

AMENDMENTS TO LB 994

(Amendments to E & R amendments, AM7178)

Introduced by Johnson, 37

1 1. Insert the following new sections:

2 Section 1. Section 71-7401, Reissue Revised Statutes of
3 Nebraska, is amended to read:

4 ~~71-7401~~ Sections ~~71-7401 to 71-7426~~ 1 to 37 of this act
5 shall be known and may be cited as the Wholesale Drug Distributor
6 Licensing Act.

7 Sec. 2. Section 71-7402, Reissue Revised Statutes of
8 Nebraska, is amended to read:

9 ~~71-7402~~ For purposes of the Wholesale Drug Distributor
10 Licensing Act, the definitions found in sections ~~71-7403 to 71-7413~~
11 shall be used 3 to 20 of this act apply.

12 Sec. 3. Section 71-7403, Reissue Revised Statutes of
13 Nebraska, is amended to read:

14 ~~71-7403~~ Blood shall ~~mean~~ means whole blood collected from
15 a single donor and processed either for transfusion or further
16 manufacturing.

17 Sec. 4. Section 71-7404, Reissue Revised Statutes of
18 Nebraska, is amended to read:

19 ~~71-7404~~ Blood component shall ~~mean~~ means that part of
20 blood separated by physical or mechanical means.

21 Sec. 5. Section 71-7405, Reissue Revised Statutes of
22 Nebraska, is amended to read:

1 ~~71-7405~~ Board ~~shall mean~~ means the Board of Pharmacy.

2 Sec. 6. Chain pharmacy warehouse means a facility
3 utilized as a central warehouse for intracompany sales or transfers
4 of prescription drugs or devices by two or more pharmacies
5 operating under common ownership or common control.

6 Sec. 7. Section 71-7406, Reissue Revised Statutes of
7 Nebraska, is amended to read:

8 ~~71-7406~~ Common control ~~shall mean~~ means that the power to
9 direct or cause the direction of the management and policies of a
10 person or an organization by ownership of stock or voting rights,
11 by contract, or otherwise is held by the same person or persons.

12 Sec. 8. Section 71-7407, Reissue Revised Statutes of
13 Nebraska, is amended to read:

14 ~~71-7407~~ Department ~~shall mean~~ means the Department of
15 Health and Human Services Regulation and Licensure.

16 Sec. 9. Section 71-7408, Reissue Revised Statutes of
17 Nebraska, is amended to read:

18 ~~71-7408~~ Drug sample ~~shall mean~~ means a unit of a
19 prescription drug intended to promote the sale of the drug and
20 not intended to be sold.

21 Sec. 10. Section 71-7409, Reissue Revised Statutes of
22 Nebraska, is amended to read:

23 ~~71-7409~~ Emergency medical reasons ~~shall mean~~ means the
24 alleviation of a temporary shortage by transfers of prescription
25 drugs between any of the following: (1) Holders of pharmacy
26 licenses, holders of pharmacy inspection certificates (2) health
27 care practitioner facilities as defined in section 71-414, (3)

1 hospitals as defined in section 71-419, and (4) practitioners as
2 defined in section 71-1,142.

3 Sec. 11. Facility means a physical structure utilized
4 by a wholesale drug distributor for the storage, handling, or
5 repackaging of prescription drugs or the offering of prescription
6 drugs for sale.

7 Sec. 12. Section 71-7410, Reissue Revised Statutes of
8 Nebraska, is amended to read:

9 ~~71-7410~~ Manufacturer shall mean means any entity engaged
10 in manufacturing, preparing, propagating, compounding, processing,
11 packaging, repackaging, or labeling a prescription drug.

12 Sec. 13. (1) Normal distribution chain means the transfer
13 of a prescription drug or the co-licensed product of the original
14 manufacturer of the finished form of a prescription drug along a
15 chain of custody directly from the manufacturer or co-licensee of
16 such drug to a patient or ultimate consumer of such drug.

17 (2) Normal distribution chain includes transfers of a
18 prescription drug or co-licensed product:

19 (a) From a manufacturer or co-licensee to a wholesale
20 drug distributor, to a pharmacy, and then to a patient or a
21 patient's agent;

22 (b) From a manufacturer or co-licensee to a wholesale
23 drug distributor, to a chain pharmacy warehouse, to a pharmacy
24 affiliated with the chain pharmacy warehouse, and to a patient or a
25 patient's agent;

26 (c) From a manufacturer or co-licensee to a chain
27 pharmacy warehouse, to a pharmacy affiliated with the chain

1 pharmacy warehouse, and to a patient or a patient's agent; or

2 (d) Recognized in rules and regulations adopted and
3 promulgated by the department in consultation with the board.

4 (3) For purposes of this section, co-licensed products
5 means pharmaceutical products that have been approved by the
6 federal Food and Drug Administration and that are the subject of an
7 arrangement by which two or more parties have the right to engage
8 in a business activity or occupation concerning the pharmaceutical
9 products.

10 Sec. 14. Pedigree means a written or electronic
11 documentation of every transfer of a prescription drug as provided
12 in sections 29 and 30 of this act.

13 Sec. 15. Section 71-7411, Reissue Revised Statutes of
14 Nebraska, is amended to read:

15 ~~71-7411~~ Prescription drug shall mean means any human
16 drug required by federal law or regulation to be dispensed
17 only by prescription, including finished dosage forms and active
18 ingredients subject to section 503(b) of the Federal Food, Drug,
19 and Cosmetic Act, as such section existed on the operative date of
20 this act.

21 Sec. 16. Repackage means repackaging or otherwise
22 changing the container, wrapper, or labeling of a prescription drug
23 to facilitate the wholesale distribution of such drug.

24 Sec. 17. Repackager means a person who repackages.

25 Sec. 18. Section 71-7412, Reissue Revised Statutes of
26 Nebraska, is amended to read:

27 ~~71-7412~~ (1) Wholesale drug distribution shall mean means

1 the distribution of prescription drugs to a person other than a
2 consumer or patient.

3 (2) Wholesale drug distribution ~~shall~~ does not include:

4 ~~(1)~~ (a) Intracompany sales ~~which shall mean of~~
5 prescription drugs, including any transaction or transfer between
6 any division, subsidiary, or parent company and an affiliated or
7 related company under common ownership or common control;

8 ~~(2)~~ The purchase ~~or other acquisition of a drug by~~
9 a hospital ~~or other health care entity that is a member of a~~
10 group purchasing organization ~~from such organization or from other~~
11 members of such organization for the use of the purchasing ~~or~~
12 acquiring hospital ~~or entity;~~

13 ~~(3)~~ (b) The sale, purchase, or trade of ~~or an offer~~
14 to sell, purchase, or trade a prescription drug by a charitable
15 organization described in section 501(c)(3) of the Internal Revenue
16 Code, a state, a political subdivision, or ~~another~~ any other
17 governmental agency to a nonprofit affiliate of the organization,
18 to the extent otherwise permitted by law;

19 ~~(4)~~ (c) The sale, purchase, or trade of ~~or an offer~~
20 to sell, purchase, or trade a prescription drug among hospitals
21 or other health care entities ~~that are~~ operating under common
22 ownership or common control;

23 ~~(5)~~ (d) The sale, purchase, or trade of ~~or an offer to~~
24 sell, purchase, or trade a prescription drug for emergency medical
25 reasons;

26 ~~(6)~~ (e) The sale, purchase, or trade of, ~~an offer to~~
27 sell, purchase, or trade, or the dispensing of a prescription drug

1 pursuant to a prescription;

2 ~~(7)~~ (f) The distribution of drug samples by
3 representatives of a manufacturer or of a wholesale drug
4 distributor; ~~or~~

5 ~~(8)~~ (g) The sale, purchase, or trade of blood and blood
6 components intended for transfusion; or

7 (h) The delivery of or the offer to deliver a
8 prescription drug by a common carrier solely in the usual course
9 of business of transporting such drugs as a common carrier if the
10 common carrier does not store, warehouse, or take legal ownership
11 of such drugs.

12 Sec. 19. Section 71-7413, Reissue Revised Statutes of
13 Nebraska, is amended to read:

14 ~~71-7413~~ (1) Wholesale drug distributor shall mean means
15 any person or entity located in this state and engaged in wholesale
16 drug distribution in this state, including manufacturers, ~~repackers~~
17 ~~repackagers~~, own-label distributors, jobbers, private-label
18 distributors, brokers, warehouses including manufacturer and
19 distributor warehouses, chain ~~drug~~ pharmacy warehouses, and
20 wholesale drug warehouses, wholesale medical gas distributors,
21 independent wholesale drug traders, and retail pharmacies that
22 ~~conduct~~ engage in wholesale drug distribution in this state.

23 (2) Wholesale drug distributor ~~shall~~ does not include any
24 a common carrier ~~for~~ hire or other person or entity hired solely
25 to transport prescription drugs if the common carrier, person, or
26 entity does not store, warehouse, or take legal ownership of such
27 drugs.

1 Sec. 20. Wholesale medical gas distributor means any
2 person engaged in the wholesale drug distribution of medical gases
3 provided to suppliers or other entities licensed or otherwise
4 authorized to use, administer, or distribute such gases.

5 Sec. 21. Section 71-7417, Reissue Revised Statutes of
6 Nebraska, is amended to read:

7 ~~71-7417~~ (1) No person ~~shall~~ or entity may act as a
8 wholesale drug distributor in this state without first obtaining
9 a wholesale drug distributor license from the department. ~~If the~~
10 ~~applicant is an individual, the application shall include the~~
11 ~~applicant's social security number.~~ The department shall issue a
12 license ~~upon the recommendation of the board that the~~ to any
13 applicant meets that satisfies the requirements for licensure
14 ~~stated in~~ under the Wholesale Drug Distributor Licensing Act.
15 Manufacturers are exempt from any licensing and other requirements
16 of the act to the extent not required by federal law or regulation
17 unless particular requirements are deemed necessary and appropriate
18 as determined by the board in its rules and regulations. ~~and upon~~
19 ~~payment of a fee established and collected as provided in section~~
20 ~~71-162.~~

21 (2) Wholesale medical gas distributors shall be exempt
22 from any licensing and other requirements of the Wholesale Drug
23 Distributor Licensing Act to the extent not required under federal
24 law but shall be licensed as wholesale drug distributors by the
25 department for the limited purpose of engaging in the wholesale
26 distribution of medical gases upon application to the department,
27 payment of a licensure fee, and inspection of the applicant's

1 facility by the department, except that the applicant may submit
2 and the department may accept an inspection accepted in another
3 state or an inspection conducted by a nationally recognized
4 accreditation program approved by the board. For purposes of
5 such licensure, wholesale medical gas distributors shall only be
6 required to provide information required under subdivisions (1)(a)
7 through (1)(c) of section 22 of this act. A separate wholesale drug
8 distributor license shall be required for each facility located
9 within this state and directly or indirectly owned or operated by
10 the same business entity or parent entity.

11 (3) The Wholesale Drug Distributor Licensing Act does not
12 apply to:

13 (a) An agent or employee of a licensed wholesale drug
14 distributor need not be licensed under the act and may lawfully
15 possess who possesses drug samples when such agent or employee is
16 acting in the usual course of his or her business or employment;
17 or -

18 (4) No license is required for any (b) Any person who (a)
19 (i) engages in a wholesale transaction relating to the manufacture,
20 distribution, sale, transfer, or delivery of medical gases the
21 gross dollar value of which does not exceed five percent of the
22 total retail sales of medical gases by such person during the
23 immediately preceding calendar year and (b) (ii) has either a
24 pharmacy permit or license or a drug dispensing permit or delegated
25 dispensing permit.

26 (5) The issuance of a license pursuant to the act shall
27 not change or affect tax liability to the State of Nebraska of any

1 ~~wholesale drug distributor.~~

2 Sec. 22. (1) Every applicant for an initial or renewal
3 license as a wholesale drug distributor shall file a written
4 application with the department. The application shall be
5 accompanied by the fee established by the department under section
6 24 of this act and proof of bond or other security required under
7 section 26 of this act and shall include the following information:

8 (a) The applicant's name, business address, type of
9 business entity, and telephone number. If the applicant is a
10 partnership, the application shall include the name of each partner
11 and the name of the partnership. If the applicant is a corporation,
12 the application shall include the name and title of each corporate
13 officer and director, all corporate names of the applicant, and
14 the applicant's state of incorporation. If the applicant is a sole
15 proprietorship, the application shall include the name of the sole
16 proprietor and name of the proprietorship;

17 (b) All trade or business names used by the applicant;

18 (c) The addresses and telephone numbers of all facilities
19 used by the applicant for the storage, handling, and wholesale
20 distribution of prescription drugs and the names of persons in
21 charge of such facilities. A separate license shall be obtained for
22 each such facility;

23 (d) A listing of all licenses, permits, or other
24 similar documentation issued to the applicant in any other state
25 authorizing the applicant to purchase or possess prescription
26 drugs;

27 (e) The names and addresses of the owner and manager

1 of the applicant's wholesale drug distribution facilities, a
2 designated representative at each such facility, and all managerial
3 employees at each such facility; and

4 (f) Other information as required by the department,
5 including affirmative evidence of the applicant's ability to comply
6 with the Wholesale Drug Distributor Licensing Act and rules and
7 regulations adopted and promulgated under the act.

8 (2) The department may require persons listed on the
9 application to pass an examination approved by the department
10 on laws pertaining to the wholesale distribution of prescription
11 drugs.

12 (3) The application shall include the applicant's social
13 security number if the applicant is an individual. The social
14 security number shall not be a public record and may only be used
15 by the department for administrative purposes.

16 (4) The application shall be signed by (a) the owner, if
17 the applicant is an individual or partnership, (b) the member, if
18 the applicant is a limited liability company with only one member,
19 or two of its members, if the applicant is a limited liability
20 company with two or more members, or (c) two of its officers, if
21 the applicant is a corporation.

22 (5) The designated representative and the supervisor
23 of the designated representative of a wholesale drug distributor
24 and each owner with greater than a ten percent interest in the
25 wholesale drug distributor, if the wholesale drug distributor
26 is a nonpublicly held company, shall be subject to a criminal
27 history record information check and shall provide the department

1 or the designated agent of the department with a complete set of
2 fingerprints for such purpose if his or her fingerprints are not
3 already on file for such purpose. The department or the designated
4 agent of the department shall forward such fingerprints to the
5 Nebraska State Patrol to be submitted to the Federal Bureau of
6 Investigation for a national criminal history record information
7 check. Such persons shall authorize the release of the results of
8 such criminal history record information check to the department,
9 and the applicant shall pay the actual cost of such fingerprinting
10 and such criminal history record information check.

11 (6) The department may waive certain requirements under
12 this section upon proof satisfactory to the department that such
13 requirements are duplicative of other requirements of law or
14 regulation and that the granting of such exemption will not
15 endanger the public safety.

16 Sec. 23. Each designated representative named under
17 subdivision (1)(e) of section 22 of this act shall provide the
18 following information prior to the issuance of an initial or
19 renewal license under such section:

20 (1) The designated representative's places of residence
21 for the immediately preceding seven years;

22 (2) The designated representative's date and place of
23 birth;

24 (3) All occupations, positions of employment, and offices
25 held by the designated representative during the immediately
26 preceding seven years and the principal businesses and the
27 addresses of any business, corporation, or other organization

1 in which such occupations, positions, or offices were held;

2 (4) Whether the designated representative has been, at
3 any time during the immediately preceding seven years, the subject
4 of any proceeding for the revocation of any license and, if so, the
5 nature of the proceeding and its disposition;

6 (5) Whether the designated representative has been, at
7 any time during the immediately preceding seven years, either
8 temporarily or permanently enjoined by a court of competent
9 jurisdiction from violations of any federal or state law regulating
10 the possession, control, or distribution of prescription drugs,
11 and, if so, the details of such order;

12 (6) A description of any involvement by the designated
13 representative during the immediately preceding seven years, other
14 than the ownership of stock in a publicly traded company or
15 mutual fund, with any business which manufactured, administered,
16 distributed, or stored prescription drugs and any lawsuits in which
17 such businesses were named as a party;

18 (7) Whether the designated representative has ever been
19 convicted of any felony and details relating to such conviction;
20 and

21 (8) A photograph of the designated representative taken
22 within the immediately preceding thirty days.

23 Sec. 24. (1) Licensure activities under the Wholesale
24 Drug Distributor Licensing Act shall be funded by license fees. An
25 applicant for an initial or renewal license under the act shall pay
26 a license fee as provided in this section.

27 (2) License fees shall include (a) a base fee of fifty

1 dollars and (b) an additional fee of not more than five hundred
2 dollars based on variable costs to the department of inspections
3 and of receiving and investigating complaints, other similar direct
4 and indirect costs, and other relevant factors as determined by the
5 department.

6 (3) If the licensure application is denied, the license
7 fee shall be returned to the applicant, except that the department
8 may retain up to twenty-five dollars as an administrative fee
9 and may retain the entire license fee if an inspection has been
10 completed prior to such denial.

11 (4) The department shall also collect a fee for
12 reinstatement of a license that has lapsed or has been suspended or
13 revoked. The department shall collect a fee of ten dollars for a
14 duplicate original license.

15 (5) The department shall remit all license fees collected
16 under this section to the State Treasurer for credit to the
17 Department of Health and Human Services Regulation and Licensure
18 Cash Fund. License fees collected under this section shall only
19 be used for activities related to the licensure of wholesale drug
20 distributors.

21 Sec. 25. Section 71-7420, Reissue Revised Statutes of
22 Nebraska, is amended to read:

23 ~~71-7420~~ A wholesale drug distributor license shall expire
24 on July 1 of each year and may be renewed. The license shall not
25 be transferable. The annual renewal fee shall be established and
26 collected as provided in section ~~71-162~~. The department shall mail
27 an application for renewal to each licensee not later than June 1

1 of each year. If an application for renewal is received from the
2 licensee after July 1, the department may impose a late fee ~~as~~
3 ~~provided in section 71-162 and the department~~ shall refuse to issue
4 the license until such late fee ~~is paid in addition to the and~~
5 renewal fee are paid. Failure to receive an application for renewal
6 shall not relieve the licensee from the late fee imposed by this
7 section.

8 Sec. 26. An applicant for an initial or renewal license
9 as a wholesale drug distributor shall submit to the department
10 proof of a bond of not less than one hundred thousand dollars or
11 other equivalent means of security acceptable to the department.
12 The bond or other security shall be given for the purpose of
13 securing payment of any fines or other penalties imposed by
14 the department and any fees or costs incurred by the department
15 relating to such applicant as authorized under the Wholesale Drug
16 Distributor Licensing Act or rules and regulations adopted and
17 promulgated under the act which remain unpaid by the applicant
18 within thirty days after such fines, penalties, and costs become
19 final. The department may make a claim against such bond or
20 security until one year after the expiration of the license issued
21 to the applicant under the act.

22 Sec. 27. Section 71-7424, Reissue Revised Statutes of
23 Nebraska, is amended to read:

24 71-7424 (1) ~~The department may conduct inspections during~~
25 ~~normal business hours upon premises purporting or appearing to~~
26 ~~be used by a wholesale drug distributor in this state. Persons~~
27 ~~conducting such inspections shall show appropriate identification~~

1 prior to being permitted access to a wholesale drug distributor's
2 premises and delivery vehicles.

3 (2) A wholesale drug distributor may keep records
4 regarding purchases and sales at a location apart from its
5 principal office or the location at which the drugs are stored
6 and from which they are shipped, if the records can be made
7 available for inspection within two working days after a request
8 by the department and the board. The records may be kept in any
9 form permissible under federal law applicable to record keeping
10 for prescription drugs. (1) Each wholesale drug distributor doing
11 business in this state shall be inspected by the department or a
12 nationally recognized accreditation program that is approved by the
13 board and that is acting on behalf of the department prior to the
14 issuance of an initial or renewal license by the department under
15 section 22 of this act.

16 (2) The department or such nationally recognized
17 accreditation program may provide for the inspection of any
18 wholesale drug distributor licensed to engage in wholesale drug
19 distribution in this state in such manner and at such times as
20 provided in rules and regulations adopted and promulgated by the
21 department. As part of any such inspection, the department may
22 require an analysis of suspected prescription drugs to determine
23 authenticity.

24 (3) The department, with the concurrence of the board,
25 may accept an inspection accepted in another state in lieu
26 of an inspection by the department or a nationally recognized
27 accreditation program under this section.

1 (4) The department or such nationally recognized
2 accreditation program may charge and collect fees for inspection
3 activities conducted under this section.

4 (5) In addition to or in lieu of the authority to
5 inspect for purposes of licensure and renewal, the department may
6 adopt and promulgate rules and regulations which permit the use
7 of alternative methods for assessing the compliance by a wholesale
8 drug distributor with the Wholesale Drug Distributor Licensing Act
9 and the rules and regulations adopted and promulgated under the
10 act.

11 Sec. 28. Section 71-7416, Reissue Revised Statutes of
12 Nebraska, is amended to read:

13 ~~71-7416~~ (1) No wholesale drug distributor, manufacturer,
14 or pharmacy shall knowingly purchase or receive any prescription
15 drug from any source other than a person or entity licensed
16 pursuant to under the Wholesale Drug Distributor Licensing Act
17 except transfers for emergency medical reasons, the gross dollar
18 value of which shall not exceed five percent of the total
19 prescription drug sales revenue of the transferor or transferee
20 holder of a pharmacy license, holder of a pharmacy inspection
21 certificate, or practitioner as defined in section 71-1,142 during
22 the immediately preceding calendar year, and except as otherwise
23 provided in the act.

24 (2) A wholesale drug distributor may receive returns or
25 exchanges of prescription drugs from a pharmacy, chain pharmacy
26 warehouse, health care practitioner facility as defined in section
27 71-414, or hospital as defined in section 71-419 pursuant to

1 the terms and conditions agreed upon between such wholesale drug
2 distributor and such pharmacy, chain pharmacy warehouse, health
3 care practitioner facility, or hospital. Such returns and exchanges
4 shall not be subject to sections 29 to 31 of this act. A
5 wholesale drug distributor shall not receive from a pharmacy, chain
6 pharmacy warehouse, health care practitioner facility, or hospital
7 an amount or quantity of a prescription drug greater than the
8 amount or quantity that was originally sold by the wholesale drug
9 distributor to such pharmacy, chain pharmacy warehouse, health care
10 practitioner facility, or hospital.

11 (3) A manufacturer or wholesale drug distributor shall
12 furnish prescription drugs only to persons licensed by the
13 department and shall verify such licensure before furnishing
14 prescription drugs to a person not known to the manufacturer
15 or wholesale drug distributor.

16 (4) Prescription drugs furnished by a manufacturer or
17 wholesale drug distributor shall be delivered only to the premises
18 listed on the license, except that a manufacturer or wholesale drug
19 distributor may furnish prescription drugs to a person licensed
20 by the department or his or her agent at the premises of the
21 manufacturer or wholesale drug distributor if:

22 (a) The identity and authorization of the recipient is
23 properly established; and

24 (b) This method of receipt is employed only to meet
25 the prescription drug needs of a particular patient of the person
26 licensed by the department.

27 (5) Prescription drugs may be furnished to a hospital

1 pharmacy receiving area. Receipt of such drugs shall be
2 acknowledged by written receipt signed by a pharmacist or other
3 authorized personnel. The receipt shall contain the time of
4 delivery and the type and quantity of the prescription drug
5 received. Any discrepancy between the signed receipt and the type
6 and quantity of prescription drug actually received shall be
7 reported by the receiving authorized pharmacy personnel to the
8 delivering manufacturer or wholesale drug distributor by the next
9 business day after the delivery to the pharmacy receiving area.

10 (6) A manufacturer or wholesale drug distributor shall
11 only accept payment or allow the use of credit to establish an
12 account for the purchase of prescription drugs from the owner
13 or owners of record, the chief executive officer, or the chief
14 financial officer listed on the license of a person or entity
15 legally authorized to receive prescription drugs. Any account
16 established for the purchase of prescription drugs shall bear the
17 name of such licensee.

18 Sec. 29. (1) A wholesale drug distributor engaged in
19 the wholesale distribution of prescription drugs in this state
20 shall establish and maintain accurate records of all transactions
21 regarding the receipt and distribution or other disposition of
22 prescription drugs as provided in this section.

23 (2) The department shall adopt and promulgate rules and
24 regulations, with the concurrence of the board, to require that
25 all prescription drugs that leave the normal distribution chain
26 be accompanied by a paper or electronic pedigree as provided in
27 section 30 of this act. Such rules and regulations shall be adopted

1 and promulgated no later than July 1, 2007.

2 (3) The department, with the concurrence of the
3 board, shall develop standards and requirements for electronic
4 pedigrees in order to effectively authenticate, track, and trace
5 prescription drugs. Prior to the development of such standards
6 and requirements, the department shall consult with the federal
7 Food and Drug Administration, manufacturers, wholesale drug
8 distributors, pharmacies, and other interested parties regarding
9 the feasibility and the ways, means, and practicality of requiring
10 that all prescription drugs that leave the normal distribution
11 chain be accompanied by an electronic pedigree. The standards and
12 requirements may prescribe the information required to be included
13 as part of the electronic pedigree. The standards and requirements
14 shall be developed no later than July 1, 2008. All prescription
15 drugs that leave the normal distribution chain shall not be
16 required to be accompanied solely by an electronic pedigree prior
17 to such date.

18 (4) A retail pharmacy or chain pharmacy warehouse shall
19 comply with the requirements of this section only if the pharmacy
20 or chain pharmacy warehouse engages in the wholesale distribution
21 of prescription drugs in this state.

22 (5) A wholesale drug distributor, other than the original
23 manufacturer of the finished form of the prescription drug, shall
24 verify all transactions listed on the pedigree before attempting to
25 further distribute such drug.

26 Sec. 30. (1) The pedigree required under section 29
27 of this act shall include all necessary identifying information

1 concerning each sale or other transfer in the chain of distribution
2 of the prescription drug from the manufacturer, through acquisition
3 and sale by any wholesale drug distributor or repackager,
4 until final sale to a pharmacy or other person dispensing or
5 administering such drug, including, but not limited to:

6 (a) Name of the prescription drug;

7 (b) Dosage form and strength of the prescription drug;

8 (c) Size of the container;

9 (d) Number of containers;

10 (e) Lot number of the prescription drug;

11 (f) Name of the original manufacturer of the finished
12 dosage form of the drug;

13 (g) Name, address, telephone number, and if available,
14 the email address of each owner of the prescription drug and
15 each wholesale drug distributor who does not take title to the
16 prescription drug;

17 (h) Name and address of each location from which the
18 product was shipped if different from the owner's;

19 (i) Transaction dates;

20 (j) Certification that each recipient has authenticated
21 the pedigree;

22 (k) Name of any repackager, if applicable; and

23 (1) Name and address of person certifying the delivery.

24 (2) Each paper or electronic pedigree shall be maintained
25 by the purchaser and the wholesale drug distributor for three years
26 from the date of sale or transfer and available for inspection or
27 use upon request of law enforcement or an authorized agent of the

1 department.

2 Sec. 31. Section 71-7423, Reissue Revised Statutes of
3 Nebraska, is amended to read:

4 ~~71-7423~~ (1) A wholesale drug distributor license may
5 be denied, refused renewal, suspended, limited, or revoked by
6 the Director of Regulation and Licensure when the director finds
7 that the applicant or licensee has violated any provisions of
8 the Wholesale Drug Distributor Licensing Act or of the rules and
9 regulations adopted and promulgated under the act or has committed
10 any acts or offenses set forth in section 71-147 or 71-148 or
11 section 33 of this act. All actions and proceedings shall be
12 carried out as specified in sections 71-147 to 71-161.19.

13 (2) For purposes of this section, applicant or licensee
14 ~~shall include~~ includes, but is not be limited to, the board of
15 directors, chief executive officer, and other officers of the
16 applicant or the entity to which the license is issued and the
17 manager of each site if more than one site is located in this
18 state.

19 Sec. 32. Section 71-7425, Reissue Revised Statutes of
20 Nebraska, is amended to read:

21 ~~71-7425~~ The department, the Attorney General, or any
22 county attorney may institute an action in the name of the
23 state for an injunction or other process against any person to
24 restrain or prevent any violation of the Wholesale Drug Distributor
25 Licensing Act or any rules and regulations adopted ~~pursuant to~~ and
26 promulgated under the act.

27 Sec. 33. Section 71-7426, Reissue Revised Statutes of

1 Nebraska, is amended to read:

2 ~~71-7426~~ (1) The department, upon issuance of a final
3 disciplinary action against a person who violates any provision
4 of section ~~71-7416~~ 28 of this act, shall assess a fine of one
5 thousand dollars against such person. For each subsequent final
6 disciplinary action for violation of such section issued by the
7 department against such person, the department shall assess a fine
8 of one thousand dollars plus one thousand dollars for each final
9 disciplinary action for violation of such section previously issued
10 against such person, not to exceed ten thousand dollars.

11 (2) The department, upon issuance of a final disciplinary
12 action against a person who fails to provide an authorized person
13 the right of entry provided in section ~~71-7424~~ 27 of this act,
14 shall assess a fine of five hundred dollars against such person.
15 For each subsequent final disciplinary action for such failure
16 issued against such person, the department shall assess a fine
17 equal to one thousand dollars times the number of such disciplinary
18 actions, not to exceed ten thousand dollars. All fines collected
19 under this section shall be remitted to the State Treasurer for
20 credit to the permanent school fund distribution in accordance with
21 Article VII, section 5, of the Constitution of Nebraska.

22 Sec. 34. (1) If the department finds there is a
23 reasonable probability that (a) a wholesale drug distributor
24 has falsified a pedigree or has sold, distributed, transferred,
25 manufactured, repackaged, handled, or held a counterfeit
26 prescription drug intended for human use and (b) such drug could
27 cause serious, adverse health consequences or death, the department

1 shall issue an order to immediately cease distribution of such
2 drug.

3 (2) Persons subjected to any order issued by the
4 department under this section shall be provided with notice and
5 an opportunity for an informal hearing to be held not later than
6 ten days after the date the order was issued. If the department
7 determines, after such hearing, that inadequate grounds exist to
8 support the actions required by the order, the department shall
9 vacate the order.

10 Sec. 35. It is unlawful for any person to commit or to
11 permit, cause, aid, or abet the commission of any of the following
12 acts in this state:

13 (1) Any violation of the Wholesale Drug Distributor
14 Licensing Act or rules and regulations adopted and promulgated
15 under the act;

16 (2) Providing the department, any of its representatives,
17 or any federal official with false or fraudulent records or making
18 false or fraudulent statements regarding any matter under the act;

19 (3) Obtaining or attempting to obtain a prescription
20 drug by fraud, deceit, or misrepresentation or engaging in
21 misrepresentation or fraud in the distribution of a prescription
22 drug;

23 (4) Except for the wholesale distribution by
24 manufacturers of a prescription drug that has been delivered into
25 commerce pursuant to an application approved under federal law
26 by the federal Food and Drug Administration, the manufacture,
27 repackaging, sale, transfer, delivery, holding, or offering for

1 sale of any prescription drug that is adulterated, misbranded,
2 counterfeit, suspected of being counterfeit, or otherwise rendered
3 unfit for distribution;

4 (5) Except for the wholesale distribution by
5 manufacturers of a prescription drug that has been delivered into
6 commerce pursuant to an application approved under federal law
7 by the federal Food and Drug Administration, the adulteration,
8 misbranding, or counterfeiting of any prescription drug;

9 (6) The receipt of any prescription drug that is
10 adulterated, misbranded, stolen, obtained by fraud or deceit,
11 counterfeit, or suspected of being counterfeit, and the delivery or
12 proffered delivery of such drug for pay or otherwise; and

13 (7) The alteration, mutilation, destruction,
14 obliteration, or removal of the whole or any part of the labeling
15 of a prescription drug or the commission of any other act with
16 respect to a prescription drug that results in the prescription
17 drug being misbranded.

18 Sec. 36. Any person who knowingly and intentionally
19 engages in wholesale drug distribution in this state in violation
20 of the Wholesale Drug Distributor Licensing Act is guilty of a
21 Class III felony.

22 Sec. 37. Section 71-7422, Reissue Revised Statutes of
23 Nebraska, is amended to read:

24 71-7422 The department upon the recommendation of the
25 board shall adopt and promulgate rules and regulations to carry out
26 the Wholesale Drug Distributor Licensing Act.

27 Sec. 69. Section 71-162, Revised Statutes Cumulative

1 Supplement, 2004, is amended to read:

2 71-162 (1) It is the intent of the Legislature that the
3 revenue to cover the cost of the credentialing system administered
4 by the department is to be derived from General Funds, cash funds,
5 federal funds, gifts, grants, or fees from individuals or entities
6 seeking credentials. The credentialing system includes the totality
7 of the credentialing infrastructure and the process of issuance and
8 renewal of credentials, examinations, inspections, investigations,
9 continuing competency, compliance assurance, and the credentialing
10 review process for the following individuals and entities that
11 provide health services and health-related services:

12 (a) Individuals in the practice of acupuncture; advanced
13 practice nursing; alcohol and drug counseling; asbestos abatement,
14 inspection, project design, and training; athletic training;
15 audiology; speech-language pathology; chiropractic; dentistry;
16 dental hygiene; environmental health; hearing aid instrument
17 dispensing and fitting; lead-based paint abatement, inspection,
18 project design, and training; medical nutrition therapy; medical
19 radiography; medication aide services; medicine and surgery;
20 mental health practice; nursing; nursing assistant or paid dining
21 assistant services; nursing home administration; occupational
22 therapy; optometry; osteopathic medicine; pharmacy; physical
23 therapy; podiatry; psychology; radon detection, measurement,
24 and mitigation; respiratory care; social work; swimming pool
25 operation; veterinary medicine and surgery; water system operation;
26 constructing or decommissioning water wells and installing water
27 well pumps and pumping equipment; and ~~wholesale drug distribution;~~

1 and

2 (b) Individuals in the practice of and entities in the
3 business of body art; cosmetology; electrology; emergency medical
4 services; esthetics; funeral directing and embalming; massage
5 therapy; and nail technology.

6 (2) The department shall determine the cost of the
7 credentialing system for such individuals and entities by
8 calculating the total of the base costs, the variable costs, and
9 any adjustments as provided in sections 71-162.01 to 71-162.03.

10 (3) When fees are to be established pursuant to section
11 71-162.04 for individuals or entities other than individuals in
12 the practice of constructing or decommissioning water wells and
13 installing water well pumps and pumping equipment, the department,
14 upon recommendation of the appropriate board if applicable, shall
15 base the fees on the cost of the credentialing system and shall
16 include usual and customary cost increases, a reasonable reserve,
17 and the cost of any new or additional credentialing activities.
18 For individuals in the practice of constructing or decommissioning
19 water wells and installing water well pumps and pumping equipment,
20 the Water Well Standards and Contractors' Licensing Board shall
21 establish the fees as otherwise provided in this subsection. All
22 such fees shall be collected as provided in section 71-163.

23 Sec. 96. Original sections 71-7401, 71-7402, 71-7403,
24 71-7404, 71-7405, 71-7406, 71-7407, 71-7408, 71-7409, 71-7410,
25 71-7411, 71-7412, 71-7413, 71-7416, 71-7417, 71-7420, 71-7422,
26 71-7423, 71-7424, 71-7425, and 71-7426, Reissue Revised Statutes
27 of Nebraska, and section 71-162, Revised Statutes Cumulative

1 Supplement, 2004, are repealed.

2 Sec. 97. The following sections are outright repealed:

3 Sections 71-7414, 71-7415, 71-7418, 71-7419, and 71-7421, Reissue
4 Revised Statutes of Nebraska.

5 2. Correct the operative date section so that the
6 sections added by this amendment become operative on August 1,
7 2006.

8 3. Renumber the remaining sections and correct internal
9 references accordingly.