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## Legislature Strengthens Pedigree Paper, Wholesaler Permit Requirements to Better Ensure Safe Prescription Drugs

### *at a glance*

Subsequent to our 2003 report, the Legislature amended state law to strengthen Florida's regulation of prescription drug wholesalers. The Legislature clarified state law to require drug wholesalers to provide pedigree papers for all drugs by 2006, provided the Department of Health additional authority to tighten the wholesaler permitting process, and increased criminal penalties for prescription drug violations related to counterfeiting and diversion.

Since that time, the Department of Health's Bureau of Statewide Pharmaceutical Services has worked to ensure wholesaler compliance with pedigree paper requirements, which is vital to ensuring the safety and integrity of Florida's wholesale prescription drug market. The bureau has implemented changes to the permitting process, thereby improving the bureau's ability to permit only legitimate wholesalers. To assess its efforts in ensuring wholesaler compliance with state law, the bureau is developing performance measures for its inspection process.

### Scope

In accordance with state law, this progress report informs the Legislature of actions taken in response to a 2003 OPPAGA examination of the Department of Health's Bureau of Statewide Pharmaceutical Services' regulation of Florida's prescription drug wholesale market.<sup>1,2</sup>

<sup>1</sup> Section 11.51(6), *F.S.*

<sup>2</sup> *Counterfeit and Diverted Drugs Threaten Public Health and Waste State Dollars*, OPPAGA [Report No. 03-18](#), February 2003.

### Background

Counterfeit and diverted prescription drugs pose a substantial public health risk and cost Floridians millions of dollars annually. Counterfeit drugs create major health risks because they contain substances that have no active ingredients or have labels indicating higher strength versions of the same drug or entirely different drugs. Offenders duplicate manufacturer packaging and falsify documents making it difficult to distinguish counterfeit products from authentic drugs. Diverted drugs circulate in environments that are neither regulated nor inspected, compromising their safety and efficacy. Diversion occurs when individuals illegally obtain drugs for prices substantially below the market value and resell these drugs to wholesalers. In addition to placing Floridians at major health risk, counterfeiters and diverters earn millions in illegal profits.

Both federal and state laws address controlling counterfeit and diverted drugs by regulating the drug market. The federal Prescription Drug Marketing Act of 1987 establishes minimum standards for the prescription drug wholesale industry. These standards require drug wholesalers to provide "pedigree papers" that document a drug's manufacturer and distribution.<sup>3</sup> The act also designates some

<sup>3</sup> A pedigree paper is a written sales history that traces each drug back to its initial manufacturer. These written histories provide an audit trail and should contain specific sales transaction information, including the name and address of each previous purchaser of the drug.

wholesalers as *authorized distributors of record* if they routinely purchase prescription drugs directly from manufacturers. It exempts these wholesalers from providing pedigree papers when they sell drugs purchased from the manufacturer to another wholesaler.<sup>4</sup>

The Florida Drug and Cosmetic Act, Ch. 499, *Florida Statutes*, incorporates the federal standards. This law directs the Department of Health to provide regulatory oversight of the manufacture and distribution of drugs, devices, and cosmetics in Florida. The Bureau of Statewide Pharmaceutical Services carries out these responsibilities, which include the regulation of Florida's wholesale prescription drug market.

The bureau regulates the wholesale market by permitting, inspecting, and investigating drug wholesalers, who 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.<sup>5</sup>

Our 2003 review found that state law did not provide adequate controls over wholesale drug marketing practices, which contributed to Florida's serious problems with counterfeit and diverted drugs. We recommended that the Legislature consider making changes to state law that would strengthen pedigree paper requirements, wholesaler permitting procedures, and criminal penalties to deter criminal behavior related to counterfeiting and diverting prescription drugs.

<sup>4</sup> This exemption assumes that *authorized distributor of record* wholesalers purchase legitimate and safe drugs directly from the manufacturer, making a chain of custody unnecessary.

<sup>5</sup> 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.

## Current Status

The Florida Legislature has amended state law to address strengthening Florida's prescription drug wholesale system.<sup>6</sup> The Legislature clarified state law related to pedigree papers, tightened the wholesaler permitting process, and increased criminal penalties for prohibited acts related to counterfeiting and diversion. The Department of Health also is developing performance measures to better assess the effectiveness of its enforcement process.

The 2003 Legislature clarified pedigree paper requirements and required that all wholesalers provide pedigree papers for all drugs by July 2006. The Legislature adopted our recommendations to clarify pedigree paper requirements and directed the department to implement these changes in two phases. The first phase, implemented in July 2003, designates an *authorized distributor of record* (ADR) as a wholesaler who purchases prescription drugs directly from the manufacturer. During this phase, wholesalers designated as ADRs do not have to provide pedigree papers except for those drugs the department has identified as being at high risk for counterfeiting or diversion.<sup>7</sup> All other wholesalers must provide pedigree papers for all prescription drugs they sell. The second phase, beginning in July 2006, will eliminate the ADR designation and require all wholesalers to provide pedigree papers for all drugs they sell.<sup>8</sup>

Under both phases, state law now requires that wholesalers verify the legitimacy of pedigree papers. This is important, because drugs can 'churn' or pass through several vendors before reaching a prescription drug retailer.

<sup>6</sup> Chapter 2003-155, *Laws of Florida*.

<sup>7</sup> The department places such drugs on a *Specified Drug List*, which it publishes on its website. The department places drugs on this list based on recommendations by an advisory council that was established by the Legislature. The council uses specific criteria for identifying drugs that have a high risk of counterfeit or diversion. As of October 2005, wholesalers were required to pass on pedigrees for 34 drugs.

<sup>8</sup> To ensure implementation of pedigree paper requirements, the bureau has provided specific guidelines for complying with the new requirements and monitors compliance through its permitting and inspection process. Starting in 2006, wholesalers must provide pedigree papers in a hard copy or electronic format approved by the department.

Verifying pedigree papers can close loopholes in the distribution chain that could allow illicit drugs into the wholesale market.

Through recent inspections, the bureau has used the new requirement to uncover instances in which wholesalers failed to verify pedigree papers resulting in potentially adulterated drugs making their way into the wholesale market in Florida. The bureau also has identified occasions where pedigree papers were falsified allowing illegally diverted drugs to enter the market, which illustrates the importance of verifying pedigree papers. For example, as shown in Exhibit 1, a closed pharmacy illegally transferred drugs out of state.<sup>9</sup> At this point the drugs were outside the legitimate wholesaler chain and no longer considered safe. Ultimately, an out-of-state wholesaler sold the drugs to a Florida wholesaler who made no attempt to verify the pedigree papers. If the wholesaler had complied

<sup>9</sup> A closed pharmacy provides prescription drugs for patients in health facilities such as hospitals and nursing homes. These pharmacies purchase drugs from wholesalers but cannot resell unused drugs back into the wholesale market.

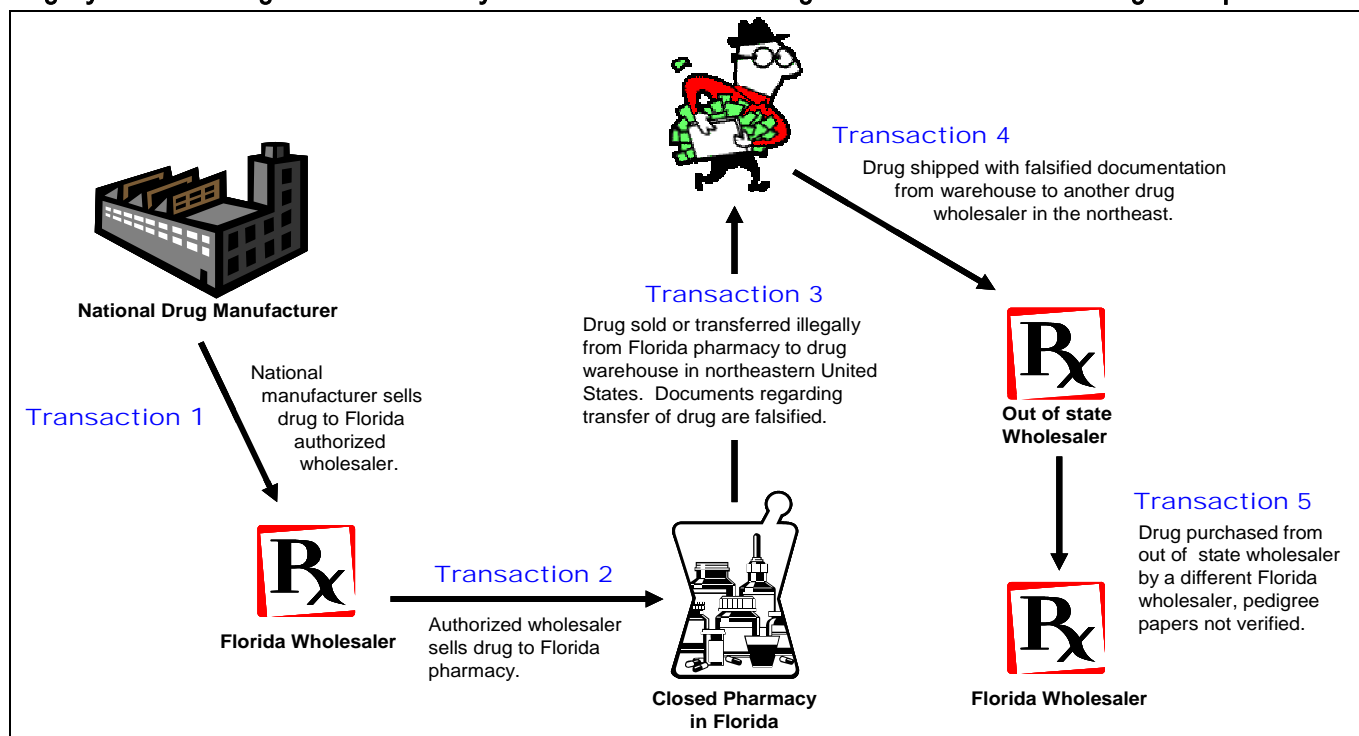
with law and taken steps to verify the drug's sales history, it would have discovered that the pedigree papers were falsified and that the drugs were not from legitimate sources.

Stronger permitting has improved the bureau's ability to permit only legitimate wholesalers. The stricter permitting process enacted by the Legislature now requires applicants to submit extensive personal background information, including fingerprint cards that are subject to state and federal criminal checks, on wholesaler owners and employees. The bureau uses this information to deny permits to persons with criminal records or who cannot demonstrate the financial standing and business experience to operate a legitimate wholesale business. In addition, the bureau no longer grants reciprocity to out-of-state wholesalers if they have a permit in their respective state and instead requires them to complete the same application as in-state wholesalers.<sup>10</sup>

<sup>10</sup> The only exception to the out-of-state wholesaler permitting process is that the bureau does not conduct on-site inspections for these applicants.

## Exhibit 1

### Illegally Diverted Drugs Made Their Way Back into the Florida Drug Market with Falsified Pedigree Papers



Source: OPPAGA analysis of information provided by the Department of Health.

As part of the strengthened permitting process, the bureau also has revised its inspection process. The bureau now conducts an on-site inspection prior to approving initial and renewal permits. Inspectors review sales and purchase history records to ensure that wholesalers only buy drugs from, and sell drugs to, authorized entities and are complying with pedigree paper requirements. Inspectors also examine drug inventory and determine whether climate controls and security systems are in place and appropriate. Following the bureau's implementation of key changes to the permitting process, the number of permitted wholesalers decreased 31%, from 1,409 in June 2003 to 972 in October 2005. The number of in-state and out-of-state permits declined 52% and 22%, respectively.<sup>11</sup>

The Legislature increased criminal penalties to deter criminal behavior. Prior to legislative changes, a third-degree felony was the most severe punishment for criminal and prohibited acts involving counterfeit or diverted drugs, even though a single case could negatively affect the health of numerous people.

As we recommended, the 2003 Legislature increased the severity of criminal penalties for prohibited acts. In addition, it created specific criminal acts and corresponding punishments related to counterfeiting and diversion.<sup>12</sup> For example, it is now a first-degree felony to knowingly sell counterfeit drugs that cause great bodily harm or death to an individual.

Bureau officials are developing performance measures to assess the effectiveness of their enforcement activities. Ultimately, the goal of the bureau's inspection process is to ensure and increase compliance with state laws. To better assess the effectiveness of its efforts, the bureau is developing performance measures to gauge how well its processes improve wholesaler compliance. In developing these measures, the bureau should consider measuring the percentage of wholesalers with serious deficiencies each year, as well as the percentage of wholesalers in compliance with specific requirements, such as those for pedigree papers. These measures would aid both the department and the Legislature in determining whether additional actions are needed to protect the safety of prescription drugs in Florida.

<sup>11</sup> The total includes 551 out-of-state wholesale permits that were reclassified as "non-resident manufacturer" permits according to changes in the 2003 law.

<sup>12</sup> We also recommended that the Legislature authorize the department to increase administrative fines. However, the changes to criminal acts and penalties and to the permitting process have mitigated the need to do so.

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