



## FULL ANALYSIS

### I. SUBSTANTIVE ANALYSIS

#### A. DOES THE BILL:

- |                                      |                              |  |   |
|--------------------------------------|------------------------------|--|---|
| 1. Reduce government?                | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> | N/A <input type="checkbox"/>            |
| 2. Lower taxes?                      | Yes <input type="checkbox"/> | No <input type="checkbox"/>            | N/A <input checked="" type="checkbox"/> |
| 3. Expand individual freedom?        | Yes <input type="checkbox"/> | No <input type="checkbox"/>            | N/A <input checked="" type="checkbox"/> |
| 4. Increase personal responsibility? | Yes <input type="checkbox"/> | No <input type="checkbox"/>            | N/A <input checked="" type="checkbox"/> |
| 5. Empower families?                 | Yes <input type="checkbox"/> | No <input type="checkbox"/>            | N/A <input checked="" type="checkbox"/> |

For any principle that received a “no” above, please explain:

The bill requires Internet pharmacies to obtain permits in Florida and provides for criminal penalties and prosecution.

#### B. EFFECT OF PROPOSED CHANGES:

HB 141 establishes a permit for Internet pharmacies that will bring an area of unregulated activity under the regulatory and enforcement arm of the Department of Health and Board of Pharmacy. The bill requires Internet pharmacies selling drugs in Florida to obtain permits and provides penalties for Internet pharmacies operating without a permit. The bill establishes grounds for discipline of pharmacists who fill prescriptions obtained without a valid practitioner-patient relationship.

#### PRESENT SITUATION:

Regulations regarding the licensure of pharmacies are currently under the jurisdiction of the Board of Pharmacy and the Division of Medical Quality Assurance of the Department of Health. Pharmacies are licensed under the provisions of chapter 465, F.S., the Pharmacy Practice Act. Sections 465.0156, 465.018 and 465.022, F.S., require the licensure of all pharmacies providing prescription drug services to patients in Florida, including those pharmacies with an Internet presence.

#### **Internet Pharmacies**

Internet pharmacies sell pharmaceutical products to consumers through their websites. The number of prescription drug websites has grown dramatically in recent years. Internet pharmacies fall into three types (Rost, Kerry “Policing the ‘Wild West’ World of Internet Pharmacies,” 76 Chicago-Kent Law Review 1333, 2000):

- Pharmacies that only dispense prescriptions that are written by a patient’s physician;
- Pharmacies that dispense prescription drugs without a physician’s prescription; and
- Pharmacies that have the patient complete a cyber consultation for a fee and then write a prescription for the patient.

The National Association of Boards of Pharmacies (NABP) considers the use of on-line consultation without a valid physician-patient relationship to be illegal. NABP believes that no additional laws are needed to regulate Internet pharmacies. The NABP focuses on the need for existing state regulators to police Internet pharmacies. To support this effort, the NABP established the Verified Internet Pharmacy Practice Sites program as a voluntary, private certification program for Internet pharmacies to help the public identify Internet pharmacies that are properly licensed. To join the program, a pharmacy must comply with licensing and inspection requirements of their state and of each state to which they dispense drugs. If there is a conflict between any state laws, the pharmacy agrees to comply with the more stringent law.

The Federal Trade Commission (FTC) has jurisdiction to take action against claims that constitute health fraud on the Internet. The FTC may take action against the owners of a website for false or misleading claims regarding the safety or effectiveness of any pharmaceuticals offered, but does not make any effort to police the practice of medicine or pharmacy.

### **Pharmacy Regulation**

Pursuant to ch. 465, F.S., the Florida Board of Pharmacy regulates the practice of pharmacy in Florida. Every pharmacy must be permitted and each pharmacy is subject to discipline for violations of applicable state or federal law relating to the practice of pharmacy. Pharmacies are subject to inspection by the Department of Health.

Any pharmacy that is located outside of Florida and that ships, mails, or delivers in any manner, a dispensed medicinal drug into this state is considered a nonresident pharmacy. Nonresident pharmacies must register with the Florida Board of Pharmacy and make specified disclosures to the board pursuant to s. 465.0156, F.S. Such disclosures include: the location, names, and titles of all principal corporate officers and the pharmacist who serves as the prescription department manager for dispensing medicinal drugs to Florida residents.

Section 465.015(3)(b), F.S., makes it unlawful for any person other than an owner of a registered pharmacy to display any sign or take any other action that would lead the public to believe that such person is engaged in the business of compounding, dispensing, or retailing any medicinal drugs. The violation of s. 465.015(3)(b), F.S., constitutes a first degree misdemeanor punishable by imprisonment for up to 1 year or a fine of up to \$1,000.

The bill provides for a criminal penalty for an unlicensed Internet pharmacy of a second degree felony, which is punishable by up to 15 years of imprisonment as provided in s. 775.082, F.S., and a fine of up to \$10,000, as provided by s. 775.083, F.S.

### **The Racketeer Influenced and Corrupt Organization (RICO) Act**

The Florida Racketeer Influenced and Corrupt Organization Act (RICO) established in ch. 895, F.S., provides for both criminal and civil proceedings against organized criminal activity to enable prosecution of those involved in organizing the activity. RICO penalties include a first degree felony and a fine of three times the gross value gained or three times the gross loss caused, whichever is greater (s. 895.04, F.S.) The Office of the Attorney General and the State Attorney are responsible for enforcement of the RICO Act for enterprises involved in continuing patterns of illegal activities that are enumerated in s. 895.02(1)(a), F.S., including fraud, theft and misleading advertising.

Under provisions of the federal Racketeer Influenced and Corrupt Organization Act (RICO), upon which the Florida statute it modeled, the government may show that the racketeering acts found to have been committed pose a threat of continued racketeering activity by proving: (1) that the acts are part of a long-term association that exists for criminal purposes, or (2) that they are a regular way of conducting the defendant's ongoing legitimate business, or (3) that they are a regular way of conducting or participating in an ongoing and legitimate enterprise. 18 U.S.C.A. § 1962(c) (West 1984).

#### **C. SECTION DIRECTORY:**

**Section 1.** Amends s. 465.003, F.S., to include a definition of "Internet pharmacy."

**Section 2.** Amends s. 465.0156, F.S., to exempt Internet pharmacies permitted under the provisions of the bill from registration as nonresident pharmacies.

**Section 3.** Amends s. 465.016, F.S., relating to grounds for disciplinary action against pharmacists, to include dispensing of a prescribed drug when the pharmacist knows or should know that the prescription is not based on a valid practitioner-patient relationship which includes a patient history and a visual encounter by the practitioner.

**Section 4.** Creates s. 465.0161, F.S., to provide that an Internet pharmacy which distributes drugs in Florida without a permit is guilty of a second degree felony.

**Section 5.** Amends s. 465.0196, F.S., to change cross references in the existing definition of a special pharmacy.

**Section 6.** Creates s. 465.0197, F.S., to establish requirements for Internet pharmacy permits that include: approval of applications by the Board of Pharmacy; having a licensed pharmacist responsible for records and security; disclosing ownership and control, having a valid license or registration in the state where the pharmacy is located and where drugs are stored; and providing patients with toll-free access to a pharmacist who has access to their patient records.

**Section 7.** Amends s. 895.02, F.S., to add the criminal offense of distributing drugs as an Internet pharmacy without a permit to the definition of racketeering activity and prosecution.

**Section 8.** Provides an effective date of July 1, 2004.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

### A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

See below.

### B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

### C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Internet pharmacies will incur additional costs to become permitted in Florida.

### D. FISCAL COMMENTS:

The Department of Health did not provide an estimate of the fiscal impact of the provisions of the bill, except that: making it a felony for an Internet pharmacy to distribute a drug to a person in this state without a permit would have the effect of increasing the enforcement activities of the Department. The administrative costs of permitting the pharmacies and promulgating rules should be met by permitting fees paid by the pharmacies (the cost of the permitting fee is not identified in the bill).

### 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:

To the extent the bill requires "Internet pharmacies" to obtain permits in Florida, the bill raises issues for the Internet retailing activities under the Commerce Clause of the United States Constitution. The Commerce clause states that "Congress shall have Power... To regulate Commerce... among the several States..." U.S. Constitution Article I, Section 8, cl. 3. Courts have used a two-tiered analysis to determine whether a statutory scheme violates the dormant Commerce clause: (1) If the scheme directly regulates or discriminates against interstate commerce, or when its effect is to favor in-state economic interests over out-of-state interests, it is generally struck down unless it advances a legitimate local purpose that cannot be adequately served by reasonable nondiscriminatory alternatives; and (2) If the statute has only indirect effects on interstate commerce and regulates evenhandedly, whether, the burden on interstate commerce clearly exceeds the local benefits. See Bainbridge v. Turner, 311 F.3d 1104 (2002).

#### B. RULE-MAKING AUTHORITY:

According to the Department of Health, because the bill does not establish specific rulemaking authority or registration and renewal fees, the Board of Pharmacy may have difficulty promulgating rules to adopt a new application process and fees for Internet pharmacy permits.

#### C. DRAFTING ISSUES OR OTHER COMMENTS:

According to the department, it may not be possible to fully enforce the permitting provision or the pharmacy practice provisions of the bill because an on-line pharmacy may be operating outside jurisdictions of the state or the United States.

The Department of Health reports that the Division of Medical Quality Assurances prosecution unit has worked closely with the federal Drug Enforcement Administration to stop non-legitimate Internet pharmacy operations in South Florida and supports the need for the bill. The department reports that the prosecution unit is concerned that the definition of Internet pharmacy is vague and does not specify the activities to be prohibited by the bill.

The Department of Health suggests adding sanctions against pharmacies in s. 465.023, F.S., to mirror sanctions provided against pharmacists in s. 465.016, F.S.

The department recommends the bill include rulemaking authority for the Board of Pharmacy to establish standards for dispensing medications with the aid of the Internet.

Amendments are prepared to clarify the definition, provide sanctions and include rulemaking authority.

### IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES