House File 833 - Reprinted

HOUSE FILE _____
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, 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:
HF 833
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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.

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.

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