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/SB 1096

SPONSOR: Appropriations Subcommittee on Health and Human Services , Health, Aging and Long-Term Care and Senator Campbell

SUBJECT: Pharmaceutical Adverse Incidents

DATE: April 18, 2001 REVISED: _____ _____ _____ _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HC	Favorable/CS
2.	Peters	Belcher	AHS	Favorable/CS
3.			AP	
4.				
5.				
6.				

I. Summary:

The bill creates the "Ernest Belles Act" to require licensed pharmacists and other health care practitioners as defined in s. 456.001, F.S., who become aware of a pharmaceutical adverse incident to report such incident to the Department of Health. The bill defines "pharmaceutical adverse incident" to mean 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 which resulted in actual harm to the patient, but does not include the dispensing of a generic equivalent medication with the patient's consent. The bill requires the Department of Health to review reported "pharmaceutical adverse incidents" to determine if the incidents potentially involve conduct by a health care practitioner who is subject to disciplinary action and specifies that disciplinary action may be taken by the appropriate regulatory board under which the health care practitioner is licensed. The bill provides an exemption to pharmacists employed by pharmacies that participate in the reporting program and pharmacists employed by pharmacies that have notified the Board of Pharmacy that they will establish a continuous quality improvement program. This bill establishes an effective date of July 1, 2003 that requires the Department of Health to review each incident and determine if a disciplinary action is needed, subject to subsequent action by the legislature and contingent upon an appropriation. The bill requires the confidentiality of all persons and entities involved in the review process of the adverse incident. **T**he bill requires the Department of Health to adopt forms and rules for administering the reporting of pharmaceutical adverse incidents by health care practitioners.

This bill creates one undesignated section of law.

II. Present Situation:

The Practice of Pharmacy and Medication Errors

Chapter 465, F.S., authorizes the regulation of the practice of pharmacy. Section 465.0276, F.S., requires any person who is not a licensed pharmacist to register with her or his regulatory board and meet other specified requirements in order to dispense drugs to her or his patients in the regular course of her or his practice for a fee or remuneration. Under s. 465.0276(5), F.S., an exception to these requirements allows a practitioner to dispense drug samples to his or her patients. Under the exception the practitioner must confine her or his activities to the dispensing of complimentary packages of medicinal drugs to the practitioner's own patients in the regular course of her or his practice, without the payment of fee or remuneration of any kind.

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 pedorthtics), 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 Office Surgery Adverse Incident Reporting

Licensed medical physicians may perform surgery in their medical offices, ambulatory surgical centers, or hospitals. 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.

III. Effect of Proposed Changes:

The bill creates the "Ernest Belles Act" to require licensed pharmacists and other health care practitioners as defined in s. 456.001, F.S., who become aware of a pharmaceutical adverse incident to report such incident to the Department of Health on forms provided by the department. The notification must be submitted in writing by certified mail and postmarked

within 15 days after the occurrence of the adverse incident. The bill defines "pharmaceutical adverse incident" to mean 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 which resulted in actual harm to the patient, but does not include the dispensing of a generic equivalent medication with the patient's consent. The bill requires the Department of Health to review reported "pharmaceutical adverse incidents" to determine if the incidents potentially involve conduct by a health care practitioner who is subject to disciplinary action and specifies that disciplinary action may be taken by the appropriate regulatory board under which the health care practitioner is licensed and establishes an effective date of July 1, 2003 that requires the Department of Health to review each incident and determine if a disciplinary action is needed, subject to subsequent action by the legislature and contingent upon an appropriation. The bill also provides an exemption to pharmacists employed by pharmacies that participate in the reporting program and pharmacists employed by pharmacies that have notified the Board of Pharmacy that they will establish a continuous quality improvement program. This bill requires that all information, persons and entities involved in the review process of the adverse incident will be confidential and exempt from the inspection, examination, and duplication of records statute. The bill requires the Department of Health to adopt forms and rules for administering the reporting of pharmaceutical adverse incidents by health care practitioners.
The effective date of the bill is July 1, 2001.

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 Art. 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 Art. III, s. 19(f) of the Florida Constitution.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Health care practitioners will incur some costs to report pharmaceutical adverse incidents to the Department of Health.

C. Government Sector Impact:

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 bill establishes an effective date of July 1, 2003 that requires the Department of Health to review each incident and determine if a disciplinary action is needed, subject to subsequent action by the legislature and contingent upon an appropriation. The Department of Health pursuant to s. 456.073(1), F.S., currently, may initiate an investigation if it has reasonable cause to believe that a licensed health care practitioner has violated a Florida statute, a rule of the department, or a rule of a board.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill does not provide any sanction against a health care practitioner who fails to report a pharmaceutical adverse incident. Section 2 of the bill does not take effect until legislation is enacted that makes the information contained in reported incidents confidential and exempt from the Public Records Law until 10 days after probable cause is found that a violation of law occurred. 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.

VIII. Amendments:

None.