HOUSE OF REPRESENTATIVES STAFF ANALYSIS

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

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee		Bell	Mitchell
2) Health Care Appropriations Committee			
3) Health & Families Council			
4)			
5)			

SUMMARY ANALYSIS

HB 489 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.

The 2003 reforms in SB 2312 currently provide for two implementation phases. Phase I was implemented on July 1, 2003 and is scheduled to sunset July 1, 2006. Phase II is set to be implemented July 1, 2006. The purpose of HB 489 is to maintain current phase I regulation in lieu of transitioning into phase II regulation. The bill maintains "current authorized distributor of record" designations, processes for "non-specified drug" transactions, the "specified drug" list, processes for "specified drug" transactions, exemptions for transactions between affiliated groups, and the current pedigree paper chain that does not require pharmacies to receive pedigree papers. The bill does not address implementation of phase II reforms in s. 499.0121, F.S, which will require comprehensive pedigree papers for all prescription drugs from manufacturer through sale to a pharmacy.

HB 489 amends s. 499.003, F.S., to clarify that a pedigree paper may be in either paper or electronic form. 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 bill was incorrectly drafted and leaves in a provision that requires pharmacies to receive pedigree papers.

The effective date of the bill is July 1, 2005.

[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 sunset provisions in phase I of the pedigree paper statute. The bill intends to maintain current regulation.

B. EFFECT OF PROPOSED CHANGES:

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

Pedigree Paper Definition

HB 489 amends s. 499.003, F.S., to clarify that a pedigree paper may be in either paper or electronic form. 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.

Pharmacy Pedigree Paper Requirements

The bill deletes a line of text that references the pedigree paper requirements for pharmacies to receive pedigrees, set to implement on July 1, 2006, but does not remove the requirement of pharmacies to receive pedigree papers as intended. The bill leaves in place the phrase that requires a pedigree paper, "from sale by a pharmaceutical manufacturer, through acquisition and sale by any wholesaler or repackager." Thus, if a wholesaler or repackager sells a prescription drug to a pharmacy, a pedigree paper is required to follow that sale.

General Pedigree Paper Requirements

HB 489 removes a sunset provision in s. 499.0121(6)(d), F.S., to continue a policy that specifies parameters for wholesalers that do not meet "authorized distributor of record" (ADR) requirements. Each person who is engaged in wholesale distribution and does not meet ADR specification must prepare and provide a pedigree paper for the distribution of a prescription drug (not listed on the "specified drug list"[3]) back to the last authorized distributor of record (rather than back to the manufacturer of the drug). ADR wholesalers do not have to meet this provision.

Authorized Distributor of Record Designation

A wholesale distributor or affiliated group with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's products can be designated as ADR. 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 the manufacturer's products handled by the wholesaler directly from the manufacturer and has total annual prescription sales of $100 million or more; and
- The wholesaler has reported to DOH sales of $100 million or more, has a verifiable account number issued by the manufacturer authorizing the wholesale distribution to purchase the manufacturer's drug product directly from that manufacturer, and that wholesale distributor makes not fewer than 12 purchases of that manufacturer's drug product directly from the manufacturer.

[3] The specified drug list is a list of prescription drugs that are most likely to be diverted. The Department of Health places drugs that meet certain requirements on the list. There are currently 31 drugs on the specified drug list.

Pedigree Requirements for "Specified Drugs"

HB 489 removes a sunset provision in s. 499.0121(6)(e), F.S., to continue a policy that requires each prescription drug wholesaler to prepare a pedigree paper for the distribution of each "specified drug" by DOH rule, that traces the distribution history of that prescription drug from the manufacturer and through the wholesale distribution chain. ADR designated wholesalers must pass pedigree papers for "specified drugs." DOH has a comprehensive procedure to create the "specified drug list." There are currently 31 drugs on the "specified drug list."

Chain Drug Store Pedigree Requirements

HB 489 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, which is a prescription drug wholesaler, may 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 for a non-specified or specified prescription drug as required in ss. 499.0121(d) or (e), F.S., respectively. Also, a repackager that is a member of the chain drug store's affiliated group may provide a statement related to the source of its repackaged prescription drugs that are distributed to affiliated group member pharmacies in lieu of the pedigree paper history required in ss. 499.0121(6)(d) or (e), F.S.

CURRENT SITUATION

On July 1, 2006, s. 499.0121, F.S., paragraphs (d), (e), and (h) are 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, before each wholesale distribution of such drug, provide to the person who receives the drug a pedigree paper defined in s. 499.003(31). On July 1, 2006 the specified drug list, ADR designation, and 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[4]

The Seventeenth Statewide Grand Jury report[5] 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[6]

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.

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

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.[7]

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.[8] The applicant must not have been found guilty, regardless of adjudication, of a violation of a law that directly relates to a drug, device, or cosmetic. The applicant must submit information on contact persons for each facility used by the applicant for the storage, handling and distribution of prescription drugs. The permit, once granted, may be renewed biennially.

An out-of-state prescription drug wholesaler 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[9] 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[10] and OPPAGA report[11] 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.

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[7] 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.

[8] 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.

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

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

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

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.

Specified Drug Provisions

"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 "specified drug" requirements.

Specified Drug Designation

The department may place any drug on the list of "specified drugs" if:

- DOH has seized or issued a stop sale notice on the prescription drug because of the adulteration, counterfeiting, or diversion of the prescription drug from 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 seven following criteria:
    1. 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;
    2. The prescription drug is available for normal prescription use in dosages or strengths that have a wholesale cost $200 or more;
    3. 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;
    4. The prescription drug is an injectable drug;
    5. The prescription drug is subject to a special, limited distribution process and is not generally sold to wholesale distributors by the manufacturer;
    6. 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
    7. A shipment of a prescription drug has been reported to a law enforcement agency as having been stolen or missing.

A prescription drug may also be placed on the list of "specified drugs" if the prescription drug satisfies any three of the 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 drug," 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.

SB 2312 authorized 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.

Currently, the "specified drug list" is set to expire July 1, 2006.

C. SECTION DIRECTORY:

Section 1. Amends s. 499.003, F.S., to clarify that pedigree papers can be in electronic form and to remove language referencing the requirement for pharmacies to hold pedigree papers starting July 1, 2006.

Section 2. Amends s. 499.0121, F.S., to remove three sunset provisions related to pedigree paper requirements. The bill seeks to continue current policy governing wholesale distribution of "non-specified drugs," an exemption from pedigree papers of "non-specified drugs for authorized distributors of record," wholesale requirements for "specified drugs," and an exemption from pedigree papers for affiliated group members conducting internal business.

Section 3. Provides an effective date of July 1, 2005.

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:

The bill does not address all the provisions that are set to come into effect July 1, 2006. Thus, if passed this bill would require wholesalers to provide somewhat duplicative information on two different pedigree documents beginning in July 1, 2006. The wholesaler will be required to provide a pedigree paper that traces the distribution of a prescription drug back to an authorized distributor of record as well as a pedigree paper than traces the distribution of that same prescription drug back to the manufacturer to wholesaler customers.

The bill does not remove the requirement of pharmacies to receive pedigree papers as intended.

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[12] and OPPAGA report on drug diversion.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

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