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LEGISLATURE OF NEBRASKA

ONE HUNDRED FOURTH LEGISLATURE

SECOND SESSION

LEGISLATIVE BILL 979

Introduced by Kuehn, 38.

Read first time January 14, 2016

Committee:

A BILL FOR AN ACT relating to drug product selection; to amend section 38-2891, Reissue Revised Statutes of Nebraska, section 71-2445, Revised Statutes Cumulative Supplement, 2014, and sections 38-2801, 38-2837, 38-28,108, 38-28,109, 38-28,110, 38-28,111, 38-28,112, 38-28,113, 38-28,114, 38-28,115, and 38-28,116, Revised Statutes Supplement, 2015; to provide for selection of interchangeable biological products by pharmacists as prescribed; to define and redefine terms; to rename the Nebraska Drug Product Selection Act; to harmonize provisions; 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, Revised Statutes Supplement, 2015, is amended to read:

38-2801 Sections 38-2801 to 38-28,107 and the Nebraska Drug or Biological Product Selection Act shall be known and may be cited as the Pharmacy Practice Act.

Sec. 2. Section 38-2837, Revised Statutes Supplement, 2015, is amended to read:

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

(2) The active practice of pharmacy means the performance of the functions set out in this section by a pharmacist as his or her principal or ordinary occupation.

Sec. 3. Section 38-2891, Reissue Revised Statutes of Nebraska, is amended to read:

38-2891 (1) A pharmacy technician shall only perform tasks which do not require professional judgment and which are subject to verification to assist a pharmacist in the practice of pharmacy.

(2) The functions and tasks which shall not be performed by pharmacy technicians include, but are not limited to:

(a) Receiving oral medical orders from a practitioner or his or her agent;

(b) Providing patient counseling;

(c) Performing any evaluation or necessary clarification of a medical order or performing any functions other than strictly clerical functions involving a medical order;

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(d) Supervising or verifying the tasks and functions of pharmacy technicians;

(e) Interpreting or evaluating the data contained in a patient's record maintained pursuant to section 38-2869;

(f) Releasing any confidential information maintained by the pharmacy;

(g) Performing any professional consultations; and

(h) Drug or biological product selection, with regard to an individual medical order, in accordance with the Nebraska Drug or Biological Product Selection Act.

(3) The director shall, with the recommendation of the board, waive any of the limitations in subsection (2) of this section for purposes of a scientific study of the role of pharmacy technicians approved by the board. Such study shall be based upon providing improved patient care or enhanced pharmaceutical care. Any such waiver shall state the length of the study and shall require that all study data and results be made available to the board upon the completion of the study. Nothing in this subsection requires the board to approve any study proposed under this subsection.

Sec. 4. Section 38-28,108, Revised Statutes Supplement, 2015, is amended to read:

38-28,108 Sections 38-28,108 to 38-28,116 shall be known and may be cited as the Nebraska Drug or Biological Product Selection Act.

Sec. 5. Section 38-28,109, Revised Statutes Supplement, 2015, is amended to read:

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

Sec. 6. Section 38-28,110, Revised Statutes Supplement, 2015, is amended to read:

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

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

(2) Biological product means a virus, a therapeutic serum, a toxin, an antitoxin, a vaccine, blood, a blood component or derivative, an allergenic product, a protein except any chemically synthesized polypeptide, or an analogous product, arsphenamine or derivative of arsphenamine, or any other trivalent organic arsenic compound which is applicable to the prevention, treatment, or cure of a disease or condition of human beings;

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

(4 ~~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 standards;

(5 ~~4~~) Drug product means any drug or device as defined in section 38-2841;

(6 ~~5~~) Drug or biological 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 biological product contained in a medical order of such practitioner;

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(7 ~~6~~) Equivalent means drug or biological products that are both chemically equivalent and bioequivalent; ~~and~~

(8 ~~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; and ~~.~~

(9) Interchangeable biological product means:

(a) A biological product licensed by the federal Food and Drug Administration and determined to be interchangeable to the prescribed biological product pursuant to 42 U.S.C. 262(k)(4); or

(b) A biological product determined by the federal Food and Drug Administration to be therapeutically equivalent to the prescribed product as set forth in the Approved Drug Products with Therapeutic Equivalence Evaluations published by the federal Food and Drug Administration.

Sec. 7. Section 38-28,111, Revised Statutes Supplement, 2015, is amended to read:

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

(a) A practitioner designates that drug or biological product selection is not permitted by specifying in the written, oral, or electronic prescription that there shall be no drug or biological product selection. For written or electronic prescriptions, the practitioner shall specify "no drug or biological product selection", "dispense as written", "brand medically necessary", or "no generic substitution" or the notation "N.D.B.P.S. ~~N.D.P.S.~~", "D.A.W.", or "B.M.N." or words or notations of similar import to indicate that drug or biological product selection is not permitted. The pharmacist shall note "N.D.B.P.S. ~~N.D.P.S.~~", "D.A.W.", "B.M.N.", "no drug or biological product selection", "dispense as written", "brand medically necessary", "no generic substitution", or words or notations of similar import on the

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prescription to indicate that drug or biological 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 or biological product select ~~a drug product~~ unless:

(a) The drug or biological 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 or biological product has been labeled with an expiration date;

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

(d) The manufacturer, distributor, or packager maintains procedures for the recall of unsafe or defective drug or biological products; and ~~.~~

(e) The pharmacy informs the patient of the drug or biological product selection.

(3) Within five business days after the dispensing of a biological product, the dispensing pharmacist or his or her designee shall make an entry of the specific product which was 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 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

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means. The communication shall not be required if (a) there is no interchangeable biological product for the biological product prescribed or (b) the biological product dispensed is based on a refilled prescription and the biological product is not changed from the prior filling of the prescription.

Sec. 8. Section 38-28,112, Revised Statutes Supplement, 2015, is amended to read:

38-28,112 (1) Whenever a drug or biological product has been prescribed with the notation that no drug or biological 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 or biological 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 or biological product when dispensed shall bear upon the label the name of the drug or device or biological product 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. 9. Section 38-28,113, Revised Statutes Supplement, 2015, is amended to read:

38-28,113 (1) The drug or biological product selection ~~of any drug product~~ by a pharmacist pursuant to the Nebraska Drug or Biological Product Selection Act shall not constitute the practice of medicine.

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(2) Drug or biological 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 or biological product selection was made within the reasonable and prudent practice of pharmacy.

(3) When drug or biological product selection by a pharmacist is permissible under the act, such drug or biological 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 or biological product selection in any case shall not constitute evidence of negligence or malpractice on the part of such prescribing practitioner.

Sec. 10. Section 38-28,114, Revised Statutes Supplement, 2015, is amended to read:

38-28,114 (1) The manufacturer, packager, or distributor of any legend drug sold, delivered, or offered for sale for human use in the State of Nebraska shall have the name and address of the manufacturer of the finished dosage form of the drug printed on the label on the container of such drug.

(2) Whenever a duly authorized agent of the department has probable cause to believe that any drug is without such labeling, the agent shall embargo such drug and shall affix an appropriate marking thereto. Such marking shall contain (a) adequate notice that the drug (i) is or is suspected of being sold, delivered, or offered for sale in violation of the Nebraska Drug or Biological Product Selection Act and (ii) has been embargoed and (b) a warning that it is unlawful for any person to remove or dispose of the embargoed drug by sale or otherwise without the permission of the agent or a court of competent jurisdiction.

Sec. 11. Section 38-28,115, Revised Statutes Supplement, 2015, is amended to read:

38-28,115 (1) In addition to any other penalties provided by law,

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any person who violates any provision of the Nebraska Drug or Biological Product Selection Act or any rule or regulation adopted and promulgated under the act is guilty of a Class IV misdemeanor for each violation.

(2) It is unlawful for any employer or such employer's agent to coerce a pharmacist to dispense a drug or biological product against the professional judgment of the pharmacist or as ordered by a prescribing practitioner.

Sec. 12. Section 38-28,116, Revised Statutes Supplement, 2015, is amended to read:

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

(2) The department shall provide and maintain a list of all biological products that the federal Food and Drug Administration has determined to be interchangeable biological products.

Sec. 13. Section 71-2445, Revised Statutes Cumulative Supplement, 2014, is amended to read:

71-2445 For purposes of the Automated Medication Systems Act:

(1) Automated medication distribution machine means a type of automated medication system that stores medication to be administered to a patient by a person credentialed under the Uniform Credentialing Act;

(2) Automated medication system means a mechanical system that performs operations or activities, other than compounding, administration, or other technologies, relative to storage and packaging for dispensing or distribution of medications and that collects, controls, and maintains all transaction information and includes, but is not limited to, a prescription medication distribution machine or an automated medication distribution machine. An automated medication system may only be used in conjunction with the provision of pharmacist care;

(3) Chart order means an order for a drug or device issued by a

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practitioner for a patient who is in the hospital where the chart is stored, for a patient receiving detoxification treatment or maintenance treatment pursuant to section 28-412, or for a resident in a long-term care facility in which a long-term care automated pharmacy is located from which drugs will be dispensed. Chart order does not include a prescription;

(4) Hospital has the definition found in section 71-419;

(5) Long-term care automated pharmacy means a designated area in a long-term care facility where an automated medication system is located, that stores medications for dispensing pursuant to a medical order to residents in such long-term care facility, that is installed and operated by a pharmacy licensed under the Health Care Facility Licensure Act, and that is licensed under section 71-2451;

(6) Long-term care facility means an intermediate care facility, an intermediate care facility for persons with developmental disabilities, a long-term care hospital, a mental health center, a nursing facility, or a skilled nursing facility, as such terms are defined in the Health Care Facility Licensure Act;

(7) Medical order means a prescription, a chart order, or an order for pharmaceutical care issued by a practitioner;

(8) Pharmacist means any person who is licensed by the State of Nebraska to practice pharmacy;

(9) Pharmacist care means the provision by a pharmacist of medication therapy management, with or without the dispensing of drugs or devices, intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process;

(10) Pharmacist remote order entry means entering an order into a computer system or drug utilization review by a pharmacist licensed to practice pharmacy in the State of Nebraska and located within the United States, pursuant to medical orders in a hospital, long-term care

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facility, or pharmacy licensed under the Health Care Facility Licensure Act;

(11) Practice of pharmacy means (a) the interpretation, evaluation, and implementation of a medical order, (b) the dispensing of drugs and devices, (c) drug or biological product selection, (d) the administration of drugs or devices, (e) drug utilization review, (f) patient counseling, (g) the provision of pharmaceutical care, and (h) the responsibility for compounding and labeling of dispensed or repackaged drugs and devices, proper and safe storage of drugs and devices, and maintenance of proper records. The active practice of pharmacy means the performance of the functions set out in this subdivision by a pharmacist as his or her principal or ordinary occupation;

(12) Practitioner means a certified registered nurse anesthetist, a certified nurse midwife, a dentist, an optometrist, a nurse practitioner, a physician assistant, a physician, a podiatrist, or a veterinarian;

(13) Prescription means an order for a drug or device issued by a practitioner for a specific patient, for emergency use, or for use in immunizations. Prescription does not include a chart order;

(14) Prescription medication distribution machine means a type of automated medication system that packages, labels, or counts medication in preparation for dispensing of medications by a pharmacist pursuant to a prescription; and

(15) Telepharmacy means the provision of pharmacist care, by a pharmacist located within the United States, using telecommunications, remote order entry, or other automations and technologies to deliver care to patients or their agents who are located at sites other than where the pharmacist is located.

Sec. 14. Original section 38-2891, Reissue Revised Statutes of Nebraska, section 71-2445, Revised Statutes Cumulative Supplement, 2014, and sections 38-2801, 38-2837, 38-28,108, 38-28,109, 38-28,110, 38-28,111, 38-28,112, 38-28,113, 38-28,114, 38-28,115, and 38-28,116,

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Revised Statutes Supplement, 2015, are repealed.