

By Representative Cusack

1 A bill to be entitled
 2 An act relating to pharmacy; providing a short
 3 title; defining the term "pharmaceutical
 4 adverse incident" and requiring that such
 5 incidents be reported to the Department of
 6 Health; providing exceptions; requiring the
 7 department to review reported incidents to
 8 determine whether the incidents potentially
 9 involve conduct by a health care practitioner
 10 that is subject to disciplinary action;
 11 specifying that any disciplinary action shall
 12 be taken by the appropriate board; providing
 13 for the adoption of forms and rules; providing
 14 effective dates.

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

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

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

27 (2) A pharmacist licensed under chapter 465, Florida
 28 Statutes, or other health care practitioner as defined in s.
 29 456.001, Florida Statutes, who becomes aware of a patient's
 30 allegation that a pharmaceutical adverse incident has occurred
 31 which was caused by a health care practitioner, must report

1 such allegation to the Department of Health on forms provided
2 by the department. This section does not apply to:

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

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

11 (3) The required notification to the department must
12 be submitted in writing by certified mail and postmarked
13 within 15 days after the pharmacist or health care
14 practitioner became aware of the patient's allegation that a
15 pharmaceutical adverse incident has occurred.

16 (4) Effective July 1, 2004, subject to subsequent act
17 of the Legislature and a specific appropriation sufficient to
18 cover the actual costs, the department shall review each
19 incident and determine whether it potentially involved conduct
20 by a pharmacist or health care practitioner who is subject to
21 disciplinary action, in which case s. 465.023, Florida
22 Statutes, applies. Disciplinary action, if any, shall be
23 taken by the board under which the pharmacist or health care
24 practitioner is licensed.

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

27 Section 3. Section 2 of this act shall take effect
28 only upon the effective date of legislation that makes any
29 such information provided to the Department of Health
30 confidential and exempt from s. 119.07(1), Florida Statutes,
31 and s. 24(a), Art. I of the State Constitution, until 10 days

1 after probable cause is found that a violation of law
2 occurred. Such legislation must also provide that information
3 may be used by the department or the Board of Pharmacy only in
4 a disciplinary proceeding brought against the pharmacist or by
5 the department in any study of adverse incidents without
6 identifying the patient, pharmacist, pharmacy, office, or
7 entity by name, location, or other identifier.

8 Section 4. Except as otherwise provided in this act,
9 this act shall take effect July 1, 2002.

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HOUSE SUMMARY

Defines "pharmaceutical adverse incident" and requires that a pharmacist or other health care practitioner report a patient's allegation of such incident to the Department of Health. Specifies pharmacists to whom the reporting requirement does not apply. Effective July 1, 2004, and subject to specific appropriation therefor and enactment of specified confidentiality provisions, requires the department to review each reported incident to determine whether conduct requiring disciplinary action by a professional licensing board may be involved. Provides department rulemaking authority.