

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/CS/CS/CS/SB 1372

SPONSOR: Appropriations Subcommittee on Health and Human Services; Finance and Taxation Committee; Criminal Justice Committee; Health, Aging, and Long-Term Care Committee and Senator Saunders

SUBJECT: Pharmacy Regulation

DATE: April 13, 2004

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Munroe</u>	<u>Wilson</u>	<u>HC</u>	<u>Fav/CS</u>
2.	<u>Cellon</u>	<u>Cannon</u>	<u>CJ</u>	<u>Fav/CS</u>
3.	<u>Keating</u>	<u>Johansen</u>	<u>FT</u>	<u>Fav/CS</u>
4.	<u>Peters</u>	<u>Belcher</u>	<u>AHS</u>	<u>Fav/CS</u>
5.	<u> </u>	<u> </u>	<u>AP</u>	<u> </u>
6.	<u> </u>	<u> </u>	<u> </u>	<u> </u>

I. Summary:

The bill requires an "Internet pharmacy" to receive a permit in order to sell medicinal drugs to persons in Florida. The bill requires any person who desires to operate an Internet pharmacy to apply to the Florida Department of Health for an Internet pharmacy permit. The bill defines "Internet pharmacy" and provides requirements for such pharmacies. A permit may not be issued to an "Internet pharmacy" unless a licensed pharmacist is designated as the prescription department manager for dispensing medicinal drugs to persons in Florida. The bill requires the Internet pharmacy and the pharmacist designated by that pharmacy to serve as prescription department manager or its equivalent to be licensed in the state of location in order to dispense drugs in Florida.

The bill makes a pharmacist subject to disciplinary action for dispensing any medicinal drug based upon a communication that purports to be a prescription when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship. A pharmacy is subject to disciplinary action for dispensing any medicinal drug based upon a communication that purports to be a prescription when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship that included documented patient evaluation.

The bill creates a criminal offense that prohibits an Internet pharmacy from distributing a medicinal drug to any person in Florida without being permitted as a pharmacy in Florida. A violation of this prohibition is a second degree felony punishable by imprisonment of up to 15 years and the imposition of a fine of up to \$10,000. The bill makes other minor technical changes to provisions that specify requirements for the issuance of special pharmacy permits by the

Florida Department of Health to conform to an existing definition of “special pharmacy” in the pharmacy practice act.

The bill adds the newly created criminal offense that prohibits an “Internet pharmacy” from distributing a medicinal drug to any person in Florida without being permitted as a pharmacy in Florida to the racketeering provisions so that the offense may be prosecuted as racketeering in appropriate cases, thereby allowing harsher sentencing for the criminal conduct and the further use of civil racketeering sanctions.

The bill revises requirements for pharmacists to display the expiration date on the outside of the container of each medicinal drug dispensed. A pharmacist is given the option of providing the purchaser either the expiration date when provided by the manufacturer, repackager, or other distributor of the drug, or an earlier beyond-use date for expiration of up to 1 year from the date of dispensing. The dispensing pharmacist or practitioner must provide information concerning the expiration date to the purchaser upon request and must provide appropriate instructions regarding the proper use and storage of the drug.

The bill provides an additional condition under which a pharmacist is not prohibited from filling or refilling a valid prescription which is on file in a pharmacy located in Florida or in another state and that has been transferred from one pharmacy to another by any means, including electronic means. The bill authorizes a licensed community pharmacy which only receives and transfers prescriptions for dispensing by another pharmacy to transfer a prescription for a medicinal drug listed under Schedule II under chapter 893. The pharmacy receiving the prescription may ship, mail, or deliver into Florida, the dispensed medicinal drug under certain conditions which are stipulated in the bill.

The bill creates certain recordkeeping requirements for chain drug entities, warehouses, and repackagers. The recordkeeping requirements expire on July 1, 2006.

This bill amends ss. 465.003, 465.0156, 465.016, 456.0196, 465.023, 465.0255, 465.026, 499.0121, and 895.02, F.S.

This bill creates ss. 465.0161 and 465.0197, F.S.

II. Present Situation:

Internet Pharmacies

An Internet pharmacy sells pharmaceutical products to consumers through its World Wide Web site. The number of prescription drug web sites 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.¹

¹ See Rost, Kerry Toth, “Policing the ‘Wild West’ World of Internet Pharmacies,” 76 Chicago-Kent Law Review 1333 (2000).

The National Association of Boards of Pharmacies (NABP) 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

Under 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, stored, or sold if such locations are not otherwise defined in ch. 465, F.S.

Every pharmacy must receive a permit and each pharmacy is subject to disciplinary action for violations of applicable state or federal law relating to pharmacy.² The initial and biennial pharmacy permit fee is \$250, plus a \$5 unlicensed activity fee. 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.³ 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. Nonresident pharmacies require the pharmacist who serves as the prescription department manager of nonresident pharmacies to be licensed.⁴

² See ss. 465.018, 465.022, 465.196, and 465.023, F.S.

³ See s. 465.0156, F.S.

⁴ The Board of Pharmacy under s. 465.005, F.S., has rulemaking authority to adopt rules to implement duties conferred upon it by ch. 465, F.S. Rule 64B16-28.840(2), F.A.C., relating to nonresident pharmacies, appears to contravene s. 465.003(10), F.S., that defines "pharmacist" as a Florida-licensed pharmacist. The rule provides that "The pharmacy and the pharmacist designated as the prescription department manager or equivalent, for dispensing into Florida, must be licensed in the state of location."

Pharmacists and permitted pharmacies may be subject to disciplinary action for violating provisions of the pharmacy practice act.⁵

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.

Section 465.0255, F.S., requires each pharmacist for a community pharmacy and each practitioner dispensing medicinal drugs on an outpatient basis to display on the outside of the container of each medicinal drug dispensed, or in other written form to the purchaser, the expiration date when provided by the manufacturer, repackager, or other distributor of the drug and appropriate instructions for proper use and storage of the drug. The Board of Pharmacy has adopted administrative rules requiring pharmacists to include along with other specified information to the purchaser on the label affixed to the container of dispensed non-controlled substances, an expiration date of the drug provided by the drug manufacturer, repackager, or distributor or an earlier expiration date when in the pharmacist's professional judgment such date is necessary for the safe use of the product.⁶ Section 465.026, F.S., specifies conditions under which a pharmacist is not prohibited from filling or refilling a valid prescription that is on file in a pharmacy located in Florida or in another state and that has been transferred from one pharmacy to another by any means, including electronic means.

Section 499.0121, F.S., authorizes the Department of Health to adopt rules as necessary for the protection of the public health with regard to the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug records.

Medicine and Osteopathic Medicine

The Board of Medicine regulates the practice of medicine in Florida.⁷ The Board of Osteopathic Medicine regulates the practice of osteopathic medicine in Florida.⁸ 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.⁹

Except for emergencies, an osteopathic physician is prohibited from providing treatment recommendations, including a prescription, via electronic or other means unless: a documented

⁵ See s. 465.016, F.S., for pharmacists, and s. 465.023, F.S., for permitted pharmacies.

⁶ See Rule 64B16-28.402, F.A.C.

⁷ See ch. 458, F.S.

⁸ See ch. 459, F.S.

⁹ See Rule 64B15-14.008, Florida Administrative Code.

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 adopted a similar rule regarding standards of practice for telemedicine applicable to medical physicians.¹⁰

III. Effect of Proposed Changes:

Section 1. Amends s. 465.003, F.S., to define “Internet pharmacy” to include locations that are not otherwise licensed or issued a permit under this chapter, within or outside Florida, which uses the Internet to communicate with or obtain information from consumers in Florida and use such communication or information to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in Florida.

Section 2. Amends s. 465.0156, F.S., to provide that the registration requirements, applicable to any pharmacy that is located outside of Florida and that ships, mails, or delivers, in any manner, a dispensed medicinal drug into this state as a nonresident pharmacy, do not apply to permitted Internet pharmacies. The registered nonresident pharmacy and the pharmacist designated by that pharmacy to serve as prescription department manager or its equivalent are required to be licensed in the state of location in order to dispense drugs in Florida.

Section 3. Amends s. 465.016, F.S., to make a pharmacist subject to disciplinary action for dispensing any medicinal drug based upon a communication that purports to be a prescription when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship.

Section 4. Creates s. 465.0161, F.S., to establish a criminal offense that prohibits an Internet pharmacy from distributing a medicinal drug to any person in Florida without receiving a permit in Florida. A violation of this prohibition is a second degree felony punishable by imprisonment of up to 15 years and the imposition of a fine of up to \$10,000.

Section 5. Amends s. 465.0196, F.S., to make other minor technical changes to provisions that specify requirements for the issuance of special pharmacy permits by the Florida Department of Health to conform to an existing definition of “special pharmacy” in the pharmacy practice act.

Section 6. Creates s. 465.0197, F.S., to require any person who desires to operate an Internet pharmacy to apply to the Florida Department of Health for an Internet pharmacy permit. If the Florida Board of Pharmacy certifies that the Internet pharmacy permit application complies with the applicable laws and rules of the board governing the practice of the profession of pharmacy, the department must issue the permit. A permit may not be issued unless a licensed pharmacist is designated as the prescription department manager for dispensing medicinal drugs to persons in

¹⁰ See Rule 64B8-9.014, F.A.C.

Florida. The licensed pharmacist must be responsible for maintaining all drug records and for providing for the security of the area in the facility in which the compounding, storing, and dispensing of medicinal drugs to persons in Florida occurs. The permitted Internet pharmacy must notify the Florida Department of Health within 30 days of any change of the licensed pharmacist responsible for maintaining all drug records and for providing for the security of the area in the facility in which the compounding, storing, and dispensing of medicinal drugs to persons in Florida occurs.

The bill requires an Internet pharmacy to provide pharmacy services at a high level of protection and competence. The Internet pharmacy must disclose to the Florida Board of Pharmacy the following information:

- That the Internet pharmacy maintains at all times a valid, unexpired license, permit, or registration to operate the pharmacy in compliance with the laws of the state in which the dispensing facility is located and from which the medicinal drugs must be dispensed.
- 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 persons in Florida. The disclosure must be made within 30 days after any change of location, principal corporate officer, or pharmacist serving as the prescription department manager for dispensing medicinal drugs to persons in Florida.
- That the Internet pharmacy complies with all lawful directions and requests for information from the regulatory or licensing agency of all states in which it is licensed as well as with all requests for information made by the Florida Board of Pharmacy. The Internet pharmacy must respond directly to all communications from the Florida Board of Pharmacy concerning emergency circumstances arising from errors in the dispensing of medicinal drugs to persons in Florida.
- That the Internet pharmacy maintains its records of medicinal drugs dispensed to patients in Florida so that the records are readily retrievable from the other business records of the pharmacy and from the records of other medicinal drugs dispensed.
- That during the Internet pharmacy's regular hours of operation but not less than 6 days per week, for a minimum of 40 hours per week, the pharmacy must provide a toll-free telephone service to facilitate communication between patients in Florida and a pharmacist at the pharmacy who has access to the patient's records. The Internet pharmacy must disclose this toll-free number on the label affixed to each container of dispensed medicinal drugs.

The bill requires the Internet pharmacy and the pharmacist designated by that pharmacy to serve as prescription department manager or its equivalent to be licensed in the state of location in order to dispense drugs in Florida.

Section 7. Amends s. 465.023, F.S., to make a pharmacy subject to disciplinary action for dispensing any medicinal drug based upon a communication that purports to be a prescription when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship that included documented patient evaluation.

Section 8. Amends s. 465.0255, F.S., to revise requirements for pharmacists to display the expiration date on the outside of the container of each medicinal drug dispensed. A pharmacist is given the option of providing the purchaser either the expiration date when provided by the manufacturer, repackager, or other distributor of the drug, or an earlier beyond-use date for expiration of up to 1 year from the date of dispensing. The dispensing pharmacist or practitioner must provide information concerning the expiration date to the purchaser upon request and must provide appropriate instructions regarding the proper use and storage of the drug.

Section 9. Amends s. 465.026, F.S., to provide an additional condition under which a pharmacist is not prohibited from filling or refilling a valid prescription which is on file in a pharmacy located in Florida or in another state and that has been transferred from one pharmacy to another by any means, including electronic means. The bill authorizes a licensed community pharmacy which only receives and transfers prescriptions for dispensing by another pharmacy to transfer a prescription for a medicinal drug listed in Schedule II under chapter 893. The pharmacy receiving the prescription may ship, mail, or deliver into Florida, the dispensed medicinal drug under the following conditions:

- The pharmacy receiving and dispensing the transferred prescription must maintain at all times a valid, unexpired license, permit, or registration to operate the pharmacy in compliance with the laws of the state in which the pharmacy is located and from which the medicinal drugs are dispensed;
- The community pharmacy and the receiving pharmacy are owned and operated by the same person and share a centralized database; and
- The community pharmacy assures its compliance with federal law and subsections (1)-(5) of s. 465.026, F.S.

Section 10. Amends s. 499.0121, F.S., to add recordkeeping requirements for “affiliated groups,” as defined in the Internal Revenue Code. The requirements expire July 1, 2006, and apply to chain drug entities including at least 50 retail pharmacies, warehouses, or repackagers, which are members of the same affiliated group.

The affiliated group is required to disclose all the names of its members and must agree in writing to provide drug purchase records of all members within 48 hours of a department request. Warehouses are required to comply with all federal and state drug wholesale permit requirements and must document, through pedigree papers, purchases from outside the affiliated group. Repackagers are required to provide a written statement under oath related to drug pedigrees, purchase all prescription drugs it repackages and to maintain records of purchases.

Section 11. Amends s. 895.02, F.S., to add the newly created criminal offense that prohibits an Internet pharmacy from distributing a medicinal drug to any person in Florida without receiving a permit as a pharmacy in Florida to the racketeering provisions so that the offense may be prosecuted as racketeering in appropriate cases, thereby allowing harsher sentencing for the criminal conduct and the further use of civil racketeering sanctions.

Section 12. The sum of \$590,051 is appropriated from the Medical Quality Assurance Trust Fund to the Department of Health, and nine full-time equivalent positions are authorized for fiscal year 2004-2005 to implement this act.

Section 13. Provides a July 1, 2004, effective date.

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.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

The Board of Pharmacy is responsible for setting the Internet pharmacy permit fee. According to the Board, it is anticipated that the permit fee will be the same for Internet pharmacies as it is for Florida-based pharmacies - \$255. The Board does not have an estimate of the number of Internet pharmacies that will be subject to the permit fee.

B. Private Sector Impact:

Internet pharmacies would have to pay the Department of Health a fee for a permit.

C. Government Sector Impact:

In fiscal year 2004-2005 the Department of Health will receive \$590,051 from the Medical Quality Assurance Trust Fund, and nine full-time equivalent positions to implement the requirements of the bill.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None..

VIII. Amendments:

None.

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