By the Committee on Health Regulation and Representative Justice

A bill to be entitled

An act relating to pharmacists; providing a short title; creating s. 465.0165, F.S.; defining the term "pharmaceutical adverse incident" and requiring that such incidents be reported to the Department of Health; providing that such incident reports are not discoverable or admissible in any civil or administrative action, except disciplinary proceedings; requiring the department to review reported incidents to determine if 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; requiring the department to publish pharmaceutical adverse incident information on its website; providing exemptions from reporting requirements; providing contingent 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. Section 465.0165, Florida Statutes, is created to read:

465.0165 Reports of pharmaceutical adverse incidents.--

(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 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.

(2)(a) A pharmacist licensed under chapter 465, or other health care practitioner as defined in s. 456.001, who becomes aware of a patient alleging that a pharmaceutical adverse incident occurred which was caused by a health care practitioner, must report such incident to the Department of Health on forms provided by the department. The pharmaceutical adverse incident report is not discoverable or admissible in any civil or administrative action, except in disciplinary proceedings by the department or the appropriate regulatory board.

(b) This subsection shall take effect only upon the effective date of legislation that makes any such information provided to the department confidential and exempt from s. 119.07(1) and s. 24(a), Art. 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 only be used by the department or the Board of Pharmacy 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.

(3) The required notification to the department must be submitted in writing by certified mail and postmarked within 15 days after the occurrence of the adverse incident.

(4) Effective July 1, 2003, 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 s. 456.073 applies. Disciplinary action, if any, shall be taken by the board under which the pharmacist or health care practitioner is licensed.

(5) The department shall adopt forms and rules for administering this section.

(6) The department shall publish on its website, no less than quarterly, a summary and trend analysis of pharmaceutical adverse incidents received pursuant to this section, which shall not include information that would identify the patients or the health care practitioners involved. The purpose of the publication of the summary and trend analysis is to promote the rapid dissemination of information relating to adverse incidents to assist in the avoidance of similar incidents and reduce patient harm.

(7) The provisions of this section shall not apply to:

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

(b) Pharmacists employed by pharmacies notifying 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.

(8) Pharmacies located in facilities that are operating medical review committees pursuant to s. 766.101(1)(a) shall be governed by the reporting requirements in Rule 64B16-27.300, Florida Administrative Code, in lieu of the requirements of this section.

Section 3. Except as otherwise provided herein, this act shall take effect on the same date as, but not be effective unless and until such time as, legislation amending s. 766.101, Florida Statutes, to include a continuous quality improvement committee of a pharmacy licensed pursuant to chapter 465, Florida Statutes, within the provisions of s. 766.101(1), Florida Statutes, if such legislation is adopted in the same legislative session or an extension thereof and becomes a law.