HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 831 Controlled Substance Prescription
SPONSOR(S): Health Quality Subcommittee; Fasano
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	11 Y, 1 N, As CS	Poche	O'Callaghan
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

House Bill 831 requires all physicians, osteopathic physicians, naturopathic physicians, podiatrists, and dentists to consult the prescription drug monitoring program (PDMP) database, as established under s. 893.055, F.S., prior to prescribing a controlled substance to any patient. The bill makes the failure to consult the PDMP database grounds for disciplinary action under the practice act for each specified prescriber.

The bill reduces the time period within which a dispensing of a controlled substance must be reported to the PDMP database, from seven days to two days.

The bill removes the prohibition against funds from prescription drug manufacturers being used to implement the PDMP.

Lastly, the bill clarifies that a physician who is required to access the PDMP database is not subject to a lawsuit, or the imposition of damages against him or her, for accessing or failing to access the PDMP database.

The bill does not appear to have a fiscal impact on state or local government.

The bill provides an effective date of July 1, 2013.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Controlled Substances

Controlled substances are drugs with the potential for abuse. Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act and classifies controlled substances into five categories, known as schedules. The distinguishing factors between the different drug schedules are the "potential for abuse"[1] of the substance contained therein and whether there is a currently accepted medical use for the substance. These schedules are used to regulate the manufacture, distribution, preparation and dispensing of the substances.[2]

Schedule I controlled substances currently have no accepted medical use in treatment in the United States and therefore may not be prescribed, administered, or dispensed for medical use. These substances have a high potential for abuse and include heroin, peyote, lysergic acid diethylamide (LSD), and cannabis. [3]

Schedule II controlled substances have severely restricted medical uses and a high potential for abuse, which may lead to severe psychological or physical dependence. These drugs include morphine and its derivatives, amphetamines, cocaine, and pentobarbital.[4]

Schedule III controlled substances have lower abuse potential than Schedule II substances and have some accepted medical use, but they may still cause psychological or physical dependence. Schedule III substances include products containing less than 15 milligrams (mg) of hydrocodone (such as Vicodin) or less than 90 mg of dihydrocodeine per dose (such as Tylenol #3), ketamine, and anabolic steroids. [5]

Schedule IV substances have a low potential for abuse and include propoxyphene (Darvocet), alprazolam (Xanax), and lorazepam (Ativan).[6]

Schedule V controlled substances have an extremely low potential for abuse and primarily consist of preparations containing limited quantities of certain narcotics, such as cough syrup.[7]

Any health care professional wishing to prescribe controlled substances must apply for a prescribing number from the federal Drug Enforcement Administration (DEA). Prescribing numbers are linked to state licenses and may be suspended or revoked upon any disciplinary action taken against a licensee. The DEA will grant prescribing numbers to a wide range of health care professionals, including physicians, nurse practitioners, physician assistants, optometrists, dentists, and veterinarians, but such professionals may only prescribe controlled substances as authorized under state law. Prescribing numbers must be renewed every three years.[8]

Controlled Substance Prescribing

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[1] S. 893.02(19), F.S.
[2] DEA, Office of Diversion Control, Controlled Substance Schedules, available at: www.deadiversion.usdoj.gov/21cfr/cfr/2108cfrt.htm (last visited March 18, 2013).
[3] S. 893.03(1), F.S.
[4] S. 893.03(2), F.S.
[5] S. 893.03(3), F.S.
[6] S. 893.03(4), F.S.
[7] S. 893.03 (5), F.S.
[8] U.S. Department of Justice, Drug Enforcement Administration, Office of Diversion Control, *Questions & Answers-Registration*, available at http://www.deadiversion.usdoj.gov/drugreg/faq.htm#3 (last viewed on March 16, 2013).

As of January 1, 2012, every physician, podiatrist, or dentist who prescribes controlled substances in the state for the treatment of chronic nonmalignant pain[9] must register as a controlled substance prescribing practitioner and comply with certain practice standards specified in statute and rule.[10] Before prescribing any controlled substances for the treatment of chronic nonmalignant pain, a practitioner must document certain characteristics about the nature of the pain, success of past treatments, any underlying health problems, and history of alcohol and substance abuse.[11] The practitioner must develop a written plan for assessing the patient's risk for aberrant drug-related behavior and monitor such behavior throughout the course of controlled substance treatment.[12] Each practitioner must also enter into a controlled substance agreement with their patients; such agreements must include:

- The risks and benefits of controlled substance use, including the risk for addiction or dependence;
- The number and frequency of permitted prescriptions and refills;
- A statement of reasons for discontinuation of therapy, including violation of the agreement; and
- The requirement that a patient's chronic nonmalignant pain only be treated by one practitioner at a time unless otherwise authorized and documented.[13]

Patients treated with controlled substances must been seen by their prescribing practitioners at least once every three months to monitor progress and compliance, and detailed medical records relating to such treatment must be maintained.[14] Patients at special risk for drug abuse or diversion may require co-monitoring by an addiction medicine physician or a psychiatrist.[15] Anyone with signs or symptoms of substance abuse must be immediately referred to a pain-management physician, an addiction medicine specialist, or an addiction medicine facility.[16]

Anesthesiologists, physiatrists, neurologists, and surgeons are exempt from these provisions.[17] Physicians who hold certain credentials relating to pain medicine are also exempt.[18]

Prescription Drug Monitoring Program

Chapter 2009-197, L.O.F, established the Prescription Drug Monitoring Program (PDMP) in s. 893.055, F.S. The PDMP uses a comprehensive electronic system/database to monitor the prescribing and dispensing of certain controlled substances.[19] Dispensers of certain controlled substances must report specified information to the PDMP database, including the name of the prescriber, the date the prescription was filled and dispensed, and the name, address, and date of birth of the person to whom the controlled substance is dispensed.[20]

Direct access to the PDMP database is presently limited to medical doctors, osteopathic physicians, dentists, podiatric physicians, advanced registered nurse practitioners, physician assistants, and pharmacists.[21] Indirect access to the PDMP database is provided to:

- DOH or its relevant health care regulatory boards;
- The Attorney General for Medicaid fraud cases;

[9] "Chronic nonmalignant pain" is defined as pain unrelated to cancer which persists beyond the usual course of disease or the injury that is the cause of the pain or more than 90 days after surgery. S. 456.44(1)(e), F.S.
[10] S. 456.44(2)(a) and (b), F.S.
[11] S. 456.44(3)(a), F.S.
[12] S. 456.44(3)(b), F.S.
[13] S. 456.44(3)(c)1.-3., F.S.
[14] S. 456.33(3)(d), F.S.
[15] S. 456.44(3)(e), F.S.
[16] S. 456.44(3)(g), F.S.
[17] Id.
[18] Id.
[19] S. 893.055(2)(a), F.S.
[20] S. 893.055(3)(a)-(c), F.S.
[21] S. 893.055(7)(b), F.S.

- A law enforcement agency; and
- A patient or the legal guardian, or designated health care surrogate of an incapacitated patient.[22]

Restrictions on how DOH may fund implementation and operation of the PDMP are also included in statute. DOH is prohibited from using state funds and any money received directly or indirectly from prescription drug manufacturers to implement the PDMP.[23] Funding for the PDMP comes from three funding sources:[24]

1. Donations procured by the Florida PDMP Foundation, Inc. (Foundation), the direct-support organization authorized by s. 893.055, F.S., to fund the continuing operation of the PDMP. The following amounts have been paid to DOH by the Foundation since the PDMP was established:

FY 2009-2010	$39,108
FY 2010-2011	$201,552
FY 2011-2012	$96,758
FY 2012-2013	$102,654
Total	**$440,072**

2. Federal Grants. The PDMP has been awarded three Harold Rogers Prescription Drug Monitoring Program grants from the U.S. Department of Justice and one additional federal grant. The award date and amount of each grant follows:

   - On May 19, 2010, DOH was awarded an "Implementation" grant of $400,000 to implement the prescription drug monitoring system.
   - On September 19, 2010, DOH was awarded an "Enhancement" grant of $400,000 for system enhancements.
   - On August 21, 2012, DOH was awarded a second "Enhancement" grant of $399,300 to enhance the PDMP.
   - On September 20, 2012, DOH was awarded a grant of $240,105 from the Substance Abuse and Mental Health Services Administration (SAMHSA) to integrate PDMP data into existing clinical workflow and technology and to expand interoperability.

   The total amount of federal grants received is $1,199,300. Of that amount, approximately $566,460 has been expended in operation of the PDMP.

3. Private grants and donations. DOH has been awarded three private grants from the National Association of State Controlled Substance Authorities. These grants, totaling $49,952, were used to create a website, to purchase office equipment, and to purchase promotional items.

Section 893.0551, F.S., provides an exemption from public records for personal information of a patient and certain information concerning health care professionals outlined in the statute.[25] The statute details exceptions for disclosure of information after DOH ensures the legitimacy of the person's request for the information.[26]

[22] S. 893.055(7)(c)1.-4., F.S.
[23] S. 893.055(10) and (11)(c), F.S.
[24] Florida Department of Health, Electronic-Florida Online Reporting of Controlled Substances Evaluation (E-FORCSE), *2011-2012 Prescription Drug Monitoring Program Annual Report*, page 7 (available at www.eforcse.com/docs/2012AnnualReport.pdf) (on file with Health Quality Subcommittee staff); information also came from Florida Department of Health document detailing the funding history of the PDMP, also on file with Health Quality Subcommittee staff.
[25] S. 893.0551(2)(a)-(h), F.S.
[26] S. 893.0551(3)(a)-(g), F.S.

The PDMP became operational on September 1, 2011, when it began receiving prescription data from pharmacies and dispensing practitioners.[27] Health care practitioners began accessing the PDMP on October 17, 2011.[28] Law enforcement began requesting data from the PDMP in support of active criminal investigations on November 14, 2011.[29]

Between 2011 and 2012, physicians and pharmacists used the PDMP database at least 2.6 million times.[30] Nearly 5,000 pharmacists entered 56 million prescriptions into the database.[31] Law enforcement queried the PDMP database more than 20,000 times in conjunction with active criminal investigations.[32]

The PDMP is currently funded through fiscal year 2012-2013.[33]

Disciplinary Actions of Health Care Practitioners

Sections 456.072, 456.073 and 456.074 F.S., provide authority for a board to take disciplinary action against a licensee. These actions include:

- Refusal to certify, or to certify with restrictions, an application for a license;
- Suspension or permanent revocation of a license;
- Restriction of a practice or a license;
- Administration of a fine not to exceed $10,000 per occurrence;
- Issuance of a reprimand or letter of concern;
- Imposition of probationary conditions on the licensee;
- Corrective action;
- Imposition of administrative fines for violations of patient rights;
- Refund of fees billed and collect from the patient or a third party on behalf of the patient; and
- Remedial education.[34]

The board can take action for any legally sufficient, written and signed complaint that is filed before it. Section 456.073(1), F.S., provides that a complaint is legally sufficient if it contains the ultimate facts that show a violation of ch. 456, F.S., the relevant practice act, or any rule adopted by DOH or the relevant board. DOH has the authority to investigate a complaint even if the original complainant withdraws or the complainant is anonymous.[35] Further, DOH may initiate an investigation if it has reasonable cause to believe that a licensee has violated a Florida statute or a rule of either the board or the department.

The subject of an investigation has twenty days to respond in writing to the complaint or document after service.[36] All information that is submitted is considered by the probable cause panel of the respective board.[37] The right to respond does not preclude the State Surgeon General from issuing a summary emergency order if it is necessary to protect the public.[38]

DOH has six months to complete an investigation and submit it to the appropriate probable cause panel.[39] A determination as to probable cause is made by a majority vote of the panel.[40] The panel

[27] See supra, FN 24 at page 4.
[28] Id.
[29] Id.
[30] Id. at page 1.
[31] Id.
[32] Id.
[33] Florida Department of Health, *Florida's Prescription Drug Monitoring Program*, Presentation to the Senate Health Policy Committee, January 23, 2013, slide 5 (on file with Health Quality Subcommittee staff).
[34] S. 456.072(2), F.S.
[35] S. 456.073(1), F.S.
[36] Id.
[37] Id.
[38] Id.
[39] S. 456.073(2), F.S.

may request additional investigative information from DOH, which must be done within fifteen days of receiving the investigative report from the department or agency.[41] The panel has thirty days from receiving the final investigative report to make a determination of probable cause.[42] The Surgeon General may grant extensions of these time limits.[43] If the panel does not make a determination within the statutory timeframe, DOH is directed to do so within ten days of the expiration of the time limit.[44]

DOH is directed to follow the determination of the probable cause panel and, if probable cause exists, is directed to file a formal complaint against the subject and prosecute pursuant to ch. 120, F.S.[45] DOH may decide not to prosecute if probable cause has been found improvidently and refer the issue back to the appropriate board, which may then choose to file a formal complaint and prosecute pursuant to ch. 120, F.S.[46] Referrals to the Division of Administrative Hearings must occur within one year of filing the complaint.[47] Chapter 120, F.S., provides the practitioner with the right to appeal the action.

DOH is further directed to notify the person who filed the complaint and, if probable cause is not found, provide them with an opportunity sixty days from the determination to bring additional information to the department.[48]

Effect of Proposed Changes

The bill requires all physicians, osteopathic physicians, naturopathic physicians, podiatrists, and dentists to consult the PDMP database and review a patient's controlled substance history prior to issuing a prescription for a controlled substance to that patient. Current law does not mandate the review of the PDMP database by a physician in advance of issuing a prescription for a controlled substance.

If a physician, who is mandated to review the PDMP database, willfully and knowingly fails to review a patient's controlled substance history prior to issuing a prescription for a controlled substance to the patient, under the bill, he or she is subject to disciplinary action under the respective practice act.

Current law permits a dispenser of a controlled substance to report to the PDMP database the dispensing of that controlled substance up to 7 days following dispensing. The bill requires such reporting of dispensing of a controlled substance to be completed within 2 days of the dispensing. By requiring a shorter time period between dispensing a controlled substance and reporting the dispensing to the PDMP database, the bill will permit physicians and pharmacists to catch individuals who now attempt to "doctor shop" and obtain as many controlled substances as possible under the current 7-day window of reporting.

Current law only allows DOH to operate the PDMP with federal grants or private funding. The bill removes the prohibition against using funds from prescription drug manufacturers to implement the PDMP. As a result, funds from prescription drug manufacturers may be obtained and used to operate the PDMP and the database.

The bill also clarifies that a physician who is required to access the PDMP database is not subject to a lawsuit, or the imposition of damages against him or her, for accessing or failing to access the PDMP database.

B. SECTION DIRECTORY:

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[40] S. 456.073(4), F.S.
[41] Id.
[42] Id.
[43] Id.
[44] Id.
[45] Id.
[46] Id.
[47] Id.
[48] S. 456.073(9)(c), F.S.

Section 1: Amends s. 458.331, F.S., relating to grounds for disciplinary action; action by the board and department.
Section 2: Amends s. 459.015, F.S., relating to grounds for disciplinary action; action by the board and department.
Section 3: Amends s. 461.013, F.S., relating to relating to grounds for disciplinary action; investigations by department.
Section 4: Amends s. 462.14, F.S., relating to grounds for disciplinary action; action by the department.
Section 5: Amends s. 466.028, F.S., relating to grounds for disciplinary action; action by the board.
Section 6: Amends s. 893.055, F.S., relating to the prescription drug monitoring program.
Section 7: Provides an effective date of July 1, 2013.

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:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

DOH and relevant boards have sufficient rule-making authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 19, 2013, the Health Quality Subcommittee adopted a strike-all amendment to House Bill 831. The strike-all:

- Requires all physicians, osteopathic physicians, naturopathic physicians, podiatrists, and dentists to consult the PDMP database to review a patient's controlled substance history prior to prescribing a controlled substance to the patient.
- Makes the failure to consult the PDMP database grounds for disciplinary action under the practice act for each of the specified prescribers required to consult the PDMP database.
- Removes the prohibition against using funds from prescription drug manufacturers to implement the PDMP.
- Reduces the time period for reporting to the PDMP database any dispensing of a controlled substance from seven days to two days.
- Clarifies that a physician who is required to access the PDMP database is not subject to a lawsuit, or the imposition of damages against him or her, for accessing or failing to access the PDMP database.

The analysis is drafted to the committee substitute as passed by the Health Quality Subcommittee.