

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 399 Public Records/Controlled Substances
SPONSOR(S): Harrell
TIED BILLS: HB 397 **IDEN./SIM. BILLS:** SB 578(s)

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Standards	9 Y, 1 N	Garner	Collins
2) Health Care			
3) State Administration			
4) Appropriations			
5)			

SUMMARY ANALYSIS

This bill allows the Department of Health to disclose a patient's or the prescriber's identity in the information of records reported under s. 893.055, F.S., which is otherwise confidential and exempt from the provisions of s. 119.07(1), F.S., and s. 24(a), Art. I of the State Constitution, to the following:

- a) A practitioner defined under Chapter 893, F.S., who requests information and certifies that it is necessary to provide medical treatment to a current patient, subject to the patient's written consent;
- b) A pharmacist licensed in this state, or a pharmacy intern or pharmacy technician designated by the pharmacists, who requests information and certifies that it is to be used to dispense controlled substances to a current patient;
- c) A state or federal criminal justice agency that enforces laws relating to drugs and that is engaged in a specific investigation involving a violation of law;
- d) An employee or agent of the Department of Health who is involved in a specific investigation involving a violation of rules regulating the alleged violator, the rules of the department, or the rules of a board regulating the alleged violator; or
- e) An employee of the Agency for Health Care Administration who is involved an investigation related to the agency's responsibilities to control fraud and abuse in the Medicaid program.

This bill ordains that any information obtained not be used for the requestor's personal advantage, and it disallows the requestor from revealing any information obtained except in a prosecution or administrative hearing for a violation of state or federal law. The information obtained, however, may be used to provide medical treatment to a current patient or to dispense controlled substances in accordance with s. 893.04, F.S., to a current patient, or to the patient for verifying the accuracy of such information. Any person who knowingly violates the provisions commits a felony of the third degree, punishable as provided in s. 775.082 or s. 775.083, F.S. A practitioner or pharmacist authorized to obtain information is not liable for either accessing or failing to access such information. Requestors obtaining information that would identify a patient must maintain the confidentiality of the information pursuant to ss. 456.057 and 465.017, F.S.

The bill states that the Legislature finds that it is a public necessity that personal identifying information reported to the Department of Health under s. 893.055, F.S., be held confidential and exempt from disclosure to facilitate and maintain compliance with the state's drug laws pertaining to the distribution of controlled substances.

The effective date of this bill is July 1, 2005, and is linked to the passage of HB 397 or similar legislation.

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

STORAGE NAME h0399a.hc.doc
DATE February 6, 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 checked="" type="checkbox"/> | N/A <input 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:

Section 24, Art. I of the State Constitution provides that “[e]very person has the right to inspect or copy any public records made or received in connection with the official business of any public body, officer, or employee of the state, or persons acting on their behalf.” This bill limits a person’s right of access to records.

B. EFFECT OF PROPOSED CHANGES:

The bill makes a patient’s personal identifying information contained in any record reported under s. 893.055, F.S., confidential and exempt from the requirements of the Public Records Law. HB 397 creates s. 893.055, F.S., to provide for a prescription drug monitoring program for certain controlled substances. The bill makes the exemption subject to the Open Government Sunset Review Act of 1995. The bill specifies requirements and procedures for a patient’s written consent for disclosures that involve medical treatment to be provided to the patient and provides guidelines for the use of such information by criminal justice agencies and state regulatory agencies. A violation of the restrictions on the use of such information is designated a felony of the third degree. The bill provides a statement of public necessity for the public records exemption and the authorized disclosures.

Section 893.055, F.S., created in HB 397 provides that on or after January 1, 2005, a person issuing a prescription or dispensing a Schedule II, Schedule III, or Schedule IV controlled substance¹ to an individual 16 years or older, must comply with specified criteria and information recorded and reported under the prescription-monitoring system administered by the Department of Health.

The provisions of the bill impose further limitations, restrictions, and requirements upon the dispensing of a controlled substance by a pharmacist. A prescription for a Schedule II controlled substance may be dispensed only upon the written prescription of a practitioner except in an emergency as defined by departmental regulation, and the supply of the controlled substance dispensed would now be limited to no more than that required for a 72-hour period. A pharmacist, prior to dispensing a controlled substance listed in Schedule II, Schedule III, or Schedule IV to an individual, would have to obtain suitable identification (i.e., containing the photograph, printed name, and signature of the individual). Limitations are imposed restricting the dispensing of no more than a 35-day supply of a Schedule III controlled substance obtained via an oral prescription.

HB 397 establishes an electronic system for monitoring the prescribing and dispensing of controlled substances. It does provide reporting exceptions such as a controlled substance administered (i.e., single dose) by a health care practitioner directly to a patient, a controlled substance dispensed to a patient less than 16 years of age, or a controlled substance dispensed to an in-patient of a facility with an institutional pharmacy permit. A pharmacy with a community pharmacy permit would be required to

¹ A Schedule II controlled substance “has a high potential for abuse and has a currently accepted but severely restricted medical use in treatment in the United States, and abuse of the substance may lead to severe psychological or physical dependence.” Section 893.03(2), F.S.

report either information on dispensed controlled substances, transmitted electronically, to the department or to an agency authorized to receive it.

In addition, the bill requires that the Department of Health to develop a "counterfeit-proof prescription blank" for use by practitioners who prescribe the previously listed monitored substances. The department must cover all costs.

HB 397 provides \$2,196,352 in appropriations from the Grants and Donations Trust Fund, and authorizes three full-time equivalent positions to the department for the purposes of implementing HB 397.

PUBLIC RECORDS LAW

Florida Constitution

Article I, s. 24(a), Florida Constitution, expresses Florida's public policy regarding access to government records as follows:

Every person has the right to inspect or copy any public record made or received in connection with the official business of any public body, officer, or employee of the state, or persons acting on their behalf, except with respect to records exempted pursuant to this section or specifically made confidential by this Constitution. This section specifically includes the legislative, executive, and judicial branches of government and each agency or department created thereunder; counties, municipalities, and districts; and each constitutional officer, board, and commission, or entity created pursuant to law or this Constitution.

Article I, s. 24(c), Florida Constitution, does, however, permit the Legislature to provide by general law for the exemption of records from the requirements of s. 24. The general law must state with specificity the public necessity justifying the exemption (public necessity statement) and must be no broader than necessary to accomplish its purpose.

Florida Statutes

Public policy regarding access to government records is also addressed in the Florida Statutes. Section 119.07(1)(a), F.S., provides:

Every person who has custody of a public record shall permit the record to be inspected and examined by any person desiring to do so, at a reasonable time, under reasonable conditions, and under supervision by the custodian of the public record or the custodian's designee.

Open Government Sunset Review Act of 1995

Section 119.15, F.S., the Open Government Sunset Review Act of 1995, provides that an exemption may be created or maintained only if it serves an identifiable public purpose and may be no broader than is necessary to meet the public purpose it serves. An identifiable public purpose is served if the exemption meets one of the following purposes, and the Legislature finds that the purpose is sufficiently compelling to override the strong public policy of open government and cannot be accomplished without the exemption:

1. Allows the state or its political subdivisions to effectively and efficiently administer a governmental program, which administration would be significantly impaired without the exemption;

2. Protects information of a sensitive personal nature concerning individuals, the release of which information would be defamatory to such individuals or cause unwarranted damage to the good name or reputation of such individuals or would jeopardize the safety of such individuals. However, in exemptions under this subparagraph, only information that would identify the individuals may be exempted; or
3. Protects information of a confidential nature concerning entities, including, but not limited to, a formula, pattern, device, combination of devices, or compilation of information which is used to protect or further a business advantage over those who do not know or use it, the disclosure of which information would injure the affected entity in the marketplace.

This bill creates a public records exemption for the patient's and prescriber's identity which is reported under s. 893.055 F.S., or contained in the Department of Health's electronic system for monitoring the prescription of controlled substances.²

This bill allows for exceptions to the public records exemption. The Department of Health may disclose a patient's identity in the information or records reported under s. 893.055, F.S., or reported in the Department of Health's electronic monitoring system to the following:

- a) A practitioner defined under Chapter 893, F.S., who requests information and certifies that it is necessary to provide medical treatment to a current patient, subject to the patient's written consent;
- b) A pharmacist licensed in this state, or a pharmacy intern or pharmacy technician designated by the pharmacist, who requests information and certifies that it is to be used to dispense controlled substances to a current patient;
- c) A state or federal criminal justice agency that enforces laws relating to drugs and that is engaged in a specific investigation involving a violation of law;
- d) An employee or agent of the Department of Health who is involved in a specific investigation involving a violation of rules regulating the alleged violator, the rules of the department, or the rules of a board regulating the alleged violator; or
- e) An employee of the Agency for Health Care Administration who is involved in an investigation related to the agency's responsibilities to control fraud and abuse in the Medicaid program.

This bill ordains that any information obtained not be used for the requestor's personal advantage, and it disallows the requestor from revealing any information obtained except in a prosecution or administrative hearing for a violation of state or federal law. The information obtained, however, may be used to provide medical treatment to a current patient or to dispense controlled substances in accordance with s. 893.04, F.S., to a current patient, or to the patient for verifying the accuracy of such information. Any person who knowingly violates the provisions commits a felony of the third degree, punishable as provided in s. 775.082 or s. 775.083, F.S. A practitioner or pharmacist authorized to obtain information is not liable for either accessing or failing to access such information. Requestors obtaining information that would identify a patient must maintain the confidentiality of the information pursuant to ss. 456.057 and 465.017, F.S.

The bill states that the Legislature finds that it is a public necessity that personal identifying information reported to the Department of Health under s. 893.055, F.S., be held confidential and exempt from disclosure to facilitate and maintain compliance with the state's drug laws pertaining to the distribution of controlled substances.

The effective date of this bill is July 1, 2005, linked to the passage of HB 397 or similar legislation.

² HB 397 creates s. 893.055, F.S.

C. SECTION DIRECTORY:

Section 1. Exempts from public records requirements information and records reported to the Department of Health under the electronic monitoring system for prescription of controlled substances listed in Schedules II-IV; providing that the Department of Health may disclose a patient's and prescriber's identity in the information reported under the electronic monitoring system whose identity is otherwise confidential to a health care practitioner, a pharmacist, a criminal justice agency, an employee or agent of the Department of Health, or the patient defined pursuant to chapter 893, F.S.; specifies that a person who obtains information under this section may not use the information for his or her personal gain or reveal any information; specifying that violation of the subsection is a felony in the third degree; and limits practitioner or pharmacist liability for accessing or failing to access such information; providing that a practitioner, pharmacist, or other agency that obtains information reported pursuant to s. 893.055, F.S., which identifies a patient or practitioner must maintain the confidentiality of such information pursuant to ss. 456.057 and 465.017, F.S.; providing for a public necessity statement; and providing for future legislative review and repeal.

Section 2. States that the Legislature finds that it is a public necessity that personal identifying information reported to the Department of Health under s. 893.055, F.S., be held confidential and exempt from disclosure to facilitate and maintain compliance with the state's drug laws pertaining to the distribution of controlled substances.

Section 3. Sets the effective date of this bill to July 1, 2005, linked to the passage of HB 397 or similar legislation.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

According to the Department of Health, this bill has no fiscal impact on the department.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

None.

2. Other:

Article I, s. 24(a), Florida Constitution, expresses Florida's public policy regarding access to government records as follows:

Every person has the right to inspect or copy any public records made or received in connection with the official business of any public body, officer, or employee of the state, or persons acting on their behalf, except with respect to records exempted pursuant to this section or specifically made confidential by this Constitution. This section specifically includes the legislative, executive, and judicial branches of government and each agency or department created thereunder; counties, municipalities, and districts; and each constitutional officer, board, and commission, or entity created pursuant to law or this Constitution.

Article I, s. 24(c), Florida Constitution, does, however, permit the Legislature to provide by general law for the exemption of records from the requirements of s. 24. The general law must state with specificity the public necessity justifying the exemption (public necessity statement) and must be no broader than necessary to accomplish its purpose.

B. RULE-MAKING AUTHORITY:

Not applicable.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

On February 4, 2004, the Subcommittee on Health Standards adopted two amendments to the bill, and then reported the bill favorably to the Committee on Health Care as amended. The amendments include the following:

Amendment #1 – Allows a patient to access the Department of Health's electronic monitoring system as established by HB 397 for the purposes of verifying the information for accuracy and reporting inaccuracies for correction if verified.

Amendment #2 – Makes a technical correction to conform the bill's language based on the changes made by the first amendment.