

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 141 w/CS Internet Pharmacies
SPONSOR(S): Homan and others
TIED BILLS: None. **IDEN./SIM. BILLS:** CS/CS/CS/SB 1372 (s)

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care	24 Y, 0 N w/CS	Mitchell	Collins
2)			
3)			
4)			
5)			

SUMMARY ANALYSIS

HB 141 addresses the problem of medicinal drugs, including controlled substances, being provided to the public through Internet pharmacies without being prescribed by a physician. The bill establishes grounds for discipline of pharmacists who fill prescriptions obtained without a valid practitioner-patient relationship. The bill requires Internet pharmacies selling drugs in Florida to obtain permits. It provides penalties for Internet pharmacies operating without a permit.

Provisions of the bill include:

- A definition of "Internet pharmacy;"
- Grounds for pharmacist discipline for dispensing of a drug when the pharmacist knows the prescription is not based on a valid practitioner-patient relationship;
- That it is a second degree felony to distribute drugs to any person in Florida as an Internet pharmacy without a permit;
- That distribution of drugs by an Internet pharmacy without a permit is a crime under the definition of racketeering activity.
- Requirements for Internet pharmacy permits that include: approval of applications by the Board of Pharmacy; having a licensed pharmacist responsible for records and security; possession of a valid license or registration in the state where the pharmacy is located and where drugs are stored; and provision of toll-free number so a patient can contact a pharmacist who has access to their patient records; and
- Requirements for displaying the expiration date on drugs;
- An appropriation of \$590,051 to the department from the Medical Quality Assurance Trust Fund to implement the bill.
- Authorization of a mail-order pharmacy to process a prescription for a controlled substance from a common warehouse when they meet the requirements of the Drug Enforcement Administration to use a common database.
- Revised record keeping requirements for chain drug entities that include at least 50 retail pharmacies, warehouses, or repackagers, which are members of the same "affiliated" group (as defined in the Internal Revenue Code) to exempt them from certain tracking documents. The exemption expires July 1, 2006, when new tracking technology will be in use.

The bill provides an effective date of July 1, 2004.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives.

STORAGE NAME: h0141a.hc.doc
DATE: March 31, 2004

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 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 record keeping requirements for chain drug entities with at least 50 retail pharmacies, warehouses, and repackagers in the same "affiliated group," as defined in the Internal Revenue Code, such as Eckerd, Walgreen and Publix. The requirements exempt these entities from what are called "pedigree paper" record keeping requirements. The requirements expire July 1, 2006, when new tracking chip technology will be in place.

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.

Types of Pharmacies

“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.

Any pharmacy that is located outside of Florida and 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.

Dispensing

“Dispense” is defined in s. 465.003(6), F.S., to mean the transfer of possession of one or more doses of a medicinal drug by a pharmacist to the ultimate consumer or her or his agent.

As an element of dispensing, the pharmacist must:

- Interpret and assess the prescription order for potential adverse reactions, interactions, and dosage regimen she or he deems appropriate in the exercise of her or his professional judgment prior to the actual physical transfer;
- Certify that the medicinal drug called for by the prescription is ready for transfer; and
- Provide counseling on proper drug usage, either orally or in writing, if in the exercise of her or his professional judgment counseling is necessary.

The actual sales transaction and delivery of such drug shall not be considered dispensing. The administration of the drug must not be considered dispensing.

Transfer of a Prescription

The Drug Enforcement Administration (DEA) restricts the transfer of prescriptions for Schedule II controlled drugs between pharmacies, but allows for communication or processing of such prescriptions between two pharmacies that are owned and operated by the same entity if both pharmacies share the same common database. DEA does not consider such communication of a prescription to be a transfer of the prescription. This allows for pharmacies to fill prescriptions from a common warehouse.

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 including: a licensed pharmacist responsible for records and security; disclosure of ownership and control, licensure in the state where the pharmacy is located and drugs are stored; and providing patients with toll-free access to a pharmacist who has access to their patient records.

Section 7. Amends s. 465.023, F.S., to make a pharmacy subject to disciplinary action for dispensing a drug based on a purported prescription that is not based upon a valid practitioner-patient relationship, including a 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, with option of the manufacturers expiration date, or an earlier beyond-use date of up to 1 year from the date of dispensing.

Section 9. Amends s. 465.026, F.S., to authorize a licensed community pharmacy to transfer a prescription for a medicinal drug listed in Schedule II under chapter 893. The community pharmacy and the receiving pharmacy must be owned and operated by the same person and share a centralized database, and be in compliance with federal law and subsections (1)-(5) of s. 465.026, F.S.

Section 10. Amends s. 499.0121, F.S., to add record keeping 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.

Section 11. 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 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 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 Fiscal Comments.

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:

The bill provides rulemaking authority to implement provisions of the bill.

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.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

On March 25, 2004, the Committee on Health Care adopted three amendments and reported the bill favorably with a committee substitute. The strike-all amendment incorporates the original provisions of the bill and includes: clarification of the definition of "internet pharmacies;" revision of requirements for displaying the expiration date; and provision for an appropriation to the department from the Medical Quality Assurance Trust Fund to implement the bill. One amendment to the strike-all amendment permits a mail-order pharmacy to process a prescription for a controlled substance under the Drug Enforcement Administration when the pharmacies use a common database to allow pharmacies to fill prescriptions from a common warehouse. Another amendment to the strike-all amendment revises record keeping requirements for chain drug entities that include at least 50 retail pharmacies, warehouses, or repackagers, that are members of the same "affiliated" group (as defined in the Internal Revenue Code) that exempts them from certain tracking documents. The exemption expires July 1, 2006, when new tracking technology will be in use.