HOUSE OF REPRESENTATIVES STAFF ANALYSIS

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

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

SUMMARY ANALYSIS

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. 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 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.

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.

The bill creates the Drug Wholesaler Advisory Council to oversee rules and make recommendations to the Department of Health. It provides for the council's organization, powers, and duties.

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.

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

On April 10, 2003, the Health Standards Subcommittee adopted a "strike-all" amendment and reported the bill favorably to the Committee on Health Care. See Section IV. AMMENDMENTS/COMMITTEE SUBSTITUTE CHANGES for details.

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 additional prohibitions against label tampering and the distribution of a drug previously dispensed by a Florida-licensed pharmacy. The bill overhauls the permitting requirements for drug wholesalers 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."

For high-risk prescription drugs, the bill requires each person engaged in the wholesale distribution of a high-risk prescription drug to 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, before any sale of such high-risk drug is made to the wholesale distributor. The written statement is required to include the lot number of the high-risk prescription drug and the sales invoice number of the invoice evidencing each previous sale of the high-risk prescription drug. The written statement must accompany the high-risk prescription drug 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.

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 wholesaler's permit from $400 to $800 annually;
- An out-of-state prescription drug wholesaler's permit no less than $300 ($200) and no greater than $600 ($300) annually;
- A retail pharmacy drug wholesaler's permit from $50 to $100, annually; and
- A restricted prescription drug distributor's permit from $300 to $600.

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 they are engaged in specified prohibited acts.

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.

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. [1] In addition, criminal prescription drug counterfeiting and diversion cases have increased from almost none in the 1990's to more than 50 since 1999.[2]

Counterfeit drugs pose major health risks. In its report, OPPAGA found that **c**riminals 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

[1] These wholesalers have suspicious pedigree papers, have bought or sold drugs without pedigree papers, or have permits but no records of conducting legitimate business.

[2] These cases involve both permitted wholesalers and individuals who are not permitted for wholesale drug distribution.

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.

Counterfeiters tend to target vulnerable populations. A current trend is to counterfeit high-priced drugs that are used to boost immune systems of cancer and HIV/AIDS patients. Because these patients are seriously ill, doctors may not immediately recognize the effects of a counterfeit drug. For example, physicians may attribute a patient's failure to respond or adverse side effects to the disease and not to a counterfeit drug.

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. [3] Diversion is a major problem in the Medicaid program, because criminals can obtain these drugs at low cost. Diverters persuade Medicaid clients to 'doctor shop', encouraging them to get prescriptions written and filled they do not plan to use. The diverters buy the drugs from the clients for a small fee, and then sell the drugs back into the wholesale market for a profit. Diverters also may obtain reduced-price drugs intended for export to charitable foreign missions or steal them from warehouses, clinics, or trucks.

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.

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

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.

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.

C. SECTION DIRECTORY:

Section 1. Amends s. 499.003, F.S., to define "affiliated party."

Section 2. Amends s. 499.005, F.S., to prohibit acts relating to previously dispensed drugs

Section 3. Amends s. 499.01, F.S., to revise permit requirements.

Section 4. Amends s. 499.012, F.S.; to provide: definitions; additional permit requirements for prescription drug wholesalers, out-of-state prescription drug wholesalers, and retail pharmacy drug wholesalers; and for renewal on an annual basis; and to require designation of a natural person as a wholesaler's representative.

Section 5. Amends s. 499.0121, F.S. to providing for wholesale distributor due diligence; to require reporting with respect to previous sales of prescription drugs, including high-risk prescription drugs; to require wholesale distributors to submit annually a list of the wholesalers from whom they purchase drugs; and to prohibit a wholesale drug distributor from paying for any drug with currency.

Section 6. Amends s. 499.0122, F.S., to conform cross references for rule authority.

Section 7. Creates s. 499.0125, F.S. to create the Drug Wholesaler Advisory Council, and provide for the council's organization, powers, and duties.

Section 8. Amends s. 499.015, F.S., to conform cross references.

Section 9. Amends s. 499.024, F.S., to conform cross references.

Section 10. Amends s. 499.03, F.S., to conform cross references.

Section 11. Amends s. 499.041, F.S. to increase permit fees for prescription drug wholesalers, out-of-state prescription drug wholesalers, and retail pharmacy drug wholesalers.

Section 12. Amends s. 499.05, F.S., to conform a cross reference.

Section 13. Amends s. 499.051, F.S., to expand authority of the Department of Health and the Department of Law Enforcement to inspect financial records and investigate complaints and violations.

Section 14. Creates s. 499.0671, F.S., to provide enforcement provisions, including cease and desist orders and removal of affiliated parties.

Section 15. Amends s. 499.069, F.S. to provide penalties.

Section 16. Provides an effective date of July 1, 2003.

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 ($200) and no greater than $600 ($300) 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:

B. RULE-MAKING AUTHORITY:

The bill provides rule making authority to the department.

C. DRAFTING ISSUES OR OTHER COMMENTS:

Section 4 of 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.