Bill No. CS for CS for SB 370

Amendment No. ____ Barcode 742614

ı	CHAMBER ACTION <u>Senate</u> <u>House</u>
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11	Senator Campbell moved the following amendment:
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13	Senate Amendment (with title amendment)
14	On page 40, between lines 22 and 23,
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16	insert:
17	Section 42. (1) This section may be cited as the
18	"Ernest Belles Act."
19	(2) As used in this section, the term "pharmaceutical
20	adverse incident" means the dispensing of a different
21	medication, a different dose, or the correct medication in a
22	container with different instructions than those specified in
23	the prescription, which dispensation results in actual harm to
24	a patient, but does not include the dispensing of a generic
25	equivalent medication with the patient's consent.
26	(3) A pharmacist licensed under chapter 465, Florida
27	Statutes, or other health care practitioner as defined in
28	section 456.001, Florida Statutes, who becomes aware of a
29	patient's allegation that a pharmaceutical adverse incident
30	has occurred which was caused by a health care practitioner,
31	must report such allegation to the Department of Health on

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forms provided by the department. This section does not apply to:

- (a) Pharmacists employed by pharmacies that participate in the program provided by Rule 64B16-27.300, Florida Administrative Code; or
- (b) Pharmacists employed by pharmacies that have notified 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.
- (4) The required notification to the department must be submitted in writing by certified mail and postmarked within 15 days after the pharmacist or health care practitioner became aware of the patient's allegation that a pharmaceutical adverse incident has occurred.
- 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 section 465.073, Florida Statutes, applies. Disciplinary action, if any, shall be taken by the board under which the pharmacist or health care practitioner is licensed.
- (6) The Department of Health shall adopt forms and rules for administering this section.
- Section 43. Section 42 of this act shall take effect only upon the effective date of legislation that makes any such information provided to the Department of Health confidential and exempt from section 119.07(1), Florida Statutes, and Section 24(a) of Article I of the State

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Constitution, until 10 days after probable cause is found that
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    a violation of law occurred. Such legislation must also
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   provide that information may be used by the department or the
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   Board of Pharmacy only in a disciplinary proceeding brought
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    against the pharmacist or by the department in any study of
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    adverse incidents without identifying the patient, pharmacist,
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   pharmacy, office, or entity by name, location, or other
    identifier.
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    (Redesignate subsequent sections.)
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    ======= T I T L E A M E N D M E N T =========
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   And the title is amended as follows:
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           On page 4, line 5, after the semicolon
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    insert:
           creating the "Ernest Belles Act"; defining the
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19
           term "pharmaceutical adverse incident" and
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           requiring that such incidents be reported to
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           the Department of Health; providing exceptions;
           requiring the department to review reported
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           incidents to determine whether the incidents
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          potentially involve conduct by a health care
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          practitioner that is subject to disciplinary
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           action; specifying that any disciplinary action
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           shall be taken by the appropriate board;
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          providing for the adoption of rules and forms;
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