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/SB 402

SPONSOR: Senator Campbell

SUBJECT: Pharmaceutical Adverse Incidents

DATE: December 5, 2001 REVISED: _____ _____ _____ _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HC	Favorable/CS
2.			AHS	
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 patient's allegation of a pharmaceutical adverse incident to report such allegation 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 results in actual harm to the patient, but does not include the dispensing of a generic equivalent medication with the patient's consent. The bill provides an exemption to pharmacists employed by pharmacies that participate in the program provided by rule and pharmacists employed by pharmacies that have notified the Board of Pharmacy that they will establish a continuous quality improvement program. Effective July 1, 2004, subject to subsequent action by the Legislature and contingent upon an appropriation, the bill requires the Department of Health to review each incident to determine if the incident potentially involves 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 effective date of the bill's requirement for pharmacists and health care practitioners to report allegations of pharmaceutical adverse incidents is contingent on the passage of separate legislation that creates a public records exemption and that provides confidentiality for all persons and entities involved in the review process of the adverse incident. The 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 three undesignated sections of law.

II. Present Situation:

The Practice of Pharmacy and Medication Errors

Chapter 465, F.S., authorizes the regulation of the practice of pharmacy by the Florida Board 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.

The Florida Board of Pharmacy, pursuant to s. 465.0155, F.S., must adopt by rule standards of practice relating to the practice of pharmacy which shall be binding on every state agency and must be applied by such agencies when enforcing or implementing any authority granted by any applicable statute, rule, or regulation, whether federal or state. The Florida Board of Pharmacy has adopted an administrative rule[1] relating to pharmacy practice standards that provides requirements for institutional pharmacies to implement a system to identify and evaluate quality-related events and improve patient care.

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.,

[1] The Florida Board of Pharmacy has adopted 64B16-27.300, Florida Administrative Code. The rule requires each institutional pharmacy to establish a "Continuous Quality Improvement Program," which must be described in the pharmacy's policy and procedure manual and which must include a process for review of events relating to the inappropriate dispensing of prescribed medication. Records maintained as a component of the Continuous Quality Improvement Program are confidential as medical-review activities under s. 766.101, F.S., and are not discoverable or admissible in any disciplinary proceeding against a licensed health care practitioner. Licensed health care practitioners who furnish information to a medical review committee, hospital internal risk management program, the Department of Health or the Agency for Health Care Administration under s. 766.101, F.S., are granted limited immunity to a civil action, if the information is not intentionally fraudulent and is within the scope of the functions of such entities.

(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, F.S., (nursing); ch. 465, F.S., (pharmacy); ch. 466, F.S., (dentistry and dental hygiene); ch. 467, F.S., (midwifery); parts I, II, III, IV, V, X, XIII, and XIV of ch. 468, F.S., (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 and IV of ch. 483, F.S., (clinical laboratory personnel or medical physics); ch. 484, F.S., (opticianry and hearing aid specialists); ch. 486, F.S., (physical therapy); ch. 490, F.S., (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 that 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.

Nursing Home and Assisted Living Facility Adverse Incident Reporting

Section 400.147, F.S., requires nursing homes to have an internal risk management and quality assurance program and report adverse incidents to the Agency for Health Care Administration. Each nursing facility must develop and implement an incident reporting system based upon the affirmative duty of all health care providers and all agents and employees of the licensed facility to report adverse incidents to the risk manager or his or her designee, within 3 business days after their occurrence. "Adverse incident" is defined as an event over which the facility staff could have exercised control and which is associated in whole or in part with the facility's intervention, rather than the condition for which the intervention occurred. Adverse incidents are those events which result in death; brain or spinal damage; permanent disfigurement; fracture or dislocation of bones or joints; a limitation of neurological, physical, or sensory function; any condition requiring medical attention to which the resident has not given his or her informed consent, including failure to honor advance directives; any condition that requires the transfer of the resident, within or outside the facility, to a unit providing a more acute level of care due to the adverse incident, rather than the resident's condition prior to the adverse incident; abuse, neglect, or exploitation; resident elopement; or an event that is reported to law enforcement.

The facility is required to notify the Agency for Health Care Administration within 1 business day after the risk manager or his or her designee receives the report of an adverse incident. The

Agency for Health Care Administration may investigate any such incident, as it deems appropriate, and is allowed to prescribe measures that must or may be taken in response to the incident. The Agency for Health Care Administration must review each incident and determine whether the incident potentially involved conduct by a health care professional who is subject to disciplinary action. If this is the case, the provisions related to disciplinary proceedings of s. 456.073, F.S., apply. The notification is confidential and not discoverable or admissible in any civil or administrative action, except disciplinary proceedings by the Agency for Health Care Administration or a regulatory board.

Each facility must complete the investigation and submit an adverse incident report to the Agency for Health Care Administration for each adverse incident within 15 calendar days after its occurrence, on a form developed by the agency. The Agency for Health Care Administration must review the information, and determine whether the incident potentially involved conduct subject to the disciplinary proceedings of s. 456.073, F.S. The adverse incident report must contain the name and license number of the risk manager. The report is confidential and not discoverable or admissible in any civil or administrative action, except disciplinary proceedings by the agency or a professional board.

Assisted living facilities, pursuant to s. 400.423, F.S., may establish a voluntary risk management program, but must report adverse incidents. Each facility is required to maintain adverse incident reports. “Adverse incident” is defined as an event over which the facility staff could have exercised control and which is associated in whole or in part with the facility’s intervention, rather than the condition for which the intervention occurred. Adverse incidents are those events which result in death; brain or spinal damage; permanent disfigurement; fracture or dislocation of bones or joints; any condition requiring medical attention to which the resident has not given his or her informed consent, including failure to honor advance directives; any condition that requires the transfer of the resident from the facility to a unit providing a more acute level of care due to the adverse incident, rather than the resident’s condition prior to the adverse incident; abuse, neglect, or exploitation; resident elopement; or an event that is reported to law enforcement.

The facility, regardless of the number of beds, is required to notify the Agency for Health Care Administration within 1 business day after the occurrence of an adverse incident. The Agency for Health Care Administration must review each incident and determine whether the incident potentially involved conduct by a health care professional who is subject to disciplinary action. If this is the case, the provisions related to disciplinary proceedings of s. 456.073, F.S., apply. The notification is confidential and not discoverable or admissible in any civil or administrative action, except disciplinary proceedings by the Agency for Health Care Administration or regulatory boards.

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 ch. 395, F.S., from an ambulatory surgical center licensed under ch. 395, F.S., or from any facility or any office maintained by a physician for the practice of medicine which is not licensed under ch. 395, F.S.; 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.

Disciplinary Procedures for Health Care Practitioners

Section 456.073, F.S., sets forth procedures the Department of Health must follow in conducting disciplinary proceedings against practitioners under its jurisdiction. The department, for the boards under its jurisdiction, must investigate all written complaints filed with it that are legally sufficient. Complaints are legally sufficient if they contain facts, which, if true, show that a licensee has violated any applicable regulations governing the licensee's profession or occupation.

When investigations of licensees within the department's jurisdiction are determined to be complete and legally sufficient, the department is required to prepare, and submit to a probable cause panel of the appropriate board, if there is a board, an investigative report along with a recommendation of the department regarding the existence of probable cause. A board has discretion over whether to delegate the responsibility of determining probable cause to the department or to retain the responsibility to do so by appointing a probable cause panel for the board. The determination as to whether probable cause exists must be made by majority vote of a probable cause panel of the appropriate board or by the department, if there is no board or if the board has delegated the probable cause determination to the department.

If the subject of the complaint makes a written request and agrees to maintain the confidentiality of the information, the subject may review the department's complete investigative file. The licensee may respond within 20 days of the licensee's review of the investigative file to information in the file before it is considered by the probable cause panel. Section 456.073(10),

F.S., provides that complaints and information obtained by the department during its investigations are exempt from the Public Records Law until 10 days after probable cause has been found to exist by the probable cause panel or the department, or until the subject of the investigation waives confidentiality. If the case is dismissed prior to a finding of probable cause, the complaints and information remain confidential in perpetuity under s. 456.073(2), F.S. Under s. 456.073(4), F.S., all proceedings of a probable cause panel are exempt from the open meetings requirements of ch. 286, F.S., until 10 days after probable cause has been found to exist or until the subject of an investigation of a disciplinary complaint waives confidentiality.

The Department of Health contracts with the Agency for Health Care Administration to investigate and prosecute disciplinary complaints. The Department of Health's clerk is the custodian designated for orders and related information regarding the discipline of a licensed health care practitioner under s. 456.073, F.S. The Department of Health and its agents may share information with law enforcement agencies or other regulatory agencies that are investigating an individual for activity within such agency's regulatory jurisdiction which may be related to activities being investigated by the department. The information provided by the department retains its confidential status in the hands of those other agencies.

Under s. 456.057(8)(a), F.S., all patient records obtained by the Department of Health and any other documents maintained by the department that identify the patient by name are confidential and exempt from the Public Records Law and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

As used in s. 456.057, F.S., "records owner" is defined to mean any health care practitioner who generates a medical record after making a physical or mental examination of, or administering treatment or dispensing legend drugs to, any person; any health care practitioner to whom records are transferred by a previous records owner; or to any health care practitioner's employer, if the contract or agreement between the employer and the health care practitioner designates the employer as the records owner. The following persons or entities are not authorized to acquire or own medical records, but are authorized under the confidentiality and disclosure requirements of s. 456.057, F.S., to maintain those documents required by regulations under which they are regulated: certified nursing assistants, *pharmacists and pharmacies*, nursing home administrators, respiratory therapists, athletic trainers, electrologists, clinical laboratory personnel, medical physicists, opticians and optical establishments, persons or entities making physical examinations for an injured person as part of personal injury protection claim, or hospitals and ambulatory surgical centers.

Public Records Law

The Public Records Law, ch. 119, F.S., and the Public Meetings Law, s. 286.011, F.S., specify the conditions under which public access must be provided to governmental records and meetings of the executive branch and other governmental agencies. While the state constitution provides that records and meetings of public bodies are to be open to the public, it also provides that the Legislature may create exemptions to these requirements by general law if a public need

exists and certain procedural requirements are met. Article I, s. 24, Florida Constitution, governs the creation and expansion of exemptions, to provide, in effect, that any legislation that creates a new exemption or that substantially amends an existing exemption must also contain a statement of the public necessity that justifies the exemption. Article I, s. 24, Florida Constitution, provides that any bill that contains an exemption may not contain other substantive provisions, although it may contain multiple exemptions.

III. Effect of Proposed Changes:

Section 1. Creates the "Ernest Belles Act."

Section 2. Requires licensed pharmacists and other health care practitioners as defined in s. 456.001, F.S., who become aware of a patient's allegation of a pharmaceutical adverse incident to report such allegation 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 pharmacist or health care practitioner became aware of the patient's allegation that a pharmaceutical adverse incident has occurred. 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 results 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 establishes an effective date of July 1, 2004, for this provision that requires the Department of Health to review each incident and determine if a disciplinary action is needed, and makes the requirement 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 program established by rule and pharmacists employed by pharmacies that have notified the Board of Pharmacy that they will establish a continuous quality improvement program. The bill requires the Department of Health to adopt forms and rules for administering the reporting of pharmaceutical adverse incidents by health care practitioners.

Section 3. Provides that Section 2 of the bill must take effect only upon the effective date of legislation that makes pharmaceutical adverse incident information provided to the Department of Health confidential and exempt from disclosure under the Public Records Law, until 10 days after probable cause is found that a violation of law occurred. Such legislation must also provide that information be used by the department or the Board of Pharmacy only in a disciplinary proceeding brought against the pharmacist or by the department in any study of adverse incidents without identifying the patient, pharmacist, pharmacy, office, or entity by name, location, or other identifier.

Section 4. Except as otherwise expressly provided, the effective date of the bill is July 1, 2002.

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 pharmaceutical adverse incident reporting requirements of the bill will become effective only upon passage of a separate public records exemption bill.

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, 2004, 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:

A totally voluntary reporting system without any immunity from liability for reporting may result in poor reporting.

The Board of Pharmacy has proposed amendments to its administrative rule 64B16-27.300, Florida Administrative Code, that would establish a continuous quality-improvement requirement on all regulated pharmacies. The proposed administrative rule change is expected to take effect on December 20, 2001. As a result, the Department of Health reports that all pharmacists and pharmacies will be exempt from the reporting requirements of the bill.

VIII. Amendments:

None.

This Senate staff analysis does not reflect the intent or official position of the bill's sponsor or the Florida Senate.