LEGISLATURE OF NEBRASKA

ONE HUNDRED FIRST LEGISLATURE

SECOND SESSION

LEGISLATIVE BILL 930

Introduced by Gloor, 35.

Read first time January 13, 2010

Committee: Health and Human Services

A BILL

FOR AN ACT relating to the Pharmacy Practice Act; to amend sections 38-2841 and 71-7447, Reissue Revised Statutes of Nebraska, and sections 38-2826, 38-2850, 38-2867, and 38-2869, Revised Statutes Supplement, 2009; to redefine terms; to change provisions relating to the practice of pharmacy and patient counseling; to harmonize provisions; and to repeal the original sections.

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

Section 1. Section 38-2826, Revised Statutes Supplement, 2009, is amended to read:

38-2826 Labeling means the process of preparing and affixing a label to any drug container or device container, exclusive of the labeling by a manufacturer, ~~packer,~~ packager, or distributor of a nonprescription drug or commercially packaged legend drug or device. Any such label shall include all information required by federal and state law or regulation. Compliance with labeling requirements under federal law for devices described in subsection (2) of section 38-2841, medical gases, and medical gas devices constitutes compliance with state law and regulations for purposes of this section.

Sec. 2. Section 38-2841, Reissue Revised Statutes of Nebraska, is amended to read:

38-2841 (1) Prescription drug or device or legend drug or device means:

~~(1)~~ (a) A drug or device which is required under federal law to be labeled with one of the following statements prior to being dispensed or delivered:

~~(a)~~ (i) Caution: Federal law prohibits dispensing without prescription;

~~(b)~~ (ii) Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian; or

~~(c)~~ (iii) "Rx Only"; or

~~(2)~~ (b) A drug or device which is required by any

applicable federal or state law to be dispensed pursuant only to a prescription or chart order or which is restricted to use by practitioners only.

(2) Prescription drug or device or legend drug or device does not include a type of device, including supplies and device components, which carries the federal Food and Drug Administration legend "Caution: federal law restricts this device to sale by or on the order of a licensed health care practitioner" or an alternative legend approved by the federal Food and Drug Administration which it recognizes, in published guidance, as conveying essentially the same message.

Sec. 3. Section 38-2850, Revised Statutes Supplement, 2009, is amended to read:

38-2850 As authorized by the Uniform Credentialing Act, the practice of pharmacy may be engaged in by a pharmacist, a pharmacist intern, or a practitioner with a pharmacy license. The practice of pharmacy shall not be construed to include:

(1) Persons who sell, offer, or expose for sale completely denatured alcohol or concentrated lye, insecticides, and fungicides in original packages;

(2) Practitioners, other than veterinarians, certified nurse midwives, certified registered nurse anesthetists, and nurse practitioners, who dispense drugs or devices as an incident to the practice of their profession, except that if such practitioner regularly engages in dispensing such drugs or devices to his or

her patients for which such patients are charged, such practitioner shall obtain a pharmacy license;

(3) Persons who sell, offer, or expose for sale nonprescription drugs or proprietary medicines, the sale of which is not in itself a violation of the Nebraska Liquor Control Act;

(4) Medical representatives, detail persons, or persons known by some name of like import, but only to the extent of permitting the relating of pharmaceutical information to health care professionals;

(5) Licensed veterinarians practicing within the scope of their profession;

(6) Certified nurse midwives, certified registered nurse anesthetists, and nurse practitioners who dispense sample medications which are provided by the manufacturer and are dispensed at no charge to the patient;

(7) Hospitals engaged in the compounding and dispensing of drugs and devices pursuant to chart orders for persons registered as patients and within the confines of the hospital, except that if a hospital engages in such compounding and dispensing for persons not registered as patients and within the confines of the hospital, such hospital shall obtain a pharmacy license or delegated dispensing permit;

(8) Optometrists who prescribe or dispense eyeglasses or contact lenses to their own patients;

(9) Registered nurses employed by a hospital who

administer pursuant to a chart order, or procure for such purpose, single doses of drugs or devices from original drug or device containers or properly labeled prepackaged drug or device containers to persons registered as patients and within the confines of the hospital;

(10) Persons employed by a facility where dispensed drugs and devices are delivered from a pharmacy for pickup by a patient or caregiver and no dispensing or storage of drugs or devices occurs;

(11) Persons who sell or purchase medical products, compounds, vaccines, or serums used in the prevention or cure of animal diseases and maintenance of animal health if such medical products, compounds, vaccines, or serums are not sold or purchased under a direct, specific, written medical order of a licensed veterinarian; ~~and~~

(12) A pharmacy or a person accredited by an accrediting body which or who, pursuant to a medical order, (a) administers, dispenses, or distributes medical gas or medical gas devices to patients or ultimate users or (b) purchases or receives medical gas or medical gas devices for administration, dispensing, or distribution to patients or ultimate users; and~~.~~

(13) A business or a person accredited by an accrediting body which or who, pursuant to a medical order, (a) sells, delivers, or distributes devices described in subsection (2) of section 38-2841 to patients or ultimate users or (b) purchases or

receives such devices with intent to sell, deliver, or distribute to patients or ultimate users.

Sec. 4. Section 38-2867, Revised Statutes Supplement, 2009, is amended to read:

38-2867 (1) Except as provided for pharmacy technicians in sections 38-2890 to 38-2897, for persons described in subdivision (12) or (13) of section 38-2850, and for individuals authorized to dispense under a delegated dispensing permit, no person other than a licensed pharmacist, a pharmacist intern, or a practitioner with a pharmacy license shall provide pharmaceutical care, compound and dispense drugs or devices, or dispense pursuant to a medical order. Notwithstanding any other provision of law to the contrary, a pharmacist or pharmacist intern may dispense drugs or devices pursuant to a medical order of a practitioner authorized to prescribe in another state if such practitioner could be authorized to prescribe such drugs or devices in this state.

(2) Except as provided for pharmacy technicians in sections 38-2890 to 38-2897, for persons described in subdivision (12) or (13) of section 38-2850, and for individuals authorized to dispense under a delegated dispensing permit, it shall be unlawful for any person to permit or direct a person who is not a pharmacist intern, a licensed pharmacist, or a practitioner with a pharmacy license to provide pharmaceutical care, compound and dispense drugs or devices, or dispense pursuant to a medical order.

(3) It shall be unlawful for any person to coerce

or attempt to coerce a pharmacist to enter into a delegated dispensing agreement or to supervise any pharmacy technician for any purpose or in any manner contrary to the professional judgment of the pharmacist. Violation of this subsection by a health care professional regulated pursuant to the Uniform Credentialing Act shall be considered an act of unprofessional conduct. A violation of this subsection by a facility shall be prima facie evidence in an action against the license of the facility pursuant to the Health Care Facility Licensure Act. Any pharmacist subjected to coercion or attempted coercion pursuant to this subsection has a cause of action against the person and may recover his or her damages and reasonable attorney's fees.

(4) Violation of this section by an unlicensed person shall be a Class III misdemeanor.

Sec. 5. Section 38-2869, Revised Statutes Supplement, 2009, is amended to read:

38-2869 (1)(a) Prior to the dispensing or the delivery of a drug or device pursuant to a medical order to a patient or caregiver, a pharmacist shall in all care settings conduct a prospective drug utilization review. Such prospective drug utilization review shall involve monitoring the patient-specific medical history described in subdivision (b) of this subsection and available to the pharmacist at the practice site for:

(i) Therapeutic duplication;

(ii) Drug-disease contraindications;

(iii) Drug-drug interactions;

(iv) Incorrect drug dosage or duration of drug treatment;

(v) Drug-allergy interactions; and

(vi) Clinical abuse or misuse.

(b) A pharmacist conducting a prospective drug utilization review shall ensure that a reasonable effort is made to obtain from the patient, his or her caregiver, or his or her practitioner and to record and maintain records of the following information to facilitate such review:

(i) The name, address, telephone number, date of birth, and gender of the patient;

(ii) The patient's history of significant disease, known allergies, and drug reactions and a comprehensive list of relevant drugs and devices used by the patient; and

(iii) Any comments of the pharmacist relevant to the patient's drug therapy.

(c) The assessment of data on drug use in any prospective drug utilization review shall be based on predetermined standards, approved by the board.

(2)(a) Prior to the dispensing or delivery of a drug or device pursuant to a prescription, the pharmacist shall ensure that a verbal offer to counsel the patient or caregiver is made. The counseling of the patient or caregiver by the pharmacist shall be on elements which, in the exercise of the pharmacist's professional judgment, the pharmacist deems significant for the patient. Such

elements may include, but need not be limited to, the following:

(i) The name and description of the prescribed drug or device;

(ii) The route of administration, dosage form, dose, and duration of therapy;

(iii) Special directions and precautions for preparation, administration, and use by the patient or caregiver;

(iv) Common side effects, adverse effects or interactions, and therapeutic contraindications that may be encountered, including avoidance, and the action required if such effects, interactions, or contraindications occur;

(v) Techniques for self-monitoring drug therapy;

(vi) Proper storage;

(vii) Prescription refill information; and

(viii) Action to be taken in the event of a missed dose.

(b) The patient counseling provided for in this subsection shall be provided in person whenever practical or by the utilization of telephone service which is available at no cost to the patient or caregiver.

(c) Patient counseling shall be appropriate to the individual patient and shall be provided to the patient or caregiver.

(d) Written information may be provided to the patient or caregiver to supplement the patient counseling provided for in this subsection but shall not be used as a substitute for such patient

counseling.

(e) This subsection shall not be construed to require a pharmacist to provide patient counseling when:

(i) The patient or caregiver refuses patient counseling;

(ii) The pharmacist, in his or her professional judgment, determines that patient counseling may be detrimental to the patient's care or to the relationship between the patient and his or her practitioner;

(iii) The patient is a patient or resident of a health care facility or health care service licensed under the Health Care Facility Licensure Act to whom prescription drugs or devices are administered by a licensed or certified staff member or consultant or a certified physician's assistant;

(iv) The practitioner authorized to prescribe drugs or devices specifies that there shall be no patient counseling unless he or she is contacted prior to such patient counseling. The prescribing practitioner shall specify such prohibition in an oral prescription or in writing on the face of a written prescription, including any prescription which is received by facsimile or electronic transmission. The pharmacist shall note "Contact Before Counseling" on the face of the prescription if such is communicated orally by the prescribing practitioner; ~~or~~

(v) A medical gas or a medical gas device is administered, dispensed, or distributed by a person described in subdivision (12) of section 38-2850; or~~.~~

(vi) A device described in subsection (2) of section 38-2841 is sold, distributed, or delivered by a business or person described in subdivision (13) of section 38-2850.

Sec. 6. Section 71-7447, Reissue Revised Statutes of Nebraska, is amended to read:

71-7447 (1) No person or entity may act as a wholesale drug distributor in this state without first obtaining a wholesale drug distributor license from the department. The department shall issue a license to any applicant that satisfies the requirements for licensure under the Wholesale Drug Distributor Licensing Act. Manufacturers are exempt from any licensing and other requirements of the act to the extent not required by federal law or regulation except for those requirements deemed necessary and appropriate under rules and regulations adopted and promulgated by the department.

(2) Wholesale medical gas distributors shall be exempt from any licensing and other requirements of the Wholesale Drug Distributor Licensing Act to the extent not required under federal law but shall be licensed as wholesale drug distributors by the department for the limited purpose of engaging in the wholesale distribution of medical gases upon application to the department, payment of a licensure fee, and inspection of the applicant's facility by the department, except that the applicant may submit and the department may accept an inspection accepted in another state or an inspection conducted by a nationally recognized

accreditation program approved by the board. For purposes of such licensure, wholesale medical gas distributors shall only be required to provide information required under subdivisions (1)(a) through (1)(c) of section 71-7448.

(3) The Wholesale Drug Distributor Licensing Act does not apply to:

(a) An agent or employee of a licensed wholesale drug distributor who possesses drug samples when such agent or employee is acting in the usual course of his or her business or employment; or

(b) Any person who (i) engages in a wholesale transaction relating to the manufacture, distribution, sale, transfer, or delivery of medical gases the gross dollar value of which does not exceed five percent of the total retail sales of medical gases by such person during the immediately preceding calendar year and (ii) has either a pharmacy permit or license ~~or a drug dispensing permit~~ or a delegated dispensing permit or is exempt from the practice of pharmacy under subsection (12) of section 38-2850.

Sec. 7. Original sections 38-2841 and 71-7447, Reissue Revised Statutes of Nebraska, and sections 38-2826, 38-2850, 38-2867, and 38-2869, Revised Statutes Supplement, 2009, are repealed.