general permitting requirements, effective July 1, 2003.

Section 12. Amends s. 499.01, F.S., relating to general permitting requirements, effective January 1, 2004.

Section 13. Amends s. 499.012, F.S., relating to wholesale distributor permits, effective July 1, 2003.

Section 14. Amends s. 499.012, F.S., relating to wholesale distributor permits, effective January 1, 2004.

Section 15. Amends s. 499.0121, F.S., relating to storage, handling and record keeping with various effective dates of July 1, 2003, January 1, 2004 and July 1, 2006.

Section 16. Amends s. 499.0121, F.S., relating to due diligence of suppliers, which becomes effective January 1, 2004.

Section 17. Creates s. 499.01211, F.S., to create Drug Wholesale Advisory Council.

Section 18. Amends s. 499.0122, F.S., to conform cross reference, effective January 1, 2004.

Section 19. Amends s. 499.0122, F.S., to conform cross reference, effective July 1, 2003.

Section 20. Amends s. 499.013, F.S., relating to manufacturers.

Section 21. Amends s. 499.014, F.S., to provide exemption for hospital distribution.

Section 22. Amends s. 499.015, F.S., to conform cross reference.

Section 23. Amends s. 499.024, F.S., to conform cross reference.

Section 24. Amends s. 499.03, F.S., to conform cross reference.

Section 25. Amends s. 499.041, F.S., increasing fees.

Section 26. Amends s. 499.05, F.S., to conform cross reference.

Section 27. Amends s. 499.051, F.S., relating to inspections.

Section 28. Amends s. 499.055, F.S., relating to reports and dissemination of information.

Section 29. Creates s. 499.065, F.S., relating to inspections of imminent dangers.

Section 30. Amends s. 499.066, F.S., to provide for civil and criminal actions to enforce provisions.

Section 31. Creates s. 499.0661, F.S., to create new cease and desist remedies.

Section 32. Amends s. 499.067, F.S., to authorize denial, suspension or revoking of permit.

Section 33. Amends s. 499.069, F.S., to provide penalties.

Section 34. Creates s. 499.0691, F.S., to provide criminal offenses.

Section 35. Amends s. 921.0022, F.S., to provide severity rankings in Criminal Punishment Code.

Section 36. Amends s. 16.56, F.S., to authorize Office of Statewide Prosecution to prosecute.

Section 37. Amends s. 895.02, F.S., to provide for racketeering prosecution.

Section 38. Amends s. 905.34, F.S., to expand jurisdiction of statewide grand jury.

Section 39. Provides a severability clause.

Section 40. Provides an effective date of July 1, 2003, except as otherwise provide in the act.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   See Fiscal Comments.

2. Expenditures:

   See Fiscal Comments.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

See Fiscal Comments.

D. FISCAL COMMENTS:

The bill increases the statutory fee caps: for a prescription drug wholesaler's permit from $400 to $800 annually; for an out-of-state prescription drug wholesaler's permit no less than $300 and no greater than $600 annually; for a retail pharmacy drug wholesaler's permit from $50 to $100, annually; and for a restricted prescription drug distributor's permit from $300 to $600.

According to the Department of Health, it 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 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.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   This bill does not require counties or municipalities to spend funds or to take an action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenues.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

The bill provides rulemaking authority to the department.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill requires an extensive disclosure of personal information of individuals and their immediate families who are applying for a prescription drug wholesale permit. Under applicable Florida law such information will be public unless otherwise exempt from the Public Records Law. It is unclear how the Department of Health will corroborate the criminal history information of any immediate family members that is submitted as part of the initial licensure application and whether subsequent renewals should include an update of such information.

The bill requires a statewide check for individuals representing pharmaceutical drug wholesalers who are subject to any subsequent permit renewals. 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.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

On April 10, 2003, the Health Standards Subcommittee adopted a “strike-all” amendment and reported the bill favorably to the Committee on Health Care.

Amendment 1 conforms HB 1481 to the provisions of the Senate bill. The amendment provides:

- Findings and intent.
- Additional definitions.
- Removes and expands permitting provisions.
- Creates criminal acts related to contraband and adulterated drugs.
- Creates sanctions for trafficking contraband legend drugs.
- Creates sanctions for sale or purchase of contraband legend drugs.
- Creates sanctions for sale or purchase of contraband legend drugs resulting in death.
- Establishes that legend drugs without pedigree papers are adulterated drugs.
- Establishes requirements for repackagers.
- Changes permit requirements.
- Provides for statutory change in requirements for wholesale distributors in 2004.
- Establishes criteria for “authorized distributor of record.”
- Requires permitting of repackagers.
- Requires reporting by department.

On April 15, 2003, the Committee on Health Care amended the amendment recommended by the subcommittee and reported the bill favorably “with a CS.”