

# SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

BILL: CS/SB 2310

SPONSOR: Health, Aging, and Long-Term Care Committee and Senator Crist

SUBJECT: Pharmacy

DATE: March 26, 2003      REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Munroe</u>	<u>Wilson</u>	<u>HC</u>	<u>Favorable/CS</u>
2.	_____	_____	_____	_____
3.	_____	_____	_____	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

## I. Summary:

The bill expresses legislative intent and findings regarding the provision of medicinal drugs to the public through on-line pharmacies without consultation with or prescription by a physician who has seen the patient. The bill provides legislative intent 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.

The bill prohibits an on-line pharmacy from selling or dispensing a controlled substance as defined in s. 893.02, F.S., to a person residing in Florida without having a written prescription for that substance provided by a “practitioner” as defined in s. 893.02, F.S. Section 893.02, F.S., defines “practitioner” to mean a Florida-licensed medical physician, dentist, veterinarian, osteopathic physician, naturopathic physician, or podiatrist, if such practitioner holds a valid federal controlled substance registry number. The prescription may be provided by facsimile transmission, if confirmed at the time by audio communication of the prescribing physician via telephonic, electronic, or similar means.

The bill amends s. 499.01, F.S., relating to permits for a distributor, manufacturer, or wholesaler regulated by the Department of Health, under part II, ch. 499, F.S., to require on-line pharmacies to obtain a permit. The bill amends s. 499.081, F.S., to provide that an on-line pharmacy may not be considered an exempt carrier that is engaged in the usual course of business for purposes of pt. I, ch. 499, F.S., the Florida Drug and Cosmetic Act.

This bill amends sections 499.01 and 499.081, F.S., and creates s. 465.0158, F.S.

## II. Present Situation:

### Internet Pharmacies

An internet pharmacy sells pharmaceutical products to consumers through its web site. The number of prescription drug websites has grown dramatically in recent years. "Internet pharmacies" have been described as fitting into one of three categories: (1) pharmacies that only dispense prescriptions that are written by a patient's physician; (2) pharmacies that have the patient complete a cyber consultation for a fee and then write a prescription for the patient; and (3) pharmacies that dispense prescription drugs without a physician's prescription.<sup>1</sup>

The National Association of Boards of Pharmacies considers the use of on-line consultation without a valid physician-patient relationship to be illegal and believes that no additional laws are needed to regulate internet pharmacies. In lieu of additional laws the NABP focuses on the need for existing state regulators to cooperate more fully to police internet pharmacies. The NABP established the Verified Internet Pharmacy Practice Sites program, a voluntary, private, certification program for internet pharmacies, to assist the public in identifying properly licensed internet pharmacies. To join the program a pharmacy must comply with licensing and inspection requirements of their state and each state to which they dispense drugs, and 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 web site 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

Pursuant to ch. 465, F.S., the Florida Board of Pharmacy regulates the practice of pharmacy in Florida. "Pharmacy" includes a community pharmacy, an institutional pharmacy, a nuclear pharmacy, and a special pharmacy. "Community pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis. "Institutional pharmacy" includes every location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility where medicinal drugs are compounded, dispensed, stored, or sold. "Nuclear pharmacy" includes every location where radioactive drugs and chemicals with the classification of medicinal drugs are compounded, dispensed, stored or sold. "Special pharmacy" includes every location where medicinal drugs are compounded, dispensed, or sold if such locations are not otherwise defined in ch. 465, F.S.

Every pharmacy must be permitted and each pharmacy is subject to discipline for violations of applicable state or federal law relating to pharmacy.<sup>2</sup> 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

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<sup>1</sup> See Rost, Kerry Toth "Policing the 'Wild West' World of Internet Pharmacies," 76 Chicago-Kent Law Review 1333 (2000).

<sup>2</sup> See ss. 465.018, 465.022, 465.196, and 465. 023, F.S.

pharmacy, and must register with the Florida Board of Pharmacy and make specified disclosures to the board. 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.

### **Medicine and Osteopathic Medicine**

The Board of Medicine regulates the practice of medicine in Florida.<sup>3</sup> The Board of Osteopathic Medicine regulates the practice of osteopathic medicine in Florida.<sup>4</sup> Each board has established standards for the physicians under that board for telemedicine practice. The Board of Osteopathic Medicine has adopted an administrative rule that provides that prescribing medications based solely on an electronic medical questionnaire constitutes the failure to practice osteopathic medicine with that level of care, skill, and treatment which is recognized by reasonably prudent osteopathic physicians as being acceptable under similar conditions and circumstances, as well as prescribing legend drugs other than in the course of an osteopathic physician's professional practice. Such practice constitutes grounds for which an osteopathic physician may be disciplined.<sup>5</sup>

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. "Emergency" situation means those situations in which the prescribing physician determines that immediate administration of the medication is necessary for the proper treatment of the patient, and that it is not reasonably possible for the prescribing physician to comply with the telemedicine rule before providing such prescription. The Board of Medicine has proposed the adoption of a similar rule regarding standards of practice for telemedicine applicable to medical physicians.<sup>6</sup>

### **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

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<sup>3</sup> See ch. 458, F.S.

<sup>4</sup> See ch. 459, F.S.

<sup>5</sup> See Rule 64B15-14.008, Florida Administrative Code.

<sup>6</sup> See proposed Rule 64B8-9.014 that was recently filed with the Joint Administrative Procedures Committee.

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. 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.

Section 893.05, F.S., allows a practitioner, in good faith and in the course of his or her professional practice only to prescribe, administer, dispense, mix, or otherwise prepare a controlled substance, or the practitioner may direct the administration of a controlled substance by a licensed nurse or an intern practitioner under his or her direction and supervision.

Section 893.04, F.S., authorizes a pharmacist, in good faith and in the course of professional practice only to 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.

Chapter 893, F.S., imposes other limitations on controlled substance prescriptions. A prescription for a Schedule II controlled substance may be dispensed only upon a written prescription of a practitioner, except in an emergency situation, as defined by regulation of the Department of Health, when such controlled substance may be dispensed upon oral prescription. No prescription for a Schedule II controlled substance may be refilled.<sup>7</sup> No prescription for a controlled substance listed in Schedules III, IV, or V may be filled or refilled more than five times within a period of 6 months after the date on which the prescription was written unless the prescription is renewed by a practitioner.<sup>8</sup> A pharmacist may dispense a one-time emergency

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<sup>7</sup> Section 893.04(1)(f), F.S.

<sup>8</sup> Section 893.04(1)(g), F.S.

refill of up to a 72-hour supply of the prescribed medication for any medicinal drug other than a medicinal drug listed in Schedule II.

### **Florida Drug and Cosmetic Act**

Pursuant to the Florida Drug and Cosmetic Act, pt. I, ch. 499, F.S., 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.

### **III. Effect of Proposed Changes:**

The bill expresses legislative intent and findings regarding the provision of medicinal drugs to the public through on-line pharmacies without consultation with or prescription by a physician who has seen the patient. The bill provides legislative intent 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.

The bill creates s. 465.0158, F.S., to prohibit an on-line pharmacy from selling or dispensing a controlled substance as defined in s. 893.02, F.S., to a person residing in Florida without having a written prescription for that substance provided by a practitioner as defined in s. 893.02, F.S. Section 893.02, F.S., defines “practitioner” to mean a Florida-licensed medical physician, dentist, veterinarian, osteopathic physician, naturopathic physician, or podiatrist, if such practitioner holds a valid federal controlled substance registry number. The prescription may be provided by facsimile transmission, if confirmed at the time by audio communication of the prescribing physician via telephonic, electronic, or similar means.

The bill amends s. 499.01, F.S., relating to permits for prescription drug manufacturers and other entities regulated by the Department of Health, under part II, ch. 499, F.S., to require on-line pharmacies to obtain a permit as a distributor, manufacturer, or wholesaler. The bill amends s. 499.081, F.S., to provide that an on-line pharmacy may not be considered an exempt carrier that is engaged in the usual course of business for purposes of pt. I, ch. 499, F.S., the Florida Drug and Cosmetic Act.

The effective date of the bill is upon becoming a law.

### **IV. Constitutional Issues:**

#### **A. Municipality/County Mandates Restrictions:**

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, s. 18 of the Florida Constitution.

**B. Public Records/Open Meetings Issues:**

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Art. I, s. 24(a) and (b) of the Florida Constitution.

**C. Trust Funds Restrictions:**

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

**D. Other Constitutional Issues:**

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 of “on-line pharmacies” 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).

**V. Economic Impact and Fiscal Note:****A. Tax/Fee Issues:**

On-line pharmacies would have to pay the Department of Health a fee for a permit under the Florida Drug and Cosmetic Act as amended by the bill.

**B. Private Sector Impact:**

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.

**C. Government Sector Impact:**

The Department of Health will incur costs to implement the bill’s regulations specifying procedures for the selling or dispensing of controlled substance via the internet.

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

The bill prohibits on-line pharmacies from selling or dispensing controlled substances to Florida residents without a prescription written by a Florida-licensed practitioner. Provisions of the bill appear to be in conflict with existing provisions of ch. 893, F.S. Section 893.04, F.S., authorizes a pharmacist, in good faith and in the course of professional practice only to dispense controlled substances upon a written or oral prescription under specified conditions.<sup>9</sup> 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. Valid controlled substance prescriptions may be dispensed if *transmitted* or written by a physician, dentist, veterinarian, or other practitioner in a state other than Florida, but only if the pharmacist called upon to fill such order (prescription) determines in the exercise of his or her professional judgment that the order was issued pursuant to a valid patient-physician relationship, that it is authentic, and that the drugs or medicinal supplies so ordered are considered necessary for the continuation of treatment of a chronic or recurrent illness.

The bill does not define the term, "on-line pharmacy." It is unclear whether the bill is referring to a web site, a company, or an actual pharmacy.

The bill requires an "on-line pharmacy" to obtain a permit as a wholesaler, distributor, or manufacturer under ch. 499, F.S. It is unclear whether the "on-line pharmacy," must also comply with the permitting requirements of Florida law for a special permit under the bill, to dispense medicinal drugs to Florida residents on the retail level.

The Department of Health indicates that it does not appear possible to fully enforce the permitting provision and the pharmacy practice provisions of the bill since an on-line pharmacy may be operating outside of the jurisdiction of Florida and the United States. The department additionally notes that the bill does not specify a penalty for an on-line pharmacy that is not in compliance with the requirements of the bill.

**VIII. Amendments:**

None.

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This Senate staff analysis does not reflect the intent or official position of the bill's sponsor or the Florida Senate.

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<sup>9</sup> Section 893.04(1)(f), F.S., provides that a prescription for a Schedule II controlled substance may be dispensed only upon a written prescription, except in an emergency situation.