Bill No. CS for CS for SB 370 Amendment No. ____ Barcode 761516 CHAMBER ACTION Senate House 1 2 3 4 5 6 7 8 9 10 Senator Campbell moved the following amendment: 11 12 13 Senate Amendment (with title amendment) On page 40, between lines 22 and 23, 14 15 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 medication, a different dose, or the correct medication in a 21 22 container with different instructions than those specified in the prescription, which dispensation results in actual harm to 23 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 section 456.001, Florida Statutes, who becomes aware of a 28 patient's allegation that a pharmaceutical adverse incident 29 30 has occurred which was caused by a health care practitioner, 31 must report such allegation to the Department of Health on 1 4:36 PM 03/14/02

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forms provided by the department. This section does not apply 1 to: 2 3 (a) Pharmacists employed by pharmacies that 4 participate in the program provided by Rule 64B16-27.300, Florida Administrative Code or health care practitioners 5 6 working in facilities that administer medications dispensed 7 from those pharmacies; or (b) Pharmacists employed by pharmacies that have 8 9 notified the Board of Pharmacy that they will establish a 10 continuous quality-improvement program consistent with the requirements of Rule 64B16-27.300, Florida Administrative 11 12 Code. (4) The required notification to the department must 13 14 be submitted in writing by certified mail and postmarked 15 within 15 days after the pharmacist or health care 16 practitioner became aware of the patient's allegation that a 17 pharmaceutical adverse incident has occurred. 18 (5) Effective July 1, 2004, subject to subsequent act of the Legislature and a specific appropriation sufficient to 19 cover the actual costs, the department shall review each 20 21 incident and determine whether it potentially involved conduct by a pharmacist or health care practitioner who is subject to 22 disciplinary action, in which case section 465.073, Florida 23 24 Statutes, applies. Disciplinary action, if any, shall be taken by the board under which the pharmacist or health care 25 practitioner is licensed. 26 27 (6) The Department of Health shall adopt forms and 28 rules for administering this section. 29 Section 43. Section 42 of this act shall take effect 30 only upon the effective date of legislation that makes any 31 such information provided to the Department of Health 2 4:36 PM 03/14/02

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confidential and exempt from section 119.07(1), Florida 1 2 Statutes, and Section 24(a) of Article I of the State 3 Constitution, until 10 days after probable cause is found that 4 a violation of law occurred. Such legislation must also provide that information may be used by the department or the 5 6 Board of Pharmacy only in a disciplinary proceeding brought 7 against the pharmacist or by the department in any study of adverse incidents without identifying the patient, pharmacist, 8 pharmacy, office, or entity by name, location, or other 9 10 identifier. 11 12 (Redesignate subsequent sections.) 13 14 15 16 And the title is amended as follows: 17 On page 4, line 5, after the semicolon 18 19 insert: 20 creating the "Ernest Belles Act"; defining the 21 term "pharmaceutical adverse incident" and requiring that such incidents be reported to 22 the Department of Health; providing exceptions; 23 24 requiring the department to review reported incidents to determine whether the incidents 25 26 potentially involve conduct by a health care 27 practitioner that is subject to disciplinary action; specifying that any disciplinary action 28 29 shall be taken by the appropriate board; 30 providing for the adoption of rules and forms; 31

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