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2017

LEGISLATURE OF NEBRASKA

ONE HUNDRED FIFTH LEGISLATURE

FIRST SESSION

# LEGISLATIVE BILL 481

FINAL READING

Introduced by Kuehn, 38.

Read first time January 17, 2017

Committee: Health and Human Services

A BILL FOR AN ACT relating to the Pharmacy Practice Act; to amend sections 38-2801, 38-2802, 38-28,109, 38-28,110, 38-28,111, 38-28,112, 38-28,113, and 38-28,116, Reissue Revised Statutes of Nebraska; to provide, change, and transfer definitions; to restate intent and change provisions relating to drug product selection; to harmonize provisions; to provide an operative date; and to repeal the original sections.

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

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

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

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

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

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

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

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

~~(2) 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;~~

~~(3) 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~~

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~~standards;~~

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

~~(5) 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;~~

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

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

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

Sec. 5. 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.

Sec. 6. 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.

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

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

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

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

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

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

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

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

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

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

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

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

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generic substitution" or the notation "N.D.P.S.", "D.A.W.", or "B.M.N." or words 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.", "no drug product selection", "dispense as written", "brand medically necessary", "no generic substitution", or words or notations of similar import on the prescription to indicate that drug product selection is not permitted if such is communicated orally by the prescribing practitioner; or

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

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

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

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

(c) The manufacturer, distributor, or packager of the drug product provides reasonable services, as determined by the board, to accept the 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.

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

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

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

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

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

(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 in the prescription or so designates orally.

(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.

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

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

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

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

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

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

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

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

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

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