

LEGISLATURE OF NEBRASKA
ONE HUNDRED SIXTH LEGISLATURE
SECOND SESSION

LEGISLATIVE BILL 847

Introduced by Arch, 14; Williams, 36.

Read first time January 08, 2020

Committee:

1 A BILL FOR AN ACT relating to public health and welfare; to amend
2 sections 38-2826, 38-28,107, 71-401, 71-2411, 71-2412, 71-2413,
3 71-2457, 71-2458, 71-2468, and 71-2479, Reissue Revised Statutes of
4 Nebraska; to define and redefine terms; to change provisions
5 relating to dispensed drugs and devices and emergency box drugs; to
6 provide requirements for assisted-living facilities, nursing
7 facilities, and skilled nursing facilities; to harmonize provisions;
8 and to repeal the original sections.
9 Be it enacted by the people of the State of Nebraska,

1 Section 1. Section 38-2826, Reissue Revised Statutes of Nebraska, is
2 amended to read:

3 38-2826 Labeling means the process of preparing and affixing a label
4 to any drug container or device container, exclusive of the labeling by a
5 manufacturer, packager, or distributor of a nonprescription drug or
6 commercially packaged legend drug or device. Any such label shall include
7 all information required by federal and state law or regulation.
8 Compliance with labeling requirements under federal law for devices
9 described in subsection (2) of section 38-2841, medical gases, and
10 medical gas devices constitutes compliance with state law and regulations
11 for purposes of this section. Labeling does not include affixing an
12 auxiliary sticker or other such notation to a container after a drug has
13 been dispensed when the sticker or notation is affixed by a credentialed
14 person in a facility licensed under the Health Care Facility Licensure
15 Act.

16 Sec. 2. Section 38-28,107, Reissue Revised Statutes of Nebraska, is
17 amended to read:

18 38-28,107 (1) To protect the public safety, dispensed drugs or
19 devices:

20 (a) May be collected in a pharmacy for disposal;

21 (b) May be returned to a pharmacy in response to a recall by the
22 manufacturer, packager, or distributor or if a device is defective or
23 malfunctioning;

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

27 (d) May be accepted ~~returned~~ from a long-term care facility by ~~to~~
28 the pharmacy from which they were dispensed for credit or for relabeling
29 and redispensing, except that:

30 (i) No controlled substance may be returned;

31 (ii) No prescription drug or medical device that has restricted

1 distribution by the federal Food and Drug Administration may be returned;

2 (iii) The decision to accept the return of the dispensed drug or
3 device shall rest solely with the pharmacist;

4 (iv) The dispensed drug or device shall have been in the control of
5 the long-term care facility at all times;

6 (v) The dispensed drug or device shall be in the original and
7 unopened labeled container with a tamper-evident seal intact, as
8 dispensed by the pharmacist. Such container shall bear the expiration
9 date or calculated expiration date and lot number; and

10 (vi) Tablets or capsules shall have been dispensed in a unit dose
11 container which is impermeable to moisture and approved by the board.

12 (2) Pharmacies may charge a fee for collecting dispensed drugs or
13 devices for disposal or from a long-term care facility for credit or for
14 relabeling and redispensing.

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

21 (4) A drug manufacturer which exercises reasonable care shall be
22 immune from civil or criminal liability for any injury, death, or loss to
23 persons or property relating to the relabeling and redispensing of drugs
24 returned from a long-term care facility.

25 (5) Notwithstanding subsection (4) of this section, the relabeling
26 and redispensing of drugs returned from a long-term care facility does
27 not absolve a drug manufacturer of any criminal or civil liability that
28 would have existed but for the relabeling and redispensing and such
29 relabeling and redispensing does not increase the liability of such drug
30 manufacturer that would have existed but for the relabeling and
31 redispensing.

1 (6) At the sole discretion of a pharmacist, the pharmacist may
2 package drugs and devices at the request of a patient or patient's
3 caregiver if the drugs and devices were originally dispensed from a
4 different pharmacy.

5 Sec. 3. Section 71-401, Reissue Revised Statutes of Nebraska, is
6 amended to read:

7 71-401 Sections 71-401 to 71-475 and section 4 of this act shall be
8 known and may be cited as the Health Care Facility Licensure Act.

9 Sec. 4. (1) In an assisted-living facility, a nursing facility, or
10 a skilled nursing facility, all drugs and devices shall be labeled in
11 accordance with currently accepted professional standards of care,
12 including the appropriate accessory and cautionary instructions and the
13 expiration date when applicable.

14 (2) If the dosage or directions for a specific drug or device to be
15 used in an assisted-living facility, a nursing facility, or a skilled
16 nursing facility are changed by a practitioner credentialed under the
17 Uniform Credentialing Act, a pharmacist shall apply a new label with the
18 correct dosage or directions to the drug or device package or reissue the
19 drug or device with the correct label. To protect the safety of the
20 resident of such a facility receiving the drug or device until the drug
21 or device can be correctly labeled, the drug or device package shall be
22 temporarily flagged with a sticker indicating dose change, drug change,
23 MAR, or words of similar import to alert nursing staff or an unlicensed
24 person responsible for providing the drug or device to a resident that
25 the dosage or directions have changed and the drug or device is to be
26 provided according to the corrected information contained in the
27 resident's medication administration record, also known as MAR.

28 Sec. 5. Section 71-2411, Reissue Revised Statutes of Nebraska, is
29 amended to read:

30 71-2411 For purposes of the Emergency Box Drug Act:

31 (1) Authorized personnel means any medical doctor, doctor of

1 osteopathy, registered nurse, licensed practical nurse, nurse
2 practitioner, pharmacist, or physician assistant;

3 (2) Calculated expiration date has the same meaning as in section
4 38-2808.01;

5 (3) ~~(2)~~ Department means the Department of Health and Human
6 Services;

7 (4) ~~(3)~~ Drug means any prescription drug or device or legend drug or
8 device defined under section 38-2841, any nonprescription drug as defined
9 under section 38-2829, any controlled substance as defined under section
10 28-405, or any device as defined under section 38-2814;

11 (5) ~~(4)~~ Emergency box drugs means drugs required to meet the
12 immediate therapeutic needs of patients when the drugs are not available
13 from any other authorized source in time to sufficiently prevent risk of
14 harm to such patients by the delay resulting from obtaining such drugs
15 from such other authorized source;

16 (6) ~~(5)~~ Long-term care facility means an intermediate care facility,
17 an intermediate care facility for persons with developmental
18 disabilities, a long-term care hospital, a mental health substance use
19 treatment center, a nursing facility, or a skilled nursing facility, as
20 such terms are defined in the Health Care Facility Licensure Act;

21 (7) MAR means a medication administration record kept by a long-term
22 care facility;

23 (8) ~~(6)~~ Multiple dose vial means any bottle in which more than one
24 dose of a liquid drug is stored or contained;

25 (9) NDC means the National Drug Code published by the United States
26 Food and Drug Administration;

27 (10) ~~(7)~~ Pharmacist means a pharmacist as defined in section 38-2832
28 who is employed by a supplying pharmacy or who has contracted with a
29 long-term care facility to provide consulting services; and

30 (11) ~~(8)~~ Supplying pharmacy means a pharmacy that supplies drugs for
31 an emergency box located in a long-term care facility. Drugs in the

1 emergency box are owned by the supplying pharmacy.

2 Sec. 6. Section 71-2412, Reissue Revised Statutes of Nebraska, is
3 amended to read:

4 71-2412 (1) Drugs may be administered to residents of a long-term
5 care facility by authorized personnel of the long-term care facility from
6 the contents of emergency boxes located within such long-term care
7 facility if such drugs and boxes meet all of the following requirements
8 of this section. ÷

9 (2) When electronic or automated emergency boxes are in use in a
10 long-term care facility, the supplying pharmacy shall have policies and
11 procedures to ensure proper utilization of the drugs in the emergency
12 boxes. Policies and procedures shall include who is allowed to retrieve
13 drugs from the emergency boxes, security for the location of the
14 emergency boxes within the long-term care facility, and other necessary
15 provisions as determined by the pharmacist-in-charge of the supplying
16 pharmacy.

17 (3) For emergency boxes that are not electronic or automated:

18 (a) (1) All emergency box drugs shall be provided by and all
19 emergency boxes containing such drugs shall be sealed by a supplying
20 pharmacy with the seal on such emergency box to be of such a nature that
21 it can be easily identified if it has been broken;

22 (b) (2) Emergency boxes shall be stored in a medication room or
23 other secured area within the long-term care facility. Only authorized
24 personnel of the long-term care facility or the supplying pharmacy shall
25 obtain access to such room or secured area, by key or combination, in
26 order to prevent unauthorized access and to ensure a proper environment
27 for preservation of the emergency box drugs;

28 (c) (3) The exterior of each emergency box shall be labeled so as to
29 clearly indicate that it is an emergency box for use in emergencies only.
30 The label shall contain a listing of the drugs contained in the box,
31 including the name, strength, route of administration, quantity, and

1 expiration date of each drug, and the name, address, and telephone number
2 of the supplying pharmacy; and

3 (d) Emergency ~~(4) All~~ emergency boxes shall be inspected by a
4 pharmacist designated by the supplying pharmacy at least once a month
5 ~~every thirty days~~ or after a reported usage of any drug to determine the
6 expiration date and quantity of the drugs in the box. Every inspection
7 shall be documented and the record retained by the long-term care
8 facility for a period of five years. ~~;~~ ~~and~~

9 (4) ~~(5)~~ All drugs in emergency boxes shall be in the original
10 manufacturer's or distributor's containers or shall be repackaged by the
11 supplying pharmacy in a tight, light-resistant container and shall
12 include the manufacturer's or distributor's name, lot number, drug name,
13 strength, dosage form, NDC number, route of administration, and
14 expiration date on a typewritten label. Any drug which is repackaged
15 shall contain on the label the calculated expiration date.

16 ~~For purposes of the Emergency Box Drug Act, calculated expiration~~
17 ~~date has the same meaning as in section 38-2808.01.~~

18 Sec. 7. Section 71-2413, Reissue Revised Statutes of Nebraska, is
19 amended to read:

20 71-2413 (1) The supplying pharmacy and the medical director and
21 quality assurance committee of the long-term care facility shall jointly
22 determine the drugs, by identity and quantity, to be included in the
23 emergency boxes. The supplying pharmacy shall maintain a list of
24 emergency box drugs which is identical to the list on the exterior of the
25 emergency box or the electronic inventory record of the emergency box and
26 shall make such list available to the department upon request. The
27 supplying pharmacy shall obtain a receipt upon delivery of the emergency
28 box to the long-term care facility signed by the director of nursing of
29 the long-term care facility or his or her designee which acknowledges
30 that the drugs initially placed in the emergency box are identical to the
31 initial list on the exterior of the emergency box or the electronic

1 inventory record of the emergency box. The receipt shall be retained by
2 the supplying pharmacy for a period of five years.

3 (2) Except for the removal of expired drugs as provided in
4 subsection (4) of this section, drugs shall be removed from emergency
5 boxes only pursuant to a prescription. Whenever access to the emergency
6 box occurs, the prescription and proof of use shall be provided to the
7 supplying pharmacy and shall be recorded on the resident's medical record
8 by authorized personnel of the long-term care facility. Removal of any
9 drug from an emergency box by authorized personnel of the long-term care
10 facility shall be recorded on a form showing the name of the resident who
11 received the drug, his or her room number, the name of the drug, the
12 strength of the drug, the quantity used, the dose administered, the route
13 of administration, the date the drug was used, the time of usage, the
14 disposal of waste, if any, and the signature or signatures of authorized
15 personnel. The form shall be maintained at the long-term care facility
16 for a period of five years from the date of removal with a copy of the
17 form to be provided to the supplying pharmacy.

18 (3) Whenever an emergency box is opened or otherwise accessed, the
19 supplying pharmacy shall be notified by the charge nurse or the director
20 of nursing of the long-term care facility within twenty-four hours and a
21 pharmacist designated by the supplying pharmacy shall restock and refill
22 the box, reseal the box if it is not an electronic or automated emergency
23 box, and update the drug listing on the exterior of the emergency box or
24 update the electronic inventory record of the emergency box as outlined
25 in the policies and procedures of the supplying pharmacy required by
26 section 71-2412 for an electronic or automated emergency box.

27 (4) Upon the expiration of any drug in the emergency box, the
28 supplying pharmacy shall replace the expired drug, reseal the box if it
29 is not an electronic or automated emergency box, and update the drug
30 listing on the exterior of the emergency box or update the electronic
31 inventory record of the emergency box as outlined in the policies and

1 procedures of the supplying pharmacy required by section 71-2412 for an
2 electronic or automated emergency box. Emergency box drugs shall be
3 considered inventory of the supplying pharmacy until such time as they
4 are removed for administration.

5 (5) Authorized personnel of the long-term care facility shall
6 examine the emergency boxes once every twenty-four hours and shall
7 immediately notify the supplying pharmacy upon discovering evidence of
8 tampering with any emergency box. Proof of examination by authorized
9 personnel of the long-term care facility shall be recorded and maintained
10 at the long-term care facility for a period of five years from the date
11 of examination.

12 (6) The supplying pharmacy and the medical director and quality
13 assurance committee of the long-term care facility shall jointly
14 establish written procedures for the safe and efficient distribution of
15 emergency box drugs.

16 Sec. 8. Section 71-2457, Reissue Revised Statutes of Nebraska, is
17 amended to read:

18 71-2457 Sections 71-2457 to 71-2483 and section 10 of this act shall
19 be known and may be cited as the Prescription Drug Safety Act.

20 Sec. 9. Section 71-2458, Reissue Revised Statutes of Nebraska, is
21 amended to read:

22 71-2458 For purposes of the Prescription Drug Safety Act, the
23 definitions found in sections 71-2459 to 71-2476 and section 10 of this
24 act apply.

25 Sec. 10. Central fill means the preparation, other than by
26 compounding, of a drug, device, or biological pursuant to a medical order
27 where the preparation occurs in a pharmacy other than the pharmacy
28 dispensing to the patient or caregiver.

29 Sec. 11. Section 71-2468, Reissue Revised Statutes of Nebraska, is
30 amended to read:

31 71-2468 Labeling means the process of preparing and affixing a label

1 to any drug container or device container, exclusive of the labeling by a
2 manufacturer, packager, or distributor of a nonprescription drug or
3 commercially packaged legend drug or device. Any such label shall include
4 all information required by section 71-2479 and federal law or
5 regulation. Compliance with labeling requirements under federal law for
6 devices described in subsection (2) of section 38-2841, medical gases,
7 and medical gas devices constitutes compliance with state law and
8 regulations for purposes of this section. Labeling does not include
9 affixing an auxiliary sticker or other such notation to a container after
10 a drug has been dispensed when the sticker or notation is affixed by a
11 person credentialed under the Uniform Credentialing Act in a facility
12 licensed under the Health Care Facility Licensure Act.

13 Sec. 12. Section 71-2479, Reissue Revised Statutes of Nebraska, is
14 amended to read:

15 71-2479 (1) Any prescription for a legend drug which is not a
16 controlled substance shall be kept by the pharmacy or the practitioner
17 who holds a pharmacy license in a readily retrievable format and shall be
18 maintained for a minimum of five years. The pharmacy or practitioner
19 shall make all such files readily available to the department and law
20 enforcement for inspection without a search warrant.

21 (2) Before dispensing a legend drug which is not a controlled
22 substance pursuant to a written, oral, or electronic prescription, a
23 label shall be affixed to the container in which the drug is dispensed.
24 Such label shall bear (a) the name, address, and telephone number of the
25 pharmacy or practitioner and the central fill pharmacy if central fill is
26 used, (b) the name of the patient, (c) the date of filling, (d) the
27 serial number of the prescription under which it is recorded in the
28 practitioner's prescription records, (e) the name of the prescribing
29 practitioner, (f) the directions for use, (g) the name of the drug,
30 device, or biological unless instructed to omit by the prescribing
31 practitioner, (h) the strength of the drug or biological, if applicable,

1 (i) the quantity of the drug, device, or biological in the container,
2 except unit-dose containers, (j) the dosage form of the drug or
3 biological, and (k) any cautionary statements contained in the
4 prescription.

5 (3) For multidrug containers, more than one drug, device, or
6 biological may be dispensed in the same container when (a) such container
7 is prepackaged by the manufacturer, packager, or distributor and shipped
8 directly to the pharmacy in this manner or (b) the container does not
9 accommodate greater than a thirty-one-day supply of compatible dosage
10 units and is labeled to identify each drug or biological in the container
11 in addition to all other information required by law.

12 Sec. 13. Original sections 38-2826, 38-28,107, 71-401, 71-2411,
13 71-2412, 71-2413, 71-2457, 71-2458, 71-2468, and 71-2479, Reissue Revised
14 Statutes of Nebraska, are repealed.