HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 489 CS Pedigree Papers
SPONSOR(S): Zapata
TIED BILLS: **IDEN./SIM. BILLS:** SB 874

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee	9 Y, 0 N, w/CS	Bell	Mitchell
2) Health Care Appropriations Committee			
3) Health & Families Council			
4)			
5)			

SUMMARY ANALYSIS

HB 489 with CS addresses pedigree paper requirements that were implemented as part of the 2003, SB 2312 reform of the Florida Drug and Cosmetic Act. The reform was in response to the Seventeenth Statewide Grand Jury[1] and the 2003 OPPAGA report[2] on drug fraud and diversion.

Pedigree papers are the key standard for control of the wholesale drug industry designed to prevent drug diversion, fraud, and counterfeiting. They require wholesalers to provide purchasers with a written sales history tracing each drug back to its initial manufacturer. 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.

HB 489 with CS removes a sunset provision in s. 499.0121, F.S., to continue a current policy that allows a chain drug store warehouse that is part of an "affiliated group," to distribute a prescription drug to another warehouse within the chain drug store's "affiliated group" without providing a pedigree paper as required. A repackager that is a member of the chain drug store's affiliated group must provide a statement of the source of its repackaged prescription drugs distributed to affiliated group member pharmacies in lieu of the pedigree paper history.

HB 489 with CS amends s. 499.003, F.S., to clarify that a pedigree paper may be in either paper or electronic form. The bill also requires a pedigree paper to include an invoice number, shipping document number, or other number uniquely identifying the transaction. Additionally, if the manufacturer or repackager has uniquely serialized the individual legend drug unit in a generally recognized standardized method, that identifier must also be included on the pedigree paper.

According to the Department of Health (DOH), current statutory language does not preclude receiving or passing on a pedigree paper in electronic form. DOH is in the process of developing a new administrative rule procedure proscribing parameters for electronic pedigrees.

The effective date of the bill is upon becoming law.

[1] First Interim Report of the Seventeenth Statewide Grand Jury, Florida Supreme Court, SC02-2645, 2003.
[2] Counterfeit and Diverted Drugs Threaten Public Health and Waste State Dollars, OPPAGA, 03-18, 2003.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide limited government – The bill removes a sunset provision to enable pharmacies to use special pedigree paper provisions for "affiliated groups" involved in wholesaling, distributing, and dispensing prescription drugs.

Safeguard Individual Liberty – If the affiliated group provisions are not sunset by the bill, smaller retail pharmacies and wholesalers may be put at a competitive disadvantage when full pedigree paper requirements are implemented on July 1, 2006.

B. EFFECT OF PROPOSED CHANGES:

HB 489 with CS addresses pedigree paper reforms that will become effective July 1, 2006. The intent of HB 489 with CS is to maintain current phase I regulation in lieu of transitioning into phase II regulation for "affiliated group" members.

Pedigree Paper Definition

HB 489 with CS amends s. 499.003, F.S., to clarify that a pedigree paper may be in either paper or electronic form. The bill also requires a pedigree paper to include an invoice number, shipping document number, or other number uniquely identifying the transaction. Additionally, if the manufacturer or repackager has uniquely serialized the individual legend drug unit in a generally recognized standardized method, that identifier must also be included on the pedigree paper.

According to the Department of Health (DOH), current statutory language does not preclude receiving or passing a pedigree paper in electronic form. DOH is in the process of developing administrative rules for electronic pedigrees.

Affiliated Group - Chain Drug Store Pedigree Requirements

HB 489 with CS removes a sunset provision in s. 499.0121(6)(h)4., F.S., to continue a policy that provides that a chain drug store warehouse that is part of an "affiliated group," can distribute a prescription drug to another warehouse within the chain drug store's affiliated group, without providing a pedigree paper that would otherwise be required by ss. 499.0121(d) or (e), F.S. A repackager that is a member of the chain drug store's affiliated group must provide a statement related to the source of its repackaged prescription drugs distributed to affiliated group member pharmacies in lieu of the pedigree paper history required in ss. 499.0121(6)(d), (e), or (f), F.S.

"**Affiliated Group" Designation**

Affiliated groups are defined by s. 1504 of the Internal Revenue code of 1986. According to s. 499.0121, F.S., "affiliated groups" are composed of chain drug entities, including at least 50 retail pharmacies, warehouses, or repackagers. Affiliated groups must:

- Disclose to the Department of Health (DOH) the names of all the members; and
- Agree in writing to provide records on prescription drug purchases by members of the same affiliated group not later than 48 hours after DOH request such records, regardless of where the records are stored.

Warehouses within the affiliated group must apply with all federal and state wholesale permit requirements and must purchase, receive, hold, and distribute prescription drugs to only a retail pharmacy or warehouse within the affiliated group.

CURRENT SITUATION

On July 1, 2006, s. 499.0121, F.S., paragraph (h) is scheduled to sunset, and the provisions in paragraph (f) will govern pedigree paper requirements. Paragraph (f) provides that each person who is engaged in the wholesale distribution of a prescription drug and who is not the manufacturer of that drug, must provide a pedigree paper defined in s. 499.003(31) to the person who receives the drug. On July 1, 2006 the special provisions for affiliated groups will phase out and all players will be required to meet the same pedigree paper requirements.

BACKGROUND

Pedigree Papers

Pedigree papers are the key standard for control of the wholesale drug industry designed to prevent drug diversion, fraud, and counterfeiting. They require wholesalers to provide purchasers with a written sales history tracing each drug back to its initial manufacturer. 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.

Seventeenth Statewide Grand Jury Report[3]

The Seventeenth Statewide Grand Jury report[4] 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.

Office of Program Policy Analysis and Government Accountability (OPPAGA) Report[5]

In February, 2003, the OPPAGA issued report No. 03-18 highlighting problems with counterfeit and diverted drugs in Florida. The findings of the report indicated that millions of dollars are lost due to counterfeit and diverted drugs in Florida's prescription drug wholesale industry. The report found a rise in drug cases involving counterfeit and diverted drugs in Florida's prescription drug industry. The report concluded that current Florida law did not provide adequate controls over wholesale drug market practices, and current administrative and criminal penalties failed to provide an adequate deterrent.

Florida Drug & Cosmetic Act

Pursuant to the Florida Drug and Cosmetic Act, pt. 1, ch. 499, F.S., DOH 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 by the department or otherwise exempt.[6]

Under the Florida Drug and Cosmetic Act (or the Act), any person who is at least 18 years of age or older and who can pay the permit fee, and after submission of specified information that all permit applicants must provide, with certain exceptions, may obtain a permit as a prescription drug wholesaler.[7] The applicant must not have been found guilty, regardless of adjudication, of a violation of

[3] First Interim Report of the Seventeenth Statewide Grand Jury, Florida Supreme Court, SC02-2645, 2003.
[4] First Interim Report of the Seventeenth Statewide Grand Jury, Florida Supreme Court, SC02-2645, 2003.
[5] Counterfeit and Diverted Drugs Threaten Public Health and Waste State Dollars, OPPAGA, 03-18, 2003.
[6] 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.
[7] 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

a law that directly relates to a drug, device, or cosmetic. The applicant must submit information on contact persons for each facility used by the applicant for the storage, handling and distribution of prescription drugs. The permit, once granted, may be renewed biennially.

An out-of-state prescription drug wholesaler distributor located outside of Florida must be permitted by the Department of Health. The department is authorized to adopt rules that allow out-of-state drug wholesalers to obtain a drug wholesale permit on the basis of reciprocity in Florida to the extent that an out-of-state drug wholesaler possesses a valid permit from another state that has requirements that are comparable to those of Florida and can show that the other state from which the wholesaler holds a permit would extend reciprocal treatment under its laws to a Florida-permitted drug wholesaler. According to the Department of Health there are approximately 450 prescription drug wholesalers located in Florida and 900[8] 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 remainders 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 Florida Drug and Cosmetic 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 $1,000 or 1 year imprisonment) if it is a second conviction for the violation of the Act.

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 sold in a wholesale market.

SB 2312: 2003 Reform of Florida Drug and Cosmetic Act (the Act)

In 2003 the Legislature revised the Florida Drug and Cosmetic Act to impose more stringent regulation on prescription drug wholesalers.

SB 2312 adopted many of the recommendations of the Seventeenth Statewide Grand Jury report[9] and OPPAGA report[10] on drug diversion. The bill significantly strengthened record keeping requirements for wholesalers and repackagers of prescription drugs. Several of these new “pedigree paper” requirements have a secondary phase-in period starting July 1, 2006.

The bill created criminal offenses relating to illicit activities involving diversion from wholesale distribution of prescription drugs. Additional prohibitions were created regarding label tampering with the intent to distribute a drug and the distribution of a drug previously dispensed by a Florida-licensed pharmacy. Effective January 1, 2004, the permitting requirements for drug wholesalers were 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.

C. SECTION DIRECTORY:

Section 1. Amends s. 499.003, F.S., to clarify that pedigree papers can be in electronic form and specify that pedigree papers must include an invoice number, shipping document number, or other number uniquely identifying the transaction.

Section 2. Amends s. 499.012, F.S., to allow the sale, purchase, or trade of a prescription drug between pharmacies as a result of a sale, transfer, merger, or consolidation of all or part of the business of the pharmacies with another pharmacy.

Section 3. Amends s. 499.0121, F.S., to remove a sunset provision to continue an exemption from pedigree papers for affiliated group members conducting internal business.

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establishment; medical oxygen retail establishment; complimentary drug distributor; or restricted prescription drug distributor.

[8] According to the Department of Health 2003 records.

[9] First Interim Report of the Seventeenth Statewide Grand Jury, Florida Supreme Court, SC02-2645, 2003.

[10] Counterfeit and Diverted Drugs Threaten Public Health and Waste State Dollars, OPPAGA, 03-18, 2003.

Section 4. Provides the bill is effective upon becoming law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Electronic pedigree papers will take advantage of technology to facilitate the tracing and tracking of prescription drugs, and eliminate a manually intensive paper system for those wholesalers wishing to take advantage of such technology.

Small pharmacies may incur costs if they choose to purchase an electronic pedigree paper system.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   This bill does not require counties or municipalities to spend funds or 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 revenue.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

No additional rulemaking authority is required to implement the provisions of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

Proponents of the bill have expressed concerns that small pharmacies will be unable to comply with the regulation of receiving pedigree papers beginning July 1, 2006. Proponents assert that storage space is often limited, and that electronic pedigree systems may be too expensive for small pharmacies.

Proponents also argue that the phase II pedigree paper requirements set to implement in July 1, 2006 will be burdensome for the industry and may increase the cost of prescription drugs. They also assert that is not practical to require companies that act as wholesalers and retailers to pass pedigrees when transferring drugs within their company.

Opponents of this bill assert that the phase II regulations will provide added safety to the Florida prescription drug supply. They also argue that requiring pedigree papers for all prescription drug transactions will increase transparency and drive drug diverters out of the market. Opponents feel that full pedigree paper requirements are needed to address the concerns raised in the Seventeenth Statewide Grand Jury report[11] and OPPAGA report on drug diversion.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

On April 13, 2004, the Health Care Regulation committee adopted a strike-all amendment proposed by the bill sponsor.

The Strike-All Amendment:

- Clarifies that a pedigree paper may be in either paper or electronic form.
- Requires a pedigree paper to include an invoice number, shipping document number, or other number uniquely identifying the transaction. Additionally, if the manufacturer or repackager has uniquely serialized the individual legend drug unit in a generally recognized standardized method, that identifier must also be included on the pedigree paper.
- Removes the sunset of special pedigree paper provisions for "affiliated groups."
- Allows the sale, purchase, or trade of a prescription drug between pharmacies as a result of a sale, transfer, merger, or consolidation of all or part of the business of the pharmacies with another pharmacy.

The bill analysis is drafted to the committee substitute.

[11] First Interim Report of the Seventeenth Statewide Grand Jury, Florida Supreme Court, SC02-2645, 2003.