

APR 4 2005  
WAYS & MEANS CALENDAR

HOUSE FILE 833  
BY COMMITTEE ON WAYS AND MEANS

(SUCCESSOR TO HF 790)  
(SUCCESSOR TO HSB 227)

Passed House, Date \_\_\_\_\_ Passed Senate, Date \_\_\_\_\_  
Vote: Ayes \_\_\_\_\_ Nays \_\_\_\_\_ Vote: Ayes \_\_\_\_\_ Nays \_\_\_\_\_  
Approved \_\_\_\_\_

**A BILL FOR**

1 An Act making changes relating to the practice of pharmacy,  
2 establishing and appropriating fees, and providing penalties.  
3 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

HF  
833

- 4
- 5
- 6
- 7
- 8
- 9
- 10
- 11
- 12
- 13
- 14
- 15
- 16
- 17
- 18
- 19
- 20
- 21

1 Section 1. Section 155A.3, subsection 11, Code 2005, is  
2 amended to read as follows:

3 11. "Dispense" means to deliver a prescription drug,  
4 device, or controlled substance to an ultimate user or  
5 research subject by or pursuant to the lawful prescription  
6 drug order or medication order of a practitioner, including  
7 the prescribing, administering, packaging, labeling, or  
8 compounding necessary to prepare the substance for that  
9 delivery.

10 Sec. 2. Section 155A.3, Code 2005, is amended by adding  
11 the following new subsection:

12 NEW SUBSECTION. 23A. "Pedigree" means a recording of each  
13 distribution of any given drug or device, from the sale by the  
14 manufacturer through acquisition and sale by any wholesaler,  
15 pursuant to rules adopted by the board.

16 Sec. 3. Section 155A.3, subsection 33, paragraph b, Code  
17 2005, is amended to read as follows:

18 b. A drug or device that under federal law is required,  
19 prior to being dispensed or delivered, to be labeled with  
20 either one of the following statements:

21 (1) Caution: Federal law prohibits dispensing without a  
22 prescription.

23 (2) Caution: Federal law restricts this drug to use by or  
24 on the order of a licensed veterinarian.

25 (3) Caution: Federal law restricts this device to sale  
26 by, or on the order of, a physician.

27 (4) Rx only.

28 Sec. 4. Section 155A.3, subsection 35, Code 2005, is  
29 amended to read as follows:

30 35. "Proprietary medicine" or "over-the-counter medicine"  
31 means a nonnarcotic drug or device that may be sold without a  
32 prescription and that is labeled and packaged in compliance  
33 with applicable state or federal law.

34 Sec. 5. Section 155A.3, subsection 38, Code 2005, is  
35 amended to read as follows:

1 38. "Wholesaler" means a person operating or maintaining,  
2 either within or outside this state, a manufacturing plant,  
3 wholesale distribution center, wholesale business, or any  
4 other business in which prescription drugs or devices,  
5 medicinal chemicals, medicines, or poisons are sold,  
6 manufactured, compounded, dispensed, stocked, exposed,  
7 distributed from, or offered for sale at wholesale in this  
8 state. "Wholesaler" does not include those wholesalers who  
9 sell only proprietary or over-the-counter medicines.

10 "Wholesaler" also does not include a commercial carrier that  
11 temporarily stores prescription drugs or devices, medicinal  
12 chemicals, medicines, or poisons while in transit.

13 Sec. 6. Section 155A.4, subsection 2, paragraph a, Code  
14 2005, is amended to read as follows:

15 a. A manufacturer-~~or~~ wholesaler to distribute prescription  
16 drugs or devices as provided by state or federal law.

17 Sec. 7. Section 155A.13, subsection 6, unnumbered  
18 paragraph 1, Code 2005, is amended to read as follows:

19 To qualify for a pharmacy license, the applicant shall  
20 submit to the board a license fee as determined by the board  
21 and a completed application on a form prescribed by the board  
22 ~~that shall include the following information and.~~ The  
23 application shall include the following and such other  
24 information as required by rules of the board and shall be  
25 given under oath:

26 Sec. 8. Section 155A.17, subsection 2, Code 2005, is  
27 amended to read as follows:

28 2. The board shall establish standards for drug wholesaler  
29 licensure and may define specific types of wholesaler  
30 licenses. The board may deny, suspend, or revoke a drug  
31 wholesale license for failure to meet the applicable standards  
32 or for a violation of the laws of this state, another state,  
33 or the United States relating to prescription drugs, devices,  
34 or controlled substances, or for a violation of this chapter,  
35 chapter 124, 124A, 124B, 126, or 205, or a rule of the board.

1     Sec. 9. Section 155A.19, subsection 1, paragraph f, Code  
2 2005, is amended by striking the paragraph and inserting in  
3 lieu thereof the following:

4     f. Change of legal name or doing-business-as name.

5     Sec. 10. Section 155A.19, Code 2005, is amended by adding  
6 the following new subsection:

7     NEW SUBSECTION. 3. A wholesaler shall report in writing  
8 to the board, pursuant to its rules, the following:

9     a. Permanent closing or discontinuation of wholesale  
10 distributions into this state.

11    b. Change of ownership.

12    c. Change of location.

13    d. Change of the wholesaler's responsible individual.

14    e. Change of legal name or doing-business-as name.

15    f. Theft or significant loss of any controlled substance  
16 on discovery of the theft or loss.

17    g. Disasters, accidents, and emergencies that may affect  
18 the strength, purity, or labeling of drugs, medications,  
19 devices, or other materials used in the diagnosis or the  
20 treatment of injury, illness, and disease.

21    h. Other information or activities as required by rule.

22     Sec. 11. Section 155A.20, subsection 1, Code 2005, is  
23 amended to read as follows:

24     1. A person, other than a pharmacy or wholesaler licensed  
25 under this chapter, shall not display in or on any store,  
26 internet site, or place of business, nor use in any  
27 advertising or promotional literature, communication, or  
28 representation, the word or words: "apothecary", "drug",  
29 "drug store", or "pharmacy", either in English or any other  
30 language, any other word or combination of words of the same  
31 or similar meaning, or any graphic representation in a manner  
32 that would mislead the public unless-it-is-a-pharmacy-or-drug  
33 wholesaler-licensed-under-this-chapter.

34     Sec. 12. Section 155A.21, Code 2005, is amended to read as  
35 follows:

1 155A.21 UNLAWFUL POSSESSION OF PRESCRIPTION DRUG OR DEVICE

2 -- PENALTY.

3 1. A person found in possession of a drug or device  
4 limited to dispensation by prescription, unless the drug or  
5 device was so lawfully dispensed, commits a serious  
6 misdemeanor.

7 2. Subsection 1 does not apply to a licensed pharmacy,  
8 licensed wholesaler, physician, veterinarian, dentist,  
9 podiatric physician, therapeutically certified optometrist,  
10 advanced registered nurse practitioner, physician assistant, a  
11 nurse acting under the direction of a physician, or the board  
12 of pharmacy examiners, its officers, agents, inspectors, and  
13 representatives, nor to a common carrier, manufacturer's  
14 representative, or messenger when transporting the drug or  
15 device in the same unbroken package in which the drug or  
16 device was delivered to that person for transportation.

17 Sec. 13. Section 155A.23, Code 2005, is amended to read as  
18 follows:

19 155A.23 PROHIBITED ACTS.

20 A person shall not perform or cause the performance of or  
21 aid and abet any of the following acts:

22 1. ~~Obtain-or-attempt~~ Obtaining or attempting to obtain a  
23 prescription drug or device or ~~procure-or-attempt~~ procuring or  
24 attempting to procure the administration of a prescription  
25 drug or device by:

26 a. ~~Fraud~~ Engaging in fraud, deceit, misrepresentation, or  
27 subterfuge.

28 b. ~~Forgery-or-alteration-of~~ Forging or altering a written,  
29 electronic, or facsimile prescription or ~~of~~ any written,  
30 electronic, or facsimile order.

31 c. ~~Concealment-of~~ Concealing a material fact.

32 d. ~~Use-of~~ Using a false name or the giving ~~of~~ a false  
33 address.

34 2. Willfully ~~make~~ making a false statement in any  
35 prescription, report, or record required by this chapter.

1     3. For the purpose of obtaining a prescription drug or  
2 device, falsely ~~assume~~ assuming the title of or ~~claim~~ claiming  
3 to be a manufacturer, wholesaler, pharmacist, pharmacy owner,  
4 physician, dentist, podiatric physician, veterinarian, or  
5 other authorized person.

6     4. ~~Make-or-utter~~ Making or uttering any false or forged  
7 oral, written, electronic, or facsimile prescription or oral,  
8 written, electronic, or facsimile order.

9     5. ~~Affix-any-false-or-forged-label-to-a-package-or~~  
10 ~~receptacle-containing-prescription-drugs~~ Forging,  
11 counterfeiting, simulating, or falsely representing any drug  
12 or device without the authority of the manufacturer, or using  
13 any mark, stamp, tag, label, or other identification device  
14 without the authorization of the manufacturer.

15     6. Manufacturing, repackaging, selling, delivering, or  
16 holding or offering for sale any drug or device that is  
17 adulterated, misbranded, counterfeit, suspected of being  
18 counterfeit, or that has otherwise been rendered unfit for  
19 distribution.

20     7. Adulterating, misbranding, or counterfeiting any drug  
21 or device.

22     8. Receiving any drug or device that is adulterated,  
23 misbranded, stolen, obtained by fraud or deceit, counterfeit,  
24 or suspected of being counterfeit, and delivering or  
25 proffering delivery of such drug or device for pay or  
26 otherwise.

27     9. Adulterating, mutilating, destroying, obliterating, or  
28 removing the whole or any part of the labeling of a drug or  
29 device or committing any other act with respect to a drug or  
30 device that results in the drug or device being misbranded.

31     10. Purchasing or receiving a drug or device from a person  
32 who is not licensed to distribute the drug or device to that  
33 purchaser or recipient.

34     11. Selling or transferring a drug or device to a person  
35 who is not authorized under the law of the jurisdiction in

1 which the person receives the drug or device to purchase or  
2 possess the drug or device from the person selling or  
3 transferring the drug or device.

4 12. Failing to maintain or provide records as required by  
5 this chapter, chapter 124, or rules of the board.

6 13. Providing the board or any of its representatives or  
7 any state or federal official with false or fraudulent records  
8 or making false or fraudulent statements regarding any matter  
9 within the scope of this chapter, chapter 124, or rules of the  
10 board.

11 14. Distributing at wholesale any drug or device that  
12 meets any of the following conditions:

13 a. The drug or device was purchased by a public or private  
14 hospital or other health care entity.

15 b. The drug or device was donated or supplied at a reduced  
16 price to a charitable organization.

17 c. The drug or device was purchased from a person not  
18 licensed to distribute the drug or device.

19 d. The drug or device was stolen or obtained by fraud or  
20 deceit.

21 15. Failing to obtain a license or operating without a  
22 valid license when a license is required pursuant to this  
23 chapter or chapter 147.

24 16. Engaging in misrepresentation or fraud in the  
25 distribution of a drug or device.

26 17. Distributing a drug or device to a patient without a  
27 prescription drug order or medication order from a  
28 practitioner licensed by law to use or prescribe the drug or  
29 device.

30 18. Distributing a drug or device that was previously  
31 dispensed by a pharmacy or distributed by a practitioner  
32 except as provided by rules of the board.

33 19. Failing to report any prohibited act.

34 Information communicated to a physician in an unlawful  
35 effort to procure a prescription drug or device or to procure

1 the administration of a prescription drug shall not be deemed  
2 a privileged communication.

3 Subsections 6 and 7 shall not apply to the wholesale  
4 distribution by a manufacturer of a prescription drug or  
5 device that has been delivered into commerce pursuant to an  
6 application approved by the federal food and drug  
7 administration.

8 Sec. 14. Section 155A.24, Code 2005, is amended to read as  
9 follows:

10 155A.24 PENALTIES.

11 1. A Except as otherwise provided in this section, a  
12 person who violates a provision of section 155A.23 or who  
13 sells or offers for sale, gives away, or administers to  
14 another person any prescription drug or device in violation of  
15 this chapter commits a public offense and shall be punished as  
16 follows:

17 a. If the prescription drug is a controlled substance, the  
18 person shall be punished pursuant to ~~section-124-401,~~  
19 ~~subsection-1, and section-124-411~~ chapter 124, division IV.

20 b. If the prescription drug is not a controlled substance,  
21 the person, upon conviction of a first offense, is guilty of a  
22 serious misdemeanor. For a second offense, or if in case of a  
23 first offense the offender previously has been convicted of  
24 any violation of the laws of the United States or of any  
25 state, territory, or district thereof relating to prescription  
26 drugs or devices, the offender is guilty of an aggravated  
27 misdemeanor. For a third or subsequent offense or if in the  
28 case of a second offense the offender previously has been  
29 convicted two or more times in the aggregate of any violation  
30 of the laws of the United States or of any state, territory,  
31 or district thereof relating to prescription drugs or devices,  
32 the offender is guilty of a class "D" felony.

33 2. A person who violates any provision of this chapter by  
34 selling, giving away, or administering any prescription drug  
35 or device to a minor is guilty of a class "C" felony.

1     3. A wholesaler who, with intent to defraud or deceive,  
2 fails to deliver to another person, when required by rules of  
3 the board, complete and accurate pedigree concerning a drug  
4 prior to transferring the drug to another person is guilty of  
5 a class "C" felony.

6     4. A wholesaler who, with intent to defraud or deceive,  
7 fails to acquire, when required by rules of the board,  
8 complete and accurate pedigree concerning a drug prior to  
9 obtaining the drug from another person is guilty of a class  
10 "C" felony.

11    5. A wholesaler who knowingly destroys, alters, conceals,  
12 or fails to maintain, as required by rules of the board,  
13 complete and accurate pedigree concerning any drug in the  
14 person's possession is guilty of a class "C" felony.

15    6. A wholesaler who is in possession of pedigree documents  
16 required by rules of the board, and who knowingly fails to  
17 authenticate the matters contained in the documents as  
18 required, and who nevertheless distributes or attempts to  
19 further distribute drugs is guilty of a class "C" felony.

20    7. A wholesaler who, with intent to defraud or deceive,  
21 falsely swears or certifies that the person has authenticated  
22 any documents related to the wholesale distribution of drugs  
23 or devices is guilty of a class "C" felony.

24    8. A wholesaler who knowingly forges, counterfeits, or  
25 falsely creates any pedigree, who falsely represents any  
26 factual matter contained in any pedigree, or who knowingly  
27 omits to record material information required to be recorded  
28 in a pedigree is guilty of a class "C" felony.

29    9. A wholesaler who knowingly purchases or receives drugs  
30 or devices from a person not authorized to distribute drugs or  
31 devices in wholesale distribution is guilty of a class "C"  
32 felony.

33    10. A wholesaler who knowingly sells, barter, brokers, or  
34 transfers a drug or device to a person not authorized to  
35 purchase the drug or device under the jurisdiction in which

1 the person receives the drug or device in a wholesale  
2 distribution is guilty of a class "C" felony.

3 11. A person who knowingly possesses, actually or  
4 constructively, any amount of a counterfeit, misbranded, or  
5 adulterated drug or device and who knowingly sells or delivers  
6 any amount of the counterfeit, misbranded, or adulterated drug  
7 or device or who possesses with intent to sell or deliver any  
8 amount of a counterfeit, misbranded, or adulterated drug or  
9 device is guilty of a class "C" felony.

10 12. A person who knowingly forges, counterfeits, or  
11 falsely creates any label for a drug or device or who falsely  
12 represents any factual matter contained on any label of a drug  
13 or device is guilty of a class "C" felony.

14 13. A person who knowingly possesses, actually or  
15 constructively, any amount of a counterfeit, misbranded, or  
16 adulterated drug or device and who knowingly manufactures,  
17 purchases, sells, delivers, or brings into the state any  
18 amount of the counterfeit, misbranded, or adulterated drug or  
19 device, is guilty of a class "D" felony.

20 14. A person who knowingly manufactures, purchases, sells,  
21 delivers, or brings into the state, or who is knowingly in  
22 actual or constructive possession of any amount of a  
23 counterfeit, misbranded, or adulterated drug or device, and  
24 whose acts result in the death of a person is guilty of a  
25 class "A" felony.

26 15. A person found guilty of any offense under this  
27 section or under chapter 124, division IV, under the authority  
28 of the court convicting and sentencing the person, shall order  
29 that the person forfeit to the state, pursuant to chapter  
30 809A, any real or personal property that meets either of the  
31 following conditions:

32 a. The property was used or intended to be used to commit,  
33 facilitate, or promote the commission of such offense.

34 b. The property constitutes, derives from, or is traceable  
35 to the gross proceeds that the defendant obtained directly or

1 indirectly as a result of the offense.

2 Any property or assets subject to forfeiture under this  
3 subsection may be seized in the manner prescribed in chapter  
4 809A, and may be held as provided in that chapter. Moneys  
5 ordered forfeited, or proceeds from the sale of other assets  
6 ordered forfeited, shall be equitably divided among the board  
7 and other agencies involved in the investigation and  
8 prosecution that led to the conviction. Other property  
9 ordered forfeited after conviction of a defendant may, at the  
10 discretion of the investigating agencies, be placed into  
11 official use by the board or the agencies involved in the  
12 investigation and prosecution that led to the conviction.

13 16. This section does not prevent a licensed practitioner  
14 of medicine, dentistry, podiatry, nursing, veterinary  
15 medicine, optometry, or pharmacy from acts necessary in the  
16 ethical and legal performance of the practitioner's  
17 profession.

18 Sec. 15. NEW SECTION. 155A.40 CRIMINAL HISTORY RECORD  
19 CHECKS.

20 1. The board may request and obtain, notwithstanding  
21 section 692.2, subsection 5, criminal history data for any  
22 applicant for an initial or renewal license or registration  
23 issued pursuant to this chapter or chapter 147, any applicant  
24 for reinstatement of a license or registration issued pursuant  
25 to this chapter or chapter 147, or any licensee or registrant  
26 who is being monitored as a result of a board order or  
27 agreement resolving an administrative disciplinary action, for  
28 the purpose of evaluating the applicant's, licensee's, or  
29 registrant's eligibility for licensure, registration, or  
30 suitability for continued practice of the profession.  
31 Criminal history data may be requested for of all owners,  
32 managers, and principal employees of a pharmacy or drug  
33 wholesaler licensed pursuant to this chapter. The board shall  
34 adopt rules pursuant to chapter 17A to implement this section.  
35 The board shall inform the applicant, licensee, or registrant

1 of the criminal history requirement and obtain a signed waiver  
2 from the applicant, licensee, or registrant prior to  
3 submitting a criminal history data request.

4 2. A request for criminal history data shall be submitted  
5 to the department of public safety, division of criminal  
6 investigation and bureau of identification, pursuant to  
7 section 692.2, subsection 1. The board may also require such  
8 applicants, licensees, and registrants to provide a full set  
9 of fingerprints, in a form and manner prescribed by the board.  
10 Such fingerprints may be submitted to the federal bureau of  
11 investigation through the state criminal history repository  
12 for a national criminal history check. The board may  
13 authorize alternate methods or sources for obtaining criminal  
14 history record information. The board may, in addition to any  
15 other fees, charge and collect such amounts as may be incurred  
16 by the board, the department of public safety, or the federal  
17 bureau of investigation in obtaining criminal history  
18 information. Amounts collected shall be considered repayment  
19 receipts as defined in section 8.2.

20 3. Criminal history information relating to an applicant,  
21 licensee, or registrant obtained by the board pursuant to this  
22 section is confidential. The board may, however, use such  
23 information in a license or registration denial proceeding.  
24 In a disciplinary proceeding, such information shall  
25 constitute investigative information under section 272C.6,  
26 subsection 4, and may be used only for purposes consistent  
27 with that section.

28 4. This section shall not apply to a manufacturer of a  
29 prescription drug or device that has been delivered into  
30 commerce pursuant to an application approved by the federal  
31 food and drug administration.

32 Sec. 16. NEW SECTION. 155A.41 CONTINUOUS QUALITY  
33 IMPROVEMENT PROGRAM.

34 1. Each licensed pharmacy shall implement or participate  
35 in a continuous quality improvement program to review pharmacy

1 procedures in order to identify methods for addressing  
2 pharmacy medication errors and for improving patient use of  
3 medications and patient care services. Under the program,  
4 each pharmacy shall assess its practices and identify areas  
5 for quality improvement.

6 2. The board shall adopt rules for the administration of a  
7 continuous quality improvement program. The rules shall  
8 address all of the following:

- 9 a. Program requirements and procedures.
- 10 b. Program record and reporting requirements.
- 11 c. Any other provisions necessary for the administration  
12 of a program.

13 EXPLANATION

14 This bill makes several technical and substantive changes  
15 regarding Code chapter 155A relating to the practice of  
16 pharmacy.

17 The bill makes changes to definitions applicable to the  
18 Code chapter. The bill expands the definition of "dispense"  
19 to include the delivery of a device, and makes several other  
20 conforming changes in the Code chapter adding a reference to  
21 "device" where a prescription drug is referred to. The bill  
22 also provides a new definition of "pedigree" to mean a  
23 recording of each distribution of any given drug or device,  
24 from the sale by the manufacturer through acquisition and sale  
25 by any wholesaler, pursuant to rules adopted by the board of  
26 pharmacy examiners. The bill adds "over-the-counter medicine"  
27 as an alternative term to "proprietary medicine" with  
28 reference to a nonnarcotic drug or device that may be sold  
29 without a prescription, and adds two new labeling statements  
30 required under federal law prior to dispensation or delivery.  
31 With reference to the definition of a "wholesaler", the bill  
32 provides that a wholesaler does not include a commercial  
33 carrier that temporarily stores prescription drugs or devices,  
34 medicinal chemicals, medicines, or poisons while in transit.  
35 The bill provides that the application form submitted by an

1 applicant for a pharmacy license shall include information  
2 specified in the statute, and other information that may be  
3 required by the board by rule, and that the board may define  
4 specific types of wholesaler licenses.

5 The bill provides that a drug wholesaler shall report in  
6 writing to the board information relating to the permanent  
7 closing or discontinuation of wholesale distributions into the  
8 state, a change of ownership or location, a change concerning  
9 the individual designated as the wholesaler's responsible  
10 individual, a change of name, the theft or significant loss of  
11 any controlled substance on discovery of the theft or loss,  
12 any disasters, accidents, and emergencies that may affect the  
13 strength, purity, or labeling of drugs, medications, devices,  
14 or other materials used in the diagnosis or the treatment of  
15 injury, illness, and disease, and other information or  
16 activities as required by rules of the board.

17 The bill extends prohibitions against the use of the word  
18 "apothecary", "drug", "drug store", or "pharmacy" by  
19 individuals other than licensed pharmacists or wholesalers, to  
20 internet sites, and to any advertising or promotional  
21 literature, communication, or representation.

22 The bill adds a number of new provisions regarding acts  
23 which are unlawful for a person to perform, or cause the  
24 performance of, or aid and abet, and therefore prohibited.  
25 The bill provides that a person shall not engage in forging,  
26 counterfeiting, simulating, or falsely representing any drug  
27 or device without the authority of the manufacturer, or using  
28 any mark, stamp, tag, label, or other identification device  
29 without manufacturer authorization; or engage in  
30 manufacturing, repackaging, selling, delivering, or holding or  
31 offering for sale any drug or device that is adulterated,  
32 misbranded, counterfeit, suspected of being counterfeit, or  
33 that has otherwise been rendered unfit for distribution; or  
34 engage in adulterating, misbranding, or counterfeiting any  
35 drug or device; or receive any drug or device that is

1 adulterated, misbranded, stolen, obtained by fraud or deceit,  
2 counterfeit, or suspected of being counterfeit; or deliver or  
3 proffer delivery of such drug or device for pay or otherwise.  
4 The bill provides that prohibitions relating to manufacturing,  
5 repackaging, selling, delivering, or holding or offering for  
6 sale any drug or device that is adulterated, misbranded,  
7 counterfeit, suspected of being counterfeit, or that has  
8 otherwise been rendered unfit for distribution, and to  
9 adulterating, misbranding, or counterfeiting any drug or  
10 device, shall not be applicable to the wholesale distribution  
11 by a manufacturer of a prescription drug or device that has  
12 been delivered into commerce pursuant to an application  
13 approved by the federal food and drug administration, whose  
14 own regulations shall apply in such instances. Further, the  
15 bill provides that a person shall not engage in adulterating,  
16 mutilating, destroying, obliterating, or removing the whole or  
17 any part of the labeling of a drug or device or committing any  
18 other act with respect to a drug or device that results in the  
19 drug or device being misbranded; or engage in purchasing or  
20 receiving a drug or device from a person that is not licensed  
21 to distribute the drug or device to that purchaser or  
22 recipient; or engage in selling or transferring a drug or  
23 device to a person that is not authorized under the law of the  
24 jurisdiction in which the person receives the drug or device  
25 to purchase or possess it; or fail to maintain or provide  
26 required records.

27 Additional prohibited acts include providing the board or  
28 any of its representatives or any state or federal official  
29 with false or fraudulent records or making false or fraudulent  
30 statements; distributing at wholesale any drug or device that  
31 was purchased by a public or private hospital or other health  
32 care entity, donated or supplied at a reduced price to a  
33 charitable organization, purchased from a person not licensed  
34 to distribute it, or stolen or obtained by fraud or deceit;  
35 failing to obtain a required license or operating without a

1 valid license; and engaging in misrepresentation or fraud in  
2 the distribution of a drug or device.

3 Finally, prohibited acts also include distributing a drug  
4 or device to a patient without a prescription drug order or  
5 medication order from a practitioner licensed by law to use or  
6 prescribe the drug or device; distributing a drug or device  
7 that was previously dispensed by a pharmacy or distributed by  
8 a practitioner except as provided by rule; and failing to  
9 report any prohibited act.

10 The bill also expands the list of penalties contained in  
11 Code section 155A.24. The bill provides that a wholesaler  
12 shall be guilty of a class "C" felony if the wholesaler, with  
13 intent to defraud or deceive, fails to deliver to another  
14 person, when required by rules of the board, complete and  
15 accurate pedigree concerning a drug prior to transferring the  
16 drug to another person; or with intent to defraud or deceive,  
17 fails to acquire, when required by rules of the board,  
18 complete and accurate pedigree concerning a drug prior to  
19 obtaining the drug from another person; or who knowingly  
20 destroys, alters, conceals, or fails to maintain, as required  
21 by rules of the board, complete and accurate pedigree  
22 concerning any drug in the person's possession; or who is in  
23 possession of pedigree documents required by rules of the  
24 board, and who knowingly fails to authenticate the matters  
25 contained in the documents as required, and who nevertheless  
26 distributes or attempts to further distribute drugs; or with  
27 intent to defraud or deceive, falsely swears or certifies that  
28 the person has authenticated any documents related to the  
29 wholesale distribution of drugs or devices. Additionally, the  
30 bill provides that a wholesaler shall be guilty of a class "C"  
31 felony if the wholesaler knowingly forges, counterfeits, or  
32 falsely creates any pedigree, who falsely represents any  
33 factual matter contained in any pedigree, or who knowingly  
34 omits to record material information required to be recorded  
35 in a pedigree; or knowingly purchases or receives drugs or

1 devices from a person not authorized to distribute drugs or  
2 devices in wholesale distribution; or knowingly sells,  
3 barterers, brokers, or transfers a drug or device to a person  
4 not authorized to purchase the drug or device under the  
5 jurisdiction in which the person receives the drug or device  
6 in a wholesale distribution.

7 The bill provides, in addition, that a person who knowingly  
8 possesses, actually or constructively, any amount of a  
9 counterfeit, misbranded, or adulterated drug or device and who  
10 knowingly sells or delivers any amount of the counterfeit,  
11 misbranded, or adulterated drug or device or who possesses  
12 with intent to sell or deliver any amount of a counterfeit,  
13 misbranded, or adulterated drug or device, shall be guilty of  
14 a class "C" felony, as is a person who knowingly forges,  
15 counterfeits, or falsely creates any label for a drug or  
16 device or who falsely represents any factual matter contained  
17 in any label of a drug or device. The bill provides that a  
18 person who knowingly possesses, actually or constructively,  
19 any amount of a counterfeit, misbranded, or adulterated drug  
20 or device and who knowingly manufactures, purchases, sells,  
21 delivers, or brings into the state any amount of the  
22 counterfeit, misbranded, or adulterated drug or device, is  
23 guilty of a class "D" felony. Further, a person who knowingly  
24 manufactures, purchases, sells, delivers, or brings into the  
25 state, or who is knowingly in actual or constructive  
26 possession of any amount of a counterfeit, misbranded, or  
27 adulterated drug or device, and whose acts result in the death  
28 of a person, shall be guilty of a class "A" felony.

29 The bill provides for the forfeiture to and seizure by the  
30 state of any real or personal property of a person found  
31 guilty.

32 The bill authorizes the board to request criminal history  
33 data for applicants, licensees, and registrants under Code  
34 chapter 147 or 155A, for the purpose of evaluating the  
35 person's eligibility for the license or registration or to

1 evaluate the person's suitability for the practice of the  
2 profession. The bill provides that such requests shall not be  
3 applicable to a manufacturer of a prescription drug or device  
4 that has been delivered into commerce pursuant to an  
5 application approved by the federal food and drug  
6 administration, whose own regulations shall apply in such  
7 instances.

8 The bill requires each licensed pharmacy to implement a  
9 continuous quality improvement program to review pharmacy  
10 procedures in order to identify methods for addressing  
11 pharmacy medication errors and for improving patient use of  
12 medications and patient care services. The bill provides that  
13 the board shall adopt rules for the administration of the  
14 program.

15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35

HOUSE FILE 833

H-1404

1 Amend the amendment, H-1382, to House File 833, as  
2 follows:

3 1. Page 1, by striking lines 4 through 8 and  
4 inserting the following:

5 "11. A person who knowingly manufacturers, sells,  
6 or delivers, or who possesses with intent to sell or  
7 deliver, a counterfeit, misbranded, or adulterated  
8 drug or device is guilty of the following:

9 a. If the person manufactures or produces a  
10 counterfeit, misbranded, or adulterated drug or  
11 device; or if the quantity of a counterfeit,  
12 misbranded, or adulterated drug or device being sold,  
13 delivered, or possessed with intent to sell or deliver  
14 exceeds one thousand units or dosages; or if the  
15 violation is a third or subsequent violation of this  
16 subsection, the person is guilty of a class "C"  
17 felony.

18 b. If the quantity of a counterfeit, misbranded,  
19 or adulterated drug or device being sold, delivered,  
20 or possessed with intent to sell or deliver exceeds  
21 one hundred units or dosages but does not exceed one  
22 thousand units or dosages; or if the violation is a  
23 second or subsequent violation of this subsection, the  
24 person is guilty of a class "D" felony.

25 c. All other violations of this subsection shall  
26 constitute an aggravated misdemeanor."

27 2. Page 1, by striking lines 11 through 14 and  
28 inserting the following:

29 "13. A person who knowingly possesses, purchases,  
30 or brings into the state a counterfeit, misbranded, or  
31 adulterated drug or device is guilty of the following:

32 a. If the quantity of a counterfeit, misbranded,  
33 or adulterated drug or device being possessed,  
34 purchased, or brought into the state exceeds one  
35 hundred units or dosages; or if the violation is a  
36 second or subsequent violation of this subsection, the  
37 person is guilty of a class "D" felony.

38 b. All other violations of this subsection shall  
39 constitute an aggravated misdemeanor."

40 3. Page 1, by inserting after line 16 the  
41 following:

42 "\_\_\_\_. Page 10, by inserting after line 17 the  
43 following:

44 "17. Subsections 1 and 2 shall not apply to a  
45 parent or legal guardian administering, in good faith,  
46 a prescription drug or device to a child of the parent  
47 or a child for whom the individual is designated a  
48 legal guardian."

49 4. By renumbering as necessary.

By ANDERSON of Page  
R. OLSON of Polk

H-1404 FILED APRIL 19, 2005

**Fiscal Services Division**  
**Legislative Services Agency**  
**Fiscal Note**

---

HF 833 - Pharmacy Practice Act (LSB 1292 HZ)

Analyst: Lisa Burk (Phone: (515) 281-7942) (lisa.burk@legis.state.ia.us)

Fiscal Note Version - New

---

**Description**

House File 833 amends various definitions with regard to the practice of pharmacy, modifies requirements for a pharmacy license application, authorizes the Board of Pharmacy Examiners to define specific types of wholesaler licenses, and requires licensed wholesalers to report specific occurrences to the Board. In addition, the Bill extends prohibitions against the use of the words, "apothecary," "drug," "drug store," or "pharmacy" by entities other than pharmacies or wholesalers.

The Bill implements a graduated system of penalties for prohibited acts in relation to the practice of pharmacy. The penalties include a serious misdemeanor, an aggravated misdemeanor, a Class D felony, numerous Class C felonies, and a Class A felony (life in prison).

House File 833 authorizes the Board of Pharmacy Examiners to request and obtain criminal history data for any pharmacist, pharmacist-intern, or pharmacy technician applicant and for all owners, managers, and principal employees of a pharmacy or drug wholesaler applicant, as well as provides for the collection of fees from these applicants for this purpose and allows the Board to process these fees as repayment receipts.

**Background**

1. In FY 2004, there were 221 convictions for crimes relating to the practice of pharmacy under Chapter 155A, Code of Iowa. Of these, 132 were for unlawful possession of prescription drugs, while 85 were for violations relating directly to pharmacies.
2. The average State costs for one serious misdemeanor conviction ranges from \$101 (court costs) to \$4,100 (court costs, jury trial, indigent defense, prison, and parole).
3. The average State costs for one aggravated misdemeanor conviction ranges from \$1,100 (court costs and probation) to \$5,700 (court costs, jury trial, indigent defense, prison, and parole).
4. The average State costs for one Class D felony conviction ranges from \$2,800 (court costs, probation, and indigent defense) to \$12,000 (court costs, jury trial, indigent defense, prison, and parole).
5. The average State costs for one Class C felony conviction ranges from \$3,100 (court costs, indigent defense, and probation) to \$23,000 (court costs, jury trial, indigent defense, prison, and parole).
6. The average State costs for one Class A felony conviction are approximately \$94,000.
7. The maximum costs will be incurred across multiple years while the offender is supervised in the correctional system, either in prison or in the community.

**Assumptions**

1. There is no data available to project the impact of the Bill on the Justice System with regard to the expansion of prohibited acts and criminal penalties relating to the practice of pharmacy under the provisions of the Bill.
2. There will be four meetings held to develop administrative rules to implement the provisions of the Bill at a cost of \$350 per meeting, which will be incurred in the first year only.

3. The Board of Pharmacy Examiners will require criminal history record checks on an estimated 1,650 licensees, registrants, and applicants annually at a cost of \$47.00 each.
4. Drug wholesalers with credential under the National Association of Boards of Pharmacy Verified-Accredited Wholesale Distributors Program and criminal history record checks performed pursuant to the Program will be accepted by the Board of Pharmacy Examiners.

### **Correctional Impact**

The creation of new offenses carries the potential for a correctional impact on court caseloads, prisons, county jails, Community-Based Corrections (CBC), and indigent defense resources. However, due to a lack of data, that correctional impact cannot be estimated.

The number of new serious or aggravated misdemeanor or Class D felony convictions under HF 833 cannot be determined due to a lack of data. It is anticipated, however, that there will not be a significant number of new convictions as these types of business violations are infrequent.

The number of new Class C felony convictions under HF 833 cannot be determined due to a lack of data. Due to the significant number of individuals employed in wholesale operations, however, the correctional impact could be substantial.

The number of Class A felony convictions cannot be determined due to a lack of data; however, the correctional impact is not anticipated to be significant.

### **Fiscal Impact**

The fiscal impact of HF 833 on the Justice System cannot be determined due to insufficient information. The fiscal impact may be substantial, if the number of Class C felony convictions of wholesalers is significant.

The fiscal impact of HF 833 on the Department of Public Health, Board of Pharmacy Examiners, is anticipated to be minimal (\$1,400) in FY 2006. It is also anticipated that the Board will collect an estimated \$78,000 annually in repayment receipts from applicants to cover the cost of criminal history background checks.

### **Sources**

Department of Corrections  
Department of Human Rights, Criminal and Juvenile Justice Planning  
Department of Public Health, Board of Pharmacy Examiners  
Judicial Branch  
Office of the State Public Defender

/s/ Holly M. Lyons

---

April 5, 2005

---

The fiscal note and correctional impact statement for this bill was prepared pursuant to Joint Rule 17 and pursuant to Section 2.56, Code of Iowa. Data used in developing this fiscal note and correctional impact statement are available from the Fiscal Services Division, Legislative Services Agency to members of the Legislature upon request.

---

HOUSE FILE 833

H-1382

1 Amend House File 833 as follows:

2 1. Page 9, by striking lines 3 through 9 and  
3 inserting the following:

4 "11. A person who knowingly manufactures, sells,  
5 or delivers, or who possesses with intent to sell or  
6 deliver any amount of a counterfeit, misbranded, or  
7 adulterated drug or device is guilty of a class "C"  
8 felony."

9 2. Page 9, by striking lines 14 through 19 and  
10 inserting the following:

11 "13. A person who knowingly possesses, purchases,  
12 or brings into the state any amount of a counterfeit,  
13 misbranded, or adulterated drug or device is guilty of  
14 a class "D" felony."

15 3. By striking page 9, line 20, through page 10,  
16 line 12.

17 4. By renumbering, redesignating, and correcting  
18 internal references as necessary.

COMMITTEE ON JUDICIARY

PAULSEN of Linn, CHAIRPERSON

H-1382 FILED APRIL 14, 2005

H-1428

1 Amend House File 833 as follows:

2 1. Page 1, by inserting before line 1 the  
3 following:

4 "Section 1. Section 22.7, Code 2005, is amended by  
5 adding the following new subsection:

6 NEW SUBSECTION. 51. The information contained in  
7 the electronic drug database established in section  
8 124.510A, except to the extent that disclosure is  
9 authorized pursuant to section 124.510C.

10 Sec. 2. NEW SECTION. 124.510A ELECTRONIC DRUG  
11 DATABASE ESTABLISHED.

12 The board shall establish and maintain an  
13 electronic drug database. The board shall use the  
14 electronic drug database to monitor the misuse, abuse,  
15 and diversion of selected controlled substances and  
16 other drugs the board includes in the database  
17 pursuant to section 124.510E, subsection 1, paragraph  
18 "i". The board shall electronically collect and  
19 disseminate information pursuant to sections 124.510C  
20 and 124.510D and rules adopted pursuant to this  
21 division. The board may contract with a third-  
22 party/private vendor to administer the electronic drug  
23 database.

24 Sec. 3. NEW SECTION. 124.510B DATA REPORTING.

25 1. Each licensed pharmacy that dispenses selected  
26 drugs identified by the board by rule to patients in  
27 the state, and each licensed pharmacy located in the  
28 state that dispenses such selected drugs to patients  
29 inside or outside the state, unless specifically  
30 excepted in this section or by rule, shall submit the  
31 following prescription information to the board or its  
32 designee:

33 a. Pharmacy identification.

34 b. Patient identification.

35 c. Prescriber identification.

36 d. The date the prescription was issued by the  
37 prescriber.

38 e. The date the prescription was dispensed.

39 f. An indication of whether the prescription  
40 dispensed is new or a refill.

41 g. Identification of the drug dispensed.

42 h. Quantity of the drug dispensed.

43 i. The number of days' supply of the drug  
44 dispensed.

45 j. Serial or prescription number assigned by the  
46 pharmacy.

47 k. Source of payment for the prescription.

48 2. Information shall be submitted electronically  
49 in the format specified by the board unless the board  
50 has granted a waiver and approved an alternate format.

H-1428

1 3. Information shall be timely transmitted as  
2 designated by the board by rule, unless the board  
3 grants an extension. The board may grant an extension  
4 if either of the following occurs:

5 a. The pharmacy suffers a mechanical or electronic  
6 failure, or cannot meet the deadline established by  
7 the board for other reasons beyond the pharmacy's  
8 control.

9 b. The board or its designee is unable to receive  
10 electronic submissions.

11 4. This section shall not apply to a prescriber  
12 furnishing, dispensing, supplying, or administering  
13 drugs to the prescriber's patient, or to dispensing by  
14 a licensed pharmacy for the purposes of inpatient  
15 hospital care, inpatient hospice care, or long-term  
16 residential facility patient care.

17 Sec. 4. NEW SECTION. 124.510C DATA ACCESS.

18 1. The board or its designee may provide  
19 information from the electronic drug database to all  
20 of the following:

21 a. A person who is a designated representative of  
22 a governmental entity responsible for the licensure,  
23 regulation, or discipline of licensed health care  
24 professionals authorized to prescribe or dispense  
25 drugs, who is involved in an investigation of a person  
26 licensed, regulated, or subject to discipline by the  
27 entity, and who is seeking access to information in  
28 the database that is relevant to the subject matter of  
29 the investigation and pursuant to a written probable  
30 cause determination.

31 b. A federal, state, county, township, or  
32 municipal officer of this or any other state, or the  
33 United States, whose duty it is to enforce the laws  
34 relating to prescription drugs and who is actively  
35 engaged in a specific investigation of a specific  
36 person and is seeking access to information in the  
37 database pursuant to a probable cause determination or  
38 warrant.

39 c. A properly convened grand jury pursuant to a  
40 subpoena properly issued.

41 d. A pharmacist or prescriber who requests the  
42 information and certifies in a form specified by the  
43 board that it is for the purpose of providing medical  
44 or pharmaceutical care to a patient of the pharmacist  
45 or prescriber.

46 e. An individual who requests the individual's own  
47 database information in accordance with the procedure  
48 established in rules of the board adopted under  
49 section 124.510E.

50 2. The board or its designee shall maintain a

1 record of each person that requests information from  
2 the database. Pursuant to rules adopted by the board  
3 under section 124.510E, the board may use the records  
4 to document and report statistics and law enforcement  
5 outcomes and to identify inappropriate access or other  
6 prohibited acts. The board or its designee may  
7 provide records of a person's requests for database  
8 information to the following persons:

9 a. Pursuant to a probable cause determination, a  
10 designated representative of a governmental entity  
11 that is responsible for the licensure, regulation, or  
12 discipline of licensed health care professionals  
13 authorized to prescribe or dispense drugs who is  
14 involved in a specific investigation of the individual  
15 who submitted the request.

16 b. Pursuant to a probable cause determination or  
17 warrant, a federal, state, county, township, or  
18 municipal officer of this or any other state or the  
19 United States, whose duty is to enforce the laws  
20 relating to prescription drugs, and who is actively  
21 engaged in a specific investigation of the specific  
22 person who submitted the request.

23 3. Information contained in the database and any  
24 information obtained from it is strictly confidential  
25 medical information, is not a public record pursuant  
26 to chapter 22, and is not subject to discovery,  
27 subpoena, or other means of legal compulsion for  
28 release except as provided in this division.

29 Information contained in the records of requests for  
30 information from the database is privileged and  
31 confidential, is not a public record, and is not  
32 subject to discovery, subpoena, or other means of  
33 legal compulsion for release except as provided in  
34 this division. Information from the database shall  
35 not be released, shared with an agency or institution,  
36 or made public except as provided in this division.

37 4. Information collected for the database shall be  
38 retained in the database for four years. The  
39 information shall then be destroyed unless a law  
40 enforcement agency or a governmental entity  
41 responsible for the licensure, regulation, or  
42 discipline of licensed health care professionals  
43 authorized to prescribe or dispense drugs has  
44 submitted a written request to the board or its  
45 designee for retention of specific information in  
46 accordance with rules adopted by the board under  
47 section 124.510E.

48 5. A pharmacist or other dispenser making a report  
49 to the database in good faith pursuant to this  
50 division is immune from any liability, civil,

1 criminal, or administrative, which might otherwise be  
2 incurred or imposed as a result of the report.  
3 6. Nothing in this section shall require a  
4 pharmacist or prescriber to obtain information about a  
5 patient from the database. A pharmacist or prescriber  
6 does not have a duty and shall not be held liable in  
7 damages to any person in any civil or derivative  
8 criminal or administrative action for injury, death,  
9 or loss to person or property on the basis that the  
10 pharmacist or prescriber did or did not seek or obtain  
11 information from the database. A pharmacist or  
12 prescriber acting in good faith is immune from any  
13 civil, criminal, or administrative liability that  
14 might otherwise be incurred or imposed for requesting  
15 or receiving information from the database.

16 7. The board shall not charge a fee to a pharmacy,  
17 pharmacist, or prescriber for the establishment,  
18 maintenance, or administration of the database. The  
19 board shall not charge a fee for the transmission of  
20 data to the database nor for the receipt of  
21 information from the database, except that the board  
22 may charge a reasonable fee to an individual who  
23 requests the individual's own database information or  
24 to a person requesting statistical, aggregate, or  
25 nonpersonally identified information from the  
26 database. A fee charged pursuant to this subsection  
27 shall not exceed the cost of providing the requested  
28 information and shall be considered a repayment  
29 receipt as defined in section 8.2.

30 Sec. 5. NEW SECTION. 124.510D DATA REVIEW AND  
31 REFERRAL.

32 The board or its designee shall review the  
33 information in the electronic drug database. If the  
34 board determines, consistent with the board's  
35 authority under this chapter or chapter 155A, that  
36 there is probable cause to believe that drug diversion  
37 or another violation of law may have occurred, the  
38 board shall notify the appropriate law enforcement  
39 agency or the governmental entity responsible for the  
40 licensure, regulation, or discipline of the licensed  
41 health care professional, and shall supply information  
42 required to initiate an investigation. The board  
43 shall not refer information relating to an individual  
44 for further investigation except upon a probable cause  
45 determination. A probable cause determination shall  
46 be consistent with guidelines developed by the  
47 advisory council established under section 124.510F.

48 Sec. 6. NEW SECTION. 124.510E RULES AND  
49 REPORTING.

50 1. The board shall adopt rules in accordance with

- 1 chapter 17A to carry out the purposes of, and to
- 2 enforce the provisions of, this division. The rules
- 3 shall include but not be limited to the development of
- 4 procedures relating to:
  - 5 a. Identifying each patient about whom information
  - 6 is entered into the electronic drug database.
  - 7 b. An electronic format for the submission of
  - 8 information from pharmacies.
  - 9 c. A waiver to submit information in another
  - 10 format for a pharmacy unable to submit information
  - 11 electronically.
  - 12 d. Granting by the board of a request from a law
  - 13 enforcement agency or a governmental entity
  - 14 responsible for the licensure, regulation, or
  - 15 discipline of licensed health care professionals
  - 16 authorized to prescribe or dispense drugs for the
  - 17 retention of information scheduled for deletion from
  - 18 the database after four years when the information
  - 19 pertains to an open investigation being conducted by
  - 20 the agency or entity.
  - 21 e. An application for an extension of time by a
  - 22 pharmacy regarding information to be transmitted to
  - 23 the board or its designee.
  - 24 f. The submission by a person or governmental
  - 25 entity to which the board is authorized to provide
  - 26 information of a request for the information and a
  - 27 procedure for the verification of the identity of the
  - 28 requestor.
  - 29 g. Use by the board of the database request
  - 30 records required by section 124.510C, subsection 2, to
  - 31 document and report statistics and law enforcement
  - 32 outcomes and to identify inappropriate access or other
  - 33 prohibited acts.
  - 34 h. Submission of a request by an individual for
  - 35 the individual's own database information and
  - 36 verification of the identity of the requestor.
  - 37 i. The development of a list of controlled
  - 38 substances and other drugs that shall be included in
  - 39 the database.
  - 40 j. Access by a pharmacist or prescriber to
  - 41 information in the database pursuant to a written
  - 42 agreement with the board.
  - 43 k. Terms and conditions of the contract, if the
  - 44 board contracts for database administration with a
  - 45 third-party or private vendor.
    - 46 1. The correction or deletion of erroneous
    - 47 information from the database.
    - 48 2. No later than January 1, 2008, and every two
    - 49 years thereafter, the board shall present to the
    - 50 general assembly and the governor a report of the

1 following:

2 a. The cost to the state of implementing and  
3 maintaining the database.

4 b. Information from pharmacies, prescribers, the  
5 board, and others regarding the usefulness of the  
6 database.

7 c. Information from pharmacies, prescribers, the  
8 board, and others regarding the board's effectiveness  
9 in providing information from the database.

10 d. Information documenting the timely transmission  
11 of information from the electronic drug database to  
12 authorized requestors.

13 Sec. 7. NEW SECTION. 124.510F ADVISORY COUNCIL  
14 ESTABLISHED.

15 The board shall establish an advisory council to  
16 provide oversight to the electronic drug database  
17 program. The board shall adopt rules specifying the  
18 duties and activities of the advisory council and  
19 related matters.

20 1. The council shall consist of three licensed  
21 pharmacists, three licensed physicians, two licensed  
22 prescribers who are not physicians, and two members of  
23 the general public. The board shall solicit  
24 recommendations for health professional council  
25 members from Iowa health professional licensing  
26 boards, associations, and societies. The license of  
27 each health professional appointed to and serving on  
28 the advisory council shall be current and in good  
29 standing with the professional's licensing board.

30 2. The council may make recommendations to advance  
31 the goals of the database, which include  
32 identification of misuse and diversion of identified  
33 controlled substances and other drugs and enhancement  
34 of the quality of health care delivery in this state.

35 3. Among other things, the council shall:

36 a. Assist the board in developing criteria for  
37 granting requests by researchers and other persons for  
38 statistical, aggregate, or nonpersonally identified  
39 information using database information, developed  
40 consistent with the goals of the database.

41 b. Assist the board in ensuring patient  
42 confidentiality and the integrity of the patient's  
43 treatment relationship with the patient's health care  
44 provider.

45 c. Make recommendations regarding the continued  
46 benefits of maintaining the electronic drug database  
47 in relationship to cost and other burdens to the  
48 board. The council's recommendations shall be  
49 included in reports required by section 124.510E,  
50 subsection 2.

1 4. Members of the advisory council shall be  
2 eligible to request and receive actual expenses for  
3 their duties as members of the advisory council,  
4 subject to reimbursement limits imposed by the  
5 department of administrative services, and shall also  
6 be eligible to receive a per diem compensation as  
7 provided in section 7E.6, subsection 1.

8 Sec. 8. NEW SECTION. 124.510G PROHIBITED ACTS  
9 AND PENALTIES.

10 The failure of a licensed pharmacist or licensed  
11 prescriber to comply with the requirements of this  
12 division, or the performance or causing the  
13 performance of, or the aiding and abetting of another  
14 person in the performance of, any of the prohibited  
15 acts identified in this section shall constitute  
16 grounds for disciplinary action against the pharmacist  
17 or prescriber by the appropriate professional  
18 licensing board. Each licensing board that licenses  
19 prescribers and drug dispensers subject to the  
20 provisions of this division may adopt rules in  
21 accordance with chapter 17A to implement the  
22 provisions of this section and may impose penalty as  
23 allowed under section 272C.3. In addition, a civil  
24 penalty not to exceed twenty-five thousand dollars for  
25 each violation may be imposed.

26 1. A pharmacist who willfully and knowingly fails  
27 to submit prescription information to the board or its  
28 designee as required by this division, or who  
29 knowingly and intentionally submits prescription  
30 information known to the pharmacist to be false or  
31 fraudulent, may be subject to disciplinary action by  
32 the board.

33 2. A person authorized to access or receive  
34 prescription information pursuant to this division who  
35 willfully and knowingly discloses or attempts to  
36 disclose such information with the intent to cause  
37 harm to another person in violation of this division  
38 is guilty of a class "D" felony.

39 3. A person who willfully and knowingly uses,  
40 releases, publishes, or otherwise makes available to  
41 another person any personally identifiable information  
42 obtained from or contained in the database is guilty  
43 of a serious misdemeanor.

44 4. A person without lawful authority who obtains  
45 or attempts to obtain information, obtains or attempts  
46 to obtain unauthorized access to, or who willfully and  
47 knowingly alters or destroys valid information  
48 contained in the database is guilty of a class "D"  
49 felony.

50 5. A person authorized to access or receive

1 prescription information pursuant to this division who  
2 knowingly and intentionally discloses confidential  
3 information to a person who is not authorized to  
4 receive the information pursuant to this division is  
5 guilty of a serious misdemeanor.

6 6. This section shall not preclude a pharmacist or  
7 prescriber who requests and receives information from  
8 the database consistent with the requirements of this  
9 chapter from otherwise lawfully providing that  
10 information to any other person for medical or  
11 pharmaceutical care purposes."

12 2. Page 12, by inserting after line 12 the  
13 following:

14 "Sec. \_\_\_\_ . EFFECTIVE DATE. The sections of this  
15 Act relating to and establishing an electronic drug  
16 database, being deemed of immediate importance, take  
17 effect upon enactment."

18 3. Title page, by striking line 2, and inserting  
19 the following: "providing for the creation of an  
20 electronic drug database, establishing and  
21 appropriating fees, providing penalties, and providing  
22 an effective date."

23 4. By renumbering as necessary.

By UPMEYER of Hancock  
SMITH of Marshall

H-1428 FILED APRIL 20, 2005

WITHDRAWN

H-1430

1 Amend House File 833 as follows:

2 1. Page 12, by inserting after line 12 the  
3 following:

4 "Sec. \_\_\_\_ . NEW SECTION. 155B.1 DEFINITIONS.

5 As used in this chapter unless the context  
6 otherwise requires:

7 1. "Commissioner" means the commissioner of  
8 insurance.

9 2. "Covered entity" means a nonprofit hospital or  
10 medical services corporation, health insurer, health  
11 benefit plan, or health maintenance organization; a  
12 health program administered by the state in the  
13 capacity of provider of health coverage; or an  
14 employer, labor union, or other group of persons  
15 organized in the state that provides health coverage  
16 to covered individuals who are employed or reside in  
17 the state. "Covered entity" does not include a self-  
18 funded plan that is exempt from state regulation  
19 pursuant to the federal Employee Retirement Income  
20 Security Act of 1974 (ERISA), as codified at 29 U.S.C.  
21 § 1001 et seq., a plan issued for coverage for federal  
22 employees, or a health plan that provides coverage  
23 only for accidental injury, specified disease,  
24 hospital indemnity, Medicare supplemental, disability  
25 income, long-term care, or other limited benefit  
26 health insurance policies and contracts.

27 3. "Covered individual" means a member,  
28 participant, enrollee, contract holder, policyholder,  
29 or beneficiary of a covered entity who is provided  
30 health coverage by the covered entity. "Covered  
31 individual" includes a dependent or other person  
32 provided health coverage through a policy, contract,  
33 or plan for a covered individual.

34 4. "Generic drug" means a chemically equivalent  
35 copy of a brand-name drug with an expired patent.

36 5. "Labeler" means an entity or person that  
37 receives prescription drugs from a manufacturer or  
38 wholesaler and repackages those drugs for later retail  
39 sale and that has a labeler code from the federal food  
40 and drug administration under 21 C.F.R. § 270.201.

41 6. "Pharmacy benefits management" means the  
42 procurement of prescription drugs at a negotiated rate  
43 for dispensing within this state to covered  
44 individuals, the administration or management of  
45 prescription drug benefits provided by a covered  
46 entity for the benefit of covered individuals, or any  
47 of the following services provided with regard to the  
48 administration of the following pharmacy benefits:

49 a. Mail service pharmacy.

50 b. Claims processing, retail network management,

H-1430

- 1 or payment of claims to pharmacies for prescription
- 2 drugs dispensed to covered individuals.
- 3 c. Clinical formulary development and management
- 4 services.
- 5 d. Rebate contracting and administration.
- 6 e. Certain patient compliance, therapeutic
- 7 intervention, or generic substitution programs.
- 8 f. Disease management programs involving
- 9 prescription drug utilization.

10 7. "Pharmacy benefits manager" means an entity  
11 that performs pharmacy benefits management services.  
12 "Pharmacy benefits manager" includes a person or  
13 entity acting for a pharmacy benefits manager in a  
14 contractual or employment relationship in the  
15 performance of pharmacy benefits management services  
16 for a covered entity. "Pharmacy benefits manager"  
17 does not include a health insurance carrier or its  
18 subsidiary when the health insurance carrier or its  
19 subsidiary is providing pharmacy benefits management  
20 services to its own insureds; or a public self-funded  
21 pool or a private single employer self-funded plan  
22 that provides such benefits or services directly to  
23 its beneficiaries.

24 8. "Prescription drug" means prescription drug as  
25 defined in section 155A.3.

26 9. "Prescription drug order" means a written order  
27 from a practitioner or an oral order from a  
28 practitioner or the practitioner's authorized agent  
29 who communicates the practitioner's instructions for a  
30 prescription drug or device to be dispensed.

31 10. "Proprietary information" means information on  
32 pricing, costs, revenue, taxes, market share,  
33 negotiating strategies, customers, or personnel held  
34 by private entities and used for that private entity's  
35 business purposes.

36 11. "Trade secret" means information, including a  
37 formula, pattern, compilation, program, device,  
38 method, technique, or process, that meets all of the  
39 following conditions:

40 a. Derives independent economic value, actual or  
41 potential, from not being generally known to, and not  
42 being readily ascertainable by proper means by, other  
43 persons who can obtain economic value from its  
44 disclosure or use.

45 b. Is the subject of efforts that are reasonable  
46 under the circumstances to maintain its secrecy.

47 Sec. \_\_\_\_ . NEW SECTION. 155B.2 PHARMACY BENEFITS  
48 MANAGER -- LICENSE.

49 1. A person shall not perform or act as a pharmacy  
50 benefits manager in this state without obtaining an

1 annual license to do business in this state from the  
2 commissioner under this section.

3 2. The commissioner shall adopt rules, pursuant to  
4 chapter 17A, relating to the issuance of a license  
5 under this section. The rules shall include but are  
6 not limited to inclusion of all of the following:

- 7 a. Definition of terms.
- 8 b. Use of prescribed forms.
- 9 c. Reporting requirements.
- 10 d. Enforcement procedures.
- 11 e. Protection of proprietary information and trade  
12 secrets.

13 Sec. \_\_\_\_ . NEW SECTION. 155B.3 MANAGER TO PERFORM  
14 DUTIES IN GOOD FAITH.

15 Each pharmacy benefits manager shall perform its  
16 duties exercising good faith and fair dealing toward  
17 the covered entity and covered individuals.

18 Sec. \_\_\_\_ . NEW SECTION. 155B.4 DISCLOSURE OF  
19 REVENUES RECEIVED FROM PHARMACEUTICAL MANUFACTURER OR  
20 LABELER UNDER CONTRACT WITH MANAGER -- CONTENT --  
21 FEES.

22 1. A covered entity may request that any pharmacy  
23 benefits manager with which it has a pharmacy benefits  
24 management services contract disclose to the covered  
25 entity, the amount of all rebate revenues and the  
26 nature, type, and amounts of all other revenues that  
27 the pharmacy benefits manager receives from each  
28 pharmaceutical manufacturer or labeler with whom the  
29 pharmacy benefits manager has a contract. The  
30 pharmacy benefits manager shall disclose all of the  
31 following in writing:

32 a. The aggregate amount and, for a list of drugs  
33 to be specified in the contract, the specific amount,  
34 of all rebates and other retrospective utilization  
35 discounts received by the pharmacy benefits manager,  
36 directly or indirectly, from each pharmaceutical  
37 manufacturer or labeler that is earned in connection  
38 with the dispensing of prescription drugs to covered  
39 individuals of the health benefit plans issued by the  
40 covered entity or for which the covered entity is the  
41 designated administrator.

42 b. The nature, type, and amount of all other  
43 revenue received by the pharmacy benefits manager  
44 directly or indirectly from each pharmaceutical  
45 manufacturer or labeler for any other products or  
46 services provided to the pharmaceutical manufacturer  
47 or labeler by the pharmacy benefits manager with  
48 respect to programs that the covered entity offers or  
49 provides to its enrollees.

50 c. Any prescription drug utilization information

1 requested by the covered entity relating to covered  
2 individuals.

3 2. A pharmacy benefits manager shall provide the  
4 information requested by the covered entity for such  
5 disclosure within thirty days of receipt of the  
6 request. If requested, the information shall be  
7 provided no less than once each year. The contract  
8 entered into between the pharmacy benefits manager and  
9 the covered entity shall specify any fees to be  
10 charged for drug utilization reports requested by the  
11 covered entity.

12 Sec. \_\_\_\_ . NEW SECTION. 155B.5 PERMISSION OF  
13 ENTITY REQUIRED TO CONTACT COVERED INDIVIDUAL --  
14 EXCEPTION.

15 A pharmacy benefits manager, unless authorized  
16 pursuant to the terms of its contract with a covered  
17 entity, shall not contact any covered individual  
18 without the express written permission of the covered  
19 entity.

20 Sec. \_\_\_\_ . NEW SECTION. 155B.6 CONFIDENTIALITY OF  
21 INFORMATION -- INJUNCTION -- DAMAGES.

22 1. With the exception of utilization information,  
23 a covered entity shall maintain any information  
24 disclosed in response to a request pursuant to section  
25 155B.4 as confidential and proprietary information,  
26 and shall not use such information for any other  
27 purpose or disclose such information to any other  
28 person except as provided in this chapter or in the  
29 pharmacy benefits management services contract between  
30 the parties.

31 2. A covered entity that discloses information in  
32 violation of this section is subject to an action for  
33 injunctive relief and is liable for any damages which  
34 are the direct and proximate result of such  
35 disclosure.

36 3. This section does not prohibit a covered entity  
37 from disclosing confidential or proprietary  
38 information to the commissioner, upon request. Any  
39 such information obtained by the commissioner is  
40 confidential and privileged and is not open to public  
41 inspection or disclosure.

42 Sec. \_\_\_\_ . NEW SECTION. 155B.7 AUDITS OF  
43 MANAGER'S RECORDS.

44 A covered entity may have the pharmacy benefits  
45 manager's records related to the rebates or other  
46 information described in section 155B.4 audited, to  
47 the extent the information relates directly or  
48 indirectly to such covered entity's contract, in  
49 accordance with the terms of the pharmacy benefits  
50 management services contract between the parties.

1 However, if the parties have not expressly provided  
2 for audit rights and the pharmacy benefits manager has  
3 advised the covered entity that other reasonable  
4 options are available and subject to negotiation, the  
5 covered entity may have such records audited as  
6 follows:

7 1. An audit may be conducted no more frequently  
8 than once in each twelve-month period upon not less  
9 than thirty business days' written notice to the  
10 pharmacy benefits manager.

11 2. The covered entity may select an independent  
12 firm to conduct the audit, and the independent firm  
13 shall sign a confidentiality agreement with the  
14 covered entity and the pharmacy benefits manager  
15 ensuring that all information obtained during the  
16 audit will be treated as confidential. The firm may  
17 not use, disclose, or otherwise reveal any such  
18 information in any manner or form to any person or  
19 entity except as otherwise permitted under the  
20 confidentiality agreement. The covered entity shall  
21 treat all information obtained as a result of the  
22 audit as confidential, and may not use or disclose  
23 such information except as may be otherwise permitted  
24 under the terms of the contract between the covered  
25 entity and the pharmacy benefits manager or if ordered  
26 by a court of competent jurisdiction for good cause  
27 shown.

28 3. Any audit shall be conducted at the pharmacy  
29 benefits manager's office where such records are  
30 located, during normal business hours, without undue  
31 interference with the pharmacy benefits manager's  
32 business activities, and in accordance with reasonable  
33 audit procedures.

34 Sec. \_\_\_\_ . NEW SECTION. 155B.8 DISPENSING OF  
35 SUBSTITUTE PRESCRIPTION DRUG FOR PRESCRIBED DRUG.

36 1. With regard to the dispensing of a substitute  
37 prescription drug for a prescribed drug to a covered  
38 individual, when the pharmacy benefits manager  
39 requests a substitution, the following provisions  
40 shall apply:

41 a. The pharmacy benefits manager may request the  
42 substitution of a lower-priced generic and  
43 therapeutically equivalent drug for a higher-priced  
44 prescribed drug.

45 b. With regard to substitutions in which the  
46 substitute drug's net cost is more for the covered  
47 individual or the covered entity than the prescribed  
48 drug, the substitution shall be made only for medical  
49 reasons that benefit the covered individual.

50 2. If a substitution is being requested pursuant

1 to this section, the pharmacy benefits manager shall  
2 obtain the approval of the prescribing health  
3 professional prior to the substitution.

4 3. A pharmacy benefits manager shall not  
5 substitute an equivalent drug product contrary to a  
6 prescription drug order that prohibits a substitution.

7 Sec. \_\_\_\_ . NEW SECTION. 155B.9 CIVIL ACTION --  
8 ENFORCEMENT OF CHAPTER -- DAMAGES.

9 A covered entity may bring a civil action to  
10 enforce the provisions of this chapter or to seek  
11 civil damages for the violation of the provisions of  
12 this chapter.

13 Sec. \_\_\_\_ . NEW SECTION. 155B.10 APPLICATION OF  
14 CHAPTER TO CERTAIN CONTRACTS.

15 The provisions of this chapter apply only to  
16 pharmacy benefits management services contracts  
17 entered into or renewed on or after July 1, 2005."

18 2. Title page, line 1, by inserting after the  
19 word "pharmacy," the following: "relating to the  
20 regulation of pharmacy benefits managers, providing  
21 civil relief,".

By BELL of Jasper

H-1430 FILED APRIL 20, 2005

WITHDRAWN

H-1432

1 Amend House File 833 as follows:

2 1. Page 1, by inserting before line 1 the  
3 following:

4 "Section 1. Section 22.7, Code 2005, is amended by  
5 adding the following new subsection:

6 NEW SUBSECTION. 51. The information contained in  
7 the electronic drug database established in section  
8 124.510A, except to the extent that disclosure is  
9 authorized pursuant to section 124.510C.

10 Sec. 2. NEW SECTION. 124.510A ELECTRONIC DRUG  
11 DATABASE ESTABLISHED.

12 The board shall establish and maintain an  
13 electronic drug database. The board shall use the  
14 electronic drug database to monitor the misuse, abuse,  
15 and diversion of selected controlled substances and  
16 other drugs the board includes in the database  
17 pursuant to section 124.510E, subsection 1, paragraph  
18 "i". The board shall electronically collect and  
19 disseminate information pursuant to sections 124.510C  
20 and 124.510D and rules adopted pursuant to this  
21 division. The board may contract with a third-  
22 party/private vendor to administer the electronic drug  
23 database.

24 Sec. 3. NEW SECTION. 124.510B DATA REPORTING.

25 1. Each licensed pharmacy that dispenses selected  
26 drugs identified by the board by rule to patients in  
27 the state, and each licensed pharmacy located in the  
28 state that dispenses such selected drugs to patients  
29 inside or outside the state, unless specifically  
30 excepted in this section or by rule, shall submit the  
31 following prescription information to the board or its  
32 designee:

33 a. Pharmacy identification.

34 b. Patient identification.

35 c. Prescriber identification.

36 d. The date the prescription was issued by the  
37 prescriber.

38 e. The date the prescription was dispensed.

39 f. An indication of whether the prescription  
40 dispensed is new or a refill.

41 g. Identification of the drug dispensed.

42 h. Quantity of the drug dispensed.

43 i. The number of days' supply of the drug  
44 dispensed.

45 j. Serial or prescription number assigned by the  
46 pharmacy.

47 k. Source of payment for the prescription.

48 2. Information shall be submitted electronically  
49 in the format specified by the board unless the board  
50 has granted a waiver and approved an alternate format.

H-1432

1 3. Information shall be timely transmitted as  
2 designated by the board by rule, unless the board  
3 grants an extension. The board may grant an extension  
4 if either of the following occurs:

5 a. The pharmacy suffers a mechanical or electronic  
6 failure, or cannot meet the deadline established by  
7 the board for other reasons beyond the pharmacy's  
8 control.

9 b. The board or its designee is unable to receive  
10 electronic submissions.

11 4. This section shall not apply to a prescriber  
12 furnishing, dispensing, supplying, or administering  
13 drugs to the prescriber's patient, or to dispensing by  
14 a licensed pharmacy for the purposes of inpatient  
15 hospital care, inpatient hospice care, or long-term  
16 residential facility patient care.

17 Sec. 4. NEW SECTION. 124.510C DATA ACCESS.

18 1. The board or its designee may provide  
19 information from the electronic drug database to all  
20 of the following:

21 a. A person who is a designated representative of  
22 a governmental entity responsible for the licensure,  
23 regulation, or discipline of licensed health care  
24 professionals authorized to prescribe or dispense  
25 drugs, who is involved in an investigation of a person  
26 licensed, regulated, or subject to discipline by the  
27 entity, and who is seeking access to information in  
28 the database that is relevant to the subject matter of  
29 the investigation and pursuant to a written probable  
30 cause determination.

31 b. A federal, state, county, township, or  
32 municipal officer of this or any other state, or the  
33 United States, whose duty it is to enforce the laws  
34 relating to prescription drugs and who is actively  
35 engaged in a specific investigation of a specific  
36 person and is seeking access to information in the  
37 database pursuant to a written probable cause  
38 determination or warrant.

39 c. A properly convened grand jury pursuant to a  
40 subpoena properly issued.

41 d. A pharmacist or prescriber who requests the  
42 information and certifies in a form specified by the  
43 board that it is for the purpose of providing medical  
44 or pharmaceutical care to a patient of the pharmacist  
45 or prescriber.

46 e. An individual who requests the individual's own  
47 database information in accordance with the procedure  
48 established in rules of the board adopted under  
49 section 124.510E.

50 2. The board or its designee shall maintain a

1 record of each person that requests information from  
2 the database. Pursuant to rules adopted by the board  
3 under section 124.510E, the board may use the records  
4 to document and report statistics and law enforcement  
5 outcomes and to identify inappropriate access or other  
6 prohibited acts. The board or its designee may  
7 provide records of a person's requests for database  
8 information to the following persons:

9 a. Pursuant to a written probable cause  
10 determination, a designated representative of a  
11 governmental entity that is responsible for the  
12 licensure, regulation, or discipline of licensed  
13 health care professionals authorized to prescribe or  
14 dispense drugs who is involved in a specific  
15 investigation of the individual who submitted the  
16 request.

17 b. Pursuant to a written probable cause  
18 determination or warrant, a federal, state, county,  
19 township, or municipal officer of this or any other  
20 state or the United States, whose duty is to enforce  
21 the laws relating to prescription drugs, and who is  
22 actively engaged in a specific investigation of the  
23 specific person who submitted the request.

24 3. Information contained in the database and any  
25 information obtained from it is strictly confidential  
26 medical information, is not a public record pursuant  
27 to chapter 22, and is not subject to discovery,  
28 subpoena, or other means of legal compulsion for  
29 release except as provided in this division.

30 Information contained in the records of requests for  
31 information from the database is privileged and  
32 confidential, is not a public record, and is not  
33 subject to discovery, subpoena, or other means of  
34 legal compulsion for release except as provided in  
35 this division. Information from the database shall  
36 not be released, shared with an agency or institution,  
37 or made public except as provided in this division.

38 4. Information collected for the database shall be  
39 retained in the database for four years. The  
40 information shall then be destroyed unless a law  
41 enforcement agency or a governmental entity  
42 responsible for the licensure, regulation, or  
43 discipline of licensed health care professionals  
44 authorized to prescribe or dispense drugs has  
45 submitted a written request to the board or its  
46 designee for retention of specific information in  
47 accordance with rules adopted by the board under  
48 section 124.510E.

49 5. A pharmacist or other dispenser making a report  
50 to the database in good faith pursuant to this

1 division is immune from any liability, civil,  
2 criminal, or administrative, which might otherwise be  
3 incurred or imposed as a result of the report.  
4 6. Nothing in this section shall require a  
5 pharmacist or prescriber to obtain information about a  
6 patient from the database. A pharmacist or prescriber  
7 does not have a duty and shall not be held liable in  
8 damages to any person in any civil or derivative  
9 criminal or administrative action for injury, death,  
10 or loss to person or property on the basis that the  
11 pharmacist or prescriber did or did not seek or obtain  
12 information from the database. A pharmacist or  
13 prescriber acting in good faith is immune from any  
14 civil, criminal, or administrative liability that  
15 might otherwise be incurred or imposed for requesting  
16 or receiving information from the database.

17 7. The board shall not charge a fee to a pharmacy,  
18 pharmacist, or prescriber for the establishment,  
19 maintenance, or administration of the database. The  
20 board shall not charge a fee for the transmission of  
21 data to the database nor for the receipt of  
22 information from the database, except that the board  
23 may charge a reasonable fee to an individual who  
24 requests the individual's own database information or  
25 to a person requesting statistical, aggregate, or  
26 nonpersonally identified information from the  
27 database. A fee charged pursuant to this subsection  
28 shall not exceed the cost of providing the requested  
29 information and shall be considered a repayment  
30 receipt as defined in section 8.2.

31 Sec. 5. NEW SECTION. 124.510D DATA REVIEW AND  
32 REFERRAL.

33 The board or its designee shall review the  
34 information in the electronic drug database. If the  
35 board determines, consistent with the board's  
36 authority under this chapter or chapter 155A, that  
37 there is probable cause to believe that drug diversion  
38 or another violation of law may have occurred, the  
39 board shall notify the appropriate law enforcement  
40 agency or the governmental entity responsible for the  
41 licensure, regulation, or discipline of the licensed  
42 health care professional, and shall supply information  
43 from the database supporting the probable cause  
44 determination. The board shall not refer information  
45 relating to an individual for further investigation  
46 except upon a probable cause determination. A  
47 probable cause determination shall be consistent with  
48 guidelines developed by the advisory council  
49 established under section 124.510F.

50 Sec. 6. NEW SECTION. 124.510E RULES AND

1 REPORTING.

2 1. The board shall adopt rules in accordance with  
3 chapter 17A to carry out the purposes of, and to  
4 enforce the provisions of, this division. The rules  
5 shall include but not be limited to the development of  
6 procedures relating to:

7 a. Identifying each patient about whom information  
8 is entered into the electronic drug database.

9 b. An electronic format for the submission of  
10 information from pharmacies.

11 c. A waiver to submit information in another  
12 format for a pharmacy unable to submit information  
13 electronically.

14 d. Granting by the board of a request from a law  
15 enforcement agency or a governmental entity  
16 responsible for the licensure, regulation, or  
17 discipline of licensed health care professionals  
18 authorized to prescribe or dispense drugs for the  
19 retention of information scheduled for deletion from  
20 the database after four years when the information  
21 pertains to an open investigation being conducted by  
22 the agency or entity.

23 e. An application for an extension of time by a  
24 pharmacy regarding information to be transmitted to  
25 the board or its designee.

26 f. The submission by a person or governmental  
27 entity to which the board is authorized to provide  
28 information of a request for the information and a  
29 procedure for the verification of the identity of the  
30 requestor.

31 g. Use by the board of the database request  
32 records required by section 124.510C, subsection 2, to  
33 document and report statistics and law enforcement  
34 outcomes and to identify inappropriate access or other  
35 prohibited acts.

36 h. Submission of a request by an individual for  
37 the individual's own database information and  
38 verification of the identity of the requestor.

39 i. The development of a list of controlled  
40 substances and other drugs that shall be included in  
41 the database.

42 j. Access by a pharmacist or prescriber to  
43 information in the database pursuant to a written  
44 agreement with the board.

45 k. Terms and conditions of the contract, if the  
46 board contracts for database administration with a  
47 third-party or private vendor.

48 1. The correction or deletion of erroneous  
49 information from the database.

50 2. No later than January 1, 2008, and every two

1 years thereafter, the board shall present to the  
2 general assembly and the governor a report of the  
3 following:

4 a. The cost to the state of implementing and  
5 maintaining the database.

6 b. Information from pharmacies, prescribers, the  
7 board, and others regarding the usefulness of the  
8 database.

9 c. Information from pharmacies, prescribers, the  
10 board, and others regarding the board's effectiveness  
11 in providing information from the database.

12 d. Information documenting the timely transmission  
13 of information from the electronic drug database to  
14 authorized requestors.

15 Sec. 7. NEW SECTION. 124.510F ADVISORY COUNCIL  
16 ESTABLISHED.

17 The board shall establish an advisory council to  
18 provide oversight to the electronic drug database  
19 program. The board shall adopt rules specifying the  
20 duties and activities of the advisory council and  
21 related matters.

22 1. The council shall consist of three licensed  
23 pharmacists, three licensed physicians, two licensed  
24 prescribers who are not physicians, and two members of  
25 the general public. The board shall solicit  
26 recommendations for health professional council  
27 members from Iowa health professional licensing  
28 boards, associations, and societies. The license of  
29 each health professional appointed to and serving on  
30 the advisory council shall be current and in good  
31 standing with the professional's licensing board.

32 2. The council may make recommendations to advance  
33 the goals of the database, which include  
34 identification of misuse and diversion of identified  
35 controlled substances and other drugs and enhancement  
36 of the quality of health care delivery in this state.

37 3. Among other things, the council shall:

38 a. Assist the board in developing criteria for  
39 granting requests by researchers and other persons for  
40 statistical, aggregate, or nonpersonally identified  
41 information using database information, developed  
42 consistent with the goals of the database.

43 b. Assist the board in ensuring patient  
44 confidentiality and the integrity of the patient's  
45 treatment relationship with the patient's health care  
46 provider.

47 c. Make recommendations regarding the continued  
48 benefits of maintaining the electronic drug database  
49 in relationship to cost and other burdens to the  
50 board. The council's recommendations shall be

1 included in reports required by section 124.510E,  
2 subsection 2.

3 4. Members of the advisory council shall be  
4 eligible to request and receive actual expenses for  
5 their duties as members of the advisory council,  
6 subject to reimbursement limits imposed by the  
7 department of administrative services, and shall also  
8 be eligible to receive a per diem compensation as  
9 provided in section 7E.6, subsection 1.

10 Sec. 8. NEW SECTION. 124.510G PROHIBITED ACTS  
11 AND PENALTIES.

12 The failure of a licensed pharmacist or licensed  
13 prescriber to comply with the requirements of this  
14 division, or the performance or causing the  
15 performance of, or the aiding and abetting of another  
16 person in the performance of, any of the prohibited  
17 acts identified in this section shall constitute  
18 grounds for disciplinary action against the pharmacist  
19 or prescriber by the appropriate professional  
20 licensing board. Each licensing board that licenses  
21 prescribers and drug dispensers subject to the  
22 provisions of this division may adopt rules in  
23 accordance with chapter 17A to implement the  
24 provisions of this section and may impose penalty as  
25 allowed under section 272C.3. In addition, a civil  
26 penalty not to exceed twenty-five thousand dollars for  
27 each violation may be imposed.

28 1. A pharmacist who willfully and knowingly fails  
29 to submit prescription information to the board or its  
30 designee as required by this division, or who  
31 knowingly and intentionally submits prescription  
32 information known to the pharmacist to be false or  
33 fraudulent, may be subject to disciplinary action by  
34 the board.

35 2. A person authorized to access or receive  
36 prescription information pursuant to this division who  
37 willfully and knowingly discloses or attempts to  
38 disclose such information with the intent to cause  
39 harm to another person in violation of this division  
40 is guilty of a class "D" felony.

41 3. A person who willfully and knowingly uses,  
42 releases, publishes, or otherwise makes available to  
43 another person any personally identifiable information  
44 obtained from or contained in the database is guilty  
45 of a serious misdemeanor.

46 4. A person without lawful authority who obtains  
47 or attempts to obtain information, obtains or attempts  
48 to obtain unauthorized access to, or who willfully and  
49 knowingly alters or destroys valid information  
50 contained in the database is guilty of a class "D"

**H-1432**

Page 8

1 felony.

2 5. A person authorized to access or receive  
3 prescription information pursuant to this division who  
4 knowingly and intentionally discloses confidential  
5 information to a person who is not authorized to  
6 receive the information pursuant to this division is  
7 guilty of a serious misdemeanor.

8 6. This section shall not preclude a pharmacist or  
9 prescriber who requests and receives information from  
10 the database consistent with the requirements of this  
11 chapter from otherwise lawfully providing that  
12 information to any other person for medical or  
13 pharmaceutical care purposes."

14 2. Page 12, by inserting after line 12 the  
15 following:

16 "Sec. \_\_\_\_ . EFFECTIVE DATE. The sections of this  
17 Act relating to and establishing an electronic drug  
18 database, being deemed of immediate importance, take  
19 effect upon enactment."

20 3. Title page, by striking line 2, and inserting  
21 the following: "providing for the creation of an  
22 electronic drug database, establishing and  
23 appropriating fees, providing penalties, and providing  
24 an effective date."

25 4. By renumbering as necessary.

By UPMEYER of Hancock  
SMITH of Marshall

**H-1432** FILED APRIL 20, 2005

ADOPTED

**HOUSE FILE 833**

**H-1435**

1 Amend House File 833 as follows:

2 1. Page 2, by inserting after line 35 the  
3 following:

4 "Sec. \_\_\_\_ . Section 155A.17, subsection 3, Code  
5 2005, is amended to read as follows:

6 3. The board shall adopt rules pursuant to chapter  
7 17A on matters pertaining to the issuance of a  
8 wholesale drug license. The rules shall provide for  
9 conditions of licensure, compliance standards,  
10 licensure fees, disciplinary action, and other  
11 relevant matters. Additionally, the rules shall  
12 establish provisions or exceptions for pharmacies,  
13 chain pharmacy distribution centers, and other types  
14 of wholesalers relating to pedigree requirements, drug  
15 or device returns, and other related matters, so as  
16 not to prevent or interfere with usual, customary, and  
17 necessary business activities."

18 2. By renumbering as necessary.

By TOMENGA of Polk

**H-1435** FILED APRIL 20, 2005

ADOPTED

HOUSE FILE 833  
BY COMMITTEE ON WAYS AND MEANS

(SUCCESSOR TO HF 790)  
(SUCCESSOR TO HSB 227)

(As Amended and Passed by the House April 20, 2005)

Passed House, Date \_\_\_\_\_ Passed Senate, Date \_\_\_\_\_  
Vote: Ayes \_\_\_\_\_ Nays \_\_\_\_\_ Vote: Ayes \_\_\_\_\_ Nays \_\_\_\_\_  
Approved \_\_\_\_\_

**A BILL FOR**

1 An Act making changes relating to the practice of pharmacy,  
2 providing for the creation of an electronic drug database,  
3 establishing and appropriating fees, providing penalties, and  
4 providing an effective date.

5 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20

House Amendments \_\_\_\_\_    
Deleted Language \*

1 Section 1. Section 22.7, Code 2005, is amended by adding  
2 the following new subsection:

3 NEW SUBSECTION. 51. The information contained in the  
4 electronic drug database established in section 124.510A,  
5 except to the extent that disclosure is authorized pursuant to  
6 section 124.510C.

7 Sec. 2. NEW SECTION. 124.510A ELECTRONIC DRUG DATABASE  
8 ESTABLISHED.

9 The board shall establish and maintain an electronic drug  
10 database. The board shall use the electronic drug database to  
11 monitor the misuse, abuse, and diversion of selected  
12 controlled substances and other drugs the board includes in  
13 the database pursuant to section 124.510E, subsection 1,  
14 paragraph "i". The board shall electronically collect and  
15 disseminate information pursuant to sections 124.510C and  
16 124.510D and rules adopted pursuant to this division. The  
17 board may contract with a third-party/private vendor to  
18 administer the electronic drug database.

19 Sec. 3. NEW SECTION. 124.510B DATA REPORTING.

20 1. Each licensed pharmacy that dispenses selected drugs  
21 identified by the board by rule to patients in the state, and  
22 each licensed pharmacy located in the state that dispenses  
23 such selected drugs to patients inside or outside the state,  
24 unless specifically excepted in this section or by rule, shall  
25 submit the following prescription information to the board or  
26 its designee:

- 27 a. Pharmacy identification.
- 28 b. Patient identification.
- 29 c. Prescriber identification.
- 30 d. The date the prescription was issued by the prescriber.
- 31 e. The date the prescription was dispensed.
- 32 f. An indication of whether the prescription dispensed is  
33 new or a refill.
- 34 g. Identification of the drug dispensed.
- 35 h. Quantity of the drug dispensed.

- 1 i. The number of days' supply of the drug dispensed.
- 2 j. Serial or prescription number assigned by the pharmacy.
- 3 k. Source of payment for the prescription.
- 4 2. Information shall be submitted electronically in the
- 5 format specified by the board unless the board has granted a
- 6 waiver and approved an alternate format.
- 7 3. Information shall be timely transmitted as designated
- 8 by the board by rule, unless the board grants an extension.
- 9 The board may grant an extension if either of the following
- 10 occurs:
- 11 a. The pharmacy suffers a mechanical or electronic
- 12 failure, or cannot meet the deadline established by the board
- 13 for other reasons beyond the pharmacy's control.
- 14 b. The board or its designee is unable to receive
- 15 electronic submissions.
- 16 4. This section shall not apply to a prescriber
- 17 furnishing, dispensing, supplying, or administering drugs to
- 18 the prescriber's patient, or to dispensing by a licensed
- 19 pharmacy for the purposes of inpatient hospital care,
- 20 inpatient hospice care, or long-term residential facility
- 21 patient care.
- 22 Sec. 4. NEW SECTION. 124.510C DATA ACCESS.
- 23 1. The board or its designee may provide information from
- 24 the electronic drug database to all of the following:
- 25 a. A person who is a designated representative of a
- 26 governmental entity responsible for the licensure, regulation,
- 27 or discipline of licensed health care professionals authorized
- 28 to prescribe or dispense drugs, who is involved in an
- 29 investigation of a person licensed, regulated, or subject to
- 30 discipline by the entity, and who is seeking access to
- 31 information in the database that is relevant to the subject
- 32 matter of the investigation and pursuant to a written probable
- 33 cause determination.
- 34 b. A federal, state, county, township, or municipal
- 35 officer of this or any other state, or the United States,

1 whose duty it is to enforce the laws relating to prescription  
2 drugs and who is actively engaged in a specific investigation  
3 of a specific person and is seeking access to information in  
4 the database pursuant to a written probable cause  
5 determination or warrant.

6 c. A properly convened grand jury pursuant to a subpoena  
7 properly issued.

8 d. A pharmacist or prescriber who requests the information  
9 and certifies in a form specified by the board that it is for  
10 the purpose of providing medical or pharmaceutical care to a  
11 patient of the pharmacist or prescriber.

12 e. An individual who requests the individual's own  
13 database information in accordance with the procedure  
14 established in rules of the board adopted under section  
15 124.510E.

16 2. The board or its designee shall maintain a record of  
17 each person that requests information from the database.  
18 Pursuant to rules adopted by the board under section 124.510E,  
19 the board may use the records to document and report  
20 statistics and law enforcement outcomes and to identify  
21 inappropriate access or other prohibited acts. The board or  
22 its designee may provide records of a person's requests for  
23 database information to the following persons:

24 a. Pursuant to a written probable cause determination, a  
25 designated representative of a governmental entity that is  
26 responsible for the licensure, regulation, or discipline of  
27 licensed health care professionals authorized to prescribe or  
28 dispense drugs who is involved in a specific investigation of  
29 the individual who submitted the request.

30 b. Pursuant to a written probable cause determination or  
31 warrant, a federal, state, county, township, or municipal  
32 officer of this or any other state or the United States, whose  
33 duty is to enforce the laws relating to prescription drugs,  
34 and who is actively engaged in a specific investigation of the  
35 specific person who submitted the request.

1 3. Information contained in the database and any  
2 information obtained from it is strictly confidential medical  
3 information, is not a public record pursuant to chapter 22,  
4 and is not subject to discovery, subpoena, or other means of  
5 legal compulsion for release except as provided in this  
6 division. Information contained in the records of requests  
7 for information from the database is privileged and  
8 confidential, is not a public record, and is not subject to  
9 discovery, subpoena, or other means of legal compulsion for  
10 release except as provided in this division. Information from  
11 the database shall not be released, shared with an agency or  
12 institution, or made public except as provided in this  
13 division.

14 4. Information collected for the database shall be  
15 retained in the database for four years. The information  
16 shall then be destroyed unless a law enforcement agency or a  
17 governmental entity responsible for the licensure, regulation,  
18 or discipline of licensed health care professionals authorized  
19 to prescribe or dispense drugs has submitted a written request  
20 to the board or its designee for retention of specific  
21 information in accordance with rules adopted by the board  
22 under section 124.510E.

23 5. A pharmacist or other dispenser making a report to the  
24 database in good faith pursuant to this division is immune  
25 from any liability, civil, criminal, or administrative, which  
26 might otherwise be incurred or imposed as a result of the  
27 report.

28 6. Nothing in this section shall require a pharmacist or  
29 prescriber to obtain information about a patient from the  
30 database. A pharmacist or prescriber does not have a duty and  
31 shall not be held liable in damages to any person in any civil  
32 or derivative criminal or administrative action for injury,  
33 death, or loss to person or property on the basis that the  
34 pharmacist or prescriber did or did not seek or obtain  
35 information from the database. A pharmacist or prescriber

1 acting in good faith is immune from any civil, criminal, or  
2 administrative liability that might otherwise be incurred or  
3 imposed for requesting or receiving information from the  
4 database.

5 7. The board shall not charge a fee to a pharmacy,  
6 pharmacist, or prescriber for the establishment, maintenance,  
7 or administration of the database. The board shall not charge  
8 a fee for the transmission of data to the database nor for the  
9 receipt of information from the database, except that the  
10 board may charge a reasonable fee to an individual who  
11 requests the individual's own database information or to a  
12 person requesting statistical, aggregate, or nonpersonally  
13 identified information from the database. A fee charged  
14 pursuant to this subsection shall not exceed the cost of  
15 providing the requested information and shall be considered a  
16 repayment receipt as defined in section 8.2.

17 Sec. 5. NEW SECTION. 124.510D DATA REVIEW AND REFERRAL.

18 The board or its designee shall review the information in  
19 the electronic drug database. If the board determines,  
20 consistent with the board's authority under this chapter or  
21 chapter 155A, that there is probable cause to believe that  
22 drug diversion or another violation of law may have occurred,  
23 the board shall notify the appropriate law enforcement agency  
24 or the governmental entity responsible for the licensure,  
25 regulation, or discipline of the licensed health care  
26 professional, and shall supply information from the database  
27 supporting the probable cause determination. The board shall  
28 not refer information relating to an individual for further  
29 investigation except upon a probable cause determination. A  
30 probable cause determination shall be consistent with  
31 guidelines developed by the advisory council established under  
32 section 124.510F.

33 Sec. 6. NEW SECTION. 124.510E RULES AND REPORTING.

34 1. The board shall adopt rules in accordance with chapter  
35 17A to carry out the purposes of, and to enforce the the

1 provisions of, this division. The rules shall include but not  
2 be limited to the development of procedures relating to:  
3 a. Identifying each patient about whom information is  
4 entered into the electronic drug database.  
5 b. An electronic format for the submission of information  
6 from pharmacies.  
7 c. A waiver to submit information in another format for a  
8 pharmacy unable to submit information electronically.  
9 d. Granting by the board of a request from a law  
10 enforcement agency or a governmental entity responsible for  
11 the licensure, regulation, or discipline of licensed health  
12 care professionals authorized to prescribe or dispense drugs  
13 for the retention of information scheduled for deletion from  
14 the database after four years when the information pertains to  
15 an open investigation being conducted by the agency or entity.  
16 e. An application for an extension of time by a pharmacy  
17 regarding information to be transmitted to the board or its  
18 designee.  
19 f. The submission by a person or governmental entity to  
20 which the board is authorized to provide information of a  
21 request for the information and a procedure for the  
22 verification of the identity of the requestor.  
23 g. Use by the board of the database request records  
24 required by section 124.510C, subsection 2, to document and  
25 report statistics and law enforcement outcomes and to identify  
26 inappropriate access or other prohibited acts.  
27 h. Submission of a request by an individual for the  
28 individual's own database information and verification of the  
29 identity of the requestor.  
30 i. The development of a list of controlled substances and  
31 other drugs that shall be included in the database.  
32 j. Access by a pharmacist or prescriber to information in  
33 the database pursuant to a written agreement with the board.  
34 k. Terms and conditions of the contract, if the board  
35 contracts for database administration with a third-party or

1 private vendor.

2 1. The correction or deletion of erroneous information  
3 from the database.

4 2. No later than January 1, 2008, and every two years  
5 thereafter, the board shall present to the general assembly  
6 and the governor a report of the following:

7 a. The cost to the state of implementing and maintaining  
8 the database.

9 b. Information from pharmacies, prescribers, the board,  
10 and others regarding the usefulness of the database.

11 c. Information from pharmacies, prescribers, the board,  
12 and others regarding the board's effectiveness in providing  
13 information from the database.

14 d. Information documenting the timely transmission of  
15 information from the electronic drug database to authorized  
16 requestors.

17 Sec. 7. NEW SECTION. 124.510F ADVISORY COUNCIL  
18 ESTABLISHED.

19 The board shall establish an advisory council to provide  
20 oversight to the electronic drug database program. The board  
21 shall adopt rules specifying the duties and activities of the  
22 advisory council and related matters.

23 1. The council shall consist of three licensed  
24 pharmacists, three licensed physicians, two licensed  
25 prescribers who are not physicians, and two members of the  
26 general public. The board shall solicit recommendations for  
27 health professional council members from Iowa health  
28 professional licensing boards, associations, and societies.  
29 The license of each health professional appointed to and  
30 serving on the advisory council shall be current and in good  
31 standing with the professional's licensing board.

32 2. The council may make recommendations to advance the  
33 goals of the database, which include identification of misuse  
34 and diversion of identified controlled substances and other  
35 drugs and enhancement of the quality of health care delivery

1 in this state.

2 3. Among other things, the council shall:

3 a. Assist the board in developing criteria for granting  
4 requests by researchers and other persons for statistical,  
5 aggregate, or nonpersonally identified information using  
6 database information, developed consistent with the goals of  
7 the database.

8 b. Assist the board in ensuring patient confidentiality  
9 and the integrity of the patient's treatment relationship with  
10 the patient's health care provider.

11 c. Make recommendations regarding the continued benefits  
12 of maintaining the electronic drug database in relationship to  
13 cost and other burdens to the board. The council's  
14 recommendations shall be included in reports required by  
15 section 124.510E, subsection 2.

16 4. Members of the advisory council shall be eligible to  
17 request and receive actual expenses for their duties as  
18 members of the advisory council, subject to reimbursement  
19 limits imposed by the department of administrative services,  
20 and shall also be eligible to receive a per diem compensation  
21 as provided in section 7E.6, subsection 1.

22 Sec. 8. NEW SECTION. 124.510G PROHIBITED ACTS AND  
23 PENALTIES.

24 The failure of a licensed pharmacist or licensed prescriber  
25 to comply with the requirements of this division, or the  
26 performance or causing the performance of, or the aiding and  
27 abetting of another person in the performance of, any of the  
28 prohibited acts identified in this section shall constitute  
29 grounds for disciplinary action against the pharmacist or  
30 prescriber by the appropriate professional licensing board.  
31 Each licensing board that licenses prescribers and drug  
32 dispensers subject to the provisions of this division may  
33 adopt rules in accordance with chapter 17A to implement the  
34 provisions of this section and may impose penalty as allowed  
35 under section 272C.3. In addition, a civil penalty not to

1 exceed twenty-five thousand dollars for each violation may be  
2 imposed.

3 1. A pharmacist who willfully and knowingly fails to  
4 submit prescription information to the board or its designee  
5 as required by this division, or who knowingly and  
6 intentionally submits prescription information known to the  
7 pharmacist to be false or fraudulent, may be subject to  
8 disciplinary action by the board.

9 2. A person authorized to access or receive prescription  
10 information pursuant to this division who willfully and  
11 knowingly discloses or attempts to disclose such information  
12 with the intent to cause harm to another person in violation  
13 of this division is guilty of a class "D" felony.

14 3. A person who willfully and knowingly uses, releases,  
15 publishes, or otherwise makes available to another person any  
16 personally identifiable information obtained from or contained  
17 in the database is guilty of a serious misdemeanor.

18 4. A person without lawful authority who obtains or  
19 attempts to obtain information, obtains or attempts to obtain  
20 unauthorized access to, or who willfully and knowingly alters  
21 or destroys valid information contained in the database is  
22 guilty of a class "D" felony.

23 5. A person authorized to access or receive prescription  
24 information pursuant to this division who knowingly and  
25 intentionally discloses confidential information to a person  
26 who is not authorized to receive the information pursuant to  
27 this division is guilty of a serious misdemeanor.

28 6. This section shall not preclude a pharmacist or  
29 prescriber who requests and receives information from the  
30 database consistent with the requirements of this chapter from  
31 otherwise lawfully providing that information to any other  
32 person for medical or pharmaceutical care purposes.

33 Sec. 9. Section 155A.3, subsection 11, Code 2005, is  
34 amended to read as follows:

35 11. "Dispense" means to deliver a prescription drug,

1 device, or controlled substance to an ultimate user or  
2 research subject by or pursuant to the lawful prescription  
3 drug order or medication order of a practitioner, including  
4 the prescribing, administering, packaging, labeling, or  
5 compounding necessary to prepare the substance for that  
6 delivery.

7 Sec. 10. Section 155A.3, Code 2005, is amended by adding  
8 the following new subsection:

9 NEW SUBSECTION. 23A. "Pedigree" means a recording of each  
10 distribution of any given drug or device, from the sale by the  
11 manufacturer through acquisition and sale by any wholesaler,  
12 pursuant to rules adopted by the board.

13 Sec. 11. Section 155A.3, subsection 33, paragraph b, Code  
14 2005, is amended to read as follows:

15 b. A drug or device that under federal law is required,  
16 prior to being dispensed or delivered, to be labeled with  
17 either one of the following statements:

18 (1) Caution: Federal law prohibits dispensing without a  
19 prescription.

20 (2) Caution: Federal law restricts this drug to use by or  
21 on the order of a licensed veterinarian.

22 (3) Caution: Federal law restricts this device to sale  
23 by, or on the order of, a physician.

24 (4) Rx only.

25 Sec. 12. Section 155A.3, subsection 35, Code 2005, is  
26 amended to read as follows:

27 35. "Proprietary medicine" or "over-the-counter medicine"  
28 means a nonnarcotic drug or device that may be sold without a  
29 prescription and that is labeled and packaged in compliance  
30 with applicable state or federal law.

31 Sec. 13. Section 155A.3, subsection 38, Code 2005, is  
32 amended to read as follows:

33 38. "Wholesaler" means a person operating or maintaining,  
34 either within or outside this state, a manufacturing plant,  
35 wholesale distribution center, wholesale business, or any

1 other business in which prescription drugs or devices,  
2 medicinal chemicals, medicines, or poisons are sold,  
3 manufactured, compounded, dispensed, stocked, exposed,  
4 distributed from, or offered for sale at wholesale in this  
5 state. "Wholesaler" does not include those wholesalers who  
6 sell only proprietary or over-the-counter medicines.  
7 "Wholesaler" also does not include a commercial carrier that  
8 temporarily stores prescription drugs or devices, medicinal  
9 chemicals, medicines, or poisons while in transit.

10 Sec. 14. Section 155A.4, subsection 2, paragraph a, Code  
11 2005, is amended to read as follows:

12 a. A ~~manufacturer~~-or wholesaler to distribute prescription  
13 drugs or devices as provided by state or federal law.

14 Sec. 15. Section 155A.13, subsection 6, unnumbered  
15 paragraph 1, Code 2005, is amended to read as follows:

16 To qualify for a pharmacy license, the applicant shall  
17 submit to the board a license fee as determined by the board  
18 and a completed application on a form prescribed by the board  
19 ~~that shall include the following information and.~~ The  
20 application shall include the following and such other  
21 information as required by rules of the board and shall be  
22 given under oath:

23 Sec. 16. Section 155A.17, subsection 2, Code 2005, is  
24 amended to read as follows:

25 2. The board shall establish standards for drug wholesaler  
26 licensure and may define specific types of wholesaler  
27 licenses. The board may deny, suspend, or revoke a drug  
28 wholesale license for failure to meet the applicable standards  
29 or for a violation of the laws of this state, another state,  
30 or the United States relating to prescription drugs, devices,  
31 or controlled substances, or for a violation of this chapter,  
32 chapter 124, 124A, 124B, 126, or 205, or a rule of the board.

33 Sec. 17. Section 155A.17, subsection 3, Code 2005, is  
34 amended to read as follows:

35 3. The board shall adopt rules pursuant to chapter 17A on

1 matters pertaining to the issuance of a wholesale drug  
2 license. The rules shall provide for conditions of licensure,  
3 compliance standards, licensure fees, disciplinary action, and  
4 other relevant matters. Additionally, the rules shall  
5 establish provisions or exceptions for pharmacies, chain  
6 pharmacy distribution centers, and other types of wholesalers  
7 relating to pedigree requirements, drug or device returns, and  
8 other related matters, so as not to prevent or interfere with  
9 usual, customary, and necessary business activities.

10 Sec. 18. Section 155A.19, subsection 1, paragraph f, Code  
11 2005, is amended by striking the paragraph and inserting in  
12 lieu thereof the following:

13 f. Change of legal name or doing-business-as name.

14 Sec. 19. Section 155A.19, Code 2005, is amended by adding  
15 the following new subsection:

16 NEW SUBSECTION. 3. A wholesaler shall report in writing  
17 to the board, pursuant to its rules, the following:

18 a. Permanent closing or discontinuation of wholesale  
19 distributions into this state.

20 b. Change of ownership.

21 c. Change of location.

22 d. Change of the wholesaler's responsible individual.

23 e. Change of legal name or doing-business-as name.

24 f. Theft or significant loss of any controlled substance  
25 on discovery of the theft or loss.

26 g. Disasters, accidents, and emergencies that may affect  
27 the strength, purity, or labeling of drugs, medications,  
28 devices, or other materials used in the diagnosis or the  
29 treatment of injury, illness, and disease.

30 h. Other information or activities as required by rule.

31 Sec. 20. Section 155A.20, subsection 1, Code 2005, is  
32 amended to read as follows:

33 1. A person, other than a pharmacy or wholesaler licensed  
34 under this chapter, shall not display in or on any store,  
35 internet site, or place of business, nor use in any

1 advertising or promotional literature, communication, or  
2 representation, the word or words: "apothecary", "drug",  
3 "drug store", or "pharmacy", either in English or any other  
4 language, any other word or combination of words of the same  
5 or similar meaning, or any graphic representation in a manner  
6 that would mislead the public unless-it-is-a-pharmacy-or-drug  
7 wholesaler-licensed-under-this-chapter.

8 Sec. 21. Section 155A.21, Code 2005, is amended to read as  
9 follows:

10 155A.21 UNLAWFUL POSSESSION OF PRESCRIPTION DRUG OR DEVICE  
11 -- PENALTY.

12 1. A person found in possession of a drug or device  
13 limited to dispensation by prescription, unless the drug or  
14 device was so lawfully dispensed, commits a serious  
15 misdemeanor.

16 2. Subsection 1 does not apply to a licensed pharmacy,  
17 licensed wholesaler, physician, veterinarian, dentist,  
18 podiatric physician, therapeutically certified optometrist,  
19 advanced registered nurse practitioner, physician assistant, a  
20 nurse acting under the direction of a physician, or the board  
21 of pharmacy examiners, its officers, agents, inspectors, and  
22 representatives, nor to a common carrier, manufacturer's  
23 representative, or messenger when transporting the drug or  
24 device in the same unbroken package in which the drug or  
25 device was delivered to that person for transportation.

26 Sec. 22. Section 155A.23, Code 2005, is amended to read as  
27 follows:

28 155A.23 PROHIBITED ACTS.

29 A person shall not perform or cause the performance of or  
30 aid and abet any of the following acts:

31 1. ~~Obtain-or-attempt~~ Obtaining or attempting to obtain a  
32 prescription drug or device or procure-or-attempt procuring or  
33 attempting to procure the administration of a prescription  
34 drug or device by:

35 a. Fraud Engaging in fraud, deceit, misrepresentation, or

1 subterfuge.

2     b. ~~Forgery-or-alteration-of~~ Forging or altering a written,  
3 electronic, or facsimile prescription or of any written,  
4 electronic, or facsimile order.

5     c. ~~Concealment-of~~ Concealing a material fact.

6     d. ~~Use-of~~ Using a false name or the giving of a false  
7 address.

8     2. Willfully ~~make~~ making a false statement in any  
9 prescription, report, or record required by this chapter.

10     3. For the purpose of obtaining a prescription drug or  
11 device, falsely ~~assume~~ assuming the title of or ~~claim~~ claiming  
12 to be a manufacturer, wholesaler, pharmacist, pharmacy owner,  
13 physician, dentist, podiatric physician, veterinarian, or  
14 other authorized person.

15     4. ~~Make-or-utter~~ Making or uttering any false or forged  
16 oral, written, electronic, or facsimile prescription or oral,  
17 written, electronic, or facsimile order.

18     5. ~~Affix-any-false-or-forged-label-to-a-package-or~~  
19 ~~receptacle-containing-prescription-drugs~~ Forging,  
20 counterfeiting, simulating, or falsely representing any drug  
21 or device without the authority of the manufacturer, or using  
22 any mark, stamp, tag, label, or other identification device  
23 without the authorization of the manufacturer.

24     6. Manufacturing, repackaging, selling, delivering, or  
25 holding or offering for sale any drug or device that is  
26 adulterated, misbranded, counterfeit, suspected of being  
27 counterfeit, or that has otherwise been rendered unfit for  
28 distribution.

29     7. Adulterating, misbranding, or counterfeiting any drug  
30 or device.

31     8. Receiving any drug or device that is adulterated,  
32 misbranded, stolen, obtained by fraud or deceit, counterfeit,  
33 or suspected of being counterfeit, and delivering or  
34 proffering delivery of such drug or device for pay or  
35 otherwise.

1 9. Adulterating, mutilating, destroying, obliterating, or  
2 removing the whole or any part of the labeling of a drug or  
3 device or committing any other act with respect to a drug or  
4 device that results in the drug or device being misbranded.

5 10. Purchasing or receiving a drug or device from a person  
6 who is not licensed to distribute the drug or device to that  
7 purchaser or recipient.

8 11. Selling or transferring a drug or device to a person  
9 who is not authorized under the law of the jurisdiction in  
10 which the person receives the drug or device to purchase or  
11 possess the drug or device from the person selling or  
12 transferring the drug or device.

13 12. Failing to maintain or provide records as required by  
14 this chapter, chapter 124, or rules of the board.

15 13. Providing the board or any of its representatives or  
16 any state or federal official with false or fraudulent records  
17 or making false or fraudulent statements regarding any matter  
18 within the scope of this chapter, chapter 124, or rules of the  
19 board.

20 14. Distributing at wholesale any drug or device that  
21 meets any of the following conditions:

22 a. The drug or device was purchased by a public or private  
23 hospital or other health care entity.

24 b. The drug or device was donated or supplied at a reduced  
25 price to a charitable organization.

26 c. The drug or device was purchased from a person not  
27 licensed to distribute the drug or device.

28 d. The drug or device was stolen or obtained by fraud or  
29 deceit.

30 15. Failing to obtain a license or operating without a  
31 valid license when a license is required pursuant to this  
32 chapter or chapter 147.

33 16. Engaging in misrepresentation or fraud in the  
34 distribution of a drug or device.

35 17. Distributing a drug or device to a patient without a

1 prescription drug order or medication order from a  
2 practitioner licensed by law to use or prescribe the drug or  
3 device.

4 18. Distributing a drug or device that was previously  
5 dispensed by a pharmacy or distributed by a practitioner  
6 except as provided by rules of the board.

7 19. Failing to report any prohibited act.

8 Information communicated to a physician in an unlawful  
9 effort to procure a prescription drug or device or to procure  
10 the administration of a prescription drug shall not be deemed  
11 a privileged communication.

12 Subsections 6 and 7 shall not apply to the wholesale  
13 distribution by a manufacturer of a prescription drug or  
14 device that has been delivered into commerce pursuant to an  
15 application approved by the federal food and drug  
16 administration.

17 Sec. 23. Section 155A.24, Code 2005, is amended to read as  
18 follows:

19 155A.24 PENALTIES.

20 1. Except as otherwise provided in this section, a  
21 person who violates a provision of section 155A.23 or who  
22 sells or offers for sale, gives away, or administers to  
23 another person any prescription drug or device in violation of  
24 this chapter commits a public offense and shall be punished as  
25 follows:

26 a. If the prescription drug is a controlled substance, the  
27 person shall be punished pursuant to ~~section-124-4017~~  
28 ~~subsection-17-and-section-124-411~~ chapter 124, division IV.

29 b. If the prescription drug is not a controlled substance,  
30 the person, upon conviction of a first offense, is guilty of a  
31 serious misdemeanor. For a second offense, or if in case of a  
32 first offense the offender previously has been convicted of  
33 any violation of the laws of the United States or of any  
34 state, territory, or district thereof relating to prescription  
35 drugs or devices, the offender is guilty of an aggravated

1 misdemeanor. For a third or subsequent offense or if in the  
2 case of a second offense the offender previously has been  
3 convicted two or more times in the aggregate of any violation  
4 of the laws of the United States or of any state, territory,  
5 or district thereof relating to prescription drugs or devices,  
6 the offender is guilty of a class "D" felony.

7 2. A person who violates any provision of this chapter by  
8 selling, giving away, or administering any prescription drug  
9 or device to a minor is guilty of a class "C" felony.

10 3. A wholesaler who, with intent to defraud or deceive,  
11 fails to deliver to another person, when required by rules of  
12 the board, complete and accurate pedigree concerning a drug  
13 prior to transferring the drug to another person is guilty of  
14 a class "C" felony.

15 4. A wholesaler who, with intent to defraud or deceive,  
16 fails to acquire, when required by rules of the board,  
17 complete and accurate pedigree concerning a drug prior to  
18 obtaining the drug from another person is guilty of a class  
19 "C" felony.

20 5. A wholesaler who knowingly destroys, alters, conceals,  
21 or fails to maintain, as required by rules of the board,  
22 complete and accurate pedigree concerning any drug in the  
23 person's possession is guilty of a class "C" felony.

24 6. A wholesaler who is in possession of pedigree documents  
25 required by rules of the board, and who knowingly fails to  
26 authenticate the matters contained in the documents as  
27 required, and who nevertheless distributes or attempts to  
28 further distribute drugs is guilty of a class "C" felony.

29 7. A wholesaler who, with intent to defraud or deceive,  
30 falsely swears or certifies that the person has authenticated  
31 any documents related to the wholesale distribution of drugs  
32 or devices is guilty of a class "C" felony.

33 8. A wholesaler who knowingly forges, counterfeits, or  
34 falsely creates any pedigree, who falsely represents any  
35 factual matter contained in any pedigree, or who knowingly

1 omits to record material information required to be recorded  
2 in a pedigree is guilty of a class "C" felony.

3 9. A wholesaler who knowingly purchases or receives drugs  
4 or devices from a person not authorized to distribute drugs or  
5 devices in wholesale distribution is guilty of a class "C"  
6 felony.

7 10. A wholesaler who knowingly sells, barter, brokers, or  
8 transfers a drug or device to a person not authorized to  
9 purchase the drug or device under the jurisdiction in which  
10 the person receives the drug or device in a wholesale  
11 distribution is guilty of a class "C" felony.

12 11. A person who knowingly manufactures, sells, or  
13 delivers, or who possesses with intent to sell or deliver, a  
14 counterfeit, misbranded, or adulterated drug or device is  
15 guilty of the following:

16 a. If the person manufactures or produces a counterfeit,  
17 misbranded, or adulterated drug or device; or if the quantity  
18 of a counterfeit, misbranded, or adulterated drug or device  
19 being sold, delivered, or possessed with intent to sell or  
20 deliver exceeds one thousand units or dosages; or if the  
21 violation is a third or subsequent violation of this  
22 subsection, the person is guilty of a class "C" felony.

23 b. If the quantity of a counterfeit, misbranded, or  
24 adulterated drug or device being sold, delivered, or possessed  
25 with intent to sell or deliver exceeds one hundred units or  
26 dosages but does not exceed one thousand units or dosages; or  
27 if the violation is a second or subsequent violation of this  
28 subsection, the person is guilty of a class "D" felony.

29 c. All other violations of this subsection shall  
30 constitute an aggravated misdemeanor.

31 12. A person who knowingly forges, counterfeits, or  
32 falsely creates any label for a drug or device or who falsely  
33 represents any factual matter contained on any label of a drug  
34 or device is guilty of a class "C" felony.

35 13. A person who knowingly possesses, purchases, or brings

1 into the state a counterfeit, misbranded, or adulterated drug  
2 or device is guilty of the following:

3 a. If the quantity of a counterfeit, misbranded, or  
4 adulterated drug or device being possessed, purchased, or  
5 brought into the state exceeds one hundred units or dosages;  
6 or if the violation is a second or subsequent violation of  
7 this subsection, the person is guilty of a class "D" felony.

8 b. All other violations of this subsection shall  
9 constitute an aggravated misdemeanor.

\*10 14. This section does not prevent a licensed practitioner  
11 of medicine, dentistry, podiatry, nursing, veterinary  
12 medicine, optometry, or pharmacy from acts necessary in the  
13 ethical and legal performance of the practitioner's  
14 profession.

15 15. Subsections 1 and 2 shall not apply to a parent or  
16 legal guardian administering, in good faith, a prescription  
17 drug or device to a child of the parent or a child for whom  
18 the individual is designated a legal guardian.

19 Sec. 24. NEW SECTION. 155A.40 CRIMINAL HISTORY RECORD  
20 CHECKS.

21 1. The board may request and obtain, notwithstanding  
22 section 692.2, subsection 5, criminal history data for any  
23 applicant for an initial or renewal license or registration  
24 issued pursuant to this chapter or chapter 147, any applicant  
25 for reinstatement of a license or registration issued pursuant  
26 to this chapter or chapter 147, or any licensee or registrant  
27 who is being monitored as a result of a board order or  
28 agreement resolving an administrative disciplinary action, for  
29 the purpose of evaluating the applicant's, licensee's, or  
30 registrant's eligibility for licensure, registration, or  
31 suitability for continued practice of the profession.  
32 Criminal history data may be requested for of all owners,  
33 managers, and principal employees of a pharmacy or drug  
34 wholesaler licensed pursuant to this chapter. The board shall  
35 adopt rules pursuant to chapter 17A to implement this section.

1 The board shall inform the applicant, licensee, or registrant  
2 of the criminal history requirement and obtain a signed waiver  
3 from the applicant, licensee, or registrant prior to  
4 submitting a criminal history data request.

5 2. A request for criminal history data shall be submitted  
6 to the department of public safety, division of criminal  
7 investigation and bureau of identification, pursuant to  
8 section 692.2, subsection 1. The board may also require such  
9 applicants, licensees, and registrants to provide a full set  
10 of fingerprints, in a form and manner prescribed by the board.  
11 Such fingerprints may be submitted to the federal bureau of  
12 investigation through the state criminal history repository  
13 for a national criminal history check. The board may  
14 authorize alternate methods or sources for obtaining criminal  
15 history record information. The board may, in addition to any  
16 other fees, charge and collect such amounts as may be incurred  
17 by the board, the department of public safety, or the federal  
18 bureau of investigation in obtaining criminal history  
19 information. Amounts collected shall be considered repayment  
20 receipts as defined in section 8.2.

21 3. Criminal history information relating to an applicant,  
22 licensee, or registrant obtained by the board pursuant to this  
23 section is confidential. The board may, however, use such  
24 information in a license or registration denial proceeding.  
25 In a disciplinary proceeding, such information shall  
26 constitute investigative information under section 272C.6,  
27 subsection 4, and may be used only for purposes consistent  
28 with that section.

29 4. This section shall not apply to a manufacturer of a  
30 prescription drug or device that has been delivered into  
31 commerce pursuant to an application approved by the federal  
32 food and drug administration.

33 Sec. 25. NEW SECTION. 155A.41 CONTINUOUS QUALITY  
34 IMPROVEMENT PROGRAM.

35 1. Each licensed pharmacy shall implement or participate

1 in a continuous quality improvement program to review pharmacy  
2 procedures in order to identify methods for addressing  
3 pharmacy medication errors and for improving patient use of  
4 medications and patient care services. Under the program,  
5 each pharmacy shall assess its practices and identify areas  
6 for quality improvement.

7 2. The board shall adopt rules for the administration of a  
8 continuous quality improvement program. The rules shall  
9 address all of the following:

10 a. Program requirements and procedures.

11 b. Program record and reporting requirements.

12 c. Any other provisions necessary for the administration  
13 of a program.

14 Sec. 26. EFFECTIVE DATE. The sections of this Act  
15 relating to and establishing an electronic drug database,  
16 being deemed of immediate importance, take effect upon  
17 enactment.

18

19

20

21

22

23

24

25

26

27

28

29

30

31

32

33

34

35

**Fiscal Services Division**  
**Legislative Services Agency**  
**Fiscal Note**

---

HF 833 - Pharmacy Practice Act (LSB 1292 HZ.1)  
Analyst: Lisa Burk (Phone: (515) 281-7942) (lisa.burk@legis.state.ia.us)  
Fiscal Note Version - As Amended and Passed by the House

---

**Description**

House File 833, as amended and passed by the House, authorizes the Board of Pharmacy Examiners to establish and administer a prescription drug database that maintains a record regarding the dispensing of prescriptions for identified controlled substances and prescription drugs, provides the requirements for reportable data, and identifies those who are authorized to request information from the database. The Board is required to review data and to notify the appropriate law enforcement agency or government entity of violations. The Board is also required to adopt administrative rules for the implementation of the database and to establish an advisory council to oversee the database. A civil penalty of up to \$25,000 may be imposed by the Board for each violation of reporting requirements relating to the prescription drug database.

The Bill also amends various definitions with regard to the practice of pharmacy, modifies requirements for a pharmacy license application, authorizes the Board of Pharmacy Examiners to define specific types of wholesaler licenses, and requires licensed wholesalers to report specific occurrences to the Board. In addition, the Bill extends prohibitions against the use of the words, "apothecary," "drug," "drug store," or "pharmacy" by entities other than pharmacies or wholesalers.

The Bill implements a graduated system of penalties for prohibited acts in relation to the practice of pharmacy. The penalties include a serious misdemeanor, an aggravated misdemeanor, a Class D felony, and numerous Class C felonies.

In addition, HF 833 authorizes the Board of Pharmacy Examiners to request and obtain criminal history data for any pharmacist, pharmacist-intern, or pharmacy technician applicant and for all owners, managers, and principal employees of a pharmacy or drug wholesaler applicant, as well as provides for the collection of fees from these applicants for this purpose and allows the Board to process these fees as repayment receipts.

**Background**

1. The Board of Pharmacy Examiners has imposed a civil penalty of \$25,000 for three violations relating to the practice of pharmacy in the last 14 years.
2. In FY 2004, there were 221 convictions for crimes relating to the practice of pharmacy under Chapter 155A, Code of Iowa. Of these, 132 were for unlawful possession of prescription drugs, while 85 were for violations relating directly to pharmacies.
3. The average State costs for one serious misdemeanor conviction ranges from \$101 (court costs) to \$4,100 (court costs, jury trial, indigent defense, prison, and parole).
4. The average State costs for one aggravated misdemeanor conviction ranges from \$1,100 (court costs and probation) to \$5,700 (court costs, jury trial, indigent defense, prison, and parole).
5. The average State costs for one Class D felony conviction ranges from \$2,800 (court costs, probation, and indigent defense) to \$12,000 (court costs, jury trial, indigent defense, prison, and parole).
6. The average State costs for one Class C felony conviction ranges from \$3,100 (court costs, indigent defense, and probation) to \$23,000 (court costs, jury trial, indigent defense, prison, and parole).

7. The maximum costs will be incurred across multiple years while the offender is supervised in the correctional system, either in prison or in the community.

### **Assumptions**

1. The Board of Pharmacy Examiners has been awarded a federal grant to cover planning and implementation costs associated with the prescription drug database and will continue to receive federal funds to maintain and improve the database.
2. There is no data available to project the impact of the Bill on the Justice System with regard to the expansion of prohibited acts and criminal penalties relating to the practice of pharmacy under the provisions of the Bill.
3. The Board of Pharmacy Examiners will hold four meetings to develop administrative rules to implement the provisions of the Bill in relation to drug wholesalers, criminal history background checks, and pharmacy continuous quality improvement programs at a cost of \$350 per meeting, which will be incurred in the first year only.
4. The Board of Pharmacy Examiners will require criminal history record checks on an estimated 1,650 licensees, registrants, and applicants annually at a cost of \$47.00 each.
5. Drug wholesalers with credential under the National Association of Boards of Pharmacy Verified-Accredited Wholesale Distributors Program and criminal history record checks performed pursuant to the Program will be accepted by the Board of Pharmacy Examiners.

### **Correctional Impact**

The creation of new offenses carries the potential for a correctional impact on court caseloads, prisons, county jails, Community-Based Corrections (CBC), and indigent defense resources. However, due to a lack of data, that correctional impact cannot be estimated.

The number of new serious or aggravated misdemeanor or Class D felony convictions under HF 833 cannot be determined due to a lack of data. It is anticipated, however, that there will not be a significant number of new convictions as these types of professional business violations are infrequent.

The number of new Class C felony convictions under HF 833 cannot be determined due to a lack of data. Due to the significant number of individuals employed in wholesale operations, however, the correctional impact could be substantial.

### **Fiscal Impact**

The fiscal impact of HF 833 on the Justice System cannot be determined due to insufficient information. The fiscal impact may be substantial, if the number of Class C felony convictions of wholesalers is significant.

The fiscal impact of HF 833 on the Department of Public Health, Board of Pharmacy Examiners, to establish and maintain the prescription drug database is estimated to be an increase of \$369,000 and 2.00 FTE positions in FY 2006 and \$224,000 in FY 2007, which will be paid from federal funds. The cost to adopt administrative rules in relation to drug wholesalers, criminal history background checks, and pharmacy continuous quality improvement programs is anticipated to be minimal (\$1,400) in FY 2006.

It is also anticipated that the Board will collect an estimated \$78,000 annually in repayment receipts from applicants to cover the cost of criminal history background checks. The Board anticipates imposing few, if any, civil penalties in relation to violations of reporting requirements in relation to the prescription drug database.

**Sources**

Department of Corrections  
Department of Human Rights, Criminal and Juvenile Justice Planning Division  
Department of Public Health, Board of Pharmacy Examiners  
Judicial Branch  
Office of the Attorney General  
Office of the State Public Defender

/s/ Holly M. Lyons

---

April 27, 2005

---

The fiscal note and correctional impact statement for this bill was prepared pursuant to Joint Rule 17 and pursuant to Section 2.56, Code of Iowa. Data used in developing this fiscal note and correctional impact statement are available from the Fiscal Services Division, Legislative Services Agency to members of the Legislature upon request.

---

HOUSE FILE 833

S-3190

- 1 Amend House File 833, as amended, passed, and
- 2 reprinted by the House, as follows:
- 3 1. Page 10, by inserting after line 6 the
- 4 following:
- 5 "Sec. \_\_\_\_ . Section 155A.3, Code 2005, is amended
- 6 by adding the following new subsection:
- 7 NEW SUBSECTION. 22A. "Logistics provider" means
- 8 an entity that provides or coordinates warehousing,
- 9 distribution, or other services on behalf of a
- 10 manufacturer or other owner of a drug, but does not
- 11 take title to the drug or have general responsibility
- 12 to direct its sale or other disposition."
- 13 2. Page 11, line 7, by inserting after the word
- 14 "carrier" the following: "or logistics provider".
- 15 3. By renumbering as necessary.

COMMITTEE ON WAYS AND MEANS  
JOE BOLKCOM, CO-CHAIRPERSON  
MARK ZIEMAN, CO-CHAIRPERSON

S-3190 FILED APRIL 27, 2005

HOUSE FILE 833

S-3191

- 1 Amend the amendment, S-3190, to House File 833, as
- 2 amended, passed, and reprinted by the House, as
- 3 follows:
- 4 1. Page 1, by striking lines 13 and 14, and
- 5 inserting the following:
- 6 "\_\_\_\_ . Page 12, line 6, by inserting after the
- 7 word "centers," the following: "logistics
- 8 providers,"."

By CHARLES W. LARSON, JR.  
MATT McCOY

S-3191 FILED APRIL 27, 2005

HOUSE FILE 833

S-3215

- 1 Amend House File 833, as amended, passed, and
- 2 reprinted by the House, as follows:
- 3 1. Page 4, line 24, by inserting after the word
- 4 "database" the following: "reasonably and".
- 5 2. Page 5, line 1, by inserting after the word
- 6 "acting" the following: "reasonably and".

By CHARLES W. LARSON, JR.

S-3215 FILED APRIL 29, 2005

*Hutter  
Tomenga  
Smith*

SUC  
S: 0833

HSB 227  
HUMAN RESOURCES

SENATE/HOUSE FILE \_\_\_\_\_  
BY (PROPOSED DEPARTMENT OF  
PUBLIC HEALTH/BOARD OF  
PHARMACY EXAMINERS BILL)

Passed Senate, Date \_\_\_\_\_ Passed House, Date \_\_\_\_\_  
Vote: Ayes \_\_\_\_\_ Nays \_\_\_\_\_ Vote: Ayes \_\_\_\_\_ Nays \_\_\_\_\_  
Approved \_\_\_\_\_

**A BILL FOR**

1 An Act making changes relating to the practice of pharmacy,  
2 establishing and appropriating fees, and providing penalties.  
3 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22

1 Section 1. Section 155A.3, subsection 11, Code 2005, is  
2 amended to read as follows:

3 11. "Dispense" means to deliver a prescription drug,  
4 device, or controlled substance to an ultimate user or  
5 research subject by or pursuant to the lawful prescription  
6 drug order or medication order of a practitioner, including  
7 the prescribing, administering, packaging, labeling, or  
8 compounding necessary to prepare the substance for that  
9 delivery.

10 Sec. 2. Section 155A.3, Code 2005, is amended by adding  
11 the following new subsection:

12 NEW SUBSECTION. 23A. "Pedigree" means a recording of each  
13 distribution of any given drug or device, from the sale by the  
14 manufacturer through acquisition and sale by any wholesaler,  
15 pursuant to rules adopted by the board.

16 Sec. 3. Section 155A.3, subsection 33, paragraph b, Code  
17 2005, is amended to read as follows:

18 b. A drug or device that under federal law is required,  
19 prior to being dispensed or delivered, to be labeled with  
20 either one of the following statements:

21 (1) Caution: Federal law prohibits dispensing without a  
22 prescription.

23 (2) Caution: Federal law restricts this drug to use by or  
24 on the order of a licensed veterinarian.

25 (3) Caution: Federal law restricts this device to sale  
26 by, or on the order of, a physician.

27 (4) Rx only.

28 Sec. 4. Section 155A.3, subsection 35, Code 2005, is  
29 amended to read as follows:

30 35. "Proprietary medicine" or "over-the-counter medicine"  
31 means a nonnarcotic drug or device that may be sold without a  
32 prescription and that is labeled and packaged in compliance  
33 with applicable state or federal law.

34 Sec. 5. Section 155A.3, subsection 38, Code 2005, is  
35 amended to read as follows:

1 38. "Wholesaler" means a person operating or maintaining,  
2 either within or outside this state, a manufacturing plant,  
3 wholesale distribution center, wholesale business, or any  
4 other business in which prescription drugs or devices,  
5 medicinal chemicals, medicines, or poisons are sold,  
6 manufactured, compounded, dispensed, stocked, exposed,  
7 distributed from, or offered for sale at wholesale in this  
8 state. "Wholesaler" does not include those wholesalers who  
9 sell only proprietary or over-the-counter medicines.

10 Sec. 6. Section 155A.4, subsection 2, paragraph a, Code  
11 2005, is amended to read as follows:

12 a. A ~~manufacturer-or~~ wholesaler to distribute prescription  
13 drugs or devices as provided by state or federal law.

14 Sec. 7. Section 155A.13, subsection 6, unnumbered  
15 paragraph 1, Code 2005, is amended to read as follows:

16 To qualify for a pharmacy license, the applicant shall  
17 submit to the board a license fee as determined by the board  
18 and a completed application on a form prescribed by the board  
19 ~~that shall include the following information and.~~ The  
20 application shall include the following and such other  
21 information as required by rules of the board and shall be  
22 given under oath:

23 Sec. 8. Section 155A.17, subsection 2, Code 2005, is  
24 amended to read as follows:

25 2. The board shall establish standards for drug wholesaler  
26 licensure and may define specific types of wholesaler  
27 licenses. The board may deny, suspend, or revoke a drug  
28 wholesale license for failure to meet the applicable standards  
29 or for a violation of the laws of this state, another state,  
30 or the United States relating to prescription drugs, devices,  
31 or controlled substances, or for a violation of this chapter,  
32 chapter 124, 124A, 124B, 126, or 205, or a rule of the board.

33 Sec. 9. Section 155A.19, subsection 1, paragraph f, Code  
34 2005, is amended by striking the paragraph and inserting in  
35 lieu thereof the following:

1 f. Change of legal name or doing-business-as name.  
2 Sec. 10. Section 155A.19, Code 2005, is amended by adding  
3 the following new subsection:

4 NEW SUBSECTION. 3. A wholesaler shall report in writing  
5 to the board, pursuant to its rules, the following:

6 a. Permanent closing or discontinuation of wholesale  
7 distributions into this state.

8 b. Change of ownership.

9 c. Change of location.

10 d. Change of the wholesaler's responsible individual.

11 e. Change of legal name or doing-business-as name.

12 f. Theft or significant loss of any controlled substance  
13 on discovery of the theft or loss.

14 g. Disasters, accidents, and emergencies that may affect  
15 the strength, purity, or labeling of drugs, medications,  
16 devices, or other materials used in the diagnosis or the  
17 treatment of injury, illness, and disease.

18 h. Other information or activities as required by rule.

19 Sec. 11. Section 155A.20, subsection 1, Code 2005, is  
20 amended to read as follows:

21 1. A person, other than a pharmacy or wholesaler licensed  
22 under this chapter, shall not display in or on any store,  
23 internet site, or place of business, nor use in any  
24 advertising or promotional literature, communication, or  
25 representation, the word or words: "apothecary", "drug",  
26 "drug store", or "pharmacy", either in English or any other  
27 language, any other word or combination of words of the same  
28 or similar meaning, or any graphic representation in a manner  
29 that would mislead the public ~~unless-it-is-a-pharmacy-or-drug~~  
30 ~~wholesaler-licensed-under-this-chapter~~.

31 Sec. 12. Section 155A.21, Code 2005, is amended to read as  
32 follows:

33 155A.21 UNLAWFUL POSSESSION OF PRESCRIPTION DRUG OR DEVICE  
34 -- PENALTY.

35 1. A person found in possession of a drug or device

1 limited to dispensation by prescription, unless the drug or  
2 device was so lawfully dispensed, commits a serious  
3 misdemeanor.

4 2. Subsection 1 does not apply to a licensed pharmacy,  
5 licensed wholesaler, physician, veterinarian, dentist,  
6 podiatric physician, therapeutically certified optometrist,  
7 advanced registered nurse practitioner, physician assistant, a  
8 nurse acting under the direction of a physician, or the board  
9 of pharmacy examiners, its officers, agents, inspectors, and  
10 representatives, nor to a common carrier, manufacturer's  
11 representative, or messenger when transporting the drug or  
12 device in the same unbroken package in which the drug or  
13 device was delivered to that person for transportation.

14 Sec. 13. Section 155A.23, Code 2005, is amended to read as  
15 follows:

16 155A.23 PROHIBITED ACTS.

17 A person shall not perform or cause the performance of or  
18 aid and abet any of the following acts:

19 1. ~~Obtain-or-attempt~~ Obtaining or attempting to obtain a  
20 prescription drug or device or ~~procure-or-attempt~~ procuring or  
21 attempting to procure the administration of a prescription  
22 drug or device by:

23 a. ~~Fraud~~ Engaging in fraud, deceit, misrepresentation, or  
24 subterfuge.

25 b. ~~Forgery-or-alteration-of~~ Forging or altering a written,  
26 electronic, or facsimile prescription or of any written,  
27 electronic, or facsimile order.

28 c. ~~Concealment-of~~ Concealing a material fact.

29 d. ~~Use-of~~ Using a false name or the giving of a false  
30 address.

31 2. Willfully ~~make~~ making a false statement in any  
32 prescription, report, or record required by this chapter.

33 3. For the purpose of obtaining a prescription drug or  
34 device, falsely ~~assume~~ assuming the title of or ~~claim~~ claiming  
35 to be a manufacturer, wholesaler, pharmacist, pharmacy owner,

1 physician, dentist, podiatric physician, veterinarian, or  
2 other authorized person.

3 4. ~~Make-or-utter~~ Making or uttering any false or forged  
4 oral, written, electronic, or facsimile prescription or oral,  
5 written, electronic, or facsimile order.

6 5. ~~Affix-any-false-or-forged-label-to-a-package-or~~  
7 ~~receptacle-containing-prescription-drugs~~ Forging,  
8 counterfeiting, simulating, or falsely representing any drug  
9 or device without the authority of the manufacturer, or using  
10 any mark, stamp, tag, label, or other identification device  
11 without the authorization of the manufacturer.

12 6. Manufacturing, repackaging, selling, delivering, or  
13 holding or offering for sale any drug or device that is  
14 adulterated, misbranded, counterfeit, suspected of being  
15 counterfeit, or that has otherwise been rendered unfit for  
16 distribution.

17 7. Adulterating, misbranding, or counterfeiting any drug  
18 or device.

19 8. Receiving any drug or device that is adulterated,  
20 misbranded, stolen, obtained by fraud or deceit, counterfeit,  
21 or suspected of being counterfeit, and delivering or  
22 proffering delivery of such drug or device for pay or  
23 otherwise.

24 9. Adulterating, mutilating, destroying, obliterating, or  
25 removing the whole or any part of the labeling of a drug or  
26 device or committing any other act with respect to a drug or  
27 device that results in the drug or device being misbranded.

28 10. Purchasing or receiving a drug or device from a person  
29 who is not licensed to distribute the drug or device to that  
30 purchaser or recipient.

31 11. Selling or transferring a drug or device to a person  
32 who is not authorized under the law of the jurisdiction in  
33 which the person receives the drug or device to purchase or  
34 possess the drug or device from the person selling or  
35 transferring the drug or device.

1 12. Failing to maintain or provide records as required by  
2 this chapter, chapter 124, or rules of the board.

3 13. Providing the board or any of its representatives or  
4 any state or federal official with false or fraudulent records  
5 or making false or fraudulent statements regarding any matter  
6 within the scope of this chapter, chapter 124, or rules of the  
7 board.

8 14. Distributing at wholesale any drug or device that  
9 meets any of the following conditions:

10 a. The drug or device was purchased by a public or private  
11 hospital or other health care entity.

12 b. The drug or device was donated or supplied at a reduced  
13 price to a charitable organization.

14 c. The drug or device was purchased from a person not  
15 licensed to distribute the drug or device.

16 d. The drug or device was stolen or obtained by fraud or  
17 deceit.

18 15. Failing to obtain a license or operating without a  
19 valid license when a license is required pursuant to this  
20 chapter or chapter 147.

21 16. Engaging in misrepresentation or fraud in the  
22 distribution of a drug or device.

23 17. Distributing a drug or device to a patient without a  
24 prescription drug order or medication order from a  
25 practitioner licensed by law to use or prescribe the drug or  
26 device.

27 18. Distributing a drug or device that was previously  
28 dispensed by a pharmacy or distributed by a practitioner  
29 except as provided by rules of the board.

30 19. Failing to report any prohibited act.

31 Information communicated to a physician in an unlawful  
32 effort to procure a prescription drug or device or to procure  
33 the administration of a prescription drug shall not be deemed  
34 a privileged communication.

35 Sec. 14. Section 155A.24, Code 2005, is amended to read as

1 follows:

2 155A.24 PENALTIES.

3 1. A Except as otherwise provided in this section, a  
4 person who violates a provision of section 155A.23 or who  
5 sells or offers for sale, gives away, or administers to  
6 another person any prescription drug or device in violation of  
7 this chapter commits a public offense and shall be punished as  
8 follows:

9 a. If the prescription drug is a controlled substance, the  
10 person shall be punished pursuant to ~~section-124-4017~~  
11 ~~subsection-17-and-section-124-411~~ chapter 124, division IV.

12 b. If the prescription drug is not a controlled substance,  
13 the person, upon conviction of a first offense, is guilty of a  
14 serious misdemeanor. For a second offense, or if in case of a  
15 first offense the offender previously has been convicted of  
16 any violation of the laws of the United States or of any  
17 state, territory, or district thereof relating to prescription  
18 drugs or devices, the offender is guilty of an aggravated  
19 misdemeanor. For a third or subsequent offense or if in the  
20 case of a second offense the offender previously has been  
21 convicted two or more times in the aggregate of any violation  
22 of the laws of the United States or of any state, territory,  
23 or district thereof relating to prescription drugs or devices,  
24 the offender is guilty of a class "D" felony.

25 2. A person who violates any provision of this chapter by  
26 selling, giving away, or administering any prescription drug  
27 or device to a minor is guilty of a class "C" felony.

28 3. A wholesaler who, with intent to defraud or deceive,  
29 fails to deliver to another person, when required by rules of  
30 the board, complete and accurate pedigree concerning a drug  
31 prior to transferring the drug to another person is guilty of  
32 a class "C" felony.

33 4. A wholesaler who, with intent to defraud or deceive,  
34 fails to acquire, when required by rules of the board,  
35 complete and accurate pedigree concerning a drug prior to

1 obtaining the drug from another person is guilty of a class  
2 "C" felony.

3 5. A wholesaler who knowingly destroys, alters, conceals,  
4 or fails to maintain, as required by rules of the board,  
5 complete and accurate pedigree concerning any drug in the  
6 person's possession is guilty of a class "C" felony.

7 6. A wholesaler who is in possession of pedigree documents  
8 required by rules of the board, and who knowingly fails to  
9 authenticate the matters contained in the documents as  
10 required, and who nevertheless distributes or attempts to  
11 further distribute drugs is guilty of a class "C" felony.

12 7. A wholesaler who, with intent to defraud or deceive,  
13 falsely swears or certifies that the person has authenticated  
14 any documents related to the wholesale distribution of drugs  
15 or devices is guilty of a class "C" felony.

16 8. A wholesaler who knowingly forges, counterfeits, or  
17 falsely creates any pedigree, who falsely represents any  
18 factual matter contained in any pedigree, or who knowingly  
19 omits to record material information required to be recorded  
20 in a pedigree is guilty of a class "C" felony.

21 9. A wholesaler who knowingly purchases or receives drugs  
22 or devices from a person not authorized to distribute drugs or  
23 devices in wholesale distribution is guilty of a class "C"  
24 felony.

25 10. A wholesaler who knowingly sells, barter, brokers, or  
26 transfers a drug or device to a person not authorized to  
27 purchase the drug or device under the jurisdiction in which  
28 the person receives the drug or device in a wholesale  
29 distribution is guilty of a class "C" felony.

30 11. A person who knowingly possesses, actually or  
31 constructively, any amount of a contraband drug or device, who  
32 knowingly sells or delivers any amount of a contraband drug or  
33 device, or who possesses with intent to sell or deliver any  
34 amount of a contraband drug or device is guilty of a class "C"  
35 felony.

1 12. A person who knowingly forges, counterfeits, or  
2 falsely creates any label for a drug or device or who falsely  
3 represents any factual matter contained on any label of a drug  
4 or device is guilty of a class "C" felony.

5 13. A person who knowingly manufactures, purchases, sells,  
6 delivers, or brings into the state, or who is knowingly in  
7 actual or constructive possession of any amount of a  
8 contraband drug or device is guilty of a class "C" felony.

9 14. A person who knowingly manufactures, purchases, sells,  
10 delivers, or brings into the state, or who is knowingly in  
11 actual or constructive possession of any amount of a  
12 contraband drug or device, and whose acts result in the death  
13 of a person is guilty of a class "A" felony.

14 15. A person found guilty of any offense under this  
15 section or under chapter 124, division IV, under the authority  
16 of the court convicting and sentencing the person, shall order  
17 that the person forfeit to the state, pursuant to chapter  
18 809A, any real or personal property that meets either of the  
19 following conditions:

20 a. The property was used or intended to be used to commit,  
21 facilitate, or promote the commission of such offense.

22 b. The property constitutes, derives from, or is traceable  
23 to the gross proceeds that the defendant obtained directly or  
24 indirectly as a result of the offense.

25 Any property or assets subject to forfeiture under this  
26 subsection may be seized in the manner prescribed in chapter  
27 809A, and may be held as provided in that chapter. Moneys  
28 ordered forfeited, or proceeds from the sale of other assets  
29 ordered forfeited, shall be equitably divided among the board  
30 and other agencies involved in the investigation and  
31 prosecution that led to the conviction. Other property  
32 ordered forfeited after conviction of a defendant may, at the  
33 discretion of the investigating agencies, be placed into  
34 official use by the board or the agencies involved in the  
35 investigation and prosecution that led to the conviction.

1     16. This section does not prevent a licensed practitioner  
2 of medicine, dentistry, podiatry, nursing, veterinary  
3 medicine, optometry, or pharmacy from acts necessary in the  
4 ethical and legal performance of the practitioner's  
5 profession.

6     Sec. 15. Section 155A.27, subsection 1, Code 2005, is  
7 amended by adding the following new paragraph:

8     NEW PARAGRAPH. g. The indication or reason for  
9 prescribing the drug or device.

10    Sec. 16. NEW SECTION. 155A.40 CRIMINAL HISTORY RECORD  
11 CHECKS.

12    1. The board may request and obtain, notwithstanding  
13 section 692.2, subsection 5, criminal history data for any  
14 applicant for an initial or renewal license or registration  
15 issued pursuant to this chapter or chapter 147, any applicant  
16 for reinstatement of a license or registration issued pursuant  
17 to this chapter or chapter 147, or any licensee or registrant  
18 who is being monitored as a result of a board order or  
19 agreement resolving an administrative disciplinary action, for  
20 the purpose of evaluating the applicant's, licensee's, or  
21 registrant's eligibility for licensure, registration, or  
22 suitability for continued practice of the profession.  
23 Criminal history data may be requested for of all owners,  
24 managers, and principal employees of a pharmacy or drug  
25 wholesaler licensed pursuant to this chapter. The board shall  
26 adopt rules pursuant to chapter 17A to implement this section.  
27 The board shall inform the applicant, licensee, or registrant  
28 of the criminal history requirement and obtain a signed waiver  
29 from the applicant, licensee, or registrant prior to  
30 submitting a criminal history data request.

31    2. A request for criminal history data shall be submitted  
32 to the department of public safety, division of criminal  
33 investigation and bureau of identification, pursuant to  
34 section 692.2, subsection 1. The board may also require such  
35 applicants, licensees, and registrants to provide a full set

1 of fingerprints, in a form and manner prescribed by the board.  
2 Such fingerprints may be submitted to the federal bureau of  
3 investigation through the state criminal history repository  
4 for a national criminal history check. The board may  
5 authorize alternate methods or sources for obtaining criminal  
6 history record information. The board may, in addition to any  
7 other fees, charge and collect such amounts as may be incurred  
8 by the board, the department of public safety, or the federal  
9 bureau of investigation in obtaining criminal history  
10 information. Amounts collected shall be considered repayment  
11 receipts as defined in section 8.2.

12 3. Criminal history information relating to an applicant,  
13 licensee, or registrant obtained by the board pursuant to this  
14 section is confidential. The board may, however, use such  
15 information in a license or registration denial proceeding.  
16 In a disciplinary proceeding, such information shall  
17 constitute investigative information under section 272C.6,  
18 subsection 4, and may be used only for purposes consistent  
19 with that section.

20 Sec. 17. NEW SECTION. 155A.41 CONTINUOUS QUALITY  
21 IMPROVEMENT PROGRAM.

22 1. Each licensed pharmacy shall implement or participate  
23 in a continuous quality improvement program to review pharmacy  
24 procedures in order to identify methods for addressing  
25 pharmacy medication errors and for improving patient use of  
26 medications and patient care services. Under the program,  
27 each pharmacy shall assess its practices and identify areas  
28 for quality improvement.

29 2. The board shall adopt rules for the administration of a  
30 continuous quality improvement program. The rules shall  
31 address all of the following:

- 32 a. Program requirements and procedures.
- 33 b. Program record and reporting requirements.
- 34 c. Any other provisions necessary for the administration  
35 of a program.

1 3. Any record or report generated solely for and  
2 maintained by a pharmacy as a component of the pharmacy's  
3 continuous quality improvement program shall not be subject to  
4 discovery in any civil proceeding. However, this subsection  
5 shall not prohibit the board or other authorized government  
6 agency from reviewing or having access to the record or report  
7 as necessary to protect the public health and safety.

8 EXPLANATION

9 This bill makes several technical and substantive changes  
10 regarding Code chapter 155A relating to the practice of  
11 pharmacy.

12 The bill makes changes to definitions applicable to the  
13 Code chapter. The bill expands the definition of "dispense"  
14 to include the delivery of a device, and makes several other  
15 conforming changes in the Code chapter adding a reference to  
16 "device" where a prescription drug is referred to. The bill  
17 also provides a new definition of "pedigree" to mean a  
18 recording of each distribution of any given drug or device,  
19 from the sale by the manufacturer through acquisition and sale  
20 by any wholesaler, pursuant to rules adopted by the board of  
21 pharmacy examiners. The bill adds "over-the-counter medicine"  
22 as an alternative term to "proprietary medicine" with  
23 reference to a nonnarcotic drug or device that may be sold  
24 without a prescription, and adds two new labeling statements  
25 required under federal law prior to dispensation or delivery.

26 The bill provides that the application form submitted by an  
27 applicant for a pharmacy license shall include information  
28 specified in the statute, and other information that may be  
29 required by the board by rule, and that the board may define  
30 specific types of wholesaler licenses.

31 The bill provides that a drug wholesaler shall report in  
32 writing to the board information relating to the permanent  
33 closing or discontinuation of wholesale distributions into the  
34 state, a change of ownership or location, a change concerning  
35 the individual designated as the wholesaler's responsible

1 individual, a change of name, the theft or significant loss of  
2 any controlled substance on discovery of the theft or loss,  
3 any disasters, accidents, and emergencies that may affect the  
4 strength, purity, or labeling of drugs, medications, devices,  
5 or other materials used in the diagnosis or the treatment of  
6 injury, illness, and disease, and other information or  
7 activities as required by rules of the board.

8 The bill extends prohibitions against the use of the word  
9 "apothecary", "drug", "drug store", or "pharmacy" by  
10 individuals other than licensed pharmacists or wholesalers, to  
11 internet sites, and to any advertising or promotional  
12 literature, communication, or representation.

13 The bill adds a number of new provisions regarding acts  
14 which are unlawful for a person to perform, or cause the  
15 performance of, or aid and abet, and therefore prohibited.  
16 The bill provides that a person shall not engage in forging,  
17 counterfeiting, simulating, or falsely representing any drug  
18 or device without the authority of the manufacturer, or using  
19 any mark, stamp, tag, label, or other identification device  
20 without manufacturer authorization; or engage in  
21 manufacturing, repackaging, selling, delivering, or holding or  
22 offering for sale any drug or device that is adulterated,  
23 misbranded, counterfeit, suspected of being counterfeit, or  
24 that has otherwise been rendered unfit for distribution; or  
25 engage in adulterating, misbranding, or counterfeiting any  
26 drug or device; or receive any drug or device that is  
27 adulterated, misbranded, stolen, obtained by fraud or deceit,  
28 counterfeit, or suspected of being counterfeit; or deliver or  
29 proffer delivery of such drug or device for pay or otherwise.  
30 Further, the bill provides that a person shall not engage in  
31 adulterating, mutilating, destroying, obliterating, or  
32 removing the whole or any part of the labeling of a drug or  
33 device or committing any other act with respect to a drug or  
34 device that results in the drug or device being misbranded; or  
35 engage in purchasing or receiving a drug or device from a

1 person that is not licensed to distribute the drug or device  
2 to that purchaser or recipient; or engage in selling or  
3 transferring a drug or device to a person that is not  
4 authorized under the law of the jurisdiction in which the  
5 person receives the drug or device to purchase or possess it;  
6 or fail to maintain or provide required records.

7 Additional prohibited acts include providing the board or  
8 any of its representatives or any state or federal official  
9 with false or fraudulent records or making false or fraudulent  
10 statements; distributing at wholesale any drug or device that  
11 was purchased by a public or private hospital or other health  
12 care entity, donated or supplied at a reduced price to a  
13 charitable organization, purchased from a person not licensed  
14 to distribute it, or stolen or obtained by fraud or deceit;  
15 failing to obtain a required license or operating without a  
16 valid license; and engaging in misrepresentation or fraud in  
17 the distribution of a drug or device.

18 Finally, prohibited acts also include distributing a drug  
19 or device to a patient without a prescription drug order or  
20 medication order from a practitioner licensed by law to use or  
21 prescribe the drug or device; distributing a drug or device  
22 that was previously dispensed by a pharmacy or distributed by  
23 a practitioner except as provided by rule; and failing to  
24 report any prohibited act.

25 The bill also expands the list of penalties contained in  
26 Code section 155A.24. The bill provides that a wholesaler  
27 shall be guilty of a class "C" felony if the wholesaler, with  
28 intent to defraud or deceive, fails to deliver to another  
29 person, when required by rules of the board, complete and  
30 accurate pedigree concerning a drug prior to transferring the  
31 drug to another person; or with intent to defraud or deceive,  
32 fails to acquire, when required by rules of the board,  
33 complete and accurate pedigree concerning a drug prior to  
34 obtaining the drug from another person; or who knowingly  
35 destroys, alters, conceals, or fails to maintain, as required

1 by rules of the board, complete and accurate pedigree  
2 concerning any drug in the person's possession; or who is in  
3 possession of pedigree documents required by rules of the  
4 board, and who knowingly fails to authenticate the matters  
5 contained in the documents as required, and who nevertheless  
6 distributes or attempts to further distribute drugs; or with  
7 intent to defraud or deceive, falsely swears or certifies that  
8 the person has authenticated any documents related to the  
9 wholesale distribution of drugs or devices. Additionally, the  
10 bill provides that a wholesaler shall be guilty of a class "C"  
11 felony if the wholesaler knowingly forges, counterfeits, or  
12 falsely creates any pedigree, who falsely represents any  
13 factual matter contained in any pedigree, or who knowingly  
14 omits to record material information required to be recorded  
15 in a pedigree; or knowingly purchases or receives drugs or  
16 devices from a person not authorized to distribute drugs or  
17 devices in wholesale distribution; or knowingly sells,  
18 barter, brokers, or transfers a drug or device to a person  
19 not authorized to purchase the drug or device under the  
20 jurisdiction in which the person receives the drug or device  
21 in a wholesale distribution.

22 The bill provides, in addition, that a person who knowingly  
23 possesses, actually or constructively, any amount of a  
24 contraband drug or device, who knowingly sells or delivers any  
25 amount of a contraband drug or device, or who possesses with  
26 intent to sell or deliver any amount of a contraband drug or  
27 device, shall be guilty of a class "C" felony, as is a person  
28 who knowingly forges, counterfeits, or falsely creates any  
29 label for a drug or device or who falsely represents any  
30 factual matter contained in any label of a drug or device, or  
31 who knowingly manufactures, purchases, sells, delivers, or  
32 brings into the state, or who is knowingly in actual or  
33 constructive possession of any amount of a contraband drug or  
34 device. Further, a person who knowingly manufactures,  
35 purchases, sells, delivers, or brings into the state, or who

1 is knowingly in actual or constructive possession of any  
2 amount of a contraband drug or device, and whose acts result  
3 in the death of a person, shall be guilty of a class "A"  
4 felony.

5 The bill provides for the forfeiture to and seizure by the  
6 state of any real or personal property of a person found  
7 guilty.

8 The bill authorizes the board to request criminal history  
9 data for applicants, licensees, and registrants under Code  
10 chapter 147 or 155A, for the purpose of evaluating the  
11 person's eligibility for the license or registration or to  
12 evaluate the person's suitability for the practice of the  
13 profession.

14 The bill requires each licensed pharmacy to implement a  
15 continuous quality improvement program to review pharmacy  
16 procedures in order to identify methods for addressing  
17 pharmacy medication errors and for improving patient use of  
18 medications and patient care services. The bill provides that  
19 the board shall adopt rules for the administration of the  
20 program.

21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35

# IOWA BOARD OF PHARMACY EXAMINERS

400 S.W. Eighth Street, Suite E

Des Moines, IA 50309-4688

515/281-5944 Voice

Website: [www.state.ia.us/ibpe](http://www.state.ia.us/ibpe)

515/281-4609 Fax

---

## M E M O R A N D U M

**DATE:** November 29, 2004

**TO:** Members of the 80<sup>th</sup> Iowa General Assembly

**FROM:** Lloyd K. Jessen  
Executive Secretary/Director

**SUBJECT:** Requested Legislative Amendment – Revise Iowa Code Chapter 155A

The Board of Pharmacy respectfully requests that the proposed amendments be made to Iowa Code chapter 155A.

This bill amends various sections of the Iowa Pharmacy Practice Act to raise standards for the retailing and wholesaling of pharmaceuticals. It also provides for the establishment of different types of licenses for drug wholesalers, with compliance standards and requirements unique to each type of wholesale distributor. These amendments are being proposed in response to the growing problem of counterfeit drugs in the marketplace and to the specialization and compartmentalization of wholesale drug distribution operations. It is also being proposed because many out-of-state wholesalers that ship pharmaceuticals into Iowa are not being inspected by their home state licensing authority. Although licensed to do business in Iowa, these firms cannot demonstrate, with evidence provided by a regulatory agency, that they are complying with the minimum standards for drug wholesale operations.

The bill provides that wholesalers and pharmacies shall report certain events to the board. It identifies certain prohibited activities and actions. Criminal penalties for violation of laws regarding the packaging, distribution, and marketing of prescription drugs and devices are established.

The bill authorizes the board of pharmacy to request and obtain a criminal history record check for all applicants, licensees, and registrants, for the purpose of evaluating the person's eligibility for licensure or registration or for evaluating the person's suitability to engage in the regulated practice. This is consistent with actions recently taken by the other professional licensing boards in Iowa, including the board of educational examiners, the board of medical examiners, and the board of dental examiners.

The bill also provides that every licensed pharmacy shall implement a continuous quality improvement program to evaluate pharmacy processes and procedures to identify system improvements, to reduce errors, and to enhance patient safety. The intent of the continuous quality improvement program is for pharmacies and pharmacists to evaluate and improve pharmacy systems and should not create evidence that could potentially increase their civil liability. Implementation of a valid and effective continuous quality improvement program must also protect the pharmacy and pharmacy staff from civil liability. The bill protects information

**BOARD OF PHARMACY EXAMINERS**

**MEMORANDUM**

November 29, 2004

Page 2

maintained in a continuous quality improvement program from discovery for purposes of civil litigation. An effective continuous quality improvement program will also function as an education and information tool, ensuring that pharmacy staff members are aware of laws and law changes affecting their practice and are familiar with the pharmacy's operational policies and procedures. The bill provides that the board of pharmacy shall adopt rules for administration of the program.

Representatives from various drug wholesalers, manufacturers, and distributors, associations, chain pharmacies, pharmacists, and other interested parties participated in the drafting and development of these proposed amendments to the Iowa Pharmacy Practice Act.