## LEGISLATURE OF NEBRASKA

## ONE HUNDRED FOURTH LEGISLATURE

FIRST SESSION

## LEGISLATIVE BILL 37

Read first time January 08, 2015

## Committee:

- 1 A BILL FOR AN ACT relating to drugs; to amend sections 28-425, 38-2810, 2 38-2833, 38-2837, 38-2811, 38-2819, 38-2831, 38-2843, 38-2866, 3 38-2884, 38-2887, 38-2890, 38-2892, 38-2895, 38-2899, 71-436, 4 71-2404, 71-2405, 71-2426, 71-2427, 71-2401, 71-2402, 71-2440, 5 71-2441, 71-2501, 71-2502, 71-2505, 71-2506, 71-2507, 71-2509, 6 71-2510, 71-2512, 71-5401.01, 71-5401.02, 71-5402, 71-5403, 71-5404, 7 71-5405, 71-5406, 71-5407, 71-5409, 71-7436, and 71-7444, Reissue Revised Statutes of Nebraska, and sections 38-2801, 8 38-2850, 38-2867, 38-2869, 38-2870, 71-401, 71-403, 71-448, 71-2421, 9 71-2453, and 71-7447, Revised Statutes Cumulative Supplement, 2014; 10 to adopt the Prescription Drug Safety Act; to transfer, provide, 11 12 change, and eliminate provisions relating to poisons, medicinal 13 substances, prescription drugs and devices, the practice of 14 pharmacy, and the licensure of pharmacies; to name the Poison 15 Control Act; to harmonize provisions; to repeal the original sections; and to outright repeal sections 28-1438, 38-2848, 71-2403, 16 and 71-2511, Reissue Revised Statutes of Nebraska, and section 17 18 28-1437, Revised Statutes Cumulative Supplement, 2014.
- 19 Be it enacted by the people of the State of Nebraska,

1 Section 1. Sections 1 to 27 of this act shall be known and may be

- 2 <u>cited as the Prescription Drug Safety Act.</u>
- 3 Sec. 2. For purposes of the Prescription Drug Safety Act, the
- 4 definitions found in sections 3 to 20 of this act apply.
- 5 Sec. 3. Administer means to directly apply a drug or device by
- 6 <u>injection</u>, inhalation, ingestion, or other means to the body of a patient
- 7 or research subject.
- 8 Sec. 4. Administration means the act of (1) administering, (2)
- 9 keeping a record of such activity, and (3) observing, monitoring,
- 10 reporting, and otherwise taking appropriate action regarding desired
- 11 <u>effect, side effect, interaction, and contraindication associated with</u>
- 12 <u>administering the drug or device.</u>
- 13 Sec. 5. Section 71-2401, Reissue Revised Statutes of Nebraska, is
- 14 amended to read:
- 15 71-2401 Adulterated drug means an article For the purpose of
- 16 section 71-2404, an article, in the case of drugs, shall be deemed
- 17 adulterated (1) if, when a drug is sold under or by the name recognized
- 18 in The the United States Pharmacopeia and The Pharmacopoeia or National
- 19 Formulary, it differs from the standard of strength, quality, or purity
- 20 as determined by the test laid down in The the United States Pharmacopeia
- 21 and The Pharmacopoeia or National Formulary official at the time of
- 22 investigation, except that ; Provided, no drug defined in The the United
- 23 States Pharmacopeia and The Pharmacopoeia or National Formulary shall be
- 24 deemed to be adulterated under this <u>subdivision</u> provision if the standard
- 25 of strength or purity is plainly stated upon the bottle, box, or other
- 26 container thereof, although the standard may differ from that determined
- 27 by the test laid down in The the United States Pharmacopeia and The
- 28 Pharmacopoeia or National Formulary,  $\dot{\tau}$  or (2) if its strength or purity
- 29 falls below the professed standard of quality under which it is sold.
- 30 Sec. 6. <u>Chart order has the definition found in section 38-2810.</u>
- 31 Sec. 7. <u>Compounding means the preparation of components into a drug</u>

- 1 product.
- 2 Sec. 8. <u>Controlled substance has the definition found in section</u>
- 3 28-401.
- 4 Sec. 9. (1) Dispense or dispensing means interpreting, evaluating,
- 5 and implementing a medical order, including preparing and delivering a
- 6 drug or device to a patient or caregiver as defined in section 38-2809 in
- 7 <u>a suitable container appropriately labeled for subsequent administration</u>
- 8 to, or use by, a patient.
- 9 (2) Dispensing includes (a) dispensing incident to practice, (b)
- 10 dispensing pursuant to a delegated dispensing permit, (c) dispensing
- 11 pursuant to a medical order, and (d) any transfer of a prescription drug
- 12 <u>or device to a patient or caregiver as defined in section 38-2809 other</u>
- 13 <u>than by administering.</u>
- 14 Sec. 10. Distribute means to deliver a drug or device, other than
- 15 by administering or dispensing.
- 16 Sec. 11. Drugs, medicines, and medicinal substances means (1)
- 17 articles recognized in The United States Pharmacopeia and The National
- 18 Formulary, the Homeopathic Pharmacopoeia of the United States, or any
- 19 supplement to any of them, (2) articles intended for use in the
- 20 diagnosis, cure, mitigation, treatment, or prevention of diseases in
- 21 humans or animals, (3) articles, except food, intended to affect the
- 22 structure or any function of the body of a human or an animal, (4)
- 23 articles intended for use as a component of any articles specified in
- 24 <u>subdivision (1), (2), or (3) of this section, except any device or its</u>
- 25 components, parts, or accessories, and (5) prescription drugs or devices.
- 26 Sec. 12. Labeling means the process of preparing and affixing a
- 27 label to any drug container or device container, exclusive of the
- 28 labeling by a manufacturer, packager, or distributor of a nonprescription
- 29 drug or commercially packaged legend drug or device. Any such label shall
- 30 include all information required by section 23 of this act and federal
- 31 law or regulation. Compliance with labeling requirements under federal

- 1 law for devices described in subsection (2) of section 38-2841, medical
- 2 gases, and medical gas devices constitutes compliance with state law and
- 3 <u>regulations for purposes of this section.</u>
- 4 Sec. 13. Medical order means a prescription, a chart order, or an
- 5 order for pharmaceutical care issued by a practitioner.
- 6 Sec. 14. Section 71-2402, Reissue Revised Statutes of Nebraska, is
- 7 amended to read:
- 8 71-2402 (1) Misbranded drug means a drug The term misbranded, as
- 9 used in section 71-2404, shall apply to all drugs, the package or label
- 10 of which <u>bears</u> <del>shall bear</del> any statement, design, or device regarding <u>a</u>
- 11 <u>drug</u> drugs, or the ingredients of substances contained therein, which <u>is</u>
- 12 shall be false or misleading in any particular, or to any drug product
- 13 which is falsely <u>labeled</u> with the name and place of business of the
- 14 <u>manufacturer</u>, <u>packager</u>, <u>or distributor</u> <del>branded as to the state</del>,
- 15 territory, place or authority in which it is manufactured or produced.
- 16 (2) Misbranded drug includes an article (a) In case of drugs, an
- 17 article shall also be deemed to be misbranded (1) if it is an imitation
- of or offered for sale under the name of another article,  $\frac{1}{7}$  ( $\frac{b}{2}$ ) if it
- 19 is shall be labeled or branded so as to deceive or mislead the purchaser
- 20 or purport to be a foreign product when not so, or if the contents of the
- 21 package as originally put up shall have been removed, in whole or in
- 22 part, and other contents shall have been placed in such package, or if
- 23 the package fails to bear a statement, on the label, of the quantity or
- 24 proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or
- 25 beta eucaine, chloroform, cannabis indica, chloral hydrate o
- 26 acetanilide, phenacetine (acetphenetidine), antipyrine, belladonna, or
- 27 any derivative or preparation of any such substance contained therein,  $\dot{\tau}$
- 28 or (c 3) if its package or label bears or contains shall bear or contain
- 29 any statement, design, or device regarding the curative or therapeutic
- 30 effect of such article, or any of the ingredients or substances contained
- 31 therein, which is false or fraudulent.

1 Sec. 15. Pharmacist means any person who is licensed by the State

- 2 <u>of Nebraska to practice pharmacy as defined in section 38-2837.</u>
- 3 Sec. 16. Pharmacy has the same meaning as in section 71-425.
- 4 Sec. 17. Practitioner means a certified registered nurse
- 5 <u>anesthetist</u>, a certified nurse midwife, a dentist, an optometrist, a
- 6 nurse practitioner, a pharmacist, a physician assistant, a physician, a
- 7 podiatrist, or a veterinarian credentialed under the Uniform
- 8 <u>Credentialing Act.</u>
- 9 Sec. 18. Prescribe means to issue a medical order.
- 10 Sec. 19. Prescription means an order for a drug or device issued by
- 11 <u>a practitioner for a specific patient, for emergency use, or for use in</u>
- 12 <u>immunizations. Prescription does not include a chart order.</u>
- 13 Sec. 20. (1) Prescription drug or device or legend drug or device
- 14 <u>means a drug or device:</u>
- 15 (a) Which is required under federal law to be labeled with one of
- the following statements prior to being dispensed or delivered:
- 17 (i) Caution: Federal law prohibits dispensing without prescription;
- 18 <u>(ii) Caution: Federal law restricts this drug to use by or on the</u>
- 19 <u>order of a licensed veterinarian; or</u>
- 20 <u>(iii) "Rx Only"; or</u>
- 21 (b) Which is required by any applicable federal or state law to be
- 22 dispensed pursuant only to a prescription or chart order or which is
- 23 restricted to use by practitioners only.
- 24 (2) Prescription drug or device or legend drug or device does not
- 25 include a type of device, including supplies and device components, which
- 26 <u>carries the federal Food and Drug Administration legend "Caution: Federal</u>
- 27 <u>law restricts this device to sale by or on the order of a licensed health</u>
- 28 care practitioner" or an alternative legend approved by the federal Food
- 29 and Drug Administration which it recognizes, in published guidance, as
- 30 <u>conveying essentially the same message.</u>
- 31 Sec. 21. (1) Nothing in the Prescription Drug Safety Act shall be

1 construed as authority for a practitioner to perform any activity he or

- 2 <u>she is not otherwise authorized to perform by another law of this state.</u>
- 3 (2) A practitioner that stores, dispenses, compounds, administers,
- 4 or otherwise provides any drug to a patient shall comply with the
- 5 <u>Prescription Drug Safety Act.</u>
- 6 (3) A practitioner or authorized person that compounds or
- 7 reconstitutes any drug shall comply with section 45 of this act.
- 8 Sec. 22. (1) Except as otherwise provided in this section or the
- 9 <u>Uniform Controlled Substances Act or except when administered directly by</u>
- 10 a practitioner to an ultimate user, a legend drug which is not a
- 11 <u>controlled substance shall not be dispensed without a written, oral, or</u>
- 12 <u>electronic prescription. Such prescription shall be valid for twelve</u>
- 13 <u>months after the date of issuance.</u>
- 14 (2) A prescription for a legend drug which is not a controlled
- 15 substance shall contain the following information prior to being filled
- 16 by a pharmacist or practitioner who holds a pharmacy license under
- 17 subdivision (1) of section 38-2850: (a) Patient's name, (b) name of the
- 18 drug, device, or biological, (c) strength of the drug or biological, if
- 19 applicable, (d) dosage form of the drug or biological, (e) quantity of
- 20 the drug, device, or biological prescribed, (f) directions for use, (g)
- 21 date of issuance, (h) number of authorized refills, (i) the prescribing
- 22 practitioner's name, and (j) if the prescription is written, the
- 23 prescribing practitioner's signature. Prescriptions for controlled
- 24 <u>substances must meet the requirements of sections 28-414 and 28-414.01.</u>
- 25 (3) A written, signed paper prescription may be transmitted to the
- 26 pharmacy via facsimile which shall serve as the original written
- 27 prescription. An electronic prescription may be electronically or
- 28 <u>digitally signed and transmitted to the pharmacy and may serve as the</u>
- 29 original prescription.
- 30 (4) It shall be unlawful for any person knowingly or intentionally
- 31 to possess or to acquire or obtain or to attempt to acquire or obtain, by

- 1 means of misrepresentation, fraud, forgery, deception, or subterfuge,
- 2 possession of any drug substance not classified as a controlled substance
- 3 under the Uniform Controlled Substances Act which can only be lawfully
- 4 dispensed, under federal statutes in effect on January 1, 2015, upon the
- 5 written or oral prescription of a practitioner authorized to prescribe
- 6 such substances.
- 7 Sec. 23. (1) Any prescription for a legend drug which is not a
- 8 controlled substance shall be kept by the practitioner who holds a
- 9 pharmacy license in a readily retrievable format and shall be maintained
- 10 <u>for a minimum of five years. The practitioner shall make all such files</u>
- 11 <u>readily available to the department and law enforcement for inspection</u>
- 12 without a search warrant.
- 13 (2) Before dispensing a legend drug which is not a controlled
- 14 <u>substance pursuant to a written, oral, or electronic prescription, a</u>
- 15 label shall be affixed to the container in which the drug is dispensed.
- 16 Such label shall bear (a) the name, address, and telephone number of the
- 17 pharmacy or practitioner, (b) the name of the patient, (c) the date of
- 18 <u>filling, (d) the serial number of the prescription under which it is</u>
- 19 recorded in the practitioner's prescription records, (e) the name of the
- 20 prescribing practitioner, (f) the directions for use, (g) name of the
- 21 drug, device, or biological unless instructed to omit by the prescribing
- 22 practitioner, (h) strength of the drug or biological, if applicable, (i)
- 23 quantity of the drug, device, or biological in the container, except
- 24 unit-dose containers, (j) dosage form of the drug or biological, and (k)
- 25 any cautionary statements contained in the prescription.
- Sec. 24. Section 71-2404, Reissue Revised Statutes of Nebraska, is
- 27 amended to read:
- 28 71-2404 Any drug which is adulterated or misbranded within the
- 29 meaning of sections 71-2401 and 71-2402, and which is sold, offered for
- 30 sale, or delivered within this state, shall be liable to be proceeded
- 31 against where the same is found and seized for confiscation by a process

- 1 of libel for condemnation. If such drug is condemned as being adulterated
- 2 or misbranded or of a poisonous or deleterious character, the drug within
- 3 the meaning of said sections, the same shall be disposed of by
- 4 destruction or sale as the court may direct, and the proceeds thereof, if
- 5 sold, less the legal costs and charges, shall be paid into the treasury
- 6 of this state, and such goods shall not be sold in any jurisdiction
- 7 contrary to the Prescription Drug Safety Act provisions of said sections
- 8 or the laws of that jurisdiction. Any libel proceeding in rem, under the
- 9 provisions of this section, may be joined with any criminal prosecution
- in personam or may be prosecuted separately.
- 11 Sec. 25. Section 71-2405, Reissue Revised Statutes of Nebraska, is
- 12 amended to read:
- 13 71-2405 No person shall, within this state, manufacture for sale
- 14 therein or have in his or her possession with intent to sell, offer or
- 15 expose for sale, or sell any remedies, medicines, or drugs which are
- 16 adulterated or misbranded within the meaning of sections 71-2401 and
- $17 \frac{71-2402}{}$
- 18 Sec. 26. Any person violating any of the provisions of section 24
- 19 or 25 of this act is guilty of a Class III misdemeanor. Any person, for a
- 20 <u>second or subsequent violation of any of the provisions of section 24 or</u>
- 21 <u>25 of this act, is guilty of a Class II misdemeanor.</u>
- 22 Sec. 27. An employee or agent of a prescribing practitioner may
- 23 <u>communicate a prescription, chart order, or refill authorization issued</u>
- 24 by the prescribing practitioner to a pharmacist or a pharmacist intern
- 25 except for an emergency oral authorization for a controlled substance
- 26 listed in Schedule II of section 28-405.
- 27 Sec. 28. Section 38-2801, Revised Statutes Cumulative Supplement,
- 28 2014, is amended to read:
- 29 38-2801 Sections 38-2801 to 38-28,103 <u>and sections 30, 34, 39, 42,</u>
- 30 44, 45, and 54 to 57 of this act and the Nebraska Drug Product Selection
- 31 Act shall be known and may be cited as the Pharmacy Practice Act.

1 Sec. 29. Section 38-2802, Revised Statutes Cumulative Supplement,

- 2 2014, is amended to read:
- 3 38-2802 For purposes of the Pharmacy Practice Act and elsewhere in
- 4 the Uniform Credentialing Act, unless the context otherwise requires, the
- 5 definitions found in sections 38-2803 to <u>38-2847 and sections 30, 34, and</u>
- 6 <u>39 of this act</u> <del>38-2848</del> apply.
- 7 Sec. 30. <u>Calculated expiration date means the expiration date on</u>
- 8 the manufacturer's, packager's, or distributor's container or one year
- 9 from the date the drug or device is repackaged, whichever is earlier.
- 10 Sec. 31. Section 38-2810, Reissue Revised Statutes of Nebraska, is
- 11 amended to read:
- 12 38-2810 Chart order means an order for a drug or device issued by a
- 13 practitioner for a patient who is in the hospital or long-term care
- 14 <u>facility</u> where the chart is stored or for a patient receiving
- 15 detoxification treatment or maintenance treatment pursuant to section
- 16 28-412. Chart order does not include a prescription and may not be used
- 17 to authorize dispensing of a controlled substance to a patient in a long-
- 18 term care facility.
- 19 Sec. 32. Section 38-2811, Reissue Revised Statutes of Nebraska, is
- 20 amended to read:
- 21 38-2811 Compounding means the preparation of components into a drug
- 22 product (1) as the result of a practitioner's medical order or initiative
- 23 occurring in the course of practice based upon the relationship between
- 24 the practitioner, patient, and pharmacist or (2) for the purpose of, or
- 25 as an incident to, research, teaching, or chemical analysis and not for
- 26 sale or dispensing. Compounding includes the preparation of drugs or
- 27 devices in anticipation of receiving medical orders based upon routine,
- 28 regularly observed prescribing patterns.
- 29 Sec. 33. Section 38-2819, Reissue Revised Statutes of Nebraska, is
- 30 amended to read:
- 31 38-2819 Drugs, medicines, and medicinal substances means (1)

- 1 articles recognized in The the official United States Pharmacopeia and
- 2 The National Formulary Pharmacopoeia, the Homeopathic Pharmacopoeia of
- 3 the United States, the official National Formulary, or any supplement to
- 4 any of them, (2) articles intended for use in the diagnosis, cure,
- 5 mitigation, treatment, or prevention of diseases in humans or animals,
- 6 (3) articles, except food, intended to affect the structure or any
- 7 function of the body of a human or an animal, (4) articles intended for
- 8 use as a component of any articles specified in subdivision (1), (2), or
- 9 (3) of this section, except any device or its components, parts, or
- 10 accessories, and (5) prescription drugs or devices.
- 11 Sec. 34. <u>Hospital pharmacy means each facility licensed as a</u>
- 12 hospital in which the compounding, preparation for administration, or
- 13 <u>dispensing of drugs or devices pursuant to a chart order occurs for</u>
- 14 patients within the confines of the hospital with oversight by a
- 15 pharmacist in charge.
- Sec. 35. Section 38-2831, Reissue Revised Statutes of Nebraska, is
- 17 amended to read:
- 18 38-2831 (1) Pharmaceutical care means the provision of drug therapy
- 19 by a pharmacist for the purpose of achieving therapeutic outcomes that
- 20 improve a patient's quality of life. Such outcomes include (a) the cure
- 21 of disease, (b) the elimination or reduction of a patient's
- 22 symptomatology, (c) the arrest or slowing of a disease process, or (d)
- 23 the prevention of a disease or symptomatology.
- 24 (2) Pharmaceutical care includes the process through which the
- 25 pharmacist works in concert with the patient and his or her caregiver,
- 26 physician, or other professionals in designing, implementing, and
- 27 monitoring a therapeutic plan that will produce specific therapeutic
- 28 outcomes for the patient.
- 29 Sec. 36. Section 38-2833, Reissue Revised Statutes of Nebraska, is
- 30 amended to read:
- 31 38-2833 Pharmacist in charge means a pharmacist who is designated on

1 a pharmacy license or designated by a hospital as being responsible for

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- 2 the practice of pharmacy in the pharmacy for which a pharmacy license is
- 3 issued <u>or in a hospital pharmacy</u> and who works within the physical
- 4 confines of such pharmacy or hospital pharmacy for a majority of the
- 5 hours per week that the pharmacy is open for business averaged over a
- 6 twelve-month period or thirty hours per week, whichever is less.
- 7 Sec. 37. Section 38-2837, Reissue Revised Statutes of Nebraska, is
- 8 amended to read:
- 9 38-2837 (1) Practice of pharmacy means (a) the interpretation,
- 10 evaluation, and implementation of a medical order, (b) the dispensing of
- 11 drugs and devices, (c) drug product selection, (d) the administration of
- 12 drugs or devices, (e) drug utilization review, (f) patient counseling,
- 13 (g) the provision of pharmaceutical care, and (h) medication therapy
- 14 <u>management</u>, and (i) the responsibility for compounding and labeling of
- 15 dispensed or repackaged drugs and devices, proper and safe storage of
- 16 drugs and devices, and maintenance of proper records.
- 17 (2) The active practice of pharmacy means the performance of the
- 18 functions set out in this section by a pharmacist as his or her principal
- 19 or ordinary occupation.
- Sec. 38. Section 38-2843, Reissue Revised Statutes of Nebraska, is
- 21 amended to read:
- 22 38-2843 Public health clinic worker means a person in a public
- 23 health clinic with a delegated dispensing permit who has completed the
- 24 approved training and has demonstrated proficiency to perform the task of
- 25 dispensing authorized refills of oral contraceptives pursuant to a
- 26 written prescription.
- 27 Sec. 39. <u>Telepharmacy means the provision of pharmacist care, by a</u>
- 28 pharmacist located within the United States, using telecommunications,
- 29 remote order entry, or other automations and technologies to deliver care
- 30 <u>to patients or their agents who are located at sites other than where the</u>
- 31 pharmacist is located.

1 Sec. 40. Section 38-2850, Revised Statutes Cumulative Supplement,

- 2 2014, is amended to read:
- 3 38-2850 As authorized by the Uniform Credentialing Act, the practice
- 4 of pharmacy may be engaged in by a pharmacist, a pharmacist intern, or a
- 5 practitioner with a pharmacy license. The practice of pharmacy shall not
- 6 be construed to include:
- 7 (1) Persons who sell, offer, or expose for sale completely denatured
- 8 alcohol or concentrated lye, insecticides, and fungicides in original
- 9 packages;
- 10  $(\underline{1} \ 2)$  Practitioners, other than veterinarians, certified nurse
- 11 midwives, certified registered nurse anesthetists, and nurse
- 12 practitioners, and physician assistants, who dispense drugs or devices as
- 13 an incident to the practice of their profession, except that if such
- 14 practitioner regularly engages in dispensing such drugs or devices to his
- 15 or her patients for which such patients are charged, such practitioner
- 16 shall obtain a pharmacy license;
- 17  $(2\ 3)$  Persons who sell, offer, or expose for sale nonprescription
- 18 drugs or proprietary medicines, the sale of which is not in itself a
- 19 violation of the Nebraska Liquor Control Act;
- 20 (3 4) Medical representatives, detail persons, or persons known by
- 21 some name of like import, but only to the extent of permitting the
- 22 relating of pharmaceutical information to health care professionals;
- 23 (45) Licensed veterinarians practicing within the scope of their
- 24 profession;
- 25 (5 6) Certified nurse midwives, certified registered nurse
- 26 anesthetists, and nurse practitioners, and physician assistants who
- 27 dispense sample medications which are provided by the manufacturer and
- 28 are dispensed at no charge to the patient;
- 29 (7) Hospitals engaged in the compounding and dispensing of drugs and
- 30 devices pursuant to chart orders for persons registered as patients and
- 31 within the confines of the hospital, except that if a hospital engages in

- 1 such compounding and dispensing for persons not registered as patients
- 2 and within the confines of the hospital, such hospital shall obtain a
- 3 pharmacy license or delegated dispensing permit;
- 4 (6 8) Optometrists who prescribe or dispense eyeglasses or contact
- 5 lenses to their own patients, including contact lenses that contain and
- 6 deliver ocular pharmaceutical agents as authorized under the Optometry
- 7 Practice Act, and ophthalmologists who prescribe or dispense eyeglasses
- 8 or contact lenses to their own patients, including contact lenses that
- 9 contain and deliver ocular pharmaceutical agents;
- 10 (7 9) Registered nurses or licensed practical nurses employed by a
- 11 hospital who administer pursuant to a chart order, or procure for such
- 12 purpose, single doses of drugs or devices from original drug or device
- 13 containers or properly labeled <u>repackaged or prepackaged drug</u> or device
- 14 containers to persons registered as patients and within the confines of
- 15 the hospital;
- 16  $(8\ 10)$  Persons employed by a facility where dispensed drugs and
- 17 devices are delivered from a pharmacy for pickup by a patient or
- 18 caregiver and no dispensing or storage of drugs or devices occurs;
- 19 (9 11) Persons who sell or purchase medical products, compounds,
- 20 vaccines, or serums used in the prevention or cure of animal diseases and
- 21 maintenance of animal health if such medical products, compounds,
- 22 vaccines, or serums are not sold or purchased under a direct, specific,
- 23 written medical order of a licensed veterinarian;
- 24  $(10 \ 12)$  A pharmacy or a person accredited by an accrediting body
- 25 which or who, pursuant to a medical order, (a) administers, dispenses, or
- 26 distributes medical gas or medical gas devices to patients or ultimate
- 27 users or (b) purchases or receives medical gas or medical gas devices for
- 28 administration, dispensing, or distribution to patients or ultimate
- 29 users; and
- 30  $(11 ext{ } 13)$  A business or a person accredited by an accrediting body
- 31 which or who, pursuant to a medical order, (a) sells, delivers, or

1 distributes devices described in subsection (2) of section 38-2841 to

- 2 patients or ultimate users or (b) purchases or receives such devices with
- 3 intent to sell, deliver, or distribute to patients or ultimate users.
- 4 Sec. 41. Section 38-2866, Reissue Revised Statutes of Nebraska, is
- 5 amended to read:
- 6 38-2866 Unless specifically limited by the board or the department,
- 7 a pharmacist may (1) engage in the practice of pharmacy and telepharmacy,
- 8 as defined in section 71-2445, (2) use automation in the practice of
- 9 pharmacy and telepharmacy, (3) use the abbreviation R.P., RP, R.Ph., or
- 10 RPh or the title licensed pharmacist or pharmacist, (4) enter into
- 11 delegated dispensing agreements, and (5) supervise pharmacy technicians
- 12 <u>and pharmacist interns, and (6) possess</u>, without dispensing, prescription
- 13 drugs and devices, including controlled substances, for purposes of
- 14 administration, repackaging, or educational use in an accredited pharmacy
- 15 program.
- 16 Sec. 42. <u>A pharmacist may supervise any combination of pharmacy</u>
- 17 <u>technicians and pharmacist interns at any time up to a total of three</u>
- 18 people. This section does not apply to a pharmacist intern who is
- 19 <u>receiving experiential training directed by the accredited pharmacy</u>
- 20 program in which he or she is enrolled.
- 21 Sec. 43. Section 38-2867, Revised Statutes Cumulative Supplement,
- 22 2014, is amended to read:
- 23 38-2867 (1) Except as provided for pharmacy technicians in sections
- 24 38-2890 to 38-2897, for persons described in subdivision (10 + 12) or (11 + 12)
- 25 13) of section 38-2850, and for individuals authorized to dispense under
- 26 a delegated dispensing permit, no person other than a licensed
- 27 pharmacist, a pharmacist intern, or a practitioner with a pharmacy
- 28 license shall provide pharmaceutical care, compound and dispense drugs or
- 29 devices, or dispense pursuant to a medical order. Notwithstanding any
- 30 other provision of law to the contrary, a pharmacist or pharmacist intern
- 31 may dispense drugs or devices pursuant to a medical order of a

- 1 practitioner authorized to prescribe in another state if such
- 2 practitioner could be authorized to prescribe such drugs or devices in
- 3 this state.
- 4 (2) Except as provided for pharmacy technicians in sections 38-2890
- 5 to 38-2897, for persons described in subdivision (10  $\frac{12}{12}$ ) or (11  $\frac{13}{12}$ ) of
- 6 section 38-2850, and for individuals authorized to dispense under a
- 7 delegated dispensing permit, it shall be unlawful for any person to
- 8 permit or direct a person who is not a pharmacist intern, a licensed
- 9 pharmacist, or a practitioner with a pharmacy license to provide
- 10 pharmaceutical care, compound and dispense drugs or devices, or dispense
- 11 pursuant to a medical order.
- 12 (3) It shall be unlawful for any person to coerce or attempt to
- 13 coerce a pharmacist to enter into a delegated dispensing agreement or to
- 14 supervise any pharmacy technician for any purpose or in any manner
- 15 contrary to the professional judgment of the pharmacist. Violation of
- 16 this subsection by a health care professional regulated pursuant to the
- 17 Uniform Credentialing Act shall be considered an act of unprofessional
- 18 conduct. A violation of this subsection by a facility shall be prima
- 19 facie evidence in an action against the license of the facility pursuant
- 20 to the Health Care Facility Licensure Act. Any pharmacist subjected to
- 21 coercion or attempted coercion pursuant to this subsection has a cause of
- 22 action against the person and may recover his or her damages and
- 23 reasonable attorney's fees.
- 24 (4) Violation of this section by an unlicensed person shall be a
- 25 Class III misdemeanor.
- Sec. 44. (1) Any person authorized to compound as provided in the
- 27 Pharmacy Practice Act shall compound in compliance with the standards of
- 28 chapters 795 and 797 of The United States Pharmacopeia and The National
- 29 Formulary, as such chapters existed on January 1, 2015, and shall
- 30 compound (a) as the result of a practitioner's medical order or
- 31 initiative occurring in the course of practice based upon the

1 relationship between the practitioner, patient, and pharmacist, (b) for

- 2 the purpose of, or as an incident to, research, teaching, or chemical
- 3 analysis and not for sale or dispensing, or (c) for office use only and
- 4 not for resale.
- 5 (2) Compounding in a hospital pharmacy may occur for any hospital
- 6 which is part of the same health care system under common ownership or
- 7 <u>which is a member of or an affiliated member of a formal network or</u>
- 8 <u>partnership agreement.</u>
- 9 (3)(a) Any authorized person may reconstitute a commercially
- 10 <u>available drug product in accordance with directions contained in</u>
- 11 approved labeling provided by the product's manufacturer and other
- 12 <u>manufacturer directions consistent with labeling.</u>
- 13 (b) Any authorized person using beyond-use dating must follow the
- 14 approved product manufacturer's labeling or the standards of The United
- 15 States Pharmacopeia and The National Formulary if the product
- 16 manufacturer's labeling does not specify beyond-use dating.
- 17 (c) Any authorized person engaged in activities listed in this
- 18 <u>subsection</u> is not engaged in compounding, except that any variance from
- 19 <u>the approved product manufacturer's labeling will result in the person</u>
- 20 being engaged in compounding.
- 21 (4) Any authorized person splitting a scored tablet along scored
- 22 lines or adding flavoring to a commercially available drug product is not
- 23 engaged in compounding.
- 24 <u>(5) No person shall compound:</u>
- 25 (a) A drug that has been identified by the federal Food and Drug
- 26 Administration as withdrawn or removed from the market because the drug
- 27 was found to be unsafe or ineffective;
- 28 (b) A drug that is essentially a copy of an approved drug unless
- 29 there is a drug shortage as determined by the board or unless a patient
- 30 <u>has an allergic reaction to the approved drug; or</u>
- 31 (c) A drug that has been identified by the federal Food and Drug

1 Administration or the board as a product which may not be compounded.

- 2 Sec. 45. (1) The pharmacist in charge of a hospital pharmacy shall,
- 3 on or before January 1, 2017, develop and implement policies and
- 4 procedures to ensure that a pharmacist reviews all medical orders prior
- 5 to the first dose being administered to a patient in the hospital. The
- 6 policies and procedures may provide for either a pharmacist onsite or the
- 7 use of telepharmacy to comply with this requirement.
- 8 (2) This section does not apply to the following situations:
- 9 (a) When the practitioner controls the ordering, dispensing, and
- 10 administration of the drug, such as in the operating room, endoscopy
- 11 <u>suite, or emergency room; or</u>
- 12 <u>(b) When time does not permit the pharmacist's review, such as (i) a</u>
- 13 stat order meaning a medical order which indicates that the medication is
- 14 to be given immediately and only once or (ii) when the clinical status of
- 15 the patient would be significantly compromised by the delay resulting
- 16 from the pharmacist's review of the order.
- 17 Sec. 46. Section 38-2869, Revised Statutes Cumulative Supplement,
- 18 2014, is amended to read:
- 19 38-2869 (1)(a) Prior to the dispensing or the delivery of a drug or
- 20 device pursuant to a medical order to a patient or caregiver, a
- 21 pharmacist shall in all care settings conduct a prospective drug
- 22 utilization review. Such prospective drug utilization review shall
- 23 involve monitoring the patient-specific medical history described in
- 24 subdivision (b) of this subsection and available to the pharmacist at the
- 25 practice site for:
- 26 (i) Therapeutic duplication;
- 27 (ii) Drug-disease contraindications;
- 28 (iii) Drug-drug interactions;
- (iv) Incorrect drug dosage or duration of drug treatment;
- 30 (v) Drug-allergy interactions; and
- 31 (vi) Clinical abuse or misuse.

1 (b) A pharmacist conducting a prospective drug utilization review

- 2 shall ensure that a reasonable effort is made to obtain from the patient,
- 3 his or her caregiver, or his or her practitioner and to record and
- 4 maintain records of the following information to facilitate such review:
- 5 (i) The name, address, telephone number, date of birth, and gender
- 6 of the patient;
- 7 (ii) The patient's history of significant disease, known allergies,
- 8 and drug reactions and a comprehensive list of relevant drugs and devices
- 9 used by the patient; and
- 10 (iii) Any comments of the pharmacist relevant to the patient's drug
- 11 therapy.
- 12 (c) The assessment of data on drug use in any prospective drug
- 13 utilization review shall be based on predetermined standards which are  $\tau$
- 14 approved by the board.
- 15 (2)(a) Prior to the dispensing or delivery of a drug or device
- 16 pursuant to a prescription, the pharmacist shall ensure that a verbal
- 17 offer to counsel the patient or caregiver is made. The refusal of the
- 18 verbal offer to counsel must be documented. The counseling of the patient
- 19 or caregiver by the pharmacist shall be on elements which, in the
- 20 exercise of the pharmacist's professional judgment, the pharmacist deems
- 21 significant for the patient. Such elements may include, but need not be
- 22 limited to, the following:
- (i) The name and description of the prescribed drug or device;
- 24 (ii) The route of administration, dosage form, dose, and duration of
- 25 therapy;
- 26 (iii) Special directions and precautions for preparation,
- 27 administration, and use by the patient or caregiver;
- 28 (iv) Common side effects, adverse effects or interactions, and
- 29 therapeutic contraindications that may be encountered, including
- 30 avoidance, and the action required if such effects, interactions, or
- 31 contraindications occur;

1 (v) Techniques for self-monitoring drug therapy;

- 2 (vi) Proper storage;
- 3 (vii) Prescription refill information; and
- 4 (viii) Action to be taken in the event of a missed dose.
- 5 (b) The patient counseling provided for in this subsection shall be
- 6 provided in person whenever practical or by the utilization of
- 7 telepharmacy telephone service which is available at no cost to the
- 8 patient or caregiver.
- 9 (c) Patient counseling shall be appropriate to the individual
- 10 patient and shall be provided to the patient or caregiver.
- 11 (d) Written information may be provided to the patient or caregiver
- 12 to supplement the patient counseling provided for in this subsection but
- 13 shall not be used as a substitute for such patient counseling.
- 14 (e) A verbal offer to counsel is not required This subsection shall
- 15 not be construed to require a pharmacist to provide patient counseling
- 16 when:
- 17 (i) The patient or caregiver refuses patient counseling;
- 18 (i $\pm$ ) The pharmacist, in his or her professional judgment, determines
- 19 that patient counseling may be detrimental to the patient's care or to
- 20 the relationship between the patient and his or her practitioner;
- 21 (iii) The patient is a patient or resident of a health care facility
- 22 or health care service licensed under the Health Care Facility Licensure
- 23 Act to whom prescription drugs or devices are administered by a licensed
- 24 or certified staff member or consultant or a certified physician's
- 25 assistant;
- 26 (iv) The practitioner authorized to prescribe drugs or devices
- 27 specifies that there shall be no patient counseling unless he or she is
- 28 contacted prior to such patient counseling. The prescribing practitioner
- 29 shall specify such prohibition in an oral prescription or in writing on
- 30 the face of a written prescription, including any prescription which is
- 31 received by facsimile or electronic transmission. The pharmacist shall

1 note "Contact Before Counseling" on the face of the prescription if such

- 2 is communicated orally by the prescribing practitioner;
- 3  $(\underline{iii} \ \forall)$  A medical gas or a medical gas device is administered,
- 4 dispensed, or distributed by a person described in subdivision ( $\frac{10}{2}$ ) of
- 5 section 38-2850; or
- 6 (iv  $\forall$ i) A device described in subsection (2) of section 38-2841 is
- 7 sold, distributed, or delivered by a <del>business or</del> person described in
- 8 subdivision (11  $\frac{13}{13}$ ) of section 38-2850.
- 9 Sec. 47. Section 38-2870, Revised Statutes Cumulative Supplement,
- 10 2014, is amended to read:
- 11 38-2870 (1) All medical orders shall be <u>written</u>, <u>oral</u>, <u>or electronic</u>
- 12 <u>and shall be</u> valid for the period stated in the medical order, except
- 13 that (a) if the medical order is for a controlled substance listed in
- 14 section 28-405, such period shall not exceed six months from the date of
- 15 issuance at which time the medical order shall expire and (b) if the
- 16 medical order is for a drug or device which is not a controlled substance
- 17 listed in section 28-405 or is an order issued by a practitioner for
- 18 pharmaceutical care, such period shall not exceed twelve months from the
- 19 date of issuance at which time the medical order shall expire.
- 20 (2) Prescription drugs or devices may only be dispensed by a
- 21 pharmacist or pharmacist intern pursuant to a medical order, by an
- 22 individual dispensing pursuant to a delegated dispensing permit, or as
- 23 otherwise provided in section 38-2850. Notwithstanding any other
- 24 provision of law to the contrary, a pharmacist or a pharmacist intern may
- 25 dispense drugs or devices pursuant to a medical order or an individual
- 26 dispensing pursuant to a delegated dispensing permit may dispense drugs
- 27 or devices pursuant to a medical order. The Pharmacy Practice Act shall
- 28 not be construed to require any pharmacist or pharmacist intern to
- 29 dispense, compound, administer, or prepare for administration any drug or
- 30 device pursuant to any medical order. A pharmacist or pharmacist intern
- 31 shall retain the professional right to refuse to dispense.

- 1 (3) Except as otherwise provided in sections 28-414 and 28-414.01 to
- 2 28-414.05, a practitioner or the practitioner's agent may transmit a
- 3 medical order to a pharmacist or pharmacist intern by the following
- 4 means: (a) In writing, (b) orally, (c) by facsimile transmission of a
- 5 written medical order or electronic transmission of a medical order
- 6 signed by the practitioner, or (d) by facsimile transmission of a written
- 7 medical order or electronic transmission of a medical order which is not
- 8 signed by the practitioner. Such <u>an unsigned medical</u> order shall be
- 9 verified with the practitioner treated the same as an oral medical order.
- 10 (4)(a) Except as otherwise provided in sections 28-414 and 28-414.01
- 11 to 28-414.05, any medical order transmitted by facsimile or electronic
- 12 transmission shall:
- 13  $(\underline{i} \ a) \ \underline{Be} \ be$  transmitted by the practitioner or the practitioner's
- 14 agent directly to a pharmacist or pharmacist intern in a licensed
- 15 pharmacy of the patient's choice. No intervening person shall be
- 16 permitted access to the medical order to alter such order or the licensed
- 17 pharmacy chosen by the patient. Such medical order may be transmitted
- 18 through a third-party intermediary who shall facilitate the transmission
- 19 of the order from the practitioner or practitioner's agent to the
- 20 pharmacy; -
- 21  $(\underline{ii} \ b)$  <u>Identify</u> identify the transmitter's telephone number or other
- 22 suitable information necessary to contact the transmitter for written or
- 23 oral confirmation, the time and date of the transmission, the identity of
- 24 the pharmacy intended to receive the transmission, and other information
- 25 as required by  $law_{L}^{2}$  and
- 26  $(\underline{iii} \ e)$  Serve as the original medical order if all other
- 27 requirements of this subsection are satisfied.
- 28 (b) Medical orders transmitted by electronic transmission shall be
- 29 signed by the practitioner either with an electronic signature for legend
- 30 <u>drugs which are not controlled substances</u> or a digital signature <u>for</u>
- 31 legend drugs which are controlled substances.

1 (5) The pharmacist shall exercise professional judgment regarding

- 2 the accuracy, validity, and authenticity of any medical order transmitted
- 3 by facsimile or electronic transmission.
- 4 Sec. 48. Section 38-2884, Reissue Revised Statutes of Nebraska, is
- 5 amended to read:
- 6 38-2884 Under a delegated dispensing permit for a public health
- 7 clinic, approved formulary drugs and devices may be dispensed by a public
- 8 health clinic worker or a health care professional licensed in Nebraska
- 9 to practice medicine and surgery or licensed in Nebraska as a registered
- 10 nurse, licensed practical nurse, or physician assistant without the
- 11 onsite services of a pharmacist if:
- 12 (1) The initial dispensing of all prescriptions for approved
- 13 formulary drugs and devices is conducted by a health care professional
- 14 licensed in Nebraska to practice medicine and surgery or pharmacy or
- 15 licensed in Nebraska as a registered nurse, licensed practical nurse, or
- 16 physician assistant;
- 17 (2) The drug or device is dispensed pursuant to a prescription
- 18 written onsite by a practitioner;
- 19 (3) The only prescriptions to be refilled under the delegated
- 20 dispensing permit are prescriptions for oral contraceptives;
- 21 (4) Prescriptions are accompanied by patient instructions and
- 22 written information approved by the director;
- 23 (5) The dispensing of authorized refills of oral contraceptives is
- 24 done by a licensed health care professional listed in subdivision (1) of
- 25 this section or by a public health clinic worker;
- 26 (6) All drugs or devices are prepackaged by the manufacturer or at a
- 27 public health clinic by a pharmacist into the quantity to be prescribed
- 28 and dispensed at the public health clinic;
- 29 (7) All drugs and devices stored, received, or dispensed under the
- 30 authority of public health clinics are properly labeled at all times. For
- 31 purposes of this subdivision, properly labeled means that the label

1 affixed to the container prior to dispensing contains the following

- 2 information:
- 3 (a) The name of the manufacturer;
- 4 (b) The lot number and expiration date from the manufacturer or, if
- 5 <u>repackaged</u> prepackaged by a pharmacist, the lot number and calculated
- 6 expiration date. Calculated expiration date means the expiration date on
- 7 the manufacturer's, packager's, or distributor's container or one year
- 8 from the date the drug or device is repackaged, whichever is earlier;
- 9 (c) Directions for patient use;
- 10 (d) The quantity of drug in the container;
- 11 (e) The name, strength, and dosage form of the drug; and
- 12 (f) Auxiliary labels as needed for proper adherence to any
- 13 prescription;
- 14 (8) The following additional information is added to the label of
- each container when the drug or device is dispensed:
- 16 (a) The patient's name;
- 17 (b) The name of the prescribing health care professional;
- 18 (c) The prescription number;
- 19 (d) The date dispensed; and
- (e) The name and address of the public health clinic;
- 21 (9) The only drugs and devices allowed to be dispensed or stored by
- 22 public health clinics appear on the formulary approved pursuant to
- 23 section 38-2881; and
- 24 (10) At any time that dispensing is occurring from a public health
- 25 clinic, the delegating pharmacist for the public health clinic or on-call
- 26 pharmacist in Nebraska is available, either in person or by telephone, to
- 27 answer questions from clients, staff, public health clinic workers, or
- 28 volunteers. This availability shall be confirmed and documented at the
- 29 beginning of each day that dispensing will occur. The delegating
- 30 pharmacist or on-call pharmacist shall inform the public health clinic if
- 31 he or she will not be available during the time that his or her

1 availability is required. If a pharmacist is unavailable, no dispensing

- 2 shall occur.
- 3 Sec. 49. Section 38-2887, Reissue Revised Statutes of Nebraska, is
- 4 amended to read:
- 5 38-2887 (1) A public health clinic worker or dialysis drug or device
- 6 distributor worker shall demonstrate proficiency to the delegating
- 7 pharmacist, according to the standards approved by the board. The
- 8 delegating pharmacist shall document proficiency for each worker. In
- 9 addition, a public health clinic worker shall be supervised by a licensed
- 10 health care professional specified in subdivision (1) of section 38-2884
- 11 for the first month that such worker is dispensing refills of oral
- 12 contraceptives.
- 13 (2) Following initial training and proficiency demonstration, the
- 14 public health clinic worker or dialysis drug or device distributor worker
- 15 shall demonstrate continued proficiency at least annually. A dialysis
- 16 drug or device distributor worker shall attend annual training programs
- 17 taught by a pharmacist. Documentation of such training shall be
- 18 maintained in the worker's employee file.
- 19 (3) The public health clinic or dialysis drug or device distributor
- 20 for which a public health clinic worker or dialysis drug or device
- 21 distributor worker is working shall be liable for acts or omissions on
- 22 the part of such worker.
- 23 Sec. 50. Section 38-2890, Reissue Revised Statutes of Nebraska, is
- 24 amended to read:
- 25 38-2890 (1) All pharmacy technicians employed by a facility licensed
- 26 under the Health Care Facility Licensure Act shall be registered with the
- 27 Pharmacy Technician Registry created in section 38-2893.
- 28 (2) To register as a pharmacy technician, an individual shall (a) be
- 29 at least eighteen years of age, (b) be a high school graduate or be
- 30 officially recognized by the State Department of Education as possessing
- 31 the equivalent degree of education, (c) have never been convicted of any

1 nonalcohol, drug-related misdemeanor or felony, (d) file an application

- 2 with the department, and (e) pay the applicable fee.
- 3 (3) A pharmacy technician shall apply for registration as provided
- 4 in this section within thirty days after being hired by a pharmacy or
- 5 facility. Pharmacy technicians employed in that capacity on September 1,
- 6 2007, shall apply for registration within thirty days after September 1,
- 7 2007.
- 8 (3) Beginning January 1, 2017, a pharmacy technician shall be
- 9 certified by a state or national certifying body approved by the board in
- 10 order to be employed as a pharmacy technician in a health care facility.
- 11 Sec. 51. Section 38-2892, Reissue Revised Statutes of Nebraska, is
- 12 amended to read:
- 13 38-2892 (1) The pharmacist in charge of a pharmacy or hospital A
- 14 pharmacy employing pharmacy technicians shall be responsible for the
- 15 supervision and performance of the pharmacy technicians.
- 16 (2) The pharmacist in charge shall be responsible for the practice
- 17 of pharmacy and the establishment of written control procedures and
- 18 guidelines governing the qualifications, onsite training, functions,
- 19 supervision, and verification of the performance of pharmacy technicians.
- 20 Except as otherwise provided in the Automated Medication Systems Act, the
- 21 The supervision of pharmacy such technicians at a pharmacy the place of
- 22 employment shall be performed by the <del>licensed</del> pharmacist who is on duty
- 23 in the facility with the pharmacy technicians or located in pharmacies
- 24 that utilize a real-time, online data base and have a pharmacist in all
- 25 pharmacies. The supervision of pharmacy technicians at a hospital
- 26 pharmacy shall be performed by the pharmacist assigned by the pharmacist
- 27 <u>in charge to be responsible for the supervision and verification of the</u>
- 28 activities of the pharmacy technicians.
- 29 (3)(a) Each pharmacy shall document, in a manner and method
- 30 specified in the written control procedures and guidelines, the basic
- 31 competence of the pharmacy technician prior to performance of tasks and

1 functions by such technician. Such basic competence shall include, but

- 2 not be limited to:
- 3 (i) Basic pharmaceutical nomenclature;
- 4 (ii) Metric system measures, both liquid and solid;
- 5 (iii) The meaning and use of Roman numerals;
- 6 (iv) Abbreviations used for dosages and directions to patients;
- 7 (v) Basic medical terms, including terms relating to ailments,
- 8 diseases, or infirmities;
- 9 (vi) The use and operation of automated dispensing and record-
- 10 keeping systems if used by the employing pharmacy;
- 11 (vii) Applicable statutes, rules, and regulations governing the
- 12 preparation, compounding, dispensing, and distribution of drugs or
- 13 devices, record keeping with regard to such functions, and the
- 14 employment, use, and functions of pharmacy technicians; and
- 15 (viii) The contents of the written control procedures and
- 16 quidelines.
- 17 (b) Written control procedures and quidelines shall specify the
- 18 functions that pharmacy technicians may perform in the employing
- 19 pharmacy. The written control procedures and guidelines shall specify the
- 20 means used by the employing pharmacy to verify that the prescribed drug
- 21 or device, the dosage form, and the directions provided to the patient or
- 22 caregiver conform to the medical order authorizing the drug or device to
- 23 be dispensed.
- 24 (c) The written control procedures and guidelines shall specify the
- 25 manner in which the verification made prior to dispensing is documented.
- 26 (4) Each pharmacy or facility shall, before using pharmacy
- 27 technicians, file with the board a copy of its written control procedures
- 28 and guidelines and receive approval of its written control procedures and
- 29 guidelines from the board. The board shall, within ninety days after the
- 30 filing of such written control procedures and guidelines, review and
- 31 either approve or disapprove them. The board shall notify the pharmacy or

- 1 facility of the approval or disapproval. The board or its representatives
- 2 shall have access to the approved written control procedures and
- 3 guidelines upon request. Any written control procedures and guidelines
- 4 for supportive pharmacy personnel that were filed by a pharmacy and
- 5 approved by the board prior to September 1, 2007, shall be deemed to be
- 6 approved and to apply to pharmacy technicians.
- 7 Sec. 52. Section 38-2895, Reissue Revised Statutes of Nebraska, is
- 8 amended to read:
- 9 38-2895 (1) If a pharmacy technician performs functions requiring
- 10 professional judgment and licensure as a pharmacist, performs functions
- 11 not specified under approved written control procedures and quidelines,
- or performs functions without supervision <u>and verification</u> and such acts
- 13 are known to the pharmacist supervising the pharmacy technician or the
- 14 pharmacist in charge or are of such a nature that they should have been
- 15 known to a reasonable person, such acts may be considered acts of
- 16 unprofessional conduct on the part of the pharmacist supervising the
- 17 pharmacy technician or the pharmacist in charge pursuant to section
- 18 38-178, and disciplinary measures may be taken against such pharmacist
- 19 supervising the pharmacy technician or the pharmacist in charge pursuant
- 20 to the Uniform Credentialing Act.
- 21 (2) Acts described in subsection (1) of this section may be grounds
- 22 for the department, with the recommendation of the board, to apply to the
- 23 district court in the judicial district in which the pharmacy is located
- 24 for an order to cease and desist from the performance of any unauthorized
- 25 acts. On or at any time after such application the court may, in its
- 26 discretion, issue an order restraining such pharmacy or its agents or
- 27 employees from the performance of unauthorized acts. After a hearing the
- 28 court shall either grant or deny the application. Such order shall
- 29 continue until the court, after a hearing, finds the basis for such order
- 30 has been removed.
- 31 Sec. 53. Section 38-2899, Reissue Revised Statutes of Nebraska, is

- 1 amended to read:
- 2 38-2899 The department, with the recommendation of the board, shall
- 3 adopt and promulgate rules and regulations as deemed necessary to
- 4 implement sections 71-2401 to 71-2405 and 71-2501 to 71-2512, the Mail
- 5 Service Pharmacy Licensure Act, the Nebraska Drug Product Selection Act,
- 6 the Pharmacy Practice Act, and the Uniform Controlled Substances Act. The
- 7 minimum standards and requirements for the practice of pharmacy,
- 8 including dispensing pursuant to a delegated dispensing permit, shall be
- 9 consistent with the minimum standards and requirements established by the
- 10 department for pharmacy licenses under the Health Care Facility Licensure
- 11 Act.
- Sec. 54. A prescription for a legend drug which is not a controlled
- 13 <u>substance must contain the following information prior to being filled by</u>
- 14 <u>a pharmacist or a practitioner who holds a pharmacy license under</u>
- 15 <u>subdivision (1) of section 38-2850: Patient's name; the name of the drug,</u>
- 16 device, or biological; strength of the drug or biological, if applicable;
- 17 dosage form of the drug or biological; quantity of drug, device, or
- 18 <u>biological prescribed; number of authorized refills; directions for use;</u>
- 19 <u>date of issuance; prescribing practitioner's name; and if the</u>
- 20 prescription is written, the prescribing practitioner's signature.
- 21 Prescriptions for controlled substances must meet the requirements of
- 22 section 28-414 and 28-414.01.
- 23 Sec. 55. <u>A chart order must contain the following information:</u>
- 24 Patient's name; date of the order; name of the drug, device, or
- 25 biological; strength of the drug or biological, if applicable; directions
- 26 <u>for administration to the patient, including the dose to be given; and</u>
- 27 <u>the prescribing practitioner's name.</u>
- Sec. 56. An employee or agent of a prescribing practitioner may
- 29 <u>communicate a prescription, chart order, or refill authorization issued</u>
- 30 by the prescribing practitioner to a pharmacist or a pharmacist intern
- 31 except for an emergency oral authorization for a controlled substance

- 1 listed in Schedule II of section 28-405.
- 2 Sec. 57. Section 71-2421, Revised Statutes Cumulative Supplement,
- 3 2014, is amended to read:
- 4  $\frac{71-2421}{}$  (1) To protect the public safety, dispensed drugs or
- 5 devices:
- 6 (a) May be collected in a pharmacy for disposal;
- 7 (b) May be returned to a pharmacy in response to a recall by the
- 8 manufacturer, packager, or distributor or if a device is defective or
- 9 malfunctioning;
- 10 (c) Shall not be returned to saleable inventory nor made available
- 11 for subsequent relabeling and redispensing, except as provided in
- 12 subdivision (1)(d) of this section; or
- (d) May be returned from a long-term care facility to the pharmacy
- 14 from which they were dispensed for credit or for relabeling and
- 15 redispensing, except that:
- 16 (i) No controlled substance may be returned;
- 17 <u>(ii) No prescription drug or medical device that has restricted</u>
- 18 distribution by the federal Food and Drug Administration may be returned;
- 19  $(\underline{iii} \ \underline{ii})$  The decision to accept the return of the dispensed drug or
- 20 device shall rest solely with the pharmacist;
- 21 (iv) iii) The dispensed drug or device shall have been in the control
- 22 of the long-term care facility at all times;
- 23  $(\underline{v} iv)$  The dispensed drug or device shall be in the original and
- 24 unopened labeled container with a tamper-evident seal intact, as
- 25 dispensed by the pharmacist. Such container shall bear the expiration
- 26 date or calculated expiration date and lot number; and
- 27 (vi ↔) Tablets or capsules shall have been dispensed in a unit dose
- 28 container which is impermeable to moisture and approved by the board
- 29 Board of Pharmacy.
- 30 (2) Pharmacies may charge a fee for collecting dispensed drugs or
- 31 devices for disposal or from a long-term care facility for credit or for

- 1 relabeling and redispensing.
- 2 (3) Any person or entity which exercises reasonable care in
- 3 collecting dispensed drugs or devices for disposal or from a long-term
- 4 care facility for credit or for relabeling and redispensing pursuant to
- 5 this section shall be immune from civil or criminal liability or
- 6 professional disciplinary action of any kind for any injury, death, or
- 7 loss to person or property relating to such activities.
- 8 (4) A drug manufacturer which exercises reasonable care shall be
- 9 immune from civil or criminal liability for any injury, death, or loss to
- 10 persons or property relating to the relabeling and redispensing of drugs
- 11 returned from a long-term care facility.
- 12 (5) Notwithstanding subsection (4) of this section, the relabeling
- 13 and redispensing of drugs returned from a long-term care facility does
- 14 not absolve a drug manufacturer of any criminal or civil liability that
- 15 would have existed but for the relabeling and redispensing and such
- 16 relabeling and redispensing does not increase the liability of such drug
- 17 manufacturer that would have existed but for the relabeling and
- 18 redispensing.
- 19 (6) For purposes of this section:
- 20 (a) Calculated expiration date means the expiration date on the
- 21 manufacturer's, packager's, or distributor's container or one year from
- 22 the date the drug or device is repackaged, whichever is earlier;
- 23 (b) Dispense, drugs, and devices are defined in the Pharmacy
- 24 Practice Act; and
- 25 (c) Long-term care facility does not include an assisted-living
- 26 facility as defined in section 71-406.
- 27 Sec. 58. Section 71-5401.01, Reissue Revised Statutes of Nebraska,
- 28 is amended to read:
- 30 and may be cited as the Nebraska Drug Product Selection Act.
- 31 Sec. 59. Section 71-5401.02, Reissue Revised Statutes of Nebraska,

- 1 is amended to read:
- 2 71-5401.02 The purposes of the Nebraska Drug Product Selection Act
- 3 are to provide for the drug product selection of equivalent drug products
- 4 and to promote the greatest possible use of such products.
- 5 Sec. 60. Section 71-5402, Reissue Revised Statutes of Nebraska, is
- 6 amended to read:
- 7 71-5402 For purposes of the Nebraska Drug Product Selection Act,
- 8 unless the context otherwise requires:
- 9 (1) Bioequivalent means drug products: (a) That are legally marketed
- 10 under regulations promulgated by the federal Food and Drug
- 11 Administration; (b) that are the same dosage form of the identical active
- ingredients in the identical amounts as the drug product prescribed; (c)
- 13 that comply with compendial standards and are consistent from lot to lot
- 14 with respect to (i) purity of ingredients, (ii) weight variation, (iii)
- uniformity of content, and (iv) stability; and (d) for which the federal
- 16 Food and Drug Administration has established bioequivalent standards or
- 17 has determined that no bioequivalence problems exist;
- 18 (2) Board means the Board of Pharmacy;
- 19  $(2\ 3)$  Brand name means the proprietary or trade name selected by the
- 20 manufacturer, distributor, or packager for a drug product and placed upon
- 21 the labeling of such product at the time of packaging;
- 22 (3 4) Chemically equivalent means drug products that contain amounts
- 23 of the identical therapeutically active ingredients in the identical
- 24 strength, quantity, and dosage form and that meet present compendial
- 25 standards;
- 26 (5) Department means the Department of Health and Human Services;
- 27  $(\underline{4} \ 6)$  Drug product means any drug or device as defined in section
- 28 38-2841;
- 29  $(\underline{5} \ 7)$  Drug product select means to dispense, without the
- 30 practitioner's express authorization, an equivalent drug product in place
- 31 of the brand-name drug product contained in a medical order of such

- 1 practitioner;
- 2  $(\underline{6} \ 8)$  Equivalent means drug products that are both chemically
- 3 equivalent and bioequivalent; and
- 4 (7 9) Generic name means the official title of a drug or drug
- 5 combination as determined by the United States Adopted Names Council and
- 6 accepted by the federal Food and Drug Administration of those drug
- 7 products having the same active chemical ingredients in the same strength
- 8 and quantity. ;
- 9 (10) Medical order has the definition found in section 38-2828;
- 10 (11) Pharmacist means a pharmacist licensed under the Pharmacy
- 11 Practice Act; and
- 12 (12) Practitioner has the definition found in section 38-2838.
- 13 Sec. 61. Section 71-5403, Reissue Revised Statutes of Nebraska, is
- 14 amended to read:
- 15  $\frac{71-5403}{}$  (1) A pharmacist may drug product select except when:
- 16 (a) A practitioner designates that drug product selection is not
- 17 permitted by specifying in the written, oral, or electronic on the
- 18 prescription or by telephonic, facsimile, or electronic transmission that
- 19 there shall be no drug product selection. For written or electronic
- 20 prescriptions, the practitioner shall specify in his or her own
- 21 handwriting on the prescription the phrase "no drug product selection",
- 22 "dispense as written", "brand medically necessary", or "no generic
- 23 substitution" or the notation "N.D.P.S.", "D.A.W.", or "B.M.N." or words
- 24 or notations of similar import to indicate that drug product selection is
- 25 not permitted. The pharmacist shall note "N.D.P.S.", "D.A.W.", "B.M.N.",
- 26 "no drug product selection", "dispense as written", "brand medically
- 27 necessary", "no generic substitution", or words or notations of similar
- 28 import on the prescription to indicate that drug product selection is not
- 29 permitted if such is communicated orally by the prescribing practitioner;
- 30 or
- 31 (b) A patient or designated representative or caregiver of such

- 1 patient instructs otherwise.
- 2 (2) A pharmacist shall not drug product select a drug product

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- 3 unless:
- 4 (a) The drug product, if it is in solid dosage form, has been marked
- 5 with an identification code or monogram directly on the dosage unit;
- 6 (b) The drug product has been labeled with an expiration date;
- 7 (c) The manufacturer, distributor, or packager of the drug product
- 8 provides reasonable services, as determined by the board, to accept the
- 9 return of drug products that have reached their expiration date; and
- 10 (d) The manufacturer, distributor, or packager maintains procedures
- 11 for the recall of unsafe or defective drug products.
- 12 Sec. 62. Section 71-5404, Reissue Revised Statutes of Nebraska, is
- 13 amended to read:
- 71-5404 (1) Whenever a drug product has been prescribed with the
- 15 notation that no drug product selection is permitted for a patient who
- 16 has a contract whereunder he or she is reimbursed for the cost of health
- 17 care, directly or indirectly, the party that has contracted to reimburse
- 18 the patient, directly or indirectly, shall make reimbursements on the
- 19 basis of the price of the brand-name drug product and not on the basis of
- 20 the equivalent drug product, unless the contract specifically requires
- 21 generic reimbursement under the Code of Federal Regulations.
- 22 (2) A prescription drug or device when dispensed shall bear upon the
- 23 label the name of the drug or device in the container unless the
- 24 practitioner writes do not label or words of similar import  $\underline{in}$  on the
- 25 prescription or so designates orally or in writing which may be
- 26 transmitted by facsimile or electronic transmission.
- 27 (3) Nothing in this section shall (a) require a pharmacy to charge
- 28 less than its established minimum price for the filling of any
- 29 prescription or (b) prohibit any hospital from developing, using, and
- 30 enforcing a formulary.
- 31 Sec. 63. Section 71-5405, Reissue Revised Statutes of Nebraska, is

- 1 amended to read:
- $\frac{71-5405}{}$  (1) The drug product selection of any drug product by a
- 3 pharmacist pursuant to the Nebraska Drug Product Selection Act shall not
- 4 constitute the practice of medicine.
- 5 (2) Drug product selection of drug products by a pharmacist pursuant
- 6 to the act or any rules and regulations adopted and promulgated under the
- 7 act shall not constitute evidence of negligence if the drug product
- 8 selection was made within the reasonable and prudent practice of
- 9 pharmacy.
- 10 (3) When drug product selection by a pharmacist is permissible under
- 11 the act, such drug product selection shall not constitute evidence of
- 12 negligence on the part of the prescribing practitioner. The failure of a
- 13 prescribing practitioner to provide that there shall be no drug product
- 14 selection in any case shall not constitute evidence of negligence or
- 15 malpractice on the part of such prescribing practitioner.
- Sec. 64. Section 71-5406, Reissue Revised Statutes of Nebraska, is
- 17 amended to read:
- 18 71-5406 (1) The manufacturer, packager, or distributor of any
- 19 legend drug sold, delivered, or offered for sale for human use in the
- 20 State of Nebraska shall have the name and address of the manufacturer of
- 21 the finished dosage form of the drug printed on the label on the
- 22 container of such drug.
- 23 (2) Whenever a duly authorized agent of the department has probable
- 24 cause to believe that any drug is without such labeling, the agent shall
- 25 embargo such drug and shall affix an appropriate marking thereto. Such
- 26 marking shall contain: (a  $\pm$ ) adequate Adequate notice that the drug (i  $\pm$ )
- 27 is or is suspected of being sold, delivered, or offered for sale in
- 28 violation of the Nebraska Drug Product Selection Act and (ii b) has been
- 29 embargoed; and  $(\underline{b} \ 2)$  a warning that it is unlawful for any person to
- 30 remove or dispose of the embargoed drug by sale or otherwise without the
- 31 permission of the agent or a court of competent jurisdiction.

1 Sec. 65. Section 71-5407, Reissue Revised Statutes of Nebraska, is

- 2 amended to read:
- $\frac{71-5407}{1}$  (1) In addition to any other penalties provided by law, any
- 4 person who violates any provision of the Nebraska Drug Product Selection
- 5 Act or any rule or regulation adopted and promulgated under the act is
- 6 guilty of a Class IV misdemeanor for each violation.
- 7 (2) It is unlawful for any employer or such employer's agent to
- 8 coerce a pharmacist to dispense a drug product against the professional
- 9 judgment of the pharmacist or as ordered by a prescribing practitioner.
- 10 Sec. 66. Section 71-5409, Reissue Revised Statutes of Nebraska, is
- 11 amended to read:
- 12 71-5409 The department may adopt and promulgate rules and
- 13 regulations necessary to implement the Nebraska Drug Product Selection
- 14 Act upon the joint recommendation of the Board of Medicine and Surgery
- 15 and the Board of Pharmacy.
- 16 Sec. 67. Section 71-401, Revised Statutes Cumulative Supplement,
- 17 2014, is amended to read:
- 18 71-401 Sections 71-401 to 71-469 <u>and sections 69 and 70 of this act</u>
- 19 shall be known and may be cited as the Health Care Facility Licensure
- 20 Act.
- 21 Sec. 68. Section 71-403, Revised Statutes Cumulative Supplement,
- 22 2014, is amended to read:
- 23 71-403 For purposes of the Health Care Facility Licensure Act,
- 24 unless the context otherwise requires, the definitions found in sections
- 25 71-404 to 71-431 and section 69 of this act shall apply.
- 26 Sec. 69. <u>Hospital pharmacy means each facility licensed as a</u>
- 27 hospital in which the compounding, preparation for administration, or
- 28 dispensing of drugs or devices pursuant to a chart order occurs for
- 29 patients within the confines of the hospital with oversight by a
- 30 pharmacist in charge.
- 31 Sec. 70. (1) A hospital in which drugs or devices are compounded,

- 1 dispensed, or administered pursuant to chart orders is not required to
- 2 obtain a separate license for the hospital pharmacy, except that if the
- 3 compounding or dispensing of drugs or devices is done in the pharmacy at
- 4 the hospital for persons not registered as patients within the confines
- 5 of the hospital, the hospital shall obtain a pharmacy license.
- 6 Compounding in a hospital pharmacy may occur for any hospital which is
- 7 part of the same health care system under common ownership or which is a
- 8 <u>member of or an affiliated member of a formal network or partnership</u>
- 9 <u>agreement</u>.
- 10 (2) Each hospital shall, on or before January 1, 2016, designate a
- 11 pharmacist licensed in this state as being the pharmacist in charge and
- 12 responsible for the practice of pharmacy and medication use procedure in
- 13 <u>such hospital, including section 45 of this act. The Board of Pharmacy or</u>
- 14 <u>its designated representatives may examine and inspect the practice of</u>
- 15 pharmacy in any hospital licensed by the department.
- 16 (3) The pharmacist in charge of a hospital pharmacy shall establish
- 17 <u>and implement policies and procedures for the practice of pharmacy and</u>
- 18 medication use in the hospital.
- 19 Sec. 71. Section 71-436, Reissue Revised Statutes of Nebraska, is
- 20 amended to read:
- 21 71-436 (1) Except as otherwise provided in section 70 of this act,
- 22 <u>an</u> An applicant for licensure under the Health Care Facility Licensure
- 23 Act shall obtain a separate license for each type of health care facility
- 24 or health care service that the applicant seeks to operate. A single
- 25 license may be issued for (a) a facility or service operating in separate
- 26 buildings or structures on the same premises under one management, (b) an
- 27 inpatient facility that provides services on an outpatient basis at
- 28 multiple locations, or (c) a health clinic operating satellite clinics on
- 29 an intermittent basis within a portion of the total geographic area
- 30 served by such health clinic and sharing administration with such
- 31 clinics.

1 (2) The department may issue one license document that indicates the

- 2 various types of health care facilities or health care services for which
- 3 the entity is licensed. The department may inspect any of the locations
- 4 that are covered by the license. If an entity is licensed in multiple
- 5 types of licensure for one location, the department shall conduct all
- 6 required inspections simultaneously for all types of licensure when
- 7 requested by the entity.
- 8 Sec. 72. Section 71-448, Revised Statutes Cumulative Supplement,
- 9 2014, is amended to read:
- 10 71-448 The Division of Public Health of the Department of Health and
- 11 Human Services may take disciplinary action against a license issued
- 12 under the Health Care Facility Licensure Act on any of the following
- 13 grounds:
- 14 (1) Violation of any of the provisions of the Assisted-Living
- 15 Facility Act, the Health Care Facility Licensure Act, the Nebraska
- 16 Nursing Home Act, or the rules and regulations adopted and promulgated
- 17 under such acts;
- 18 (2) Committing or permitting, aiding, or abetting the commission of
- 19 any unlawful act;
- 20 (3) Conduct or practices detrimental to the health or safety of a
- 21 person residing in, served by, or employed at the health care facility or
- 22 health care service;
- 23 (4) A report from an accreditation body or public agency
- 24 sanctioning, modifying, terminating, or withdrawing the accreditation or
- 25 certification of the health care facility or health care service;
- 26 (5) Failure to allow an agent or employee of the Department of
- 27 Health and Human Services access to the health care facility or health
- 28 care service for the purposes of inspection, investigation, or other
- 29 information collection activities necessary to carry out the duties of
- 30 the Department of Health and Human Services;
- 31 (6) Discrimination or retaliation against a person residing in,

1 served by, or employed at the health care facility or health care service

- 2 who has submitted a complaint or information to the Department of Health
- 3 and Human Services;
- 4 (7) Discrimination or retaliation against a person residing in,
- 5 served by, or employed at the health care facility or health care service
- 6 who has presented a grievance or information to the office of the state
- 7 long-term care ombudsman;
- 8 (8) Failure to allow a state long-term care ombudsman or an
- 9 ombudsman advocate access to the health care facility or health care
- 10 service for the purposes of investigation necessary to carry out the
- 11 duties of the office of the state long-term care ombudsman as specified
- in the rules and regulations adopted and promulgated by the Department of
- 13 Health and Human Services;
- 14 (9) Violation of the Emergency Box Drug Act<u>or the Pharmacy Practice</u>
- 15 Act;
- 16 (10) Failure to file a report required by section 38-1,127 or
- 17 71-552;
- 18 (11) Violation of the Medication Aide Act;
- 19 (12) Failure to file a report of suspected abuse or neglect as
- 20 required by sections 28-372 and 28-711; or
- 21 (13) Violation of the Automated Medication Systems Act.
- 22 Sec. 73. Section 71-2426, Reissue Revised Statutes of Nebraska, is
- 23 amended to read:
- 24 71-2426 (1) A cancer drug shall only be accepted or dispensed under
- 25 the program if such drug is in its original, unopened, sealed, and
- 26 tamper-evident packaging. A cancer drug packaged in single unit doses may
- 27 be accepted and dispensed if the outside packaging is opened but the
- 28 single-unit-dose packaging is unopened. There shall be no limitation on
- 29 the number of doses that can be donated to the program as long as the
- 30 donated drugs meet the requirements of this section. An injectable cancer
- 31 drug may be accepted if it does not have temperature requirements other

- 1 than controlled room temperature.
- 2 (2) A cancer drug shall not be accepted or dispensed under the
- 3 program if (a) such drug bears an expiration date prior to the date of
- 4 donation, (b) such drug is adulterated or misbranded as defined described
- 5 in section 5 or 14 of this act, 71-2401 or 71-2402, or (c) such drug has
- 6 expired while in the repository, or (d) such drug has restricted
- 7 distribution by the federal Food and Drug Administration.
- 8 (3) Subject to limitations provided in this section, unused cancer
- 9 drugs dispensed under the medical assistance program established pursuant
- 10 to the Medical Assistance Act may be accepted and dispensed under the
- 11 program.
- 12 Sec. 74. Section 71-2427, Reissue Revised Statutes of Nebraska, is
- 13 amended to read:
- 14 71-2427 (1) A participant shall comply with all applicable
- 15 provisions of state and federal law relating to the storage,
- 16 distribution, and dispensing of donated cancer drugs and shall inspect
- 17 all such drugs prior to dispensing to determine if they are adulterated
- 18 or misbranded as <u>defined</u> <del>described</del> in section <u>5 or 14 of this act</u> <del>71-2401</del>
- 19 or 71-2402. Such drugs shall only be dispensed pursuant to a prescription
- 20 issued by a prescribing practitioner. Such drugs may be distributed to
- 21 another participant for dispensing.
- 22 (2) A participant may charge a handling fee for distributing or
- 23 dispensing cancer drugs under the program. Such fee shall be established
- 24 in rules and regulations adopted and promulgated by the department.
- 25 Cancer drugs donated under the program shall not be resold.
- 26 Sec. 75. Section 71-2440, Reissue Revised Statutes of Nebraska, is
- 27 amended to read:
- 28 71-2440 (1) An immunosuppressant drug shall only be accepted or
- 29 dispensed under the program if such drug is in its original, unopened,
- 30 sealed, and tamper-evident packaging. An immunosuppressant drug packaged
- 31 in single unit doses may be accepted and dispensed if the outside

1 packaging is opened but the single-unit-dose packaging is unopened. There

- 2 shall be no limitation on the number of doses that can be donated to the
- 3 program as long as the donated drugs meet the requirements of this
- 4 section.
- 5 (2) An immunosuppressant drug shall not be accepted or dispensed
- 6 under the program if (a) such drug bears an expiration date prior to the
- 7 date of donation, or (b) such drug is adulterated or misbranded as
- 8 <u>defined</u> described in section 5 or 14 of this act, or (c) such drug has
- 9 <u>restricted distribution by the federal Food and Drug Administration</u>
- 10 <del>71-2401 or 71-2402</del>.
- 11 (3) Subject to limitations provided in this section, unused
- 12 immunosuppressant drugs dispensed under the medical assistance program
- 13 may be accepted and dispensed under the immunosuppressant drug repository
- 14 program.
- 15 Sec. 76. Section 71-2441, Reissue Revised Statutes of Nebraska, is
- 16 amended to read:
- 17 71-2441 (1) A participant shall comply with all applicable
- 18 provisions of state and federal law relating to the storage,
- 19 distribution, and dispensing of donated immunosuppressant drugs and shall
- 20 inspect all such drugs prior to dispensing to determine if the drugs are
- 21 adulterated or misbranded as defined <del>described</del> in section 5 or 14 of this
- 22 act 71-2401 or 71-2402 or if the drugs bear an expiration date prior to
- 23 the date of dispensing. Such drugs shall only be dispensed pursuant to a
- 24 prescription issued by a prescribing practitioner. Such drugs may be
- 25 distributed to another participant for dispensing.
- 26 (2) Immunosuppressant drugs donated under the program shall not be
- 27 resold.
- 28 Sec. 77. Section 71-2453, Revised Statutes Cumulative Supplement,
- 29 2014, is amended to read:
- 30 71-2453 (1) Prescription drugs or devices which have been dispensed
- 31 pursuant to a valid prescription and delivered to a Department of

- 1 Correctional Services facility, a criminal detention facility, a juvenile
- 2 detention facility, or a jail for administration to a prisoner or
- 3 detainee held at such facility or jail, but which are not administered to
- 4 such prisoner or detainee, may be returned to the pharmacy from which
- 5 they were dispensed under contract with the facility or jail for credit
- 6 or for relabeling and redispensing and administration to another prisoner
- 7 or detainee held at such facility or jail pursuant to a valid
- 8 prescription as provided in this section.
- 9 (2)(a) The decision to accept return of a dispensed prescription
- 10 drug or device for credit or for relabeling and redispensing rests solely
- 11 with the pharmacist at the contracting pharmacy.
- 12 (b) A dispensed prescription drug or device shall be properly stored
- 13 and in the control of the facility or jail at all times prior to the
- 14 return of the drug or device for credit or for relabeling and
- 15 redispensing. The drug or device shall be returned in the original and
- 16 unopened labeled container dispensed by the pharmacist with the tamper-
- 17 evident seal intact, and the container shall bear the expiration date or
- 18 calculated expiration date and lot number of the drug or device.
- 19 (c) A prescription drug or device shall not be returned or relabeled
- 20 and redispensed under this section if the drug or device is a controlled
- 21 substance, if the drug has restricted distribution by the federal Food
- 22 <u>and Drug Administration</u>, or if the relabeling and redispensing is
- 23 otherwise prohibited by law.
- 24 (3) For purposes of this section:
- 25 (a) Administration has the definition found in section 38-2807;
- 26 (b) Calculated expiration date has the definition found in section
- 27 <u>30 of this act</u> <del>71-2421</del>;
- 28 (c) Criminal detention facility has the definition found in section
- 29 83-4, 125;
- 30 (d) Department of Correctional Services facility has the definition
- 31 of facility found in section 83-170;

1 (e) Dispense or dispensing has the definition found in section

- 2 38-2817;
- 3 (f) Jail has the definition found in section 47-117;
- 4 (g) Juvenile detention facility has the definition found in section
- 5 83-4, 125;
- 6 (h) Prescription has the definition found in section 38-2840; and
- 7 (i) Prescription drug or device has the definition found in section
- 8 38-2841.
- 9 (4) The Jail Standards Board, in consultation with the Board of
- 10 Pharmacy, shall adopt and promulgate rules and regulations relating to
- 11 the return of dispensed prescription drugs or devices for credit,
- 12 relabeling, or redispensing under this section, including, but not
- 13 limited to, rules and regulations relating to (a) education and training
- 14 of persons authorized to administer the prescription drug or device to a
- 15 prisoner or detainee, (b) the proper storage and protection of the drug
- 16 or device consistent with the directions contained on the label or
- 17 written drug information provided by the pharmacist for the drug or
- 18 device, (c) limits on quantity to be dispensed, (d) transferability of
- 19 drugs or devices for prisoners or detainees between facilities, (e)
- 20 container requirements, (f) establishment of a drug formulary, and (g)
- 21 fees for the pharmacy to accept the returned drug or device.
- 22 (5) Any person or entity which exercises reasonable care in
- 23 accepting, distributing, or dispensing prescription drugs or devices
- 24 under this section or rules and regulations adopted and promulgated under
- 25 this section shall be immune from civil or criminal liability or
- 26 professional disciplinary action of any kind for any injury, death, or
- 27 loss to person or property relating to such activities.
- 28 Sec. 78. <u>This section, sections 71-2501 to 71-2512, and section 86</u>
- 29 of this act shall be known and may be cited as the Poison Control Act.
- 30 Sec. 79. Section 71-2501, Reissue Revised Statutes of Nebraska, is
- 31 amended to read:

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1 71-2501 <del>(1)</del> For purposes of <u>the Poison Control Act</u> sections 71-2501

2 <del>to 71-2510</del>:

- (1 a) Poison includes shall include: Arsenic, metallic or elemental, 3 4 and all poisonous compounds and preparations thereof; 5 sublimate; white precipitate; red precipitate, mercuric iodide; nitrate of mercury; hydrocyanic acid and all its salts and poisonous compounds; 6 aconitine, arecoline, atropine, brucine, colchicine, coniine, daturine, 7 delphinine, gelsemine, gelseminine, homatropine, hyoscine, hyoscyamine, 8 9 lobeline, pelletierine, physostigmine, pilocarpine, sparteine, 10 strychnine, veratrine, and all other poisonous alkaloids and their salts, poisonous compounds, and preparations; volatile or essential oil of 11 bitter almonds, natural and artificial; aconite, belladonna, calabar 12 bean, cantharides, colchicum, conium cotton root, cocculus indicum, 13 14 datura, ergot, gelsemium, henbane, ignatia, lobelia, nux vomica, savin, scopolamine, solanum, stramonium, staphisagra, strophanthus, veratrum 15 viride, and their pharmaceutical preparations and compounds; cantharidin, 16 17 picrotoxin, elaterin, santonin, their poisonous chemical compounds and derivatives and preparations; ascaridol; volatile oil of mustard, natural 18 19 and synthetic; oil of tansy; oil of savin, glacial acetic acid; trichloracetic acid; aniline oil; benzaldehyde; bromoform; carbolic acid; 20 cresylic acid; chloral hydrate; chromic acid; croton oil; dinitrophenol; 21 22 mineral acids; oxalic acid; nitrobenzene; phosphorous; paraldehyde; picric acid; salts of antimony; salts of barium, except the sulphate, 23 24 salts of cobalt, salts of chromium; salts of lead; salts of thallium; salts of zinc; carbon tetrachloride, and silver nitrate; and 25
  - (<u>2</u> <del>b</del>) Poison <u>does</u> <del>shall</del> not include:
- (<u>a</u> <u>i</u>) Agricultural or garden spray, insecticides, concentrated lye, fungicides, rodent destroyers, and other preparations of whatever ingredients, preservative or otherwise for animal or poultry use, for commercial, industrial, manufacturing, <u>or</u> fire protection purposes, or any combination of such purposes, and not for human use, when the same

- 1 are properly packaged, prepared, and labeled with official poison labels
- 2 in conformity with the terms and provisions of section 71-2502 or the
- 3 Federal Food, Drug, and Cosmetic Act, as such act existed on May 1, 2001,
- 4 or the Federal Insecticide, Fungicide, and Rodenticide Act, as such act
- 5 existed on May 1, 2001;
- 6 ( $\underline{b}$   $\pm i$ ) Preparations prepared by or under the supervision of a
- 7 governmental agency for use by it or under its direction in the
- 8 suppression of injurious insect pests and plant diseases destructive to
- 9 the agricultural and horticultural interests of the state; and
- 10 (c iii) Preparations for the destruction of rodents, predatory
- 11 animals, or noxious weeds.
- 12 (2) Sections 71-2501 to 71-2511 shall not apply to the sale of
- 13 patent or proprietary medicines in the original package of the
- 14 manufacturer, when labeled in conformity with section 71-2502.
- 15 Sec. 80. Section 71-2502, Reissue Revised Statutes of Nebraska, is
- 16 amended to read:
- 17 71-2502 It shall be unlawful for any person to vend, sell, dispense,
- 18 give away, furnish, or otherwise dispose of, or cause to be vended, sold,
- 19 dispensed, given away, furnished, or otherwise disposed of, either
- 20 directly or indirectly, any poison as defined in section 71-2501, without
- 21 affixing, or causing to be affixed, to the bottle, box, vessel, or
- 22 package containing the same, a label, printed or plainly written,
- 23 containing the name of the article, the word poison, the name and place
- 24 of business of the seller, manufacturer, packager, packer or distributor,
- 25 and the date of sale; nor shall it be lawful for any person to deliver
- 26 any of such poisons until he or she has satisfied himself or herself that
- 27 the person to whom delivery is made is aware of and understands the
- 28 poisonous nature of the article<sub>T</sub> and that such poison is to be used for a
- 29 legitimate purpose.
- 30 Sec. 81. Section 71-2505, Reissue Revised Statutes of Nebraska, is
- 31 amended to read:

- 1 71-2505 (1) The Poison Control Act does provisions of sections
- 2 <del>71-2503 and 71-2504 shall</del> not apply to the dispensing of poisons or
- 3 preparation of medicines by those practitioners credentialed under the
- 4 Uniform Credentialing Act who are duly authorized by law to administer or
- 5 professionally use those poisons specifically named in section 71-2501.
- 6 (2) The Poison Control Act does not apply to the sale of patent or
- 7 proprietary medicines in the original package of the manufacturer,
- 8 packager, or distributor when labeled in conformity with section 71-2502.
- 9 Sec. 82. Section 71-2506, Reissue Revised Statutes of Nebraska, is
- 10 amended to read:
- 11 71-2506 (1) Whenever, in the judgment of the Department of Health
- 12 and Human Services, it <u>becomes</u> shall become necessary for the protection
- of the public, to add any poison, not specifically enumerated in section
- 14 71-2501, the department shall have printed a revised schedule of all
- 15 poisons coming under section 71-2501. The department shall forward by
- 16 mail one copy to each person registered upon its books and to every
- 17 person applying for same, and the revised schedule shall carry an
- 18 effective date for the new poisons added. No poison shall be added by the
- 19 department under this section unless the same shall be as toxic in its
- 20 effect as any of the poisons enumerated under section 71-2501.
- 21 (2) Whenever the department <u>proposes</u> shall propose to bring any
- 22 additional poisons under such section 71-2501, the proposal shall be set
- 23 down for hearing. At least ten days' notice of such hearing shall be
- 24 given by the department. The notice shall designate the poison to be
- 25 added and shall state the time and place of the hearing. Such notice
- 26 shall be given by such means as the department determines shall determine
- 27 to be reasonably calculated to notify the various interested parties. The
- 28 department <u>may</u> shall have the power to adopt and promulgate such rules
- 29 and regulations with respect to the conduct of such hearings as may be
- 30 necessary.
- 31 (3) Any person aggrieved by any order of the department passed

1 pursuant to this section may appeal such order, and the appeal shall be

- 2 in accordance with the Administrative Procedure Act.
- 3 Sec. 83. Section 71-2507, Reissue Revised Statutes of Nebraska, is
- 4 amended to read:
- 5 71-2507 It shall be unlawful for any person, other than a duly
- 6 registered pharmacist, to sell or dispense poisons as named in section
- 7 71-2501, except as otherwise provided in said section 71-2501.
- 8 Sec. 84. Section 71-2509, Reissue Revised Statutes of Nebraska, is
- 9 amended to read:
- 10 71-2509 The Department of Health and Human Services may adopt and
- 11 <u>promulgate rules and regulations</u>, <del>by regulation</del>, whenever such action
- 12 becomes necessary for the protection of the public, <u>to</u>prohibit the sale
- 13 of any poison, subject to the provisions of this section, except upon the
- 14 original written, oral, or electronic medical order or prescription of
- 15 those practitioners credentialed under the Uniform Credentialing Act who
- 16 are duly authorized by law to administer or professionally use those
- 17 poisons specifically named in section 71-2501. Whenever in the opinion of
- 18 the department it is in the interest of the public health, the department
- 19 <u>may</u> is empowered to adopt and promulgate rules and regulations, not
- 20 inconsistent with the Poison Control Act sections 71-2501 to 71-2511,
- 21 further restricting or prohibiting the retail sale of any poison. The
- 22 rules and regulations must be applicable to all persons alike. The
- 23 <u>department shall</u>, and it shall be the duty of the department, upon
- 24 request by  $\frac{by}{r}$  to furnish any person authorized by the Poison Control Act
- 25 sections 71-2501 to 71-2511 to sell or dispense any poisons, furnish such
- 26 person with a list of all articles, preparations, and compounds the sale
- 27 of which is prohibited or regulated by the Poison Control Act such
- 28 sections.
- 29 Sec. 85. Section 71-2510, Reissue Revised Statutes of Nebraska, is
- 30 amended to read:
- 31 71-2510 The Poison Control Act does provisions of sections 71-2502

- 1 to 71-2511 shall not apply to sales of poisons made to those
- 2 practitioners credentialed under the Uniform Credentialing Act who are
- 3 duly authorized by law to administer or professionally use those poisons
- 4 specifically named in section 71-2501, to sales made by any manufacturer,
- 5 wholesale dealer, or licensed pharmacist to another manufacturer,
- 6 wholesale dealer, or licensed pharmacist, to a hospital, college, school,
- 7 or scientific or public institution, or to any person using any of such
- 8 poisons in the arts or for industrial, manufacturing, or agricultural
- 9 purposes and believed to be purchasing any poison for legitimate use, or
- 10 to the sales of pesticides used in agricultural and industrial arts or
- 11 products used for the control of insect or animal pests or weeds or
- 12 fungus diseases, if in all such cases, except sales for use in industrial
- 13 arts, manufacturing, or processing, the poisons are labeled in accordance
- 14 with the provisions of section 71-2502.
- 15 Sec. 86. Section 28-425, Reissue Revised Statutes of Nebraska, is
- 16 amended to read:
- 17 <del>28-425</del> (1) No person, firm, corporation, partnership, or limited
- 18 liability company shall manufacture, give away, sell, expose for sale, or
- 19 deliver any embalming fluid or other fluids of whatsoever name, to be
- 20 used for or intended for use in the embalming of dead human bodies, which
- 21 contain arsenic or strychnine, or preparations, compounds, or salts
- 22 thereof, without having the words arsenic contained herein or strychnine
- 23 contained herein, as the case may be, written or printed upon a label
- 24 pasted on the bottle, cask, flask, or carboy in which such fluid shall be
- 25 contained.
- 26 (2) No undertaker or other person shall embalm with, inject into, or
- 27 place upon any dead human body, any fluid or preparation of any kind
- 28 which contains arsenic or strychnine, or preparations, compounds, or
- 29 salts thereof.
- 30 (3) Any person, firm, corporation, partnership, or limited liability
- 31 company violating any of the provisions of subsection (1) or (2) of this

- 1 section shall be guilty of a Class III misdemeanor.
- 2 Sec. 87. Section 71-2512, Reissue Revised Statutes of Nebraska, is
- 3 amended to read:
- 4 71-2512 Any person violating any of the provisions of the Poison
- 5 Control Act sections 71-2401 to 71-2405 and 71-2501 to 71-2511, except as
- 6 specific penalties are otherwise imposed, is shall be guilty of a Class
- 7 III misdemeanor. Any person, for a second or subsequent violation of any
- 8 of the provisions of the Poison Control Act such sections, when another
- 9 specific penalty is not expressly imposed, <u>is</u> shall be guilty of a Class
- 10 II misdemeanor.
- 11 Sec. 88. Section 71-7436, Reissue Revised Statutes of Nebraska, is
- 12 amended to read:
- 13 71-7436 (1) Emergency medical reasons means the alleviation of a
- 14 temporary shortage by transfers of prescription drugs between any of the
- 15 following: (<u>a</u>  $\pm$ ) Holders of pharmacy licenses, (<u>b</u>  $\pm$ ) health care
- 16 practitioner facilities as defined in section 71-414, and  $(c \ 3)$  hospitals
- 17 as defined in section 71-419, and (4) practitioners as defined in section
- 18 <del>38-2838</del>.
- 19 (2) Emergency medical reasons does not include regular and
- 20 <u>systematic</u> sales to practitioners as defined in section 38-2838 of
- 21 prescription drugs that will be used for routine office procedures.
- 22 Sec. 89. Section 71-7444, Reissue Revised Statutes of Nebraska, is
- 23 amended to read:
- 24 71-7444 (1) Wholesale drug distribution means the distribution of
- 25 prescription drugs to a person other than a consumer or patient.
- 26 (2) Wholesale drug distribution does not include:
- 27 (a) Intracompany sales of prescription drugs, including any
- 28 transaction or transfer between any division, subsidiary, or parent
- 29 company and an affiliated or related company under common ownership or
- 30 common control;
- 31 (b) The sale, purchase, or trade of or an offer to sell, purchase,

- 1 or trade a prescription drug by a charitable organization described in
- 2 section 501(c)(3) of the Internal Revenue Code, a state, a political
- 3 subdivision, or any other governmental agency to a nonprofit affiliate of
- 4 the organization, to the extent otherwise permitted by law;
- 5 (c) The sale, purchase, or trade of or an offer to sell, purchase,
- 6 or trade a prescription drug among hospitals or other health care
- 7 entities operating under common ownership or common control;
- 8 (d) The sale, purchase, or trade of or an offer to sell, purchase,
- 9 or trade a prescription drug for emergency medical reasons or for a
- 10 practitioner to use for routine office procedures, not to exceed five
- 11 percent of sales as provided in section 71-7454;
- 12 (e) The sale, purchase, or trade of, an offer to sell, purchase, or
- 13 trade, or the dispensing of a prescription drug pursuant to a
- 14 prescription;
- 15 (f) The distribution of drug samples by representatives of a
- 16 manufacturer or of a wholesale drug distributor;
- 17 (g) The sale, purchase, or trade of blood and blood components
- 18 intended for transfusion; or
- (h) The delivery of or the offer to deliver a prescription drug by a
- 20 common carrier solely in the usual course of business of transporting
- 21 such drugs as a common carrier if the common carrier does not store,
- 22 warehouse, or take legal ownership of such drugs.
- Sec. 90. Section 71-7447, Revised Statutes Cumulative Supplement,
- 24 2014, is amended to read:
- 25 71-7447 (1) No person or entity may act as a wholesale drug
- 26 distributor in this state without first obtaining a wholesale drug
- 27 distributor license from the department. The department shall issue a
- 28 license to any applicant that satisfies the requirements for licensure
- 29 under the Wholesale Drug Distributor Licensing Act. Manufacturers are
- 30 exempt from any licensing and other requirements of the act to the extent
- 31 not required by federal law or regulation except for those requirements

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- 1 deemed necessary and appropriate under rules and regulations adopted and
- 2 promulgated by the department.

section 71-7448.

- 3 (2) Wholesale medical gas distributors shall be exempt from any 4 licensing and other requirements of the Wholesale Drug Distributor 5 Licensing Act to the extent not required under federal law but shall be licensed as wholesale drug distributors by the department for the limited 6 7 purpose of engaging in the wholesale distribution of medical gases upon application to the department, payment of a licensure fee, and inspection 8 9 of the applicant's facility by the department, except that the applicant may submit and the department may accept an inspection accepted in 10 another state or an inspection conducted by a nationally recognized 11 accreditation program approved by the board. For purposes of such 12 13 licensure, wholesale medical gas distributors shall only be required to provide information required under subdivisions (1)(a) through (1)(c) of 14
- 16 (3) The Wholesale Drug Distributor Licensing Act does not apply to:
- (a) An agent or employee of a licensed wholesale drug distributor
  who possesses drug samples when such agent or employee is acting in the
  usual course of his or her business or employment; or
- (b) Any person who (i) engages in a wholesale transaction relating to the manufacture, distribution, sale, transfer, or delivery of medical gases the gross dollar value of which does not exceed five percent of the total retail sales of medical gases by such person during the immediately preceding calendar year and (ii) has either a pharmacy permit or license or a delegated dispensing permit or is exempt from the practice of pharmacy under subdivision (10 12) of section 38-2850.
- Sec. 91. Original sections 28-425, 38-2810, 38-2811, 38-2819, 38-2831, 38-2833, 38-2837, 38-2843, 38-2866, 38-2884, 38-2887, 38-2890, 29 38-2892, 38-2895, 38-2899, 71-436, 71-2401, 71-2402, 71-2404, 71-2405, 71-2426, 71-2427, 71-2440, 71-2441, 71-2501, 71-2502, 71-2505, 71-2506, 31 71-2507, 71-2509, 71-2510, 71-2512, 71-5401.01, 71-5401.02, 71-5402,

1 71-5403, 71-5404, 71-5405, 71-5406, 71-5407, 71-5409, 71-7436, and

- 2 71-7444, Reissue Revised Statutes of Nebraska, and sections 38-2801,
- 3 38-2802, 38-2850, 38-2867, 38-2869, 38-2870, 71-401, 71-403, 71-448,
- 4 71-2421, 71-2453, and 71-7447, Revised Statutes Cumulative Supplement,
- 5 2014, are repealed.
- 6 Sec. 92. The following sections are outright repealed: Sections
- 7 28-1438, 38-2848, 71-2403, and 71-2511, Reissue Revised Statutes of
- 8 Nebraska, and section 28-1437, Revised Statutes Cumulative Supplement,
- 9 2014.