

By Senator Campbell

33-230-02

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 rules and forms; 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 those specified in the prescription, which dispensation
25 results in actual harm to a patient, but does not include the
26 dispensing of a generic equivalent medication with the
27 patient's consent.

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

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

4 (a) Pharmacists employed by pharmacies that
5 participate in the reporting program provided by Rule
6 64B16-27.300, Florida Administrative Code; or

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

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

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

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

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

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

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

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12 SENATE SUMMARY

13 Requires health care practitioners to report certain
14 prescription-filling incidents to the Department of
15 Health. Provides for the adoption of rules and forms.
16 Defines the term, "pharmaceutical adverse incident".
17 Specifies that a pharmacist or other health care
18 practitioner is required to report a "pharmaceutical
19 adverse incident" if he or she is aware of a patient
20 allegation that such an incident was caused by the health
21 care practitioner. Makes exceptions for which certain
22 pharmacists may be excluded from reporting requirements.
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