Sixtieth
Legislative Assembly
of North Dakota

HOUSE BILL NO. 1455

Introduced by

Representatives Thoreson, Koppelman, Price

Senators Dever, J. Lee, Warner

A BILL for an Act to create and enact chapter 43-15.3 of the North Dakota Century Code, relating to the pedigree for wholesale drugs; and to amend and reenact section 12-60-24 of the North Dakota Century Code, relating to criminal history record checks.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. AMENDMENT. Section 12-60-24 of the North Dakota Century Code is amended and reenacted as follows:

12-60-24. Criminal history record checks.

1. a. ~~The agencies and entities named in subsection 2 shall require each~~ Each applicant, employee, or petitioner for adoption ~~to~~ who is subject to a criminal history record check under subsection 2 shall consent to a statewide and nationwide criminal history record check for the purpose of determining suitability or fitness for a permit, license, employment, or adoption.

   b. Each applicant, employee, or petitioner for adoption subject to a criminal history check shall provide to the requesting agency or entity written consent to conduct the check, two sets of fingerprints from a law enforcement agency or other local agency authorized to take fingerprints, any other identifying information requested, and a statement indicating whether the applicant or employee has ever been convicted of a crime.

   c. The agency or entity shall submit these fingerprints to the bureau of criminal investigation for nationwide criminal history record information that includes resubmission of the fingerprints by the bureau of criminal investigation to the federal bureau of investigation. Except if otherwise provided by law, federal bureau of investigation criminal history record information obtained by an agency or entity is confidential. For a request for nationwide criminal history

record information made under this section, the bureau of criminal investigation is the sole source to receive the fingerprint submissions and responses from the federal bureau of investigation. A person who takes fingerprints under this section may charge a reasonable fee to offset the cost of fingerprinting. Unless otherwise provided by law, the bureau of criminal investigation may charge appropriate fees for criminal history information.

2. The bureau of criminal investigation shall provide to each agency or entity listed in this subsection who has requested a statewide and nationwide criminal history record check, the response of the federal bureau of investigation and any statewide criminal history record information that may lawfully be made available under this chapter:

   a. The governing body of a city or a county, by ordinance or resolution, for each applicant for a specified occupation with the city or county.

   b. The agriculture commissioner for each applicant for a license to grow industrial hemp under section 4-41-02.

   c. The education standards and practices board for initial and reciprocal teacher licenses under sections 15.1-13-14 and 15.1-13-20 and school guidance and counseling services under section 15.1-13-23.

   d. The medical examiners board for licenses or disciplinary investigations under section 43-17-07.1, except that criminal history record checks need not be made unless required by the board.

   e. The private investigative and security board for licenses or registrations under section 43-30-06.

   f. The <u>department of</u> human services ~~department~~ for foster care licenses under section 50-11-06.8, appointments of legal guardians under section 50-11.3-01, and petitions for adoptions under section 50-12-03.2, except that the criminal history record investigation must be conducted in accordance with those sections.

   g. The <u>department of</u> human services ~~department~~ for carecheck registrations under section 50-11.1-06.2.

h. The chief information officer of the information technology department for certain employees under section 54-59-20.

i. A public peace officer training school that has been approved by the peace officer standards and training board for enrollees in the school. The school may only disclose the criminal history record information as authorized by law. The school shall pay the costs for securing the fingerprints, any criminal history record information made available under this chapter, and for the nationwide criminal history background check. This subdivision does not apply to the highway patrol law enforcement training center and enrollees who have a limited license under section 12-63-09.

j. The North Dakota public employees retirement board for individuals first employed by the public employees retirement board after July 31, 2005, who have unescorted physical access to the office or any security-sensitive area of the office as designated by the executive director.

k. The executive director of the retirement and investment office for individuals first employed by the retirement and investment office after July 31, 2005, who have unescorted physical access to the office or any security-sensitive area of the office as designated by the executive director.

l. The Bank of North Dakota for each applicant for a specified occupation with the Bank as designated by the president.

m. Job service North Dakota for each applicant for a specified occupation with job service as designated by the executive director.

n. The state department of health for employees assigned duties related to bioterrorism and homeland security issues as designated by the state health officer; a nurse aide seeking to have a finding of neglect removed from the nurse aide registry; or an individual being investigated by the state department of health who holds a license, certificate, or registration in a health-related field.

<u>o. The state board of pharmacy for a wholesale drug distributor seeking licensure under chapter 43-15.3.</u>

SECTION 2. Chapter 43-15.3 of the North Dakota Century Code is created and enacted as follows:

43-15.3-01. Definitions. As used in this chapter, unless the context otherwise requires:

1. "Authentication" means to affirmatively verify before any wholesale distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred.
2. "Authorized distributor of record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug. An ongoing relationship is deemed to exist between the wholesale distributor and a manufacturer when the wholesale distributor, including any affiliated group of the wholesale distributor as defined in section 1504 of the Internal Revenue Code [26 U.S.C. 1504], complies with any one of the following:
   a. The wholesale distributor has a written agreement currently in effect with the manufacturer evidencing the ongoing relationship; or
   b. The wholesale distributor is listed on the manufacturer's current list of authorized distributors of record, which is updated by the manufacturer on no less than a monthly basis.
3. "Board" means the state board of pharmacy.
4. "Chain pharmacy warehouse" means a physical location for prescription drugs which acts as a central warehouse and performs intracompany sales or transfers of the drugs to a group of chain pharmacies that have the same common ownership and control.
5. "Colicensed product" means a prescription drug in which two or more parties have the right to engage in the manufacturing or marketing or in the manufacturing and marketing of the drug.
6. "Drop shipment" means the sale of a prescription drug to a wholesale distributor by the manufacturer of the prescription drug, or that manufacturer's colicensed product partner, that manufacturer's third-party logistics provider, or that manufacturer's exclusive distributor, under the terms of which the wholesale distributor or chain pharmacy warehouse takes title but not physical possession of

the prescription drug and the wholesale distributor invoices the pharmacy or chain pharmacy warehouse, or other person authorized by law to dispense or administer the drug to a patient, and the pharmacy or chain pharmacy warehouse or other authorized person receives delivery of the prescription drug directly from the manufacturer, or that manufacturer's third-party logistics provider, or that manufacturer's exclusive distributor.

7. "Facility" means a facility of a wholesale distributor where prescription drugs are store, handled, repackaged, or offered for sale.

8. "Manufacturer" means a person licensed or approved by the federal food and drug administration to engage in the manufacture of drugs or devices.

9. "Manufacturer's exclusive distributor" means any person that contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer and which takes title to that manufacturer's prescription drug, but which does not have general responsibility to direct the sale or disposition of the manufacturer's prescription drug. The manufacturer's exclusive distributor must be licensed as a wholesale distributor under this chapter, and to be considered part of the normal distribution channel also must be an authorized distributor of record.

10. "Normal distribution channel" means a chain of custody for a prescription drug which goes from a manufacturer of the prescription drug, from that manufacturer to that manufacturer's colicensed partner, from that manufacturer to that manufacturer's third-party logistics provider, or from that manufacturer to that manufacturer's exclusive distributor to:

a. A pharmacy, to a patient or other designated person authorized by law to dispense or administer the drug to a patient;

b. A wholesale distributor, to a pharmacy, to a patient or other designated person authorized by law to dispense or administer the drug to a patient;

c. A wholesale distributor, to a chain pharmacy warehouse, to that chain pharmacy warehouse's intracompany pharmacy, to a patient or other designated person authorized by law to dispense or administer the drug to a patient; or

d. A chain pharmacy warehouse, to the chain pharmacy warehouse's intracompany pharmacy, to a patient or other designated person authorized by law to dispense or administer the drug to a patient.

11. "Pedigree" means a document or an electronic file containing information that records each distribution of any given prescription drug.

12. "Prescription drug" means any drug, including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices, required by federal law, including federal regulation, to be dispensed only by a prescription, including finished dosage forms and bulk drug substances subject to section 503(b) of the federal Food, Drug and Cosmetic Act [21 U.S.C. 3539(b)].

13. "Repackage" means repackaging or otherwise changing the container, wrapper, or labeling to further the distribution of a prescription drug, excluding actions completed by the pharmacists responsible for dispensing product to the patient.

14. "Repackager" means an individual who repackages.

15. "Third-party logistics provider" means anyone who contracts with a prescription drug manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer, but does not take title to the prescription drug or have general responsibility to direct the prescription drug's sale or disposition. The third-party logistics provider must be licensed as a wholesale distributor under this chapter and to be considered part of the normal distribution channel must also be an authorized distributor of record.

16. "Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient. The term does not include:

a. Intracompany sales of prescription drugs, meaning any transaction or transfer between any division, subsidiary, parent or affiliated or related company under common ownership and control of a corporate entity, or any transaction or transfer between colicensees of a colicensed product.

b. The sale, purchase, distribution, trade, or transfer of a prescription drug or offer to sell, purchase, distribute, trade, or transfer a prescription drug for emergency medical reasons.

c. The distribution of prescription drug samples by manufacturers' representatives.

d. Drug returns, when conducted by a hospital, health care entity, or charitable institution in accordance with title 21, Code of Federal Regulations, section 203.23.

e. The sale of minimal quantities of prescription drugs by retail pharmacies to licensed practitioners for office use.

f. The sale, purchase, or trade of a drug; an offer to sell, purchase, or trade a drug; or the dispensing of a drug pursuant to a prescription.

g. The sale, transfer, merger, or consolidation of all or part of the business of a pharmacy from or with another pharmacy, whether accomplished as a purchase and sale of stock or business assets.

h. The sale, purchase, distribution, trade, or transfer of a prescription drug from one authorized distributor of record to one additional authorized distributor of record when the manufacturer has stated in writing to the receiving authorized distributor of record that the manufacturer is unable to supply such prescription drug and the supplying authorized distributor of record states in writing that the prescription drug being supplied had until that time been exclusively in the normal distribution channel.

i. The delivery of, or offer to deliver, a prescription drug by a common carrier solely in the common carrier's usual course of business of transporting prescription drugs, and the common carrier does not store, warehouse, or take legal ownership of the prescription drug.

j. The sale or transfer from a retail pharmacy or chain pharmacy warehouse of expired, damaged, returned, or recalled prescription drugs to the original manufacturer or to a third-party returns processor.

17. "Wholesale distributor" means anyone engaged in the wholesale distribution of prescription drugs, including, manufacturers; repackagers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses; manufacturer's exclusive distributors; authorized distributors of record; drug wholesalers or distributors; independent wholesale drug

traders; specialty wholesale distributors; third-party logistics providers; retail pharmacies that conduct wholesale distribution; and chain pharmacy warehouses that conduct wholesale distribution. To be considered part of the normal distribution channel such wholesale distributor must also be an authorized distributor of record.

43-15.3-02. Rulemaking authority. The board shall adopt rules that conform with wholesale drug distributor licensing guidelines adopted by the federal food and drug administration, including rules necessary to carry out the purposes of this chapter, that incorporate and set detailed standards for meeting each of the license prerequisites set forth in this chapter, and that establish reasonable fees to carry out this chapter.

43-15.3-03. Wholesale drug distributor licensing requirement - Minimum requirements for licensure.

1. A wholesale distributor that engages in the wholesale distribution of prescription drugs must be licensed by the board under this chapter and must be properly licensed in any other state in which the wholesale distributor engages in the distribution of prescription drugs before engaging in wholesale distributions of wholesale prescription drugs in this state. The board shall exempt manufacturers distributing their own federal food and drug administration-approved drugs and devices from any licensing and other requirements of this section, to the extent not required by federal law or regulation, unless particular requirements are deemed necessary and appropriate following rulemaking.
2. The board shall require the following minimum information from each wholesale distributor applying to get a license under subsection 1:
   a. The name, full business address, and telephone number of the licensee.
   b. All trade or business names used by the licensee.
   c. Addresses, telephone numbers, and the names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of prescription drugs.
   d. The type of ownership or operation.
   e. The name of every owner and operator of the licensee, including:
      (1) If an individual, the name of the individual;

(2) If a partnership, the name of each partner, and the name of the partnership;

(3) If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation; and

(4) If a sole proprietorship, the full name of the sole proprietor and the name of the business entity.

f. A list of all licenses and permits issued to the applicant by any other state that authorizes the applicant to purchase or possess prescription drugs.

g. The name of the applicant's designated representative for the facility, together with the personal information statement and fingerprints, required pursuant to subdivision h for the individual.

h. Each individual required by subdivision g to provide a personal information statement and fingerprints shall provide the following information to the state:

(1) The individual's places of residence for the past seven years;

(2) The individual's date and place of birth;

(3) The individual's occupations, positions of employment, and offices held during the past seven years;

(4) The principal business and address of any business, corporation, or other organization in which each office of the individual was held or in which each occupation or position of employment was carried on;

(5) Whether the individual has been, during the past seven years, the subject of any proceeding for the revocation of any license or any criminal violation and, if so, the nature of the proceeding and the disposition of the proceeding;

(6) Whether, during the past seven years, the individual has been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating any federal or state law regulating the possession, control, or distribution of prescription drugs or criminal violations, together with details concerning any of those events;

(7) A description of any involvement by the individual with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund, during the past seven years, which manufactured, administered, prescribed, distributed, or stored pharmaceutical products and any lawsuits in which the businesses were names as a party;

(8) A description of any misdemeanor or felony criminal offense of which the individual, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the individual pled guilty or nolo contendere. If the individual indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of that criminal offense, the applicant must, within fifteen days after the disposition of the appeal, submit to the state a copy of the final written order of disposition; and

(9) A photograph of the individual taken in the previous thirty days.

3. The information required under subsection 2 must be provided under oath.

4. The board may not issue a wholesale distributor license to an applicant, unless the board:

a. Conducts a physical inspection of the facility at the address provided by the applicant as required under subdivision a of subsection 2; and

b. Determines that the designated representative meets the following qualifications:

(1) Is at least twenty-one years of age;

(2) Has been employed full time for at least three years in a pharmacy or with a wholesale distributor in a capacity related to the dispensing and distribution of, and recordkeeping relating to, prescription drugs;

(3) Is employed by the applicant full time in a managerial level position;

(4) Is actively involved in and aware of the actual daily operation of the wholesale distributor;

(5) Is physically present at the facility of the applicant during regular business hours, except when the absence of the designated representative is authorized, including sick leave and vacation leave;

(6) Is serving in the capacity of a designated representative for only one applicant at a time, except where more than one licensed wholesale distributor is colocated in the same facility and the wholesale distributors are members of an affiliated group, as defined in section 15-04 of the Internal Revenue Code [26 U.S.C. 1504];

(7) Does not have any convictions under any federal, state, or local laws relating to wholesale or retail prescription drug distribution or distribution of controlled substances; and

(8) Does not have any felony conviction under federal, state, or local laws.

5. The board shall submit the fingerprints provided by an individual with a license application for a statewide and nationwide criminal history check. The nationwide criminal history check must be conducted in the manner provided in section 12-60-24. All costs associated with the background check are the responsibility of the applicant.

6. The board shall require every wholesale distributor applying for a license to submit a bond of at least one hundred thousand dollars, or other equivalent means of security acceptable to the state, including an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to a fund established by the state under subsection 7. A chain pharmacy warehouse that is engaged only in intracompany transfers is not subject to the bond requirement. The purpose of the bond is to secure payment of any fines or penalties imposed by the state and any fees and costs incurred by the state regarding that license which are authorized under state law and which the licensee fails to pay thirty days after the fines, penalties, or costs become final. The state may make a claim against the bond or security until one year after the licensee's license ceases to be valid. A single bond may cover all facilities operated by the applicant in the state.

7. The board shall establish a fund in which to deposit the wholesale distributor bonds. Money in the fund is appropriated to the board on a continuing basis.

8. If a wholesale distributor distributes prescription drugs from more than one facility, the wholesale distributor shall obtain a license for each facility.

9. In accordance with each licensure renewal, the board shall send to each wholesale distributor licensed under this section a form setting forth the information that the wholesale distributor provided pursuant to subsection 2. Within thirty days of receiving the form, the wholesale distributor must identify and state under oath to the state licensing authority all changes or corrections to the information that was provided under subsection 2. Changes in, or corrections to, any information in subsection 2 must be submitted to the board as required by that authority. The board may suspend or revoke the license of a wholesale distributor if the board determines that the wholesale distributor no longer qualifies for the license issued under this section.

10. The designated representative identified pursuant to subdivision g of subsection 2 must receive and complete continuing training in applicable federal and state laws governing wholesale distribution of prescription drugs.

11. Information provided under this section may not be disclosed to any person other than a government agency that needs the information for licensing or monitoring purposes.

43-15.3-04. Requirements to distribute prescription drugs.

1. A person may not engage in wholesale distributions of prescription drugs without, after December 31, 2007, obtaining and maintaining accreditation or certification from the national association of boards of pharmacy's verified accredited wholesale distributor or an accreditation body approved by the board under subsection 4, obtaining and maintaining a license issued by the board, and paying any reasonable fee required by the board.

2. The board may not issue or renew the license of a wholesale drug distributor that does not comply with this chapter. The board shall require a separate license for each facility or location where wholesale distribution operations are conducted. An agent or employee of any licensed wholesale drug distributor does not need a license and may lawfully posses pharmaceutical drugs when acting in the usual course of business or employment. The issuance of a license under this chapter

does not affect tax liability imposed by the tax department on any wholesale drug distributor.

3. The board may adopt rules that permit out-of-state wholesale drug distributors to obtain a license on the basis of reciprocity if an out-of-state wholesale drug distributor possesses a valid license granted by another state and the legal standards for licensure in the other state are comparable to the standards under this chapter and the other state extends reciprocity to wholesale drug distributors licensed in this state. However, if the requirements for licensure under this chapter are more restrictive than the standards of the other state, the out-of-state wholesale drug distributor must comply with the additional requirements of this chapter to obtain a license under this chapter.

4. The board may adopt rules to approve an accreditation body to evaluate a wholesale drug distributor's operations to determine compliance with professional standards, this chapter and any other applicable law, and perform inspections of each facility and location where wholesale distribution operations are conducted by the wholesale drug distributor.

43-15.3-05. Restrictions on transactions.

1. A wholesale distributor shall receive prescription drug returns or exchanges from a pharmacy or chain pharmacy warehouse under the terms and conditions of the agreement between the wholesale distributor and the pharmacy or between the wholesale distributor and the chain pharmacy warehouse, including the returns of expired, damaged, and recalled pharmaceutical product to either the original manufacturer or a third-party returns processor, and the returns or exchanges are not subject to the pedigree requirement of section 43-15.3-06 if they are exempt from pedigree under the federal food and drug administration's currently applicable guidance for the federal Prescription Drug Marketing Act of 1987 [Pub. L. 100-293; 102 Stat. 95]. Wholesale distributors and pharmacies must ensure that the aspects of this operation are secure and do not permit the entry of adulterated and counterfeit product.

2. A manufacturer or wholesale distributor shall furnish prescription drugs only to a person licensed by the appropriate state licensing authorities. Before furnishing

prescription drugs to a person not known to the manufacturer or wholesale distributor, the manufacturer or wholesale distributor shall affirmatively verify that the person is legally authorized to receive the prescription drugs by contacting the appropriate state licensing authorities.

3. Prescription drugs furnished by a manufacturer or wholesale distributor may be delivered only to the premises listed on the license. The manufacturer or wholesale distributor may furnish prescription drugs to an individual or agent of that individual at the premises of the manufacturer or wholesale distributor if:

   a. The identity and authorization of the recipient are properly established; and

   b. This method of receipt is employed only to meet the immediate needs of a particular patient of the authorized individual.

4. Prescription drugs may be furnished to a hospital pharmacy receiving area if a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt showing the type and quantity of the prescription drug so received. Any discrepancy between receipt and the type and quantity of the prescription drug actually received must be reported to the delivering manufacturer or wholesale distributor by the next business day after the delivery to the pharmacy receiving area.

5. A manufacturer or wholesale distributor may not accept payment for or allow the use of a person's credit to establish an account for the purchase of prescription drugs from any individual other than the owner of record, the chief executive officer, or the chief financial officer listed on the license of an individual legally authorized to receive prescription drugs. Any account established for the purchase of prescription drugs must bear the name of the licensee.

43-15.3-06. Pedigree.

1. Each person who is engaged in wholesale distribution of prescription drugs, including repackagers but excluding the original manufacturer of the finished form of the prescription drug which leave or have ever left the normal distribution channel, before each wholesale distribution of the drug, must provide a pedigree to the person who receives the drug.

a. A retail pharmacy or chain pharmacy warehouse must comply with the requirements of this section only if the pharmacy or chain pharmacy warehouse engages in wholesale distribution of prescription drugs.

b. The board shall determine by July 1, 2009, a targeted implementation date for electronic track and trace pedigree technology. The determination must be based on consultation with manufacturers, distributors, and pharmacies responsible for the sale and distribution of prescription drug products in this state. After consultation with interested stakeholders and before implementation of the electronic track and trace pedigree technology, the board must determine that the technology is universally available across the entire prescription pharmaceutical supply chain. The implementation date for the mandated electronic track and trace pedigree technology may not be before July 1, 2010, and may be extended by the board in one year increments if it appears the technology is not universally available across the entire prescription pharmaceutical supply chain.

2. Each person engaged in the wholesale distribution of a prescription drug, including a repackager but excluding the original manufacturer of the finished form of the prescription drug, that is provided a pedigree for a prescription drug and attempts to further distribute that prescription drug shall verify affirmatively before any distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred.

3. The pedigree must:

a. Include all necessary identifying information concerning each sale in the chain of distribution of the product from the manufacturer, or the manufacturer's third-party logistics provider, colicensed product partner, or manufacturer's exclusive distributor, through acquisition and sale by any wholesale distributor or repackager, until final sale to a pharmacy or other person dispensing or administering the drug. At minimum, the necessary chain of distribution information must include:

(1) The name, address, telephone number, and if available, the e-mail address, of each owner of the prescription drug, and each wholesale distributor of the prescription drug;

(2) The name and address of each location from which the product was shipped, if different from the owner's;

(3) The transaction dates; and

(4) A certification that each recipient has authenticated the pedigree.

b. At minimum, the pedigree must also include the:

(1) Name of the prescription drug;

(2) Dosage form and strength of the prescription drug;

(3) Size of the container;

(4) Number of containers;

(5) Lot number of the prescription drug; and

(6) Name of the manufacturer of the finished dosage form.

4. Each pedigree or electronic file must be:

a. Maintained by the purchaser and the wholesale distributor for three years from the date of sale or transfer; and

b. Available for inspection or use within five business days upon a request of an authorized officer of the law.

5. The board shall adopt rules and a form relating to the requirements of this section.

43-15.3-07. Order to cease distribution.

1. The board shall issue an order requiring the appropriate person, including the distributors or retailers of the drug, to immediately cease distribution of the drug within the state if the board finds that there is a reasonable probability that:

a. A wholesale distributor, other than a manufacturer, has violated a provision in this chapter or falsified a pedigree or sold, distributed, transferred, manufactured, repackaged, handled, or held a counterfeit prescription drug intended for human use;

b. The prescription drug at issue as a result of a violation in subdivision a could cause serious, adverse health consequences or death; and

c. Other procedures would result in unreasonable delay.

2. An order under subsection 1 must provide the individual subject to the order with an opportunity for an informal hearing, to be held not later than ten days after the date of the issuance of the order, on the actions required by the order. If, after providing an opportunity for such a hearing, the board determines that inadequate grounds exist to support the actions required by the order, the board shall vacate the order.

43-15.3-08. Prohibited acts - Penalty.

1. Except as otherwise provided under section 43-15.3-09, it is a class B misdemeanor for a person to perform or cause the performance of or aid and abet any of the following acts in this state:
   a. Failing to obtain a license under this chapter or operating without a valid license when a license is required by this chapter.
   b. If the requirements of subsection 1 of section 43-15.3-05 are applicable and are not met, purchasing or otherwise receiving a prescription drug from a pharmacy.
   c. If a state license is required under subsection 2 of section 43-15.3-05, selling, distributing, or transferring a prescription drug to a person that is not authorized under the law of the jurisdiction in which the person receives the prescription drug to receive the prescription drug.
   d. Failing to deliver prescription drugs to specified premises, as required by subsection 3 of section 43-15.3-05.
   e. Accepting payment or credit for the sale of prescription drugs in violation of subsection 5 of section 43-15.3-05.
   f. Failing to maintain or provide pedigrees as required by this chapter.
   g. Failing to obtain, pass, or authenticate a pedigree, as required by this chapter.
   h. Providing the board or any of the board's representatives or any federal official with false or fraudulent records or making false or fraudulent statements regarding any matter within the provisions of this chapter.
   i. Obtaining or attempting to obtain a prescription drug by fraud, deceit, misrepresentation, or engaging in misrepresentation or fraud in the distribution of a prescription drug.

j. Except for the wholesale distribution by manufacturers of a prescription drug that has been delivered into commerce pursuant to an application approved under federal law by the federal food and drug administration, manufacturing, repacking, selling, transferring, delivering, holding, or offering for sale any prescription drug that is adulterated, misbranded, counterfeit, suspected of being counterfeit, or has otherwise been rendered unfit for distribution.

k. Except for the wholesale distribution by a manufacturer of a prescription drug that has been delivered into commerce under an application approved under federal law by the federal food and drug administration, adultering, misbranding, or counterfeiting any prescription drug.

l. Receiving any prescription drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected of being counterfeit, and the delivery or proffered delivery of such drug for pay or otherwise.

m. Altering, multilating, destroying, obliterating, or removing the whole or any part of the labeling of a prescription drug or the commission of any other act with respect to a prescription drug that results in the prescription drug being misbranded.

2. The prohibited acts in subsection 1 do not include a prescription drug manufacturer or agent of a prescription drug manufacturer obtaining or attempting to obtain a prescription drug for the sole purpose of testing the prescription drug for authenticity.

43-15.3-09. Penalties.

1. The board may impose the following sanctions if, after a hearing under chapter 28-32, the board finds that a person has violated section 43-15.3-08:

a. Revoke the wholesale drug distributor's license issued under this chapter if the person is a wholesale drug distributor; or

b. Assess a civil penalty against the person. A civil penalty assessed may not exceed ten thousand dollars per violation.

2. The board, upon a showing of a violation of this chapter, may revoke, suspend, or limit a license issued under this chapter after a proceeding under chapter 28-32. After a proceeding under chapter 28-32, the board may assess a civil penalty

against a licensed wholesale drug distributor of not more than one thousand dollars for each occurrence. If the licensed wholesale drug distributor fails to pay the civil penalty within the time specified by the board, the board may suspend the license without additional proceedings.

3. Upon application by the board, a court may grant an injunction, a restraining order, or other order to enjoin a person from offering to engage or engaging in the performance of any practices for which a permit or license is required by any applicable federal or state law including this chapter, upon a showing that the practices were or are likely to be performed or offered to be performed without a permit or license. An action brought under this subsection must be commenced either in the county where the conduct occurred or is likely to occur or in the county where the defendant resides. An action brought under this subsection is in addition to any other penalty provided by law and may be brought concurrently with other actions to enforce this chapter.

4. A person that knowingly purchases or receives a prescription drug through any source other than a person licensed under this chapter, including a wholesale distributor, manufacturer, pharmacy distributor, or pharmacy commits a class A misdemeanor. A subsequent unrelated violation of this subsection is a class C felony.

5. A person who knowingly or intentionally engages in the wholesale distribution of a prescription drug without a license issued under this chapter commits a class C felony. A person is guilty of a class C felony if that person engages in the wholesale distribution of a prescription drug and with intent to defraud or deceive fails to obtain or deliver to another person a complete and accurate required pedigree concerning a prescription drug before obtaining the prescription drug from another person or transferring the prescription drug to another person or falsely swears or certifies that the person has authenticated any documents to the wholesale distribution of prescription drugs.

6. A person is guilty of a class C felony if that person engages in the wholesale distribution of a prescription drug and knowingly or intentionally:

a. Destroys, alters, conceals, or fails to maintain a complete and accurate required pedigree concerning a prescription drug in the person's possession;

b. Purchases or receives prescription drugs from a person not authorized to distribute prescription drugs in wholesale distribution;

c. Sells, barters, brokers, or transfers a prescription drug to a person not authorized to purchase the prescription drug in the jurisdiction in which the person receives the prescription drug in a wholesale distribution;

d. Forges, counterfeits, or falsely creates a pedigree;

e. Falsely represents a factual matter contained in a pedigree; or

f. Fails to record material information required to be recorded in a pedigree.

7. A person is guilty of a class C felony if that person engages in the wholesale distribution of a prescription drug and possesses a required pedigree concerning a prescription drug, knowingly or intentionally fails to authenticate the matters contained in the pedigree as required, and distributes or attempts to further distribute the prescription drug.