LEGISLATURE OF NEBRASKA

ONE HUNDRED FOURTH LEGISLATURE

FIRST SESSION

LEGISLATIVE BILL 37

Introduced by Krist, 10; Campbell, 25; Cook, 13; Crawford, 45; Gloor, 35; Howard, 9; Mello, 5; Watermeier, 1. Read first time January 08, 2015 Committee: Health and Human Services

1	A BILL FOR AN ACT relating to drugs; to amend sections 28-425, 38-2810,
2	38-2811, 38-2819, 38-2831, 38-2833, 38-2837, 38-2843, 38-2866,
3	38-2884, 38-2887, 38-2890, 38-2892, 38-2895, 38-2899, 71-436,
4	71-2401, 71-2402, 71-2404, 71-2405, 71-2426, 71-2427, 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
8	Revised Statutes of Nebraska, and sections 38-2801, 38-2802,
9	38-2850, 38-2867, 38-2869, 38-2870, 71-401, 71-403, 71-448, 71-2421,
10	71-2453, and 71-7447, Revised Statutes Cumulative Supplement, 2014;
11	to adopt the Prescription Drug Safety Act; to transfer, provide,
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
16	sections; and to outright repeal sections 28-1438, 38-2848, 71-2403,
17	and 71-2511, Reissue Revised Statutes of Nebraska, and section
18	28-1437, Revised Statutes Cumulative Supplement, 2014.
19	Be it enacted by the people of the State of Nebraska,

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Section 1. <u>Sections 1 to 27 of this act shall be known and may be</u>
 <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.

Sec. 3. <u>Administer means to directly apply a drug or device by</u>
<u>injection, inhalation, ingestion, or other means to the body of a patient</u>
<u>or research subject.</u>

8 Sec. 4. <u>Administration means the act of (1) administering, (2)</u> 9 <u>keeping a record of such activity, and (3) observing, monitoring,</u> 10 <u>reporting, and otherwise taking appropriate action regarding desired</u> 11 <u>effect, side effect, interaction, and contraindication associated with</u> 12 <u>administering the drug or device.</u>

Sec. 5. Section 71-2401, Reissue Revised Statutes of Nebraska, is amended to read:

Adulterated drug means an article For the purpose of 15 71-2401 section 71-2404, an article, in the case of drugs, shall be deemed 16 17 adulterated (1) if, when a drug is sold under or by the name recognized in The the United States Pharmacopeia and The Pharmacopoeia or National 18 Formulary, it differs from the standard of strength, quality_L or purity 19 as determined by the test laid down in The the United States Pharmacopeia 20 and The Pharmacopoeia or National Formulary official at the time of 21 22 investigation, except that ; Provided, no drug defined in The the United States Pharmacopeia and The Pharmacopoeia or National Formulary shall be 23 deemed to be adulterated under this <u>subdivision</u> provision if the standard 24 25 of strength or purity is plainly stated upon the bottle, box, or other container thereof, although the standard may differ from that determined 26 27 by the test laid down in The the United States Pharmacopeia and The Pharmacopoeia or National Formulary, $\dot{\tau}$ or (2) if its strength or purity 28 falls below the professed standard of quality under which it is sold. 29 30 Sec. 6. Chart order has the definition found in section 38-2810.

Sec. 7. <u>Compounding means the preparation of components into a drug</u>

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1	product.
2	Sec. 8. <u>Controlled substance has the definition found in section</u>
3	<u>28-401.</u>
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	a suitable container appropriately labeled for subsequent administration
8	<u>to, or use by, a patient.</u>
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	or device to a patient or caregiver as defined in section 38-2809 other
13	<u>than by administering.</u>
14	Sec. 10. <u>Distribute means to deliver a drug or device, other than</u>
15	<u>by administering or dispensing.</u>
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	<u>diagnosis, cure, mitigation, treatment, or prevention of diseases in</u>
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	subdivision (1), (2), or (3) of this section, except any device or its
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 <u>law for devices described in subsection (2) of section 38-2841, medical</u>

2 gases, and medical gas devices constitutes compliance with state law and

3 <u>regulations for purposes of this section.</u>

Sec. 13. <u>Medical order means a prescription, a chart order, or an</u>
<u>order for pharmaceutical care issued by a practitioner.</u>

6 Sec. 14. Section 71-2402, Reissue Revised Statutes of Nebraska, is7 amended to read:

(1) Misbranded drug means a drug The term misbranded, as 8 71-2402 used in section 71-2404, shall apply to all drugs, the package or label 9 10 of which bears shall bear any statement, design, or device regarding a drug drugs, or the ingredients of substances contained therein, which is 11 12 shall be false or misleading in any particular, or to any drug product which is falsely labeled with the name and place of business of the 13 <u>manufacturer</u>, <u>packager</u>, <u>or</u> <u>distributor</u> <u>branded</u> <u>as</u> <u>to</u> <u>the</u> <u>state</u>, 14 15 territory, place or authority in which it is manufactured or produced.

(2) Misbranded drug includes an article (a) In case of drugs, an 16 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 \div (b 2) if it 18 is shall be labeled or branded so as to deceive or mislead the purchaser 19 or purport to be a foreign product when not so, or if the contents of the 20 package as originally put up shall have been removed, in whole or in 21 22 part, and other contents shall have been placed in such package, or if the package fails to bear a statement, on the label, of the quantity or 23 proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or 24 25 beta eucaine, chloroform, cannabis indica, chloral hydrate or acetanilide, phenacetine (acetphenetidine), antipyrine, belladonna, or 26 27 any derivative or preparation of any such substance contained therein, $\dot{\tau}$ or $(c \exists)$ if its package or label bears or contains shall bear or contain 28 any statement, design, or device regarding the curative or therapeutic 29 effect of such article, or any of the ingredients or substances contained 30 therein, which is false or fraudulent. 31

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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. <u>Practitioner means a certified registered nurse</u>
5	anesthetist, 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	Credentialing Act.
9	Sec. 18. Prescribe means to issue a medical order.
10	Sec. 19. <u>Prescription means an order for a drug or device issued by</u>
11	a practitioner for a specific patient, for emergency use, or for use in
12	immunizations. Prescription does not include a chart order.
13	Sec. 20. (1) Prescription drug or device or legend drug or device
14	<u>means a drug or device:</u>
15	<u>(a) Which is required under federal law to be labeled with one of</u>
16	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	order of a licensed veterinarian; or
20	<u>(iii) "Rx Only"; or</u>
21	<u>(b) Which is required by any applicable federal or state law to be</u>
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	carries the federal Food and Drug Administration legend "Caution: Federal
27	law restricts this device to sale by or on the order of a licensed health
28	care practitioner" or an alternative legend approved by the federal Food
29	and Drug Administration which it recognizes, in published guidance, as
30	conveying essentially the same message.
31	Sec. 21. (1) Nothing in the Prescription Drug Safety Act shall be

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2 she is not otherwise authorized to perform by another law of this state.

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

3 (2) A practitioner that stores, dispenses, compounds, administers,
4 or otherwise provides any drug to a patient shall comply with the
5 Prescription Drug Safety Act.

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 Uniform Controlled Substances Act or except when administered directly by 10 a practitioner to an ultimate user, a legend drug which is not a 11 controlled substance shall not be dispensed without a written, oral, or 12 electronic prescription. Such prescription shall be valid for twelve 13 months after the date of issuance.

(2) A prescription for a legend drug which is not a controlled 14 15 substance shall contain the following information prior to being filled by a pharmacist or practitioner who holds a pharmacy license under 16 17 subdivision (1) of section 38-2850: (a) Patient's name, (b) name of the drug, device, or biological, (c) strength of the drug or biological, if 18 19 applicable, (d) dosage form of the drug or biological, (e) quantity of the drug, device, or biological prescribed, (f) directions for use, (g) 20 date of issuance, (h) number of authorized refills, (i) the prescribing 21 22 practitioner's name, and (j) if the prescription is written, the 23 prescribing practitioner's signature. Prescriptions for controlled 24 substances must meet the requirements of sections 28-414 and 28-414.01.

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 digitally signed and transmitted to the pharmacy and may serve as the 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

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means of misrepresentation, fraud, forgery, deception, or subterfuge, 1 2 possession of any drug substance not classified as a controlled substance under the Uniform Controlled Substances Act which can only be lawfully 3 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 (1) Any prescription for a legend drug which is not a Sec. 23. controlled substance shall be kept by the practitioner who holds a 8 9 pharmacy license in a readily retrievable format and shall be maintained 10 for a minimum of five years. The practitioner shall make all such files

11 <u>readily available to the department and law enforcement for inspection</u>
12 <u>without a search warrant.</u>

13 (2) Before dispensing a legend drug which is not a controlled substance pursuant to a written, oral, or electronic prescription, a 14 15 label shall be affixed to the container in which the drug is dispensed. Such label shall bear (a) the name, address, and telephone number of the 16 17 pharmacy or practitioner, (b) the name of the patient, (c) the date of filling, (d) the serial number of the prescription under which it is 18 19 recorded in the practitioner's prescription records, (e) the name of the prescribing practitioner, (f) the directions for use, (g) name of the 20 21 drug, device, or biological unless instructed to omit by the prescribing 22 practitioner, (h) strength of the drug or biological, if applicable, (i) guantity of the drug, device, or biological in the container, except 23 24 unit-dose containers, (j) dosage form of the drug or biological, and (k) 25 any cautionary statements contained in the prescription.

26 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

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of libel for condemnation. If such drug is condemned as being adulterated 1 2 or misbranded or of a poisonous or deleterious character, the drug within the meaning of said sections, the same shall be disposed of by 3 4 destruction or sale as the court may direct, and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the treasury 5 of this state, and such goods shall not be sold in any jurisdiction 6 7 contrary to the Prescription Drug Safety Act provisions of said sections or the laws of that jurisdiction. Any libel proceeding in rem, under the 8 9 provisions of this section, may be joined with any criminal prosecution 10 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 <u>or her</u> 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 71-2402.

Sec. 26. Any person violating any of the provisions of section 24
 or 25 of this act is guilty of a Class III misdemeanor. Any person, for a
 second or subsequent violation of any of the provisions of section 24 or
 25 of this act, is guilty of a Class II misdemeanor.

22 Sec. 27. <u>An employee or agent of a prescribing practitioner may</u> 23 <u>communicate a prescription, chart order, or refill authorization issued</u> 24 <u>by the prescribing practitioner to a pharmacist or a pharmacist intern</u> 25 <u>except for an emergency oral authorization for a controlled substance</u> 26 <u>listed in Schedule II of section 28-405.</u>

27 Sec. 28. Section 38-2801, Revised Statutes Cumulative Supplement, 28 2014, is amended to read:

38-2801 Sections 38-2801 to 38-28,103 and sections 30, 34, 39, 42,
44, 45, and 54 to 57 of this act and the Nebraska Drug Product Selection
Act shall be known and may be cited as the Pharmacy Practice Act.

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

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articles recognized in The the official United States Pharmacopeia and 1 2 The National Formulary Pharmacopoeia, the Homeopathic Pharmacopoeia of the United States, the official National Formulary, or any supplement to 3 4 any of them, (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases in humans or animals, 5 (3) articles, except food, intended to affect the structure or any 6 7 function of the body of a human or an animal, (4) articles intended for use as a component of any articles specified in subdivision (1), (2), or 8 (3) of this section, except any device or its components, parts, or 9 10 accessories, and (5) prescription drugs or devices.

11 Sec. 34. <u>Hospital pharmacy means each facility licensed as a</u> 12 <u>hospital in which the compounding, preparation for administration, or</u> 13 <u>dispensing of drugs or devices pursuant to a chart order occurs for</u> 14 <u>patients within the confines of the hospital with oversight by a</u> 15 <u>pharmacist in charge.</u>

Sec. 35. Section 38-2831, Reissue Revised Statutes of Nebraska, is amended to read:

38-2831 (1) Pharmaceutical care means the provision of drug therapy 18 by a pharmacist for the purpose of achieving therapeutic outcomes that 19 improve a patient's quality of life. Such outcomes include (a) the cure 20 elimination or 21 of disease, (b) the reduction of a patient's 22 symptomatology, (c) the arrest or slowing of a disease process, or (d) the prevention of a disease or symptomatology. 23

(2) Pharmaceutical care includes the process through which the
pharmacist works in concert with the patient and his or her caregiver,
physician, or other professionals in designing, implementing, and
monitoring a therapeutic plan that will produce specific therapeutic
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

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a pharmacy license or designated by a hospital as being responsible for the practice of pharmacy in the pharmacy for which a pharmacy license is issued <u>or in a hospital pharmacy</u> and who works within the physical confines of such pharmacy <u>or hospital pharmacy</u> for a majority of the hours per week that the pharmacy is open for business averaged over a twelve-month period or thirty hours per week, whichever is less.

Sec. 37. Section 38-2837, Reissue Revised Statutes of Nebraska, isamended to read:

9 38-2837 (1) Practice of pharmacy means (a) the interpretation, evaluation, and implementation of a medical order, (b) the dispensing of 10 drugs and devices, (c) drug product selection, (d) the administration of 11 drugs or devices, (e) drug utilization review, (f) patient counseling, 12 (g) the provision of pharmaceutical care, and (h) medication therapy 13 14 management, and (i) the responsibility for compounding and labeling of dispensed or repackaged drugs and devices, proper and safe storage of 15 drugs and devices, and maintenance of proper records. 16

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.

20 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 <u>pharmacist located within the United States, using telecommunications,</u> 29 <u>remote order entry, or other automations and technologies to deliver care</u> 30 <u>to patients or their agents who are located at sites other than where the</u> 31 <u>pharmacist is located.</u> Sec. 40. Section 38-2850, Revised Statutes Cumulative Supplement,
 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 $(\underline{1} \ \underline{2})$ Practitioners, other than veterinarians, certified nurse certified registered 11 midwives, nurse anesthetists, and nurse practitioners, and physician assistants, who dispense drugs or devices as 12 13 an incident to the practice of their profession, except that if such practitioner regularly engages in dispensing such drugs or devices to his 14 or her patients for which such patients are charged, such practitioner 15 shall obtain a pharmacy license; 16

17 (<u>2</u> 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 (<u>3</u> 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;

(<u>4</u> 5) Licensed veterinarians practicing within the scope of their
 profession;

 $(5 \ 6)$ Certified nurse midwives, certified registered nurse anesthetists, and nurse practitioners, and physician assistants who dispense sample medications which are provided by the manufacturer and are dispensed at no charge to the patient;

(7) Hospitals engaged in the compounding and dispensing of drugs and
 devices pursuant to chart orders for persons registered as patients and
 within the confines of the hospital, except that if a hospital engages in

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such compounding and dispensing for persons not registered as patients and within the confines of the hospital, such hospital shall obtain a pharmacy license or delegated dispensing permit;

4 (<u>6</u> 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 (<u>7</u> 9) Registered nurses <u>or licensed practical nurses</u> 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</u> drug or device 14 containers to persons registered as patients and within the confines of 15 the hospital;

(<u>8</u> 10) Persons employed by a facility where dispensed drugs and
 devices are delivered from a pharmacy for pickup by a patient or
 caregiver and no dispensing or storage of drugs or devices occurs;

(9 11) Persons who sell or purchase medical products, compounds,
 vaccines, or serums used in the prevention or cure of animal diseases and
 maintenance of animal health if such medical products, compounds,
 vaccines, or serums are not sold or purchased under a direct, specific,
 written medical order of a licensed veterinarian;

24 (<u>10</u> <u>12</u>) 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 (<u>11</u> 13) A business or a person accredited by an accrediting body 31 which or who, pursuant to a medical order, (a) sells, delivers, or

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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.

Sec. 41. Section 38-2866, Reissue Revised Statutes of Nebraska, is
amended to read:

38-2866 Unless specifically limited by the board or the department, 6 7 a pharmacist may (1) engage in the practice of pharmacy and telepharmacy, as defined in section $71-2445_7$ (2) use automation in the practice of 8 pharmacy and telepharmacy, (3) use the abbreviation R.P., RP, R.Ph., or 9 10 <u>RPh</u> or the title licensed pharmacist or pharmacist, (4) enter into delegated dispensing agreements, and (5) supervise pharmacy technicians 11 and pharmacist interns, and (6) possess, without dispensing, prescription 12 13 drugs and devices, including controlled substances, for purposes of administration, repackaging, or educational use in an accredited pharmacy 14 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 <u>people. This section does not apply to a pharmacist intern who is</u> 19 <u>receiving experiential training directed by the accredited pharmacy</u> 20 <u>program in which he or she is enrolled.</u>

Sec. 43. Section 38-2867, Revised Statutes Cumulative Supplement,
2014, is amended to read:

38-2867 (1) Except as provided for pharmacy technicians in sections 23 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 a delegated dispensing permit, no person other than a licensed 26 27 pharmacist, a pharmacist intern, or a practitioner with a pharmacy 28 license shall provide pharmaceutical care, compound and dispense drugs or devices, or dispense pursuant to a medical order. Notwithstanding any 29 other provision of law to the contrary, a pharmacist or pharmacist intern 30 may dispense drugs or devices pursuant to a medical order of a 31

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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.

(2) Except as provided for pharmacy technicians in sections 38-2890 4 to 38-2897, for persons described in subdivision $(10 \frac{12}{12})$ or $(11 \frac{13}{13})$ of 5 section 38-2850, and for individuals authorized to dispense under a 6 delegated dispensing permit, it shall be unlawful for any person to 7 permit or direct a person who is not a pharmacist intern, a licensed 8 9 pharmacist, or a practitioner with a pharmacy license to provide 10 pharmaceutical care, compound and dispense drugs or devices, or dispense pursuant to a medical order. 11

(3) It shall be unlawful for any person to coerce or attempt to 12 coerce a pharmacist to enter into a delegated dispensing agreement or to 13 supervise any pharmacy technician for any purpose or in any manner 14 contrary to the professional judgment of the pharmacist. Violation of 15 this subsection by a health care professional regulated pursuant to the 16 Uniform Credentialing Act shall be considered an act of unprofessional 17 conduct. A violation of this subsection by a facility shall be prima 18 19 facie evidence in an action against the license of the facility pursuant to the Health Care Facility Licensure Act. Any pharmacist subjected to 20 coercion or attempted coercion pursuant to this subsection has a cause of 21 action against the person and may recover his or her damages and 22 reasonable attorney's fees. 23

(4) Violation of this section by an unlicensed person shall be aClass III misdemeanor.

Sec. 44. <u>(1) Any person authorized to compound as provided in the</u> <u>Pharmacy Practice Act shall compound in compliance with the standards of</u> <u>chapters 795 and 797 of The United States Pharmacopeia and The National</u> <u>Formulary, as such chapters existed on January 1, 2015, and shall</u> <u>compound (a) as the result of a practitioner's medical order or</u> <u>initiative occurring in the course of practice based upon the</u>

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LB37 2015 relationship between the practitioner, patient, and pharmacist, (b) for 1 2 the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing, or (c) for office use only and 3 not for resale. 4 (2) Compounding in a hospital pharmacy may occur for any hospital 5 6 which is part of the same health care system under common ownership or 7 which is a member of or an affiliated member of a formal network or 8 partnership agreement. 9 (3)(a) Any authorized person may reconstitute a commercially 10 available drug product in accordance with directions contained in approved labeling provided by the product's manufacturer and other 11 12 manufacturer directions consistent with labeling. 13 (b) Any authorized person using beyond-use dating must follow the approved product manufacturer's labeling or the standards of The United 14 States Pharmacopeia and The National Formulary if the product 15 manufacturer's labeling does not specify beyond-use dating. 16 17 (c) Any authorized person engaged in activities listed in this subsection is not engaged in compounding, except that any variance from 18 the approved product manufacturer's labeling will result in the person 19 20 being engaged in compounding. (4) Any authorized person splitting a scored tablet along scored 21 22 lines or adding flavoring to a commercially available drug product is not engaged in compounding. 23 24 (5) No person shall compound: 25 (a) A drug that has been identified by the federal Food and Drug Administration as withdrawn or removed from the market because the drug 26 27 was found to be unsafe or ineffective; 28 (b) A drug that is essentially a copy of an approved drug unless there is a drug shortage as determined by the board or unless a patient 29

- 30 has an allergic reaction to the approved drug; or
- (c) A drug that has been identified by the federal Food and Drug 31

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

<u>(2) This section does not apply to the following situations:</u>

9 <u>(a) When the practitioner controls the ordering, dispensing, and</u> 10 <u>administration of the drug, such as in the operating room, endoscopy</u> 11 suite, or emergency room; or

(b) When time does not permit the pharmacist's review, such as (i) a stat order meaning a medical order which indicates that the medication is to be given immediately and only once or (ii) when the clinical status of the patient would be significantly compromised by the delay resulting from the pharmacist's review of the order.

Sec. 46. Section 38-2869, Revised Statutes Cumulative Supplement,
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;

29 (iv) Incorrect drug dosage or duration of drug treatment;

30 (v) Drug-allergy interactions; and

31 (vi) Clinical abuse or misuse.

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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 gender6 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 drug11 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 τ 14 approved by the board.

(2)(a) Prior to the dispensing or delivery of a drug or device 15 pursuant to a prescription, the pharmacist shall ensure that a verbal 16 17 offer to counsel the patient or caregiver is made. The refusal of the verbal offer to counsel must be documented. The counseling of the patient 18 19 or caregiver by the pharmacist shall be on elements which, in the exercise of the pharmacist's professional judgment, the pharmacist deems 20 significant for the patient. Such elements may include, but need not be 21 22 limited to, the following:

23 (i) The name and description of the prescribed drug or device;

(ii) The route of administration, dosage form, dose, and duration oftherapy;

(iii) Special directions and precautions for preparation,
administration, and use by the patient or caregiver;

(iv) Common side effects, adverse effects or interactions, and
 therapeutic contraindications that may be encountered, including
 avoidance, and the action required if such effects, interactions, or
 contraindications occur;

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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 <u>telepharmacy</u> telephone service which is available at no cost to the 8 patient or caregiver.

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9 (c) Patient counseling shall be appropriate to the individual 10 patient and shall be provided to the patient or caregiver.

(d) Written information may be provided to the patient or caregiver
to supplement the patient counseling provided for in this subsection but
shall not be used as a substitute for such patient counseling.

(e) <u>A verbal offer to counsel is not required</u> This subsection shall
not be construed to require a pharmacist to provide patient counseling
when:

17 (i) The patient or caregiver refuses patient counseling;

(ii) The pharmacist, in his or her professional judgment, determines
 that patient counseling may be detrimental to the patient's care or to
 the relationship between the patient and his or her practitioner;

(iii) The patient is a patient or resident of a health care facility or health care service licensed under the Health Care Facility Licensure Act to whom prescription drugs or devices are administered by a licensed or certified staff member or consultant or a certified physician's 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 (<u>iii</u> *) A medical gas or a medical gas device is administered,
4 dispensed, or distributed by a person described in subdivision (<u>10</u> 12) of
5 section 38-2850; or

6 (<u>iv</u> vi) A device described in subsection (2) of section 38-2841 is
7 sold, distributed, or delivered by a business or person described in
8 subdivision (<u>11</u> 13) of section 38-2850.

9 Sec. 47. Section 38-2870, Revised Statutes Cumulative Supplement,
10 2014, is amended to read:

38-2870 (1) All medical orders shall be written, oral, or electronic 11 and shall be valid for the period stated in the medical order, except 12 that (a) if the medical order is for a controlled substance listed in 13 section 28-405, such period shall not exceed six months from the date of 14 issuance at which time the medical order shall expire and (b) if the 15 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 pharmaceutical care, such period shall not exceed twelve months from the 18 date of issuance at which time the medical order shall expire. 19

(2) Prescription drugs or devices may only be dispensed by a 20 pharmacist or pharmacist intern pursuant to a medical order, by an 21 22 individual dispensing pursuant to a delegated dispensing permit, or as 23 otherwise provided in section 38-2850. Notwithstanding any other provision of law to the contrary, a pharmacist or a pharmacist intern may 24 dispense drugs or devices pursuant to a medical order or an individual 25 dispensing pursuant to a delegated dispensing permit may dispense drugs 26 or devices pursuant to a medical order. The Pharmacy Practice Act shall 27 28 not be construed to require any pharmacist or pharmacist intern to dispense, compound, administer, or prepare for administration any drug or 29 device pursuant to any medical order. A pharmacist or pharmacist intern 30 shall retain the professional right to refuse to dispense. 31

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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 medical order to a pharmacist or pharmacist intern by the following 3 4 means: (a) In writing, (b) orally, (c) by facsimile transmission of a written medical order or electronic transmission of a medical order 5 signed by the practitioner, or (d) by facsimile transmission of a written 6 medical order or electronic transmission of a medical order which is not 7 signed by the practitioner. Such an unsigned medical order shall be 8 9 verified with the practitioner treated the same as an oral medical order.

(4)(a) Except as otherwise provided in sections 28-414 and 28-414.01
 to 28-414.05, any medical order transmitted by facsimile or electronic
 transmission shall:

13 $(\underline{i} \ \underline{a})$ Be be transmitted by the practitioner or the practitioner's agent directly to a pharmacist or pharmacist intern in a licensed 14 pharmacy of the patient's choice. No intervening person shall be 15 16 permitted access to the medical order to alter such order or the licensed pharmacy chosen by the patient. Such medical order may be transmitted 17 through a third-party intermediary who shall facilitate the transmission 18 of the order from the practitioner or practitioner's agent to the 19 20 pharmacy; -

21 (<u>ii</u> 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; $_{T}$ and

26 (<u>iii</u> e) <u>Serve</u> as the original medical order if all other
 27 requirements of this subsection are satisfied.

(b) Medical orders transmitted by electronic transmission shall be
 signed by the practitioner either with an electronic signature <u>for legend</u>
 <u>drugs which are not controlled substances</u> or a digital signature <u>for</u>
 <u>legend drugs which are controlled substances</u>.

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(5) The pharmacist shall exercise professional judgment regarding
 the accuracy, validity, and authenticity of any medical order transmitted
 by facsimile or electronic transmission.

Sec. 48. Section 38-2884, Reissue Revised Statutes of Nebraska, is
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:

(1) The initial dispensing of all prescriptions for approved
formulary drugs and devices is conducted by a health care professional
licensed in Nebraska to practice medicine and surgery or pharmacy or
licensed in Nebraska as a registered nurse, licensed practical nurse, or
physician assistant;

17 (2) The drug or device is dispensed pursuant to a prescription18 written onsite by a practitioner;

19 (3) The only prescriptions to be refilled under the delegated
20 dispensing permit are prescriptions for oral contraceptives;

(4) Prescriptions are accompanied by patient instructions and
written information approved by the director;

(5) The dispensing of authorized refills of oral contraceptives is
done by a licensed health care professional listed in subdivision (1) of
this section or by a public health clinic worker;

(6) All drugs or devices are prepackaged by the manufacturer or at a
public health clinic by a pharmacist into the quantity to be prescribed
and dispensed at the public health clinic;

(7) All drugs and devices stored, received, or dispensed under the
authority of public health clinics are properly labeled at all times. For
purposes of this subdivision, properly labeled means that the label

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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, <u>packager's</u>, <u>or distributor's</u> container or one year 8 from the date the drug <u>or device</u> 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 of15 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

20 (e) The name and address of the public health clinic;

(9) The only drugs and devices allowed to be dispensed or stored by public health clinics appear on the formulary approved pursuant to section 38-2881; and

(10) At any time that dispensing is occurring from a public health 24 25 clinic, the delegating pharmacist for the public health clinic or on-call pharmacist in Nebraska is available, either in person or by telephone, to 26 answer questions from clients, staff, public health clinic workers, or 27 volunteers. This availability shall be confirmed and documented at the 28 beginning of each day that dispensing will occur. The delegating 29 pharmacist or on-call pharmacist shall inform the public health clinic if 30 he or she will not be available during the time that his or her 31

availability is required. If a pharmacist is unavailable, no dispensing
 shall occur.

3 Sec. 49. Section 38-2887, Reissue Revised Statutes of Nebraska, is
4 amended to read:

38-2887 (1) A public health clinic worker or dialysis drug or device 5 distributor worker shall demonstrate proficiency to the delegating 6 7 pharmacist, according to the standards approved by the board. The delegating pharmacist shall document proficiency for each worker. In 8 9 addition, a public health clinic worker shall be supervised by a licensed health care professional specified in subdivision (1) of section 38-2884 10 for the first month that such worker is dispensing refills of oral 11 contraceptives. 12

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.

(3) The public health clinic or dialysis drug or device distributor for which a public health clinic worker or dialysis drug or device distributor worker is working shall be liable for acts or omissions on the part of such worker.

Sec. 50. Section 38-2890, Reissue Revised Statutes of Nebraska, is
 amended to read:

38-2890 (1) All pharmacy technicians employed by a facility licensed
under the Health Care Facility Licensure Act shall be registered with the
Pharmacy Technician Registry created in section 38-2893.

(2) To register as a pharmacy technician, an individual shall (a) be
at least eighteen years of age, (b) be a high school graduate or be
officially recognized by the State Department of Education as possessing
the equivalent degree of education, (c) have never been convicted of any

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nonalcohol, drug-related misdemeanor or felony, (d) file an application
 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 <u>(3) Beginning January 1, 2017, a pharmacy technician shall be</u> 9 <u>certified by a state or national certifying body approved by the board in</u> 10 <u>order to be employed as a pharmacy technician in a health care facility.</u>

11 Sec. 51. Section 38-2892, Reissue Revised Statutes of Nebraska, is 12 amended to read:

38-2892 (1) <u>The pharmacist in charge of a pharmacy or hospital</u> A
 pharmacy employing pharmacy technicians shall be responsible for the
 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. Except as otherwise provided in the Automated Medication Systems Act, the 20 The supervision of pharmacy such technicians at a pharmacy the place of 21 22 employment shall be performed by the licensed 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 pharmacies. The supervision of pharmacy technicians at a hospital 25 pharmacy shall be performed by the pharmacist assigned by the pharmacist 26 in charge to be responsible for the supervision and verification of the 27 28 activities of the pharmacy technicians.

(3)(a) Each pharmacy shall document, in a manner and method
 specified in the written control procedures and guidelines, the basic
 competence of the pharmacy technician prior to performance of tasks and

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LB37 LB37 2015 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 employment, use, and functions of pharmacy technicians; and 14 (viii) The contents of the written control procedures and 15 16 quidelines. 17 (b) Written control procedures and guidelines shall specify the 18 functions that pharmacy technicians may perform in the employing 19 pharmacy. The written control procedures and guidelines shall specify the means used by the employing pharmacy to verify that the prescribed drug 20 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

30 filing of such written control procedures and guidelines, review and

guidelines from the board. The board shall, within ninety days after the

31 either approve or disapprove them. The board shall notify the pharmacy or facility of the approval or disapproval. The board or its representatives shall have access to the approved written control procedures and guidelines upon request. Any written control procedures and guidelines for supportive pharmacy personnel that were filed by a pharmacy and approved by the board prior to September 1, 2007, shall be deemed to be approved and to apply to pharmacy technicians.

Sec. 52. Section 38-2895, Reissue Revised Statutes of Nebraska, isamended to read:

9 38-2895 (1) If a pharmacy technician performs functions requiring 10 professional judgment and licensure as a pharmacist, performs functions not specified under approved written control procedures and guidelines, 11 or performs functions without supervision and verification and such acts 12 13 are known to the pharmacist supervising the pharmacy technician or the pharmacist in charge or are of such a nature that they should have been 14 known to a reasonable person, such acts may be considered acts of 15 16 unprofessional conduct on the part of the pharmacist supervising the 17 pharmacy technician or the pharmacist in charge pursuant to section 38-178, and disciplinary measures may be taken against such pharmacist 18 19 supervising the pharmacy technician or the pharmacist in charge pursuant to the Uniform Credentialing Act. 20

(2) Acts described in subsection (1) of this section may be grounds 21 for the department, with the recommendation of the board, to apply to the 22 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 acts. On or at any time after such application the court may, in its 25 discretion, issue an order restraining such pharmacy or its agents or 26 employees from the performance of unauthorized acts. After a hearing the 27 28 court shall either grant or deny the application. Such order shall continue until the court, after a hearing, finds the basis for such order 29 has been removed. 30

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Sec. 53. Section 38-2899, Reissue Revised Statutes of Nebraska, is

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1 amended to read:

2 38-2899 The department, with the recommendation of the board, shall adopt and promulgate rules and regulations as deemed necessary to 3 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, the Pharmacy Practice Act, and the Uniform Controlled Substances Act. The 6 7 minimum standards and requirements for the practice of pharmacy, including dispensing pursuant to a delegated dispensing permit, shall be 8 9 consistent with the minimum standards and requirements established by the 10 department for pharmacy licenses under the Health Care Facility Licensure Act. 11

Sec. 54. A prescription for a legend drug which is not a controlled 12 13 substance must contain the following information prior to being filled by a pharmacist or a practitioner who holds a pharmacy license under 14 subdivision (1) of section 38-2850: Patient's name; the name of the drug, 15 device, or biological; strength of the drug or biological, if applicable; 16 17 dosage form of the drug or biological; quantity of drug, device, or biological prescribed; number of authorized refills; directions for use; 18 date of issuance; prescribing practitioner's name; and if the 19 prescription is written, the prescribing practitioner's signature. 20 Prescriptions for controlled substances must meet the requirements of 21 22 section 28-414 and 28-414.01.

23 Sec. 55. <u>A chart order must contain the following information:</u> 24 <u>Patient's name; date of the order; name of the drug, device, or</u> 25 <u>biological; strength of the drug or biological, if applicable; directions</u> 26 <u>for administration to the patient, including the dose to be given; and</u> 27 <u>the prescribing practitioner's name.</u>

28 Sec. 56. <u>An employee or agent of a prescribing practitioner may</u> 29 <u>communicate a prescription, chart order, or refill authorization issued</u> 30 <u>by the prescribing practitioner to a pharmacist or a pharmacist intern</u> 31 <u>except for an emergency oral authorization for a controlled substance</u>

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1 listed in Schedule II of section 28-405.

Sec. 57. Section 71-2421, Revised Statutes Cumulative Supplement,
2014, is amended to read:

4 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;

(c) Shall not be returned to saleable inventory nor made available
for subsequent relabeling and redispensing, except as provided in
subdivision (1)(d) of this section; or

13 (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 (ii) No prescription drug or medical device that has restricted
 18 distribution by the federal Food and Drug Administration may be returned;

(<u>iii</u> ii) The decision to accept the return of the dispensed drug or
 device shall rest solely with the pharmacist;

21 (<u>iv</u> iii) The dispensed drug or device shall have been in the control 22 of the long-term care facility at all times;

23 $(\underline{v} i \cdot v)$ 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 $(\underline{vi} +)$ Tablets or capsules shall have been dispensed in a unit dose 28 container which is impermeable to moisture and approved by the <u>board</u> 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

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relabeling and redispensing. 1

2 (3) Any person or entity which exercises reasonable care in collecting dispensed drugs or devices for disposal or from a long-term 3 care facility for credit or for relabeling and redispensing pursuant to 4 5 this section shall be immune from civil or criminal liability or professional disciplinary action of any kind for any injury, death, or 6 7 loss to person or property relating to such activities.

(4) A drug manufacturer which exercises reasonable care shall be 8 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 returned from a long-term care facility. 11

(5) Notwithstanding subsection (4) of this section, the relabeling 12 13 and redispensing of drugs returned from a long-term care facility does not absolve a drug manufacturer of any criminal or civil liability that 14 would have existed but for the relabeling and redispensing and such 15 relabeling and redispensing does not increase the liability of such drug 16 17 manufacturer that would have existed but for the relabeling and 18 redispensing.

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(6) For purposes of this section:

(a) Calculated expiration date means the expiration date on the 20 manufacturer's, packager's, or distributor's container or one year from 21 22 the date the drug or device is repackaged, whichever is earlier;

(b) Dispense, drugs, and devices are defined in the Pharmacy 23 24 Practice Act; and

25 (c) Long-term care facility does not include an assisted-living facility as defined in section 71-406. 26

27 Sec. 58. Section 71-5401.01, Reissue Revised Statutes of Nebraska, is amended to read: 28

29 71-5401.01 Sections 58 to 66 71-5401.01 to 71-5409 shall be known and may be cited as the Nebraska Drug Product Selection Act. 30

Sec. 59. Section 71-5401.02, Reissue Revised Statutes of Nebraska, 31

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1 is amended to read:

71-5401.02 The purposes of the Nebraska Drug Product Selection Act
are to provide for the drug product selection of equivalent drug products
and to promote the greatest possible use of such products.

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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 Administration; (b) that are the same dosage form of the identical active 11 ingredients in the identical amounts as the drug product prescribed; (c) 12 13 that comply with compendial standards and are consistent from lot to lot with respect to (i) purity of ingredients, (ii) weight variation, (iii) 14 uniformity of content, and (iv) stability; and (d) for which the federal 15 Food and Drug Administration has established bioequivalent standards or 16 17 has determined that no bioequivalence problems exist;

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(2) Board means the Board of Pharmacy;

(<u>2</u> 3) Brand name means the proprietary or trade name selected by the
 manufacturer, distributor, or packager for a drug product and placed upon
 the labeling of such product at the time of packaging;

(<u>3</u> 4) Chemically equivalent means drug products that contain amounts
of the identical therapeutically active ingredients in the identical
strength, quantity, and dosage form and that meet present compendial
standards;

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(5) Department means the Department of Health and Human Services;

27 (<u>4</u> 6) Drug product means any drug or device as defined in section
 28 38-2841;

(5 7) Drug product select means to dispense, without the
 practitioner's express authorization, an equivalent drug product in place
 of the brand-name drug product contained in a medical order of such

practitioner; 1

 $(\underline{6} \ \underline{8})$ Equivalent means drug products that are both chemically 2 3 equivalent and bioequivalent; and

 $(7 \ 9)$ Generic name means the official title of a drug or drug 4 combination as determined by the United States Adopted Names Council and 5 accepted by the federal Food and Drug Administration of those drug 6 7 products having the same active chemical ingredients in the same strength and quantity. \div 8

(10) Medical order has the definition found in section 38-2828; 9

10 (11) Pharmacist means a pharmacist licensed under the Pharmacy Practice Act; and 11

12 (12) Practitioner has the definition found in section 38-2838.

13 Sec. 61. Section 71-5403, Reissue Revised Statutes of Nebraska, is amended to read: 14

71-5403 (1) A pharmacist may drug product select except when: 15

16 (a) A practitioner designates that drug product selection is not 17 permitted by specifying in the written, oral, or electronic on the prescription or by telephonic, facsimile, or electronic transmission that 18 there shall be no drug product selection. For written or electronic 19 prescriptions, the practitioner shall specify in his or her own 20 handwriting on the prescription the phrase "no drug product selection", 21 "dispense as written", "brand medically necessary", or "no generic 22 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 not permitted. The pharmacist shall note "N.D.P.S.", "D.A.W.", "B.M.N.", 25 "no drug product selection", "dispense as written", "brand medically 26 necessary", "no generic substitution", or words or notations of similar 27 28 import on the prescription to indicate that drug product selection is not permitted if such is communicated orally by the prescribing practitioner; 29 30 or

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(b) A patient or designated representative or caregiver of such

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2 (2) A pharmacist shall not drug product select a drug product3 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

(d) The manufacturer, distributor, or packager maintains procedures
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 14 notation that no drug product selection is permitted for a patient who 15 has a contract whereunder he or she is reimbursed for the cost of health 16 17 care, directly or indirectly, the party that has contracted to reimburse the patient, directly or indirectly, shall make reimbursements on the 18 basis of the price of the brand-name drug product and not on the basis of 19 the equivalent drug product, unless the contract specifically requires 20 generic reimbursement under the Code of Federal Regulations. 21

(2) A prescription drug or device when dispensed shall bear upon the label the name of the drug or device in the container unless the practitioner writes do not label or words of similar import <u>in</u> on the prescription or so designates orally<u>or in writing which may be</u> transmitted by facsimile or electronic transmission.

(3) Nothing in this section shall (a) require a pharmacy to charge
less than its established minimum price for the filling of any
prescription or (b) prohibit any hospital from developing, using, and
enforcing a formulary.

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Sec. 63. Section 71-5405, Reissue Revised Statutes of Nebraska, is

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1 amended to read:

71-5405 (1) The drug product selection of any drug product by a
pharmacist pursuant to the Nebraska Drug Product Selection Act shall not
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.

16 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 embargo such drug and shall affix an appropriate marking thereto. Such 25 marking shall contain; (a \pm) adequate Adequate notice that the drug (i \pm) 26 is or is suspected of being sold, delivered, or offered for sale in 27 28 violation of the Nebraska Drug Product Selection Act and (ii b) has been embargoed; and $(\underline{b} \ 2)$ a warning that it is unlawful for any person to 29 remove or dispose of the embargoed drug by sale or otherwise without the 30 31 permission of the agent or a court of competent jurisdiction.

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Sec. 65. Section 71-5407, Reissue Revised Statutes of Nebraska, is
 amended to read:

71-5407 (1) In addition to any other penalties provided by law, any
person who violates any provision of the Nebraska Drug Product Selection
Act or any rule or regulation adopted and promulgated under the act is
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.

Sec. 66. Section 71-5409, Reissue Revised Statutes of Nebraska, is 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.

Sec. 67. Section 71-401, Revised Statutes Cumulative Supplement,
2014, is amended to read:

71-401 Sections 71-401 to 71-469 <u>and sections 69 and 70 of this act</u>
shall be known and may be cited as the Health Care Facility Licensure
Act.

21 Sec. 68. Section 71-403, Revised Statutes Cumulative Supplement, 22 2014, is amended to read:

71-403 For purposes of the Health Care Facility Licensure Act,
unless the context otherwise requires, the definitions found in sections
71-404 to 71-431 <u>and section 69 of this act</u> shall apply.

Sec. 69. <u>Hospital pharmacy means each facility licensed as a</u> <u>hospital in which the compounding, preparation for administration, or</u> <u>dispensing of drugs or devices pursuant to a chart order occurs for</u> <u>patients within the confines of the hospital with oversight by a</u> <u>pharmacist in charge.</u>

31 Sec. 70. (1) A hospital in which drugs or devices are compounded,

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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	<u>part of the same health care system under common ownership or which is a</u>
8	<u>member of or an affiliated member of a formal network or partnership</u>
9	agreement.
10	<u>(2) Each hospital shall, on or before January 1, 2016, designate a</u>
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	such hospital, including section 45 of this act. The Board of Pharmacy or
14	its designated representatives may examine and inspect the practice of
15	pharmacy in any hospital licensed by the department.

(3) The pharmacist in charge of a hospital pharmacy shall establish
 and implement policies and procedures for the practice of pharmacy and
 medication use in the hospital.

Sec. 71. Section 71-436, Reissue Revised Statutes of Nebraska, isamended to read:

71-436 (1) Except as otherwise provided in section 70 of this act, 21 an An applicant for licensure under the Health Care Facility Licensure 22 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 inpatient facility that provides services on an outpatient basis at 27 28 multiple locations, or (c) a health clinic operating satellite clinics on an intermittent basis within a portion of the total geographic area 29 served by such health clinic and sharing administration with such 30 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:

(1) Violation of any of the provisions of the Assisted-Living
Facility Act, the Health Care Facility Licensure Act, the Nebraska
Nursing Home Act, or the rules and regulations adopted and promulgated
under such acts;

18 (2) Committing or permitting, aiding, or abetting the commission of19 any unlawful act;

(3) Conduct or practices detrimental to the health or safety of a
person residing in, served by, or employed at the health care facility or
health care service;

(4) A report from an accreditation body or public agency
sanctioning, modifying, terminating, or withdrawing the accreditation or
certification of the health care facility or health care service;

(5) Failure to allow an agent or employee of the Department of
Health and Human Services access to the health care facility or health
care service for the purposes of inspection, investigation, or other
information collection activities necessary to carry out the duties of
the Department of Health and Human Services;

31 (6) Discrimination or retaliation against a person residing in,

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served by, or employed at the health care facility or health care service
 who has submitted a complaint or information to the Department of Health
 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 12 in the rules and regulations adopted and promulgated by the Department of 13 Health and Human Services;

(9) Violation of the Emergency Box Drug Act<u>or the Pharmacy Practice</u>
 <u>Act;</u>

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 tamper-evident packaging. A cancer drug packaged in single unit doses may 26 be accepted and dispensed if the outside packaging is opened but the 27 28 single-unit-dose packaging is unopened. There shall be no limitation on the number of doses that can be donated to the program as long as the 29 donated drugs meet the requirements of this section. An injectable cancer 30 drug may be accepted if it does not have temperature requirements other 31

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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 <u>defined described</u> 5 in section <u>5 or 14 of this act</u>, 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.

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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.

Sec. 74. Section 71-2427, Reissue Revised Statutes of Nebraska, is amended to read:

71-2427 (1) A participant shall comply with all applicable 14 provisions of state and federal 15 law relating to the storage, distribution, and dispensing of donated cancer drugs and shall inspect 16 all such drugs prior to dispensing to determine if they are adulterated 17 or misbranded as defined described in section 5 or 14 of this act 71-2401 18 19 or 71-2402. Such drugs shall only be dispensed pursuant to a prescription issued by a prescribing practitioner. Such drugs may be distributed to 20 another participant for dispensing. 21

(2) A participant may charge a handling fee for distributing or
dispensing cancer drugs under the program. Such fee shall be established
in rules and regulations adopted and promulgated by the department.
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:

71-2440 (1) An immunosuppressant drug shall only be accepted or dispensed under the program if such drug is in its original, unopened, sealed, and tamper-evident packaging. An immunosuppressant drug packaged in single unit doses may be accepted and dispensed if the outside

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packaging is opened but the single-unit-dose packaging is unopened. There shall be no limitation on the number of doses that can be donated to the program as long as the donated drugs meet the requirements of this 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 described</u> in section <u>5 or 14 of this act, or (c) such drug has</u> 9 <u>restricted distribution by the federal Food and Drug Administration</u> 10 71-2401 or 71-2402.

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.

Sec. 76. Section 71-2441, Reissue Revised Statutes of Nebraska, is amended to read:

17 71-2441 (1) A participant shall comply with all applicable provisions of state and federal law relating to the 18 storage, distribution, and dispensing of donated immunosuppressant drugs and shall 19 inspect all such drugs prior to dispensing to determine if the drugs are 20 adulterated or misbranded as defined described in section 5 or 14 of this 21 22 act 71-2401 or 71-2402 or if the drugs bear an expiration date prior to the date of dispensing. Such drugs shall only be dispensed pursuant to a 23 24 prescription issued by a prescribing practitioner. Such drugs may be 25 distributed to another participant for dispensing.

(2) Immunosuppressant drugs donated under the program shall not beresold.

Sec. 77. Section 71-2453, Revised Statutes Cumulative Supplement,
2014, is amended to read:

71-2453 (1) Prescription drugs or devices which have been dispensed
 pursuant to a valid prescription and delivered to a Department of

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Correctional Services facility, a criminal detention facility, a juvenile 1 detention facility, or a jail for administration to a prisoner or 2 detainee held at such facility or jail, but which are not administered to 3 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 or for relabeling and redispensing and administration to another prisoner 6 7 or detainee held at such facility or jail pursuant to a valid prescription as provided in this section. 8

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.

(b) A dispensed prescription drug or device shall be properly stored and in the control of the facility or jail at all times prior to the return of the drug or device for credit or for relabeling and redispensing. The drug or device shall be returned in the original and unopened labeled container dispensed by the pharmacist with the tamperevident seal intact, and the container shall bear the expiration date or calculated expiration date and lot number of the drug or device.

(c) A prescription drug or device shall not be returned or relabeled and redispensed under this section if the drug or device is a controlled substance, if the drug has restricted distribution by the federal Food and Drug Administration, or if the relabeling and redispensing is otherwise prohibited by law.

24 (3) For purposes of this section:

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(a) Administration has the definition found in section 38-2807;

(b) Calculated expiration date has the definition found in section
 <u>30 of this act</u> 71-2421;

(c) Criminal detention facility has the definition found in section
83-4,125;

30 (d) Department of Correctional Services facility has the definition
31 of facility found in section 83-170;

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(e) Dispense or dispensing has the definition found in section
 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 section8 38-2841.

(4) The Jail Standards Board, in consultation with the Board of 9 Pharmacy, shall adopt and promulgate rules and regulations relating to 10 the return of dispensed prescription drugs or devices for credit, 11 relabeling, or redispensing under this section, including, 12 but not 13 limited to, rules and regulations relating to (a) education and training of persons authorized to administer the prescription drug or device to a 14 prisoner or detainee, (b) the proper storage and protection of the drug 15 or device consistent with the directions contained on the label or 16 written drug information provided by the pharmacist for the drug or 17 device, (c) limits on quantity to be dispensed, (d) transferability of 18 19 drugs or devices for prisoners or detainees between facilities, (e) container requirements, (f) establishment of a drug formulary, and (g) 20 fees for the pharmacy to accept the returned drug or device. 21

(5) Any person or entity which exercises reasonable care in accepting, distributing, or dispensing prescription drugs or devices under this section or rules and regulations adopted and promulgated under this section shall be immune from civil or criminal liability or professional disciplinary action of any kind for any injury, death, or 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 <u>of this act shall be known and may be cited as the Poison Control Act.</u>

30 Sec. 79. Section 71-2501, Reissue Revised Statutes of Nebraska, is 31 amended to read:

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71-2501 (1) For purposes of <u>the Poison Control Act</u> sections 71-2501
 to 71-2510:

(1 a) Poison includes shall include: Arsenic, metallic or elemental, 3 4 and all poisonous compounds and preparations thereof; corrosive 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

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(<u>2</u> b) Poison <u>does</u> shall not include:

27 (<u>a</u> \pm) Agricultural or garden spray, insecticides, concentrated lye, 28 fungicides, rodent destroyers, and other preparations of whatever 29 ingredients, preservative or otherwise for animal or poultry use, for 30 commercial, industrial, manufacturing, <u>or</u> fire protection purposes₇ or 31 any combination of such purposes, and not for human use, when the same

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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;

(<u>b</u> ii) Preparations prepared by or under the supervision of a
governmental agency for use by it or under its direction in the
suppression of injurious insect pests and plant diseases destructive to
the agricultural and horticultural interests of the state; and

(<u>c</u> iii) Preparations for the destruction of rodents, predatory
 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.

Sec. 80. Section 71-2502, Reissue Revised Statutes of Nebraska, is amended to read:

17 71-2502 It shall be unlawful for any person to vend, sell, dispense, give away, furnish, or otherwise dispose of, or cause to be vended, sold, 18 dispensed, given away, furnished, or otherwise disposed of, either 19 directly or indirectly, any poison as defined in section 71-2501, without 20 affixing, or causing to be affixed, to the bottle, box, vessel, or 21 22 package containing the same, a label, printed or plainly written, containing the name of the article, the word poison, the name and place 23 of business of the seller, manufacturer, <u>packager</u>, packer or distributor, 24 25 and the date of sale; nor shall it be lawful for any person to deliver any of such poisons until he or she has satisfied himself or herself that 26 the person to whom delivery is made is aware of and understands the 27 28 poisonous nature of the article_{τ} and that such poison is to be used for a legitimate purpose. 29

30 Sec. 81. Section 71-2505, Reissue Revised Statutes of Nebraska, is 31 amended to read:

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1 71-2505 (1) The Poison Control Act does provisions of sections 2 71-2503 and 71-2504 shall 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:

71-2506 (1) Whenever, in the judgment of the Department of Health 11 and Human Services, it becomes shall become necessary for the protection 12 of the public, to add any poison, not specifically enumerated in section 13 71-2501, the department shall have printed a revised schedule of all 14 poisons coming under section 71-2501. The department shall forward by 15 16 mail one copy to each person registered upon its books and to every person applying for same, and the revised schedule shall carry an 17 effective date for the new poisons added. No poison shall be added by the 18 department under this section unless the same shall be as toxic in its 19 effect as any of the poisons enumerated under section 71-2501. 20

(2) Whenever the department proposes shall propose to bring any 21 additional poisons under such section 71-2501, the proposal shall be set 22 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 shall be given by such means as the department determines shall determine 26 to be reasonably calculated to notify the various interested parties. The 27 28 department may 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

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pursuant to this section may appeal such order, and the appeal shall be
 in accordance with the Administrative Procedure Act.

Sec. 83. Section 71-2507, Reissue Revised Statutes of Nebraska, is
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 <u>said</u> section <u>71-2501</u>.

8 Sec. 84. Section 71-2509, Reissue Revised Statutes of Nebraska, is9 amended to read:

10 71-2509 The Department of Health and Human Services may adopt and promulgate rules and regulations, by regulation, whenever such action 11 becomes necessary for the protection of the public, to prohibit the sale 12 13 of any poison, subject to the provisions of this section, except upon the original written, oral, or electronic medical order or prescription of 14 those practitioners credentialed under the Uniform Credentialing Act who 15 are duly authorized by law to administer or professionally use those 16 17 poisons specifically named in section 71-2501. Whenever in the opinion of the department it is in the interest of the public health, the department 18 may is empowered to adopt and promulgate rules and regulations, not 19 inconsistent with the Poison Control Act sections 71-2501 to 71-2511, 20 further restricting or prohibiting the retail sale of any poison. The 21 22 rules and regulations must be applicable to all persons alike. The <u>department shall</u>, and it shall be the duty of the department, upon 23 request by τ to furnish any person τ authorized by the Poison Control Act 24 25 sections 71-2501 to 71-2511 to sell or dispense any poisons, furnish such person with a list of all articles, preparations, and compounds the sale 26 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 <u>Poison Control Act does</u> provisions of sections 71-2502

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to 71-2511 shall not apply to sales of poisons made to those 1 2 practitioners credentialed under the Uniform Credentialing Act who are duly authorized by law to administer or professionally use those poisons 3 specifically named in section 71-2501, to sales made by any manufacturer, 4 5 wholesale dealer, or licensed pharmacist to another manufacturer, wholesale dealer, or licensed pharmacist, to a hospital, college, school, 6 or scientific or public institution, or to any person using any of such 7 poisons in the arts or for industrial, manufacturing, or agricultural 8 9 purposes and believed to be purchasing any poison for legitimate use, or to the sales of pesticides used in agricultural and industrial arts or 10 products used for the control of insect or animal pests or weeds or 11 fungus diseases, if in all such cases, except sales for use in industrial 12 arts, manufacturing, or processing, the poisons are labeled in accordance 13 with the provisions of section 71-2502. 14

Sec. 86. Section 28-425, Reissue Revised Statutes of Nebraska, is amended to read:

17 28-425 (1) No person, firm, corporation, partnership, or limited liability company shall manufacture, give away, sell, expose for sale, or 18 deliver any embalming fluid or other fluids of whatsoever name, to be 19 used for or intended for use in the embalming of dead human bodies, which 20 contain arsenic or strychnine, or preparations, compounds, or salts 21 thereof, without having the words arsenic contained herein or strychnine 22 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.

(2) No undertaker or other person shall embalm with, inject into, or
 place upon any dead human body, any fluid or preparation of any kind
 which contains arsenic or strychnine, or preparations, compounds, or
 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

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section shall be guilty of a Class III misdemeanor. 1

2 Sec. 87. Section 71-2512, Reissue Revised Statutes of Nebraska, is amended to read: 3

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 specific penalties are otherwise imposed, is shall be quilty of a Class 6 7 III misdemeanor. Any person, for a second or subsequent violation of any of the provisions of the Poison Control Act such sections, when another 8 9 specific penalty is not expressly imposed, is shall be quilty of a Class 10 II misdemeanor.

Sec. 88. Section 71-7436, Reissue Revised Statutes of Nebraska, is 11 amended to read: 12

13 71-7436 (1) Emergency medical reasons means the alleviation of a temporary shortage by transfers of prescription drugs between any of the 14 15 following: $(\underline{a} \ \underline{1})$ Holders of pharmacy licenses, $(\underline{b} \ \underline{2})$ health care practitioner facilities as defined in section 71-414, and (c = 3) hospitals 16 17 as defined in section 71-419, and (4) practitioners as defined in section 38 - 2838. 18

(2) Emergency medical reasons does not include regular and 19 systematic sales to practitioners as defined in section 38-2838 of 20 prescription drugs that will be used for routine office procedures. 21

22 Sec. 89. Section 71-7444, Reissue Revised Statutes of Nebraska, is amended to read: 23

24 71-7444 (1) Wholesale drug distribution means the distribution of 25 prescription drugs to a person other than a consumer or patient.

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(2) Wholesale drug distribution does not include:

Intracompany sales of prescription drugs, including 27 (a) any transaction or transfer between any division, subsidiary, or parent 28 company and an affiliated or related company under common ownership or 29 common control; 30

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(b) The sale, purchase, or trade of or an offer to sell, purchase,

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or trade a prescription drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code, a state, a political subdivision, or any other governmental agency to a nonprofit affiliate of 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<u>or for a</u>
10 practitioner to use for routine office procedures, not to exceed five
11 percent of sales as provided in section 71-7454;

(e) The sale, purchase, or trade of, an offer to sell, purchase, or
trade, or the dispensing of a prescription drug pursuant to a
prescription;

(f) The distribution of drug samples by representatives of a
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
common carrier solely in the usual course of business of transporting
such drugs as a common carrier if the common carrier does not store,
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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deemed necessary and appropriate under rules and regulations adopted and
 promulgated by the department.

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 section 71-7448. 15

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 (<u>10</u> 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,
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,
71-2507, 71-2509, 71-2510, 71-2512, 71-5401.01, 71-5401.02, 71-5402,

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71-5403, 71-5404, 71-5405, 71-5406, 71-5407, 71-5409, 71-7436, and
 71-7444, Reissue Revised Statutes of Nebraska, and sections 38-2801,
 38-2802, 38-2850, 38-2867, 38-2869, 38-2870, 71-401, 71-403, 71-448,
 71-2421, 71-2453, and 71-7447, Revised Statutes Cumulative Supplement,
 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.