Bill No. CS/HB 913, 2nd Eng. Amendment No. ____ Barcode 332360 CHAMBER ACTION Senate House 1 2 3 4 5 6 7 8 9 10 11 Senator Campbell moved the following amendment to amendment 12 (913362): 13 Senate Amendment (with title amendment) 14 15 On page 79, between lines 14 and 15, 16 17 insert: 18 Section 27. (1) This section may be cited as the 19 "Ernest Belles Act." 20 (2) As used in this section, the term "pharmaceutical adverse incident" means the dispensing of a different 21 medication, a different dose, or the correct medication in a 22 23 container with different instructions than those specified in the prescription, which dispensation results in actual harm to 24 25 a patient, but does not include the dispensing of a generic 26 equivalent medication with the patient's consent. 27 (3) A pharmacist licensed under chapter 465, Florida 28 Statutes, or other health care practitioner as defined in 29 section 456.001, Florida Statutes, who becomes aware of a 30 patient's allegation that a pharmaceutical adverse incident has occurred which was caused by a health care practitioner, 31 1 9:23 PM 03/20/02 h0913c1c-332p2

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must report such allegation to the Department of Health on 1 forms provided by the department. This section does not apply 2 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 Code. 13 (4) The required notification to the department must 14 15 be submitted in writing by certified mail and postmarked within 15 days after the pharmacist or health care 16 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 of the Legislature and a specific appropriation sufficient to 20 21 cover the actual costs, the department shall review each incident and determine whether it potentially involved conduct 22 by a pharmacist or health care practitioner who is subject to 23 24 disciplinary action, in which case section 465.073, Florida Statutes, applies. Disciplinary action, if any, shall be 25 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 28. Section 80 of this act shall take effect only upon the effective date of legislation that makes any 31 2 9:23 PM 03/20/02 h0913c1c-332p2

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such information provided to the Department of Health 1 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 a violation of law occurred. Such legislation must also 5 6 provide that information may be used by the department or the 7 Board of Pharmacy only in a disciplinary proceeding brought against the pharmacist or by the department in any study of 8 adverse incidents without identifying the patient, pharmacist, 9 10 pharmacy, office, or entity by name, location, or other 11 identifier. 12 13 (Redesignate subsequent sections.) 14 15 16 17 And the title is amended as follows: On page 85, page 26, after the semicolon 18 19 20 insert: 21 creating the "Ernest Belles Act"; defining the term "pharmaceutical adverse incident" and 22 requiring that such incidents be reported to 23 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 practitioner that is subject to disciplinary 28 29 action; specifying that any disciplinary action 30 shall be taken by the appropriate board; 31 providing for the adoption of rules and forms;

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