

MAR 15 2005
WAYS AND MEANS

HOUSE FILE 790
BY COMMITTEE ON HUMAN RESOURCES

(SUCCESSOR TO HSB 227)

Passed House, Date _____ Passed Senate, Date _____
Vote: Ayes _____ Nays _____ Vote: Ayes _____ Nays _____
Approved _____

A BILL FOR

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

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HF 790

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

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

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

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

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

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

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

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

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

27 (4) Rx only.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

8 b. Change of ownership.

9 c. Change of location.

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

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

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

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

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

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

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

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

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

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

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

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

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

16 155A.23 PROHIBITED ACTS.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

30 19. Failing to report any prohibited act.

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

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

1 follows:

2 155A.24 PENALTIES.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

27 2. A request for criminal history data shall be submitted
28 to the department of public safety, division of criminal
29 investigation and bureau of identification, pursuant to
30 section 692.2, subsection 1. The board may also require such
31 applicants, licensees, and registrants to provide a full set
32 of fingerprints, in a form and manner prescribed by the board.
33 Such fingerprints may be submitted to the federal bureau of
34 investigation through the state criminal history repository
35 for a national criminal history check. The board may

1 authorize alternate methods or sources for obtaining criminal
2 history record information. The board may, in addition to any
3 other fees, charge and collect such amounts as may be incurred
4 by the board, the department of public safety, or the federal
5 bureau of investigation in obtaining criminal history
6 information. Amounts collected shall be considered repayment
7 receipts as defined in section 8.2.

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

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

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

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

- 28 a. Program requirements and procedures.
- 29 b. Program record and reporting requirements.
- 30 c. Any other provisions necessary for the administration
31 of a program.

32 3. Any record or report generated solely for and
33 maintained by a pharmacy as a component of the pharmacy's
34 continuous quality improvement program shall not be subject to
35 discovery in any civil proceeding. However, this subsection

1 shall not prohibit the board or other authorized government
2 agency from reviewing or having access to the record or report
3 as necessary to protect the public health and safety.

4

EXPLANATION

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

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

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

27 The bill provides that a drug wholesaler shall report in
28 writing to the board information relating to the permanent
29 closing or discontinuation of wholesale distributions into the
30 state, a change of ownership or location, a change concerning
31 the individual designated as the wholesaler's responsible
32 individual, a change of name, the theft or significant loss of
33 any controlled substance on discovery of the theft or loss,
34 any disasters, accidents, and emergencies that may affect the
35 strength, purity, or labeling of drugs, medications, devices,

1 or other materials used in the diagnosis or the treatment of
2 injury, illness, and disease, and other information or
3 activities as required by rules of the board.

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

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

1 person receives the drug or device to purchase or possess it;
2 or fail to maintain or provide required records.

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

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

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

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

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

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

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

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

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SF **0190**

**HSB 227
HUMAN RESOURCES**

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

Passed Senate, Date _____ Passed House, Date _____
Vote: Ayes _____ Nays _____ Vote: Ayes _____ Nays _____
Approved _____

A BILL FOR

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2 establishing and appropriating fees, and providing penalties.
3 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

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

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

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

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

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

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

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

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

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

27 (4) Rx only.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

8 b. Change of ownership.

9 c. Change of location.

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

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

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

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

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

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

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

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

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

34 -- PENALTY.

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

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

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

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

16 155A.23 PROHIBITED ACTS.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

30 19. Failing to report any prohibited act.

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

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

1 follows:

2 155A.24 PENALTIES.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

12 1. The board may request and obtain, notwithstanding
13 section 692.2, subsection 5, criminal history data for any
14 applicant for an initial or renewal license or registration
15 issued pursuant to this chapter or chapter 147, any applicant
16 for reinstatement of a license or registration issued pursuant
17 to this chapter or chapter 147, or any licensee or registrant
18 who is being monitored as a result of a board order or
19 agreement resolving an administrative disciplinary action, for
20 the purpose of evaluating the applicant's, licensee's, or
21 registrant's eligibility for licensure, registration, or
22 suitability for continued practice of the profession.

23 Criminal history data may be requested for of all owners,
24 managers, and principal employees of a pharmacy or drug
25 wholesaler licensed pursuant to this chapter. The board shall
26 adopt rules pursuant to chapter 17A to implement this section.
27 The board shall inform the applicant, licensee, or registrant
28 of the criminal history requirement and obtain a signed waiver
29 from the applicant, licensee, or registrant prior to
30 submitting a criminal history data request.

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

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

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

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

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

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

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

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

8 EXPLANATION

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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IOWA BOARD OF PHARMACY EXAMINERS

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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

BOARD OF PHARMACY EXAMINERS

MEMORANDUM

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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.