HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 7095 PCB HCR 09-01 Manufacturers and Purchasers of Prescription Drugs
SPONSOR(S): Health Care Regulation Policy Committee, Patronis
TIED BILLS: **IDEN./SIM. BILLS:**

	REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
Orig. Comm.:	Health Care Regulation Policy Committee	7 Y, 0 N	Lowell	Calamas
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4)				
5)				

SUMMARY ANALYSIS

Part I of Chapter 499 requires the Department of Health to regulate drugs, devices, and cosmetics. A significant majority of the regulations relate to the distribution of prescription drugs into and within Florida. In particular, the regulations require licensure of various entities in the distribution chain, such as prescription drug manufacturers and prescription drug wholesale distributors.

During the 2008 session, the Legislature passed House Bill 7049, which made two significant changes to these regulations. First, HB 7049 created a new Health Care Clinic Establishment permit to authorize physician and veterinarian clinics to purchase and possess prescription drugs in the name of the clinic. Prior to the passage of the bill, a clinic was not authorized to possess prescription drugs; only a licensed practitioner authorized by law to prescribe prescription drugs, or any person under the licensed practitioner's supervision, was authorized to possess prescription drugs. The Proposed Committee Bill expands the types of business entities that may qualify for the permit to include any form of corporation, partnership, association, cooperative, joint venture, business trust, or sole proprietorship that provides health care or veterinary services and employs a qualifying practitioner.

Second, HB 7049 also expanded the definition of “manufacturer” to recognize other entities involved in the manufacturing process, such as contract distributors. Prior to the passage of the bill, a manufacturer was defined as a person that “prepares, derives, manufactures, or produces a drug, device, or cosmetic.” Subsequent to the passage of HB 7049, a conflicting statutory provision was identified that would still prohibit many of these manufacturer entities from being permitted as a manufacturer. The Proposed Committee Bill expands the definition of manufacturer to recognize a manufacturer who distributes another manufacturer’s product under contract, and a distributor who only distributes products manufactured by members of its affiliated group (generally, subsidiary or parent entities under the same corporate structure).

The Proposed Committee Bill appears to have no fiscal impact on state or local government.

The Proposed Committee Bill is effective October 1, 2009.

HOUSE PRINCIPLES

Members are encouraged to evaluate proposed legislation in light of the following guiding principles of the House of Representatives

- Balance the state budget.
- Create a legal and regulatory environment that fosters economic growth and job creation.
- Lower the tax burden on families and businesses.
- Reverse or restrain the growth of government.
- Promote public safety.
- Promote educational accountability, excellence, and choice.
- Foster respect for the family and for innocent human life.
- Protect Florida's natural beauty.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Regulation of Drugs, Devices, and Cosmetics

Part I of Chapter 499 requires the Department of Health (department) to regulate drugs, devices, and cosmetics. A significant majority of the regulations relate to the distribution of prescription drugs into and within Florida. In particular, the regulations require licensure of various entities in the distribution chain, such as prescription drug manufacturers and prescription drug wholesale distributors. In total, Florida has 20 distinct permits for these entities.

Among many other provisions, the chapter provides for:

- Criminal prohibitions against the distribution of contraband and misbranded prescription drugs.
- Regulation of the advertising and labeling of drugs, devices, and cosmetics.
- Establishment of permits for manufacturing and distributing drugs, devices, and cosmetics.
- Regulation of the wholesale distribution of prescription drugs, which includes pedigree papers.
- Regulation of the provision of drug samples.
- Establishment of the Cancer Drug Donation Program.
- Establishment of numerous enforcement avenues for the Department of Health, including seizure and condemnation of drugs, devices, and cosmetics.

Many of these regulations have been significantly strengthened in recent years, including:

- A significantly stronger wholesale distributor permit, requiring, among other items, a posting of a bond and extensive background information for various employees of the wholesale distributor.[1]
- More thorough documentation of the distribution of prescription drugs, including broader application of the pedigree paper to most wholesale distributions.[2]
- Enhanced criminal penalties for, among other things, distribution of contraband prescription drugs.[3]

[1] *See* s. 499.01(2)(d), F.S. (2008) (requiring $100,000 bond or other means of equivalent security) and s. 499.012(8) and (9), F.S. (requiring, e.g., place of residence for past 7 years, fingerprints, photograph taken within 30 days, and name, address, occupation, and date and place of birth of each member of the person's immediate family who is 18 years of age or older).

[2] *See* s. 499.01212, F.S. (2008) ("Each person who is engaged in the wholesale distribution of a prescription drug must, prior to or simultaneous with each wholesale distribution, provide a pedigree paper to the person who receives the drug.")

- Stronger departmental enforcement authority to protect the prescription drug supply chain.[4]

These stricter regulations were primarily prompted by the report of a Grand Jury convened by the Florida Supreme Court in 2002 at the request of Governor Jeb Bush.[5] The Grand Jury noted that "first tier" wholesale distributors (AmerisourceBergen, Cardinal Health, and McKesson) controlled approximately 90 percent of wholesale prescription drug distribution market. This is the "primary market." The remaining stock was purchased from "second tier" wholesale distributors, a "secondary market" of hundreds of smaller wholesale distributors. In this secondary market, prescription drugs may move "up, down, and sideways through the distribution system, [creating] opportunities for adulterated drugs that have been diverted from other sources to enter the distribution system." It is this secondary tier that the Grand Jury, much like Congress in the 1980s,[6] identified as one of the primary points of introduction of counterfeit or adulterated drugs. Neither the Grand Jury nor Congress attributed fault to the prescription drug manufacturers in knowingly participating in the introduction of contraband drugs in the secondary market.[7]

During the 2008 session, the Legislature passed House Bill 7049, which significantly reorganized chapter 499 to improve the clarity of the law. Among other changes, the bill created a new Health Care Clinic Establishment (HCCE) permit to authorize physician and veterinarian clinics to purchase and possess prescription drugs in the name of the clinic. Prior to the passage of the bill, a clinic was not authorized to possess prescription drugs; only a licensed practitioner authorized by law to prescribe prescription drugs, or any person under the licensed practitioner's supervision, was authorized to possess prescription drugs.[8] Consequently, in group medical practices, prescription drugs were typically ordered in the name of an individual physician under his or her own license number. The HCCE permit is limited to a place of business at one general physical location, owned and operated by a professional corporation or professional limited liability company or a corporation that employs a veterinarian as a qualifying practitioner.[9] According to the department, of the 2,857 HCCE applications submitted since enactment of House Bill 7049, 1,489 have been approved, 290 are pending, 164 were withdrawn, and 914 did not qualify. According to the department, the 914 non-qualified clinics did not qualify because the clinic was not a professional corporation, professional limited liability company, or a corporation that employs a veterinarian.

In addition to the HCCE permit, House Bill 7049 expanded the definition of "manufacturer" to recognize other entities involved in the manufacturing process, such as contract distributors. Prior to the passage of the bill, a manufacturer was defined as a person "prepares, derives, manufactures, or produces a drug, device, or cosmetic."[10] However, the manufacture and distribution to the wholesale market of a prescription drug is a process that may involve multiple entities, including contract manufacturing by other manufacturers and distribution of the final product to contract or wholly-owned subsidiary distributors, who then distribute the product into the primary or secondary wholesale market. The previous definition of "manufacturer" would not recognize these manufacturing arrangements. The

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[3] *See* s. 499.0051(6), F.S. (2008) (imposing a second degree felony for "a person who is knowingly in actual or constructive possession of any amount of contraband prescription drugs, who knowingly sells or delivers, or who possesses with intent to sell or deliver any amount of contraband prescription drugs").

[4] *See* s. 499.065, F.S. (2008) (authorizing the department to immediately close a wholesale facility if it constitutes an imminent danger to public health).

[5] *See* First Interim Report of the Seventeenth Statewide Grand Jury, Case No. SC02-2645 (2003).

[6] *See* Pub. L. No. 100-293 (1988) (finding that "the existence and operation of a wholesale submarket, commonly known as the 'diversion submarket,' prevents effective control over or even routine knowledge of the true sources of prescription drugs in a significant number of cases.")

[7] *See* H.R. Rep. No. 100-76 (1987) and S. Rep. No. 100-303 (1988). The report did note that two practices—providing drug samples and discount sales to health care institutions (e.g., hospitals)—provided *potential opportunity* for abuse. In particular, "the existing system of providing [drug] samples of pharmaceutical products to physicians through manufacturers' sales representatives *invites* abuse" (emphasis added). In addition, "the resale of prescription drugs by health care entities to persons outside the corporate umbrella of the [entity] *helps fuel* the diversion market. Such sales . . . are economical only because many manufacturers sell much more cheaply to certain institutions than to wholesale customers" (emphasis added).

[8] *See* s. 499.03(1), F.S. (2007).

[9] *See* s. 499.01(2)(t), F.S. (2008).

[10] *See* s. 499.003(28), F.S. (2007).

alternative for a company that did not qualify as a manufacturer would be to obtain a prescription drug wholesale distributor permit, which contains significantly more stringent requirements than a manufacturer permit. Subsequent to the passage of the bill, a conflicting statutory provision was identified that would still prohibit many of these manufacturer entities from being permitted as a manufacturer.[11] According to the department, approximately 5 entities currently permitted as manufacturers are affected by this conflicting provision.

Effect of Proposed Changes

The bill expands the definition of manufacturer to recognize:

- A manufacturer who distributes another manufacturer's product under contract.
- A distributor who only distributes products manufactured by members of its affiliated group (generally, subsidiary or parent entities under the same corporate structure).

The bill also expands the types of business entities that may qualify for the HCCE permit to include any form of corporation, partnership, association, cooperative, joint venture, business trust, or sole proprietorship that provides health care or veterinary services and employs a qualifying practitioner.

Finally, the bill makes a small number of technical corrections and clarifications.

B. SECTION DIRECTORY:

Section 1. Amends s. 499.003, F.S., relating to definitions.

Section 2. Amends s. 499.01, F.S., relating to permits.

Section 3. Amends s. 499.0121, F.S., relating to storage and handling of prescription drugs; recordkeeping.

Section 4. Provides an effective date of October 1, 2009.

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:

The proposed bill will likely prevent a significant increase in regulation for prescription drug manufacturers by recognizing additional entities that are a legitimate part of the manufacturing process.

[11] *See* s. 499.01(2)(c)1., F.S. (2008).

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. This bill does not require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not produce 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 department appears to have sufficient rulemaking authority to implement the provisions of the bill

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES