LEGISLATURE OF NEBRASKA

ONE HUNDRED NINTH LEGISLATURE

FIRST SESSION

LEGISLATIVE BILL 697

Introduced by Strommen, 47; Bosn, 25; DeBoer, 10; DeKay, 40; Dover, 19; Dungan, 26; Fredrickson, 20; Guereca, 7; Hallstrom, 1; Holdcroft, 36; Hunt, 8; Ibach, 44; Kauth, 31; Lonowski, 33; Quick, 35; Rountree, 3; Sorrentino, 39; Spivey, 13; Storer, 43.

Read first time January 22, 2025

Committee:

A BILL FOR AN ACT relating to the Pharmacy Practice Act; to amend sections 38-2849 and 38-2884, Reissue Revised Statutes of Nebraska, and section 38-2867.01, Revised Statutes Cumulative Supplement, 2024; to change requirements for the Board of Pharmacy; to change requirements relating to compounding and delegated dispensing permits; and to repeal the original sections.

7 Be it enacted by the people of the State of Nebraska,

Section 1. Section 38-2849, Reissue Revised Statutes of Nebraska, is
 amended to read:

3 38-2849 The board shall be composed of <u>eight</u> five members, including 4 <u>five</u> four actively practicing pharmacists, at least one of whom practices 5 within the confines of a hospital, <u>one pharmacy technician</u>, and <u>two one</u> 6 public <u>members</u> member who <u>are</u> is interested in the health of the people 7 of Nebraska.

8 Sec. 2. Section 38-2867.01, Revised Statutes Cumulative Supplement,
9 2024, is amended to read:

10 38-2867.01 (1) Any person authorized to compound shall compound in compliance with the standards of chapters 795 and 797 of The United 11 States Pharmacopeia and The National Formulary, as such chapters existed 12 13 on January 1, 2023, and shall compound (a) as the result of a practitioner's medical order or initiative occurring in the course of 14 practice based upon the relationship between the practitioner, patient, 15 and pharmacist, (b) for the purpose of, or as an incident to, research, 16 17 teaching, or chemical analysis and not for sale or dispensing, or (c) for office use only and not for resale by an outsourcing facility operating 18 pursuant to 21 U.S.C. 353b or section 71-470. 19

20 (2) Compounding in a hospital pharmacy may occur for any hospital 21 which is part of the same health care system under common ownership or 22 which is a member of or an affiliated member of a formal network or 23 partnership agreement.

(3)(a) Any authorized person may reconstitute a commercially
 available drug product in accordance with directions contained in
 approved labeling provided by the product's manufacturer and other
 manufacturer directions consistent with labeling.

(b) Any authorized person using beyond-use dating must follow the
approved product manufacturer's labeling or the standards of The United
States Pharmacopeia and The National Formulary if the product
manufacturer's labeling does not specify beyond-use dating.

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1 (c) Any authorized person engaged in activities listed in this 2 subsection is not engaged in compounding, except that any variance from 3 the approved product manufacturer's labeling will result in the person 4 being engaged in compounding.

5 (4) Any authorized person splitting a scored tablet along scored 6 lines or adding flavoring to a commercially available drug product is not 7 engaged in compounding.

8 (5) No person shall compound:

9 (a) A drug that has been identified by the federal Food and Drug 10 Administration as withdrawn or removed from the market because the drug 11 was found to be unsafe or ineffective;

(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
has an allergic reaction to the approved drug; or

15 (c) A drug that has been identified by the federal Food and Drug16 Administration or the board as a product which may not be compounded.

Sec. 3. Section 38-2884, Reissue Revised Statutes of Nebraska, is amended to read:

19 38-2884 Under a delegated dispensing permit for a public health 20 clinic, approved formulary drugs and devices may be dispensed by a public 21 health clinic worker or a health care professional licensed in Nebraska 22 to practice medicine and surgery or licensed in Nebraska as a registered 23 nurse, licensed practical nurse, or physician assistant without the 24 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;

30 (2) The drug or device is dispensed pursuant to a prescription
 31 written onsite by a practitioner or by a practitioner licensed in

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1 <u>Nebraska working in affiliation with a public health clinic pursuant to a</u>

2 <u>delegated dispensing permit;</u>

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

5 (4) Prescriptions are accompanied by patient instructions and6 written information approved by the director;

7 (5) The dispensing of authorized refills of contraceptives is done
8 by a licensed health care professional listed in subdivision (1) of this
9 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;

13 (7) All drugs and devices stored, received, or dispensed under the 14 authority of public health clinics are properly labeled at all times. For 15 purposes of this subdivision, properly labeled means that the label 16 affixed to the container prior to dispensing contains the following 17 information:

18 (a) The name of the manufacturer;

(b) The lot number and expiration date from the manufacturer or, if
repackaged by a pharmacist, the lot number and calculated expiration
date;

22 (c) Directions for patient use;

23 (d) The quantity of drug in the container;

24 (e) The name, strength, and dosage form of the drug; and

25 (f) Auxiliary labels as needed for proper adherence to any 26 prescription;

(8) The following additional information is added to the label of
each container when the drug or device is dispensed:

29 (a) The patient's name;

30 (b) The name of the prescribing health care professional;

31 (c) The prescription number;

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1 (d) The date dispensed; and

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

3 (9) The only drugs and devices allowed to be dispensed or stored by 4 public health clinics appear on the formulary approved pursuant to 5 section 38-2881; and

(10) At any time that dispensing is occurring from a public health 6 7 clinic, the delegating pharmacist for the public health clinic or on-call 8 pharmacist in Nebraska is available, either in person or by telephone, to answer questions from clients, staff, public health clinic workers, or 9 volunteers. This availability shall be confirmed and documented at the 10 beginning of each day that dispensing will occur. The delegating 11 pharmacist or on-call pharmacist shall inform the public health clinic if 12 he or she will not be available during the time that his or her 13 availability is required. If a pharmacist is unavailable, no dispensing 14 shall occur. 15

Sec. 4. Original sections 38-2849 and 38-2884, Reissue Revised
Statutes of Nebraska, and section 38-2867.01, Revised Statutes Cumulative
Supplement, 2024, are repealed.