

LEGISLATURE OF NEBRASKA  
ONE HUNDRED FIFTH LEGISLATURE  
FIRST SESSION

**LEGISLATIVE BILL 481**

Introduced by Kuehn, 38.

Read first time January 17, 2017

Committee: Health and Human Services

1 A BILL FOR AN ACT relating to the Pharmacy Practice Act; to amend  
2 sections 38-2801, 28-2802, 38-28,109, 38-28,110, 38-28,111,  
3 38-28,112, 38-28,113, and 38-28,116, Reissue Revised Statutes of  
4 Nebraska; to provide, change, and transfer definitions; to restate  
5 intent and change provisions relating to drug product selection; to  
6 harmonize provisions; to provide an operative date; and to repeal  
7 the original sections.  
8 Be it enacted by the people of the State of Nebraska,

1 Section 1. Section 38-2801, Reissue Revised Statutes of Nebraska, is  
2 amended to read:

3 38-2801 Sections 38-2801 to 38-28,107 and sections 3 to 11 of this  
4 act and the Nebraska Drug Product Selection Act shall be known and may be  
5 cited as the Pharmacy Practice Act.

6 Sec. 2. Section 38-2802, Reissue Revised Statutes of Nebraska, is  
7 amended to read:

8 38-2802 For purposes of the Pharmacy Practice Act and elsewhere in  
9 the Uniform Credentialing Act, unless the context otherwise requires, the  
10 definitions found in sections 38-2803 to 38-2847 and sections 3 to 11 of  
11 this act apply.

12 Sec. 3. Section 38-28,110, Reissue Revised Statutes of Nebraska, is  
13 amended to read:

14 ~~38-28,110 For purposes of the Nebraska Drug Product Selection Act,~~  
15 ~~unless the context otherwise requires:~~

16 (1) Bioequivalent means drug products: (1) (a) That are legally  
17 marketed under regulations promulgated by the federal Food and Drug  
18 Administration; (2) (b) that are the same dosage form of the identical  
19 active ingredients in the identical amounts as the drug product  
20 prescribed; (3) (c) that comply with compendial standards and are  
21 consistent from lot to lot with respect to (a) (i) purity of ingredients,  
22 (b) (ii) weight variation, (c) (iii) uniformity of content, and (d) (iv)  
23 stability; and (4) (d) for which the federal Food and Drug Administration  
24 has established bioequivalent standards or has determined that no  
25 bioequivalence problems exist. ÷

26 (2) ~~Brand name means the proprietary or trade name selected by the~~  
27 ~~manufacturer, distributor, or packager for a drug product and placed upon~~  
28 ~~the labeling of such product at the time of packaging;~~

29 (3) ~~Chemically equivalent means drug products that contain amounts~~  
30 ~~of the identical therapeutically active ingredients in the identical~~  
31 ~~strength, quantity, and dosage form and that meet present compendial~~

1 standards;

2 ~~(4) Drug product means any drug or device as defined in section~~  
3 ~~38-2841;~~

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

8 ~~(6) Equivalent means drug products that are both chemically~~  
9 ~~equivalent and bioequivalent; and~~

10 ~~(7) Generic name means the official title of a drug or drug~~  
11 ~~combination as determined by the United States Adopted Names Council and~~  
12 ~~accepted by the federal Food and Drug Administration of those drug~~  
13 ~~products having the same active chemical ingredients in the same strength~~  
14 ~~and quantity.~~

15 Sec. 4. Biological product has the same meaning as in 42 U.S.C.  
16 262, as such section existed on January 1, 2017.

17 Sec. 5. Brand name means the proprietary or trade name selected by  
18 the manufacturer, distributor, or packager for a drug product and placed  
19 upon the labeling of such product at the time of packaging.

20 Sec. 6. Chemically equivalent means drug products that contain  
21 amounts of the identical therapeutically active ingredients in the  
22 identical strength, quantity, and dosage form and that meet present  
23 compendial standards.

24 Sec. 7. Drug product means any drug or device as defined in section  
25 38-2841.

26 Sec. 8. Drug product select means to dispense, without the  
27 practitioner's express authorization, an equivalent drug product or an  
28 interchangeable biological product in place of the brand-name drug or the  
29 biological product contained in a medical order of such practitioner.

30 Sec. 9. Equivalent means drug products that are both chemically  
31 equivalent and bioequivalent.

1           Sec. 10. Generic name means the official title of a drug or drug  
2 combination as determined by the United States Adopted Names Council and  
3 accepted by the federal Food and Drug Administration of those drug  
4 products having the same active chemical ingredients in the same strength  
5 and quantity.

6           Sec. 11. Interchangeable biological product means a biological  
7 product that the federal Food and Drug Administration:

8           (1) Has licensed and has determined meets the standards for  
9 interchangeability pursuant to 42 U.S.C. 262(k)(4), as such section  
10 existed on January 1, 2017, or as set forth in the Lists of Licensed  
11 Biological Products with Reference Product Exclusivity and Biosimilarity  
12 or Interchangeability Evaluations published by the federal Food and Drug  
13 Administration, as such publication existed on January 1, 2017; or

14           (2) Has determined is therapeutically equivalent as set forth in the  
15 Approved Drug Products with Therapeutic Equivalence Evaluations of the  
16 federal Food and Drug Administration, as such publication existed on  
17 January 1, 2017.

18           Sec. 12. Section 38-28,109, Reissue Revised Statutes of Nebraska, is  
19 amended to read:

20           38-28,109 The purposes of the Nebraska Drug Product Selection Act  
21 are to provide for the drug product selection of equivalent drug products  
22 or interchangeable biological products and to promote the greatest  
23 possible use of such products.

24           Sec. 13. Section 38-28,111, Reissue Revised Statutes of Nebraska, is  
25 amended to read:

26           38-28,111 (1) A pharmacist may drug product select except when:

27           (a) A practitioner designates that drug product selection is not  
28 permitted by specifying in the written, oral, or electronic prescription  
29 that there shall be no drug product selection. For written or electronic  
30 prescriptions, the practitioner shall specify "no drug product  
31 selection", "dispense as written", "brand medically necessary", or "no

1 generic substitution" or the notation "N.D.P.S.", "D.A.W.", or "B.M.N."  
2 or words or notations of similar import to indicate that drug product  
3 selection is not permitted. The pharmacist shall note "N.D.P.S.",  
4 "D.A.W.", "B.M.N.", "no drug product selection", "dispense as written",  
5 "brand medically necessary", "no generic substitution", or words or  
6 notations of similar import on the prescription to indicate that drug  
7 product selection is not permitted if such is communicated orally by the  
8 prescribing practitioner; or

9 (b) A patient or designated representative or caregiver of such  
10 patient instructs otherwise.

11 (2) A pharmacist shall not drug product select a ~~drug product~~  
12 unless:

13 (a) The drug product, if it is in solid dosage form, has been marked  
14 with an identification code or monogram directly on the dosage unit;

15 (b) The drug product has been labeled with an expiration date;

16 (c) The manufacturer, distributor, or packager of the drug product  
17 provides reasonable services, as determined by the board, to accept the  
18 return of drug products that have reached their expiration date; and

19 (d) The manufacturer, distributor, or packager maintains procedures  
20 for the recall of unsafe or defective drug products.

21 (3) If a pharmacist receives a prescription for a biological product  
22 and chooses to dispense an interchangeable biological product for the  
23 prescribed product, the pharmacist must advise the patient or the  
24 patient's caregiver that drug product selection has occurred.

25 (4) Within three business days after the dispensing of a biological  
26 product, the dispensing pharmacist or the pharmacist's designee shall  
27 make an entry of the specific product provided to the patient, including  
28 the name of the product and the manufacturer. The communication shall be  
29 conveyed by making an entry that is electronically accessible to the  
30 prescriber through an interoperable electronic medical records system,  
31 electronic prescribing technology, a pharmacy benefit management system,

1 or a pharmacy record. Entry into an electronic records system described  
2 in this subsection is presumed to provide notice to the prescriber.  
3 Otherwise, the pharmacist shall communicate the biological product  
4 dispensed to the prescriber using facsimile, telephone, electronic  
5 transmission, or other prevailing means, except that communication shall  
6 not be required if (a) there is no interchangeable biological product  
7 approved by the federal Food and Drug Administration for the product  
8 prescribed or (b) a refill prescription is not changed from product  
9 dispensed on the prior filling.

10       Sec. 14. Section 38-28,112, Reissue Revised Statutes of Nebraska, is  
11 amended to read:

12       38-28,112 (1) Whenever a drug product has been prescribed with the  
13 notation that no drug product selection is permitted for a patient who  
14 has a contract whereunder he or she is reimbursed for the cost of health  
15 care, directly or indirectly, the party that has contracted to reimburse  
16 the patient, directly or indirectly, shall make reimbursements on the  
17 basis of the price of the brand-name drug product and not on the basis of  
18 the equivalent drug product or interchangeable biological product, unless  
19 the contract specifically requires generic reimbursement under the Code  
20 of Federal Regulations.

21       (2) A prescription drug or device when dispensed shall bear upon the  
22 label the name of the drug or device in the container unless the  
23 practitioner writes do not label or words of similar import in the  
24 prescription or so designates orally.

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

29       Sec. 15. Section 38-28,113, Reissue Revised Statutes of Nebraska, is  
30 amended to read:

31       38-28,113 (1) Drug ~~The drug product selection of any drug product~~ by

1 a pharmacist pursuant to the Nebraska Drug Product Selection Act shall  
2 not constitute the practice of medicine.

3 (2) Drug product selection of ~~drug products~~ by a pharmacist pursuant  
4 to the act or any rules and regulations adopted and promulgated under the  
5 act shall not constitute evidence of negligence if the drug product  
6 selection was made within the reasonable and prudent practice of  
7 pharmacy.

8 (3) When drug product selection by a pharmacist is permissible under  
9 the act, such drug product selection shall not constitute evidence of  
10 negligence on the part of the prescribing practitioner. The failure of a  
11 prescribing practitioner to provide that there shall be no drug product  
12 selection in any case shall not constitute evidence of negligence or  
13 malpractice on the part of such prescribing practitioner.

14 Sec. 16. Section 38-28,116, Reissue Revised Statutes of Nebraska, is  
15 amended to read:

16 38-28,116 (1) The department may adopt and promulgate rules and  
17 regulations necessary to implement the Nebraska Drug Product Selection  
18 Act upon the joint recommendation of the Board of Medicine and Surgery  
19 and the Board of Pharmacy.

20 (2) The department shall maintain a link on its web site to the  
21 current list of all biological products that the federal Food and Drug  
22 Administration has determined to be interchangeable biological products.

23 Sec. 17. This act becomes operative on January 1, 2018.

24 Sec. 18. Original sections 38-2801, 38-2802, 38-28,109, 38-28,110,  
25 38-28,111, 38-28,112, 38-28,113, and 38-28,116, Reissue Revised Statutes  
26 of Nebraska, are repealed.