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

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

HF 833

TLSB 1292HZ 81
rn/pj/5

S.F. _____ H.F. 833

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

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

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

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

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

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

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

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

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

(4) Rx only.

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

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

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

38. "Wholesaler" means a person operating or maintaining, either within or outside this state, a manufacturing plant, wholesale distribution center, wholesale business, or any other business in which prescription drugs or devices, medicinal chemicals, medicines, or poisons are sold, manufactured, compounded, dispensed, stocked, exposed, distributed from, or offered for sale at wholesale in this state. "Wholesaler" does not include those wholesalers who sell only proprietary or over-the-counter medicines. "Wholesaler" also does not include a commercial carrier that temporarily stores prescription drugs or devices, medicinal chemicals, medicines, or poisons while in transit.

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

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

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

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

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

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

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

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

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

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

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

b. Change of ownership.

c. Change of location.

d. Change of the wholesaler's responsible individual.

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

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

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

h. Other information or activities as required by rule.

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

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

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

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

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

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

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

155A.23 PROHIBITED ACTS.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

19. Failing to report any prohibited act.

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

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

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

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

155A.24 PENALTIES.

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

a. If the prescription drug is a controlled substance, the person shall be punished pursuant to ~~section 124.401, subsection 1, and section 124.411~~ chapter 124, division IV.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

indirectly as a result of the offense.

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

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

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

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

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

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

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

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

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

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

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

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

a. Program requirements and procedures.

b. Program record and reporting requirements.

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

EXPLANATION

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

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

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

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

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

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

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

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

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

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

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

devices from a person not authorized to distribute drugs or devices in wholesale distribution; or knowingly sells, barters, brokers, or transfers a drug or device to a person not authorized to purchase the drug or device under the jurisdiction in which the person receives the drug or device in a wholesale distribution.

The bill provides, in addition, that a person who knowingly possesses, actually or constructively, any amount of a counterfeit, misbranded, or adulterated drug or device and who knowingly sells or delivers any amount of the counterfeit, misbranded, or adulterated drug or device or who possesses with intent to sell or deliver any amount of a counterfeit, misbranded, or adulterated drug or device, shall be guilty of a class "C" felony, as is a person who knowingly forges, counterfeits, or falsely creates any label for a drug or device or who falsely represents any factual matter contained in any label of a drug or device. The bill provides that a person who knowingly possesses, actually or constructively, any amount of a counterfeit, misbranded, or adulterated drug or device and who knowingly manufactures, purchases, sells, delivers, or brings into the state any amount of the counterfeit, misbranded, or adulterated drug or device, is guilty of a class "D" felony. Further, a person who knowingly manufactures, purchases, sells, delivers, or brings into the state, or who is knowingly in actual or constructive possession of any amount of a counterfeit, misbranded, or adulterated drug or device, and whose acts result in the death of a person, shall be guilty of a class "A" felony.

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

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

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

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

HOUSE FILE 833

H-1404

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

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

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

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

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

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

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

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

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

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

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

"___. Page 10, by inserting after line 17 the following:

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

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

Amend House File 833 as follows:

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

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

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

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

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

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

COMMITTEE ON JUDICIARY
PAULSEN of Linn, CHAIRPERSON

H-1382 FILED APRIL 14, 2005

H-1428

Amend House File 833 as follows:

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

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

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

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

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

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

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

a. Pharmacy identification.

b. Patient identification.

c. Prescriber identification.

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

e. The date the prescription was dispensed.

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

g. Identification of the drug dispensed.

h. Quantity of the drug dispensed.

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

j. Serial or prescription number assigned by the pharmacy.

k. Source of payment for the prescription.

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

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

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

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

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

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

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

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

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

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

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

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

2. The board or its designee shall maintain a

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

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

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

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

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

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

criminal, or administrative, which might otherwise be incurred or imposed as a result of the report.

6. Nothing in this section shall require a pharmacist or prescriber to obtain information about a patient from the database. A pharmacist or prescriber does not have a duty and shall not be held liable in damages to any person in any civil or derivative criminal or administrative action for injury, death, or loss to person or property on the basis that the pharmacist or prescriber did or did not seek or obtain information from the database. A pharmacist or prescriber acting in good faith is immune from any civil, criminal, or administrative liability that might otherwise be incurred or imposed for requesting or receiving information from the database.

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

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

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

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

1. The board shall adopt rules in accordance with

chapter 17A to carry out the purposes of, and to enforce the provisions of, this division. The rules shall include but not be limited to the development of procedures relating to:

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

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

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

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

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

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

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

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

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

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

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

l. The correction or deletion of erroneous information from the database.

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

following:

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

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

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

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

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

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

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

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

3. Among other things, the council shall:

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

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

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

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

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

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

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

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

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

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

5. A person authorized to access or receive

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

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

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

"Sec. ___. EFFECTIVE DATE. The sections of this Act relating to and establishing an electronic drug database, being deemed of immediate importance, take effect upon enactment."

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

4. By renumbering as necessary.

By UPMEYER of Hancock
SMITH of Marshall

H-1428 FILED APRIL 20, 2005
WITHDRAWN

H-1430

Amend House File 833 as follows:

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

"Sec. ___. NEW SECTION. 155B.1 DEFINITIONS.

As used in this chapter unless the context otherwise requires:

1. "Commissioner" means the commissioner of insurance.

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

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

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

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

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

a. Mail service pharmacy.

b. Claims processing, retail network management,

or payment of claims to pharmacies for prescription drugs dispensed to covered individuals.

c. Clinical formulary development and management services.

d. Rebate contracting and administration.

e. Certain patient compliance, therapeutic intervention, or generic substitution programs.

f. Disease management programs involving prescription drug utilization.

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

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

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

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

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

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

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

Sec. ___. NEW SECTION. 155B.2 PHARMACY BENEFITS MANAGER -- LICENSE.

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

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

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

a. Definition of terms.

b. Use of prescribed forms.

c. Reporting requirements.

d. Enforcement procedures.

e. Protection of proprietary information and trade secrets.

Sec. ___. NEW SECTION. 155B.3 MANAGER TO PERFORM DUTIES IN GOOD FAITH.

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

Sec. ___. NEW SECTION. 155B.4 DISCLOSURE OF REVENUES RECEIVED FROM PHARMACEUTICAL MANUFACTURER OR LABELER UNDER CONTRACT WITH MANAGER -- CONTENT -- FEES.

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

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

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

c. Any prescription drug utilization information

requested by the covered entity relating to covered individuals.

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

Sec. ___. NEW SECTION. 155B.5 PERMISSION OF ENTITY REQUIRED TO CONTACT COVERED INDIVIDUAL -- EXCEPTION.

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

Sec. ___. NEW SECTION. 155B.6 CONFIDENTIALITY OF INFORMATION -- INJUNCTION -- DAMAGES.

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

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

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

Sec. ___. NEW SECTION. 155B.7 AUDITS OF MANAGER'S RECORDS.

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

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

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

2. The covered entity may select an independent firm to conduct the audit, and the independent firm shall sign a confidentiality agreement with the covered entity and the pharmacy benefits manager ensuring that all information obtained during the audit will be treated as confidential. The firm may not use, disclose, or otherwise reveal any such information in any manner or form to any person or entity except as otherwise permitted under the confidentiality agreement. The covered entity shall treat all information obtained as a result of the audit as confidential, and may not use or disclose such information except as may be otherwise permitted under the terms of the contract between the covered entity and the pharmacy benefits manager or if ordered by a court of competent jurisdiction for good cause shown.

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

Sec. ___. NEW SECTION. 155B.8 DISPENSING OF SUBSTITUTE PRESCRIPTION DRUG FOR PRESCRIBED DRUG.

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

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

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

2. If a substitution is being requested pursuant

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

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

Sec. ___. NEW SECTION. 155B.9 CIVIL ACTION -- ENFORCEMENT OF CHAPTER -- DAMAGES.

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

Sec. ___. NEW SECTION. 155B.10 APPLICATION OF CHAPTER TO CERTAIN CONTRACTS.

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

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

By BELL of Jasper

H-1430 FILED APRIL 20, 2005
WITHDRAWN

H-1432

Amend House File 833 as follows:

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

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

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

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

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

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

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

a. Pharmacy identification.

b. Patient identification.

c. Prescriber identification.

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

e. The date the prescription was dispensed.

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

g. Identification of the drug dispensed.

h. Quantity of the drug dispensed.

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

j. Serial or prescription number assigned by the pharmacy.

k. Source of payment for the prescription.

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

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

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

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

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

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

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

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

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

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

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

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

2. The board or its designee shall maintain a

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

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

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

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

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

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

division is immune from any liability, civil, criminal, or administrative, which might otherwise be incurred or imposed as a result of the report.

6. Nothing in this section shall require a pharmacist or prescriber to obtain information about a patient from the database. A pharmacist or prescriber does not have a duty and shall not be held liable in damages to any person in any civil or derivative criminal or administrative action for injury, death, or loss to person or property on the basis that the pharmacist or prescriber did or did not seek or obtain information from the database. A pharmacist or prescriber acting in good faith is immune from any civil, criminal, or administrative liability that might otherwise be incurred or imposed for requesting or receiving information from the database.

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

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

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

Sec. 6. NEW SECTION. 124.510E RULES AND

REPORTING.

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

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

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

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

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

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

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

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

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

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

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

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

l. The correction or deletion of erroneous information from the database.

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

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

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

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

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

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

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

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

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

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

3. Among other things, the council shall:

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

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

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

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

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

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

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

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

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

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

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

felony.

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

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

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

"Sec. ___. EFFECTIVE DATE. The sections of this Act relating to and establishing an electronic drug database, being deemed of immediate importance, take effect upon enactment."

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

4. By renumbering as necessary.

By UPMEYER of Hancock
SMITH of Marshall

H-1432 FILED APRIL 20, 2005
ADOPTED

HOUSE FILE 833

H-1435

Amend House File 833 as follows:

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

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

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

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

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

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

House Amendments _____ ⊏⊐
Deleted Language *

S.F. _____ H.F. 833

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

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

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

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

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

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

a. Pharmacy identification.

b. Patient identification.

c. Prescriber identification.

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

e. The date the prescription was dispensed.

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

g. Identification of the drug dispensed.

h. Quantity of the drug dispensed.

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

j. Serial or prescription number assigned by the pharmacy.

k. Source of payment for the prescription.

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

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

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

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

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

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

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

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

b. A federal, state, county, township, or municipal officer of this or any other state, or the United States,

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

provisions of, this division. The rules shall include but not be limited to the development of procedures relating to:

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

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

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

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

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

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

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

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

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

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

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

private vendor.

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

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

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

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

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

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

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

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

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

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

in this state.

3. Among other things, the council shall:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(4) Rx only.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

b. Change of ownership.

c. Change of location.

d. Change of the wholesaler's responsible individual.

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

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

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

h. Other information or activities as required by rule.

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

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

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

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

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

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

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

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

155A.23 PROHIBITED ACTS.

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

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

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

subterfuge.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

19. Failing to report any prohibited act.

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

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

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

155A.24 PENALTIES.

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

a. If the prescription drug is a controlled substance, the person shall be punished pursuant to ~~section 124.401, subsection 1, and section 124.411~~ chapter 124, division IV.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1. Each licensed pharmacy shall implement or participate

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

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

a. Program requirements and procedures.

b. Program record and reporting requirements.

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

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

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

Amend House File 833, as amended, passed, and reprinted by the House, as follows:

1. Page 10, by inserting after line 6 the following:

"Sec. ___. Section 155A.3, Code 2005, is amended by adding the following new subsection:

NEW SUBSECTION. 22A. "Logistics provider" means an entity that provides or coordinates warehousing, distribution, or other services on behalf of a manufacturer or other owner of a drug, but does not take title to the drug or have general responsibility to direct its sale or other disposition."

2. Page 11, line 7, by inserting after the word "carrier" the following: "or logistics provider".

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

Amend the amendment, S-3190, to House File 833, as amended, passed, and reprinted by the House, as follows:

1. Page 1, by striking lines 13 and 14, and inserting the following:

"___. Page 12, line 6, by inserting after the word "centers," the following: "logistics providers,"."

By CHARLES W. LARSON, JR.
MATT McCOY

S-3191 FILED APRIL 27, 2005

HOUSE FILE 833

S-3215

Amend House File 833, as amended, passed, and reprinted by the House, as follows:

1. Page 4, line 24, by inserting after the word "database" the following: "reasonably and".

2. Page 5, line 1, by inserting after the word "acting" the following: "reasonably and".

By CHARLES W. LARSON, JR.

S-3215 FILED APRIL 29, 2005

HSB 227
HUMAN RESOURCES

Hutter
Tomenga
Smith

Suc
S 0833

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

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

TLSB 1292DP 81
rn/pj/5

S.F. _____ H.F. _____

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

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

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

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

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

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

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

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

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

(4) Rx only.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

b. Change of ownership.

c. Change of location.

d. Change of the wholesaler's responsible individual.

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

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

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

h. Other information or activities as required by rule.

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

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

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

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

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

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

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

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

155A.23 PROHIBITED ACTS.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

19. Failing to report any prohibited act.

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

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

follows:

155A.24 PENALTIES.

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

a. If the prescription drug is a controlled substance, the person shall be punished pursuant to ~~section 124.401, subsection 1, and section 124.411~~ chapter 124, division IV.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

a. Program requirements and procedures.

b. Program record and reporting requirements.

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

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

EXPLANATION

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

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

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

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

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

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

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

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

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

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

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

by rules of the board, complete and accurate pedigree concerning any drug in the person's possession; or who is in possession of pedigree documents required by rules of the board, and who knowingly fails to authenticate the matters contained in the documents as required, and who nevertheless distributes or attempts to further distribute drugs; or with intent to defraud or deceive, falsely swears or certifies that the person has authenticated any documents related to the wholesale distribution of drugs or devices. Additionally, the bill provides that a wholesaler shall be guilty of a class "C" felony if the wholesaler knowingly forges, counterfeits, or falsely creates any pedigree, who falsely represents any factual matter contained in any pedigree, or who knowingly omits to record material information required to be recorded in a pedigree; or knowingly purchases or receives drugs or devices from a person not authorized to distribute drugs or devices in wholesale distribution; or knowingly sells, barters, brokers, or transfers a drug or device to a person not authorized to purchase the drug or device under the jurisdiction in which the person receives the drug or device in a wholesale distribution.

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

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

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

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

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

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** **515/281-4609 Fax**

M E M O R A N D U M

DATE: November 29, 2004

TO: Members of the 80th 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

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.