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HOUSE OF REPRESENTATIVES
COMMITTEE ON
HEALTH REGULATION
ANALYSIS

BILL #: CS/HB 813

RELATING TO: Pharmaceutical Adverse Incident

SPONSOR(S): Committee on Health Regulation and Representative Justice

TIED BILL(S): None.

ORIGINATING COMMITTEE(S)/COUNCIL(S)/COMMITTEE(S) OF REFERENCE:

(1) HEALTH REGULATION YEAS 7 NAYS 0
(2) COUNCIL FOR HEALTHY COMMUNITIES
(3)
(4)
(5)

I. SUMMARY:

This bill, entitled the "Ernest Belles Act," defines a "pharmaceutical adverse incident" and requires such incidents to be reported within 15 days, in writing, by licensed health care practitioners to the Department of Health when the practitioner becomes aware of an incident being alleged by a patient. The bill requires the department to review each incident and determine if it involved conduct which constitutes a ground for disciplinary action. It requires the department to adopt forms and rules for administering this section. Furthermore, the bill requires the department to quarterly publish on its website a summary and trend analysis of pharmaceutical adverse incidents received pursuant to the reporting requirements of the bill.

This bill does not apply to pharmacies participating in the continuous quality improvement program of the Board of Pharmacy, nor does it apply to pharmacies located in facilities that operate medical review committees.

The Agency for Health Care Administration reports that this bill will have a significant fiscal impact. Please see the Fiscal Comments section for details.

SUBSTANTIVE ANALYSIS:

A. DOES THE BILL SUPPORT THE FOLLOWING PRINCIPLES:

1.	Less Government	Yes []	No [x]	N/A []
2.	Lower Taxes	Yes []	No []	N/A [x]
3.	Individual Freedom	Yes []	No [x]	N/A []
4.	Personal Responsibility	Yes [x]	No []	N/A []
5.	Family Empowerment	Yes []	No []	N/A [x]

For any principle that received a “no” above, please explain:

This bill requires pharmacists and other health care practitioners to file reports with state government when an adverse incident occurs, including self-reporting. The patient need not file a complaint.

B. PRESENT SITUATION:

Medication Errors

According to a recent survey developed by the United States Department of Health and Human Services, prescription errors by physicians and pharmacists could cause up to 7,000 deaths this year. In 1983 prescription errors accounted for 2,900 deaths. Some experts are calling for more education, focusing on understanding why medication errors occur, instead of trying to cover up the errors or punishing pharmacists for reporting individual mistakes. In an effort to end the silence surrounding medical errors, 56 of the nation's 6,000 hospitals -- recently joined by more that 200 additional facilities -- have for the past 12 months "openly report[ed]" pharmaceutical "blunders" in a "first-of-its-kind" database called MedMARx®, providing a "glimpse into causes of medication errors." During the first year of the program, designed to "curb the miscues" in prescribing and administering drugs, the hospitals reported 6,224 drug therapy errors that injured 187 patients and killed one.

Definition of Health Care Practitioner

Chapter 456, F.S., provides the general regulatory provisions for health care professions within the Division of Medical Quality Assurance in the Department of Health. Section 456.001, F.S., defines “health care practitioner” to mean any person licensed under ch. 457, F.S., (acupuncture), ch. 458, F.S., (medicine), ch. 459, F.S., (osteopathic medicine), ch. 460, F.S., (chiropractic medicine), ch. 461, F.S., (podiatric medicine), ch. 462, F.S., (naturopathic medicine), ch. 463, F.S., (optometry), ch. 464, (nursing), ch. 465, F.S., (pharmacy), ch. 466 (dentistry and dental hygiene), ch. 467 (midwifery), Parts I, II, III, IV, V, X, XIII, or XIV of ch. 468 (speech-language pathology, nursing home administration, occupational therapy, respiratory therapy, dietetics and nutrition practice, athletic trainers, and orthotics, prosthetics, and pedorthics), ch. 478, F.S., (electrology or electrolysis), ch. 480, F.S., (massage therapy), parts III or IV of ch. 483, F.S., (clinical laboratory personnel or medical physics), ch. 484, F.S., (opticianry and hearing aid specialists), ch. 486 (physical therapy), ch. 490 (psychology), and ch. 491, F.S. (psychotherapy).

Hospital Adverse Incident Reporting

Ambulatory surgical centers and hospitals must be licensed under chapter 395, F.S. Chapter 395, F.S., imposes requirements on ambulatory surgical centers and hospitals which include inspection and accreditation, and reporting of adverse incidents that result in serious patient injury. Ambulatory surgical centers and hospitals, under s. 395.0197(8), F.S., must report the following incidents within 15 calendar days after they occur to the Agency for Health Care Administration:

- death of a patient;
- brain or spinal damage to a patient;
- performance of a surgical procedure on the wrong patient;
- performance of a wrong-site surgical procedure;
- performance of a wrong surgical procedure;
- performance of a surgical procedure that is medically unnecessary or otherwise unrelated to the patient's diagnosis or medical condition;
- surgical repair of damage resulting to the patient from a planned surgical procedure where damage is not a recognized specific risk, as disclosed to the patient and documented through the informed consent process; or
- performance of procedures to remove unplanned foreign objects remaining in a patient following surgery.

Physician Adverse Incident Reporting

Sections 458.351 and 459.026, F.S., require any medical physician, osteopathic physician, or physician assistant to notify the Department of Health of any adverse incident that involved the physician or physician assistant which occurred on or after January 1, 2000, in any office maintained by the physician for the practice of medicine that is not licensed under chapter 395, F.S., relating to licensure for hospitals and ambulatory surgical centers. The sections require any medical physician, osteopathic physician, or physician assistant to notify the department in writing and by certified mail of the adverse incident within 15 days after the adverse incident occurred. The notice must be postmarked within 15 days after the adverse incident occurred.

"Adverse incident" is defined under ss. 458.351 and 459.026, F.S., to mean an event over which the physician or physician assistant could exercise control and which is associated in whole or in part with a medical intervention, rather than the condition for which such intervention occurred, and which results in the following patient injuries:

- death of a patient;
- brain or spinal damage to a patient;
- performance of a surgical procedure on the wrong patient;
- any condition that required the transfer of a patient to a hospital licensed under chapter 395, F.S., from an ambulatory surgical center licensed under chapter 395, F.S., or from any facility or any office maintained by a physician for the practice of medicine which is not licensed under chapter 395; or
- performance of a procedure to remove unplanned foreign objects remaining from a surgical procedure.

Under the definition of adverse incident, a medical physician, osteopathic physician, or physician assistant must provide notice of patient injuries only if they result in death, brain or spinal damage, permanent disfigurement, fracture or dislocation of bones or joints, a limitation of neurological, physical or sensory function, or any condition that required the transfer of the patient. The

Department of Health must review each adverse incident and determine whether the incident potentially involved conduct by a health care professional who is subject to disciplinary action, and provides that the procedures for handling disciplinary complaints under s. 456.073, F.S., apply.

The Practice of Pharmacy

Chapter 465, F.S., regulates the practice of pharmacy in Florida. Section 465.016(1)(g), F.S., provides a ground for disciplinary action against the license of a pharmacist if the pharmacist uses "in the compounding of a prescription, or furnishing upon prescription, an ingredient or article different in any manner from the ingredient or article prescribed" except where substitution is specifically allowable in certain types of institutions or relating to generic drug substitution. Therefore, it is currently a ground for discipline if the pharmacist misfills a prescription.

Florida also has "snitch" laws which require health care practitioners to report to the department violations of the various practice acts. See sections 456.072(1)(i) and 465.016(1)(o), F.S.

C. EFFECT OF PROPOSED CHANGES:

This bill, entitled the "Ernest Belles Act," defines a "pharmaceutical adverse incident" as "the dispensing of a different medication, a different dose, or the correct medication in a container with different instructions than that specified in the prescription, but does not include the dispensing of a generic equivalent medication with the patient's consent." It requires such incidents to be reported within 15 days, in writing, by licensed health care practitioners to the Department of Health when the practitioner becomes aware of an incident being alleged by a patient. The bill requires the department to review each incident and determine if it involved conduct which constitutes a ground for disciplinary action. It requires the department to adopt forms and rules for administering this section. Furthermore, the bill requires the department to quarterly publish on its website a summary and trend analysis of pharmaceutical adverse incidents received pursuant to the reporting requirements of the bill.

This bill does not apply to pharmacies participating in the continuous quality improvement program of the Board of Pharmacy, nor does it apply to pharmacies located in facilities that operate medical review committees.

D. SECTION-BY-SECTION ANALYSIS:

Section 1. Provides short title of "Ernest Belles Act."

Section 2. Amends s. 456.0165, F.S., to provide a definition of "pharmaceutical adverse incident." Provides that all health care practitioners who become aware of a pharmaceutical adverse incident must report such incident to the department within 15 days on forms provided by the department. Provides rulemaking authority to the department to adopt forms and rules. Requires the department to review each incident for possible disciplinary action and requires the department to publish certain information on its website.

Section 2. Provides that the bill shall only become effective if legislation is passed which becomes law providing for continuous quality improvement committees to be included within the definition of medical review committees in s. 766.101, F.S.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT:

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

See Fiscal Comments section.

2. Expenditures:

See Fiscal Comments section.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

See Fiscal Comments section.

2. Expenditures:

See Fiscal Comments section.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

To the extent that health care practitioners would have to file written reports with state government, there would be indeterminable costs associated with the completion and filing of such reports.

D. FISCAL COMMENTS:

The Department of Health reports that this bill would likely impact the County Health Department's 16 pharmacies and over 100 health care practitioners. The fiscal impact would equal the workload associated with reporting plus any fines levied on the pharmacy permits of the County Health Departments for errors committed therein.

The Agency for Health Care Administration estimates that a total of 83 new FTEs and approximately $4.66 million would be necessary to handle the additional workload presuming that the intent of the bill is to investigate these errors to determine if disciplinary action is warranted.

III. CONSEQUENCES OF ARTICLE VII, SECTION 18 OF THE FLORIDA CONSTITUTION:

A. APPLICABILITY OF THE MANDATES PROVISION:

The bill does not require a city or county to expend funds or to take any action requiring the expenditure of funds.

B. REDUCTION OF REVENUE RAISING AUTHORITY:

This bill does not reduce the authority that municipalities or counties have to raise revenues in the aggregate.

C. REDUCTION OF STATE TAX SHARED WITH COUNTIES AND MUNICIPALITIES:

This bill does not reduce the percentage of state tax shared with counties or municipalities.

IV. COMMENTS:

A. CONSTITUTIONAL ISSUES:

A Fifth Amendment privilege issue could potentially be raised when a licensed person is required to assist in proving his own guilt. See State ex rel. Vining v. Florida Real Estate Commission, 281 So.2d 487 (Fla. 1973), which held that the right to remain silent applied not only to a traditional criminal case, but also to proceedings which were "penal" in nature. Also, see Boedy v. Department of Professional Regulation, 463 So.2d 215 (Fla. 1985), which recognized a limited exception to the privilege against compelled self incrimination.

B. RULE-MAKING AUTHORITY:

The bill provides rulemaking authority to the Department of Health to adopt forms and rules for administering the provisions of the bill.

C. OTHER COMMENTS:

The bill does not provide any sanction against a health care practitioner who fails to report a pharmaceutical adverse incident.

The bill also does not address the confidentiality, discoverability, admissibility as evidence in court, or exemption from public access of information obtained by the department in the adverse incident reports. A totally voluntary reporting system without any immunity from liability for reporting and protections for sensitive information may result in poor reporting and possible release of sensitive personal medical information.

The definition of "pharmaceutical adverse incident" may not capture all of the dispensing errors that occur, such as dispensing a medication that has contraindications for the patient or dispensing the wrong amount of a prescribed medication.

V. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

The original bill did not include the trend analysis nor the review for potential disciplinary action.

VI. SIGNATURES:

COMMITTEE ON HEALTH REGULATION:

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