By the Committee on Health, Aging and Long-Term Care; and Senator Campbell

317-835-02

A bill to be entitled

An act relating to pharmacy; providing a short title; defining the term "pharmaceutical adverse incident" and requiring that such incidents be reported to the Department of Health; providing exceptions; requiring the department to review reported incidents to determine whether the incidents potentially involve conduct by a health care practitioner that is subject to disciplinary action; specifying that any disciplinary action shall be taken by the appropriate board; providing for the adoption of rules and forms; providing effective dates.

Be It Enacted by the Legislature of the State of Florida:

Section 1. This act may be cited as the "Ernest Belles Act."

Section 2. (1) As used in this section, the term "pharmaceutical adverse incident" means the dispensing of a different medication, a different dose, or the correct medication in a container with different instructions than those specified in the prescription, which dispensation results in actual harm to a patient, but does not include the dispensing of a generic equivalent medication with the patient's consent.

(2) A pharmacist licensed under chapter 465, Florida Statutes, or other health care practitioner as defined in section 456.001, Florida Statutes, who becomes aware of a patient's allegation that a pharmaceutical adverse incident

has occurred which was caused by a health care practitioner, must report such allegation to the Department of Health on forms provided by the department. This section does not apply to:

(a) Pharmacists employed by pharmacies that participate in the program provided by Rule 64B16-27.300, Florida Administrative Code; or

(b) Pharmacists employed by pharmacies that have notified the Board of Pharmacy that they will establish a continuous quality-improvement program consistent with the requirements of Rule 64B16-27.300, Florida Administrative Code.

(3) The required notification to the department 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.

(4) Effective July 1, 2004, subject to subsequent act of the Legislature and a specific appropriation sufficient to cover the actual costs, the department shall review each incident and determine whether it potentially involved conduct by a pharmacist or health care practitioner who is subject to disciplinary action, in which case section 465.073, Florida Statutes, applies. Disciplinary action, if any, shall be taken by the board under which the pharmacist or health care practitioner is licensed.

(5) The Department of Health shall adopt forms and rules for administering this section.

Section 3. Section 2 of this act shall take effect only upon the effective date of legislation that makes any such information provided to the Department of Health

confidential and exempt from section 119.07(1), Florida Statutes, and Section 24(a) of Article I of the State Constitution, until 10 days after probable cause is found that a violation of law occurred. Such legislation must also provide that information may 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 in this act, this act shall take effect July 1, 2002.

STATEMENT OF SUBSTANTIAL CHANGES CONTAINED IN COMMITTEE SUBSTITUTE FOR Senate Bill 402

The Committee Substitute for Senate Bill 402 clarifies that 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 must report such allegation rather than the actual incident, itself, to the Department of Health. 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.