

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 allegation to the Department of Health on  
3 forms provided by the department. This section does not apply  
4 to:

5 (a) Pharmacists employed by pharmacies that  
6 participate in the program provided by Rule 64B16-27.300,  
7 Florida Administrative Code or health care practitioners  
8 working in facilities that administer medications dispensed  
9 from those pharmacies; or

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

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

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

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

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1           Section 3. Section 2 of this act shall take effect  
2 only upon the effective date of legislation that makes any  
3 such information provided to the Department of Health  
4 confidential and exempt from section 119.07(1), Florida  
5 Statutes, and Section 24(a) of Article I of the State  
6 Constitution, until 10 days after probable cause is found that  
7 a violation of law occurred. Such legislation must also  
8 provide that information may be used by the department or the  
9 Board of Pharmacy only in a disciplinary proceeding brought  
10 against the pharmacist or by the department in any study of  
11 adverse incidents without identifying the patient, pharmacist,  
12 pharmacy, office, or entity by name, location, or other  
13 identifier.

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

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