

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 creates a new state permit for “on-line pharmacies” in chapter 499, F.S., and requires such pharmacies to obtain a prescription from a physician licensed in the state prior to dispensing a controlled substance.

B. EFFECT OF PROPOSED CHANGES:

HB 1517 establishes findings that the state has a compelling interest in placing reasonable limitations on on-line pharmacies to protect the health, safety, and welfare of the public, for reasons that include:

- Medicinal drugs, including controlled substances, are being provided to the public through on-line pharmacies without consultation of or prescription by a physician the patient has seen in person;
- These drugs may be inappropriate for the patient, potentially deadly and endanger persons who are addicted or disposed to addiction; and
- They may be obtained in quantities large enough to be used for illicit sale in circumvention of drug abuse laws.

HB 1517 creates s. 465.0158, F.S., which restricts the dispensing of controlled substances as defined in s. 893.02, F.S., by on-line pharmacies without presentation of a written or facsimile prescription prescribed by a physician licensed in this state. The bill creates a new permit for “on-line pharmacies” in chapter 499, F.S.

The bill provides that on-line pharmacies may not be considered as carriers in interstate commerce for the purpose of exemption from the provisions of ss. 499.001-499.081, F.S., known as the Florida Drug and Cosmetic Act.

The bill provides an effective date of upon becoming law.

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.

Part I of chapter 499, F.S., known as the Florida Drug and Cosmetic Act, is established to protect the public from injury by product use and by merchandising deceit involving drugs, devices and cosmetics. It provides legislation in conformity with the Federal Food, Drug and Cosmetic Act and the Federal Trade Commission Act that expressly prohibits the false advertisement of drugs, devices and cosmetics. Provisions of the act provide for the permitting of manufacturers, wholesalers, and

distributors. The Department of Health 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 or otherwise exempt. Carriers in interstate commerce are not subject to the regulation of part I, ch. 499, F.S., if they are engaged in the usual course of business as carriers.

Section 893.02(19), F.S., relating to drug abuse prevention and controls, provides for the definition of a valid controlled substance prescription.

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 have the patient complete a cyber consultation for a fee and then write a prescription for the patient; and
- Pharmacies that dispense prescription drugs without a physician's prescription.

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 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, and 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.

Regulation of Physician Practice of Online Medicine:

The Board of Medicine regulates the practice of medicine in Florida. The Board of Osteopathic Medicine regulates the practice of osteopathic medicine in Florida. Each board has established standards for the physicians under that board for telemedicine practice.

The Board of Osteopathic Medicine has adopted an administrative rule (64B15-14.008, F.A.C.) that provides that prescribing medications based solely on an electronic medical questionnaire constitutes the failure to practice osteopathic medicine with the level of care, skill, and treatment which is recognized by reasonably prudent osteopathic physicians as being acceptable under similar conditions and circumstances. Such practice constitutes grounds for which an osteopathic physician may be disciplined.

Except for emergencies, an osteopathic physician is prohibited from providing treatment recommendations, including a prescription, via electronic or other means unless: a documented patient evaluation is made, including history and physical examination, adequate to establish the diagnosis for which any drug is prescribed; sufficient dialogue has occurred between the physician and patient regarding treatment options and risks and benefits of treatment; and contemporaneous medical records have been maintained.

The Board of Medicine has proposed the adoption of a similar rule regarding standards of practice for telemedicine applicable to medical physicians (See proposed Rule 64B8-9.014 that was recently filed with the Joint Administrative Procedures Committee.)

Controlled Substances:

Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act. The chapter classifies controlled substances into five schedules in order to regulate the manufacture, distribution, preparation, and dispensing of the substances.

- Substances in Schedule I have a high potential for abuse and have no currently accepted medical use in the United States.
- Schedule II drugs have a high potential for abuse and a severely restricted medical use. Cocaine and morphine are examples of Schedule II drugs.
- Schedule III controlled substances have less potential for abuse than Schedule I or Schedule II substances and have some accepted medical use. Substances listed in Schedule III include anabolic steroids, codeine, and derivatives of barbituric acid.

Schedule IV and Schedule V substances have a low potential for abuse, compared to substances in Schedules I, II, and III, and currently have accepted medical use.

- Substances in Schedule IV include phenobarbital, librium, and valium.
- Substances in Schedule V include certain stimulants and narcotic compounds.

Prescribing of Controlled Substances:

Section 893.02, F.S., defines "practitioner" to mean a licensed medical physician, a licensed dentist, a licensed veterinarian, a licensed osteopathic physician, a licensed naturopathic physician, or a licensed podiatrist, if such practitioner holds a valid federal controlled substance registry number.

The prescribing of controlled substances is a privilege that is separate from the regulation of the practice of the prescribing practitioner.

Required Records for Dispensing of Controlled Substances:

Section 893.04, F.S., authorizes a pharmacist, in good faith and in the course of professional practice to only dispense controlled substances upon a written or oral prescription under specified conditions. An oral prescription for controlled substances must be promptly reduced to writing by the pharmacist.

The written prescription must be dated and signed by the prescribing practitioner on the day when issued. There must appear on the face of the prescription or written record for the controlled substance: the full name and address of the person for whom, or the owner of the animal for which, the controlled substance is dispensed; the full name and address of the prescribing practitioner and the prescriber's federal controlled substance registry number must be printed thereon; if the prescription is for an animal, the species of animal for which the controlled substance is prescribed; the name of the controlled substance prescribed and the strength, quantity, and directions for the use thereof; the number of the prescription, as recorded in the prescription files of the pharmacy in which it is filed; and the initials of the pharmacist filling the prescription and the date filled.

Section 893.04(1)(d), F.S., requires the proprietor of the pharmacy in which a prescription for controlled substances is filled to retain the prescription on file for a period of 2 years. The chapter requires the original container in which a controlled substance is dispensed to bear a label with specified information.

C. SECTION DIRECTORY:

Section 1. Creates s. 465.0158, F.S., relating to requirements for dispensing of controlled substances by on-line pharmacies.

Section 2. Amends s. 499.01, F.S., relating to permits for manufacturing, wholesaling or distributing of drugs, cosmetics and household products, to include on-line pharmacies.

Section 3. Amends s. 499.081, F.S., relating to exemptions of carriers in interstate commerce from required permits for distributing drugs, cosmetics and household products to prohibit exemption of on-line pharmacies.

Section 4. Establishes an effective date of upon becoming law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

See Fiscal Comments.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

According to the department, entities that own “on-line pharmacies” may incur additional costs if they have to hire Florida-licensed practitioners to prescribe and write prescriptions in order to sell or dispense controlled substances to Florida residents.

D. FISCAL COMMENTS:

According to the Department of Health, there is a potential fiscal impact on the department that is indeterminate. Because “on-line pharmacy” is not defined, it is difficult to project the number of establishments that would be required to obtain the special permit. The department predicts there are start-up and recurring costs associated with application development.

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 “on-line pharmacies” to use Florida-licensed practitioners to prescribe and write prescriptions in order to sell or dispense controlled substances to Florida residents, 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:

There is no rulemaking authority provided in the bill. The Department of Health reports it would be difficult to develop implementing rules for start-up and maintenance of the program.

C. DRAFTING ISSUES OR OTHER COMMENTS:

According to the department, the bill needs a definition of the term “on-line pharmacy.” The wording in the bill is unclear whether it is referring to a website, a company, or an actual pharmacy. Many of the properly licensed community pharmacies (i.e. Walgreens chain stores) may be considered on-line pharmacies and subject to the provisions of this bill.

According to the department, it may not be possible to fully enforce the permitting provision or the pharmacy practice provisions of the bill since an on-line pharmacy may be operating outside jurisdictions of the state or the United States. There does not appear to be a penalty for an on-line pharmacy not complying with the provisions of this bill.

The department is concerned that there is no rulemaking authority provided in the bill, so that it would be difficult to develop implementing rules for start-up and maintenance of the program to monitor and discipline pharmacists to ensure compliance with the bill's provisions.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

On April 2, 2003, the Health Standards Subcommittee adopted a "strike-all" amendment to the bill which:

- Puts provisions for the bill in current s. 465.061, F.S., relating to disciplinary actions for pharmacists, instead of creating a new section 465.0158, F.S., relating to violations.
- Provides for disciplinary action against pharmacists for filling prescriptions that are written without a valid professional relationship with the prescribing health care practitioner.
- Amends s. 465.003 to provide a definition for "internet pharmacy."
- Creates s. 656.0161, F.S., which provides a penalty of a second degree felony for an internet pharmacy that distributes drugs to persons in Florida with being licensed in Florida.