

Bill No. CS for CS for SB 370

Amendment No.      Barcode 585264

<u>Senate</u>	CHAMBER ACTION	<u>House</u>
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Senator Campbell moved the following **amendment to amendment** (104940):

**Senate Amendment (with title amendment)**

On page 97, between lines 23 and 24,

insert:

- Section 80. (1) This section may be cited as the "Ernest Belles Act."
- (2) 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.
- (3) 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,

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

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

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

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

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

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

30 Section 81. Section 80 of this act shall take effect  
31 only upon the effective date of legislation that makes any

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

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13 (Redesignate subsequent sections.)

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16 ===== T I T L E A M E N D M E N T =====

17 And the title is amended as follows:

18 On page 107, line 21, after the semicolon

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20 insert:

21 creating the "Ernest Belles Act"; defining the  
22 term "pharmaceutical adverse incident" and  
23 requiring that such incidents be reported to  
24 the Department of Health; providing exceptions;  
25 requiring the department to review reported  
26 incidents to determine whether the incidents  
27 potentially involve conduct by a health care  
28 practitioner that is subject to disciplinary  
29 action; specifying that any disciplinary action  
30 shall be taken by the appropriate board;  
31 providing for the adoption of rules and forms;