ONE HUNDRED THIRD LEGISLATURE - SECOND SESSION - 2014
COMMITTEE STATEMENT
LB869

Hearing Date: Friday January 24, 2014
Committee On: Health and Human Services
Introducer: Gloor
One Liner: Change and transfer provisions on prescriptions and controlled substances

Roll Call Vote - Final Committee Action:
Advanced to General File

Vote Results:

Aye:	7	Senators Watermeier, Krist, Howard, Gloor, Campbell, Cook, Crawford
Nay:		
Absent:		
Present Not Voting:		

Proponents:	**Representing:**
Senator Mike Gloor	District #35
Kevin Borcher	Nebraska Pharmacist Association
Opponents:	**Representing:**
Neutral:	**Representing:**

Summary of purpose and/or changes:
LB 869 (Gloor): relating to the Uniform Controlled Substances Act; to amend sections 28-413, 28-415, 28-418, 28-1437, 28-1438.01, 28-1439, 38-2870, and 71-2417, Reissue Revised Statutes of Nebraska, sections 28-401.01 and 28-414, Revised Statutes Cumulative Supplement, 2012, and section 28-401, Revised Statutes Supplement, 2013; to define and redefine terms; to change and transfer provisions relating to prescriptions and controlled substances; to harmonize provisions; and to repeal the original sections.

The purpose of this act is to update language and references, as well as to substantively change some of the prescription requirements for controlled substances.

Throughout all sections, references to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq. are updated from 2009 to 2014.

In Section 1, a number of vocabulary substitutions are made to eliminate "shall" and "may" from 28-401: "shall mean" becomes "means"; "shall not" becomes "does not"; "shall include" becomes "includes"; and "may include" becomes "includes".

(42) is added to clarify that "Compounding" has the same meaning as in section 382811. (38-2811. Compounding, defined. Compounding means the preparation of components into a drug product (1) as the result of a practitioner's medical order or initiative occurring in the course of practice based upon the relationship between the practitioner, patient, and pharmacist or (2) for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing. Compounding includes the preparation of drugs or devices in anticipation of receiving medical orders based upon routine, regularly observed prescribing patterns.).

In Section 2, 28-401.01 is amended to add sections 5 to 11 of that act to the Uniform Controlled Substances Act.

In Section 3, 28-413 is amended to clarify that controlled substances listed in Schedules I and II of 28-405 shall be distributed pursuant either to an order form or the electronic controlled substance orderings system. Conforms to federal law that allows pharmacies to order Schedule II controlled substances via the DEA electronic controlled substances ordering system. CSOS)

In Section 4, 28-414) Adds the requirements for a Schedule II Controlled Substance prescription and requirements for electronic prescribing of Schedule II Controlled Substances: (1) is amended to clarify that a Schedule II controlled substance requires a prescription from an authorized practitioner; and (2). is added to required that such a prescription must contain the following information prior to being filled: (a) Patient's name and address, (b) name of the drug, device, or biological, (c) strength of the prescription, (d) dosage form, if applicable, (e) quantity prescribed, (f) directions for use, (g) date of issuance, (h) prescribing practitioner%u2019s name and address, and (i) DEA number of prescribing practitioner. The prescription must have a proper signature, whether manual or electronic in conformance with 21 U.S.C. 801 et seq.

(3) is amended so that in emergency situations, a Schedule II controlled substance may be dispensed pursuant to an oral prescription reduced to writing in accordance with (2). Eliminates "faxing" of emergency Schedule II Controlled Substances, which is not allowed in federal law.

(4)(a) is amended to clarify in nonemergency situations the requirements of paper prescriptions, oral prescriptions and electronic prescription prescriptions for a Schedule II controlled substance.must be made on paper

(5) is amended to clarify that a pharmacist may make the various required notations either on the face of the prescription or in the electronic record. Language is added to allow for those notations to also be made in an electronic record if the prescription is an electronic prescription in compliance with federal law.

In Section 5, (1) is added to clarify that Schedule III, IV, or V controlled substances shall not be dispensed without a written, oral, or electronic medical order except as otherwise provided in that section or when administered directly by a practitioner to an ultimate user.

(2) is added to mirror the amended 28-414(2) exactly except that Schedule II, IV, or V controlled substance prescriptions additionally require the number of refills, not to exceed five refills within six months after the date of issuance.

(3) is added to clarify that Schedule III, IV, or V controlled substances may be dispensed pursuant to a facsimile of a written, signed paper prescription, which serves as the original for purposes of this subsection.

(4) is added to allow partially fillings of Schedule III, IV, or V controlled substances if the partial fills are (a) recorded in the same manner as a refilling, (b) not cumulatively in excess of the total quantity prescribed, and (c) dispensed within six months of the issuance of the prescription.

In Section 6, New language that clearly authorizes electronic prescribing of controlled substances, as well as clarifies the storage requirement so electronic prescription, inconformity with federal law: (1) is added to require that all records related to a prescription that is created, signed, transmitted, and received electronically are maintained electronically.

(2) Electronic records must be maintained electronically for five years after the date of their creation or receipt.

(3) Records regarding controlled substances must be readily retrievable from all other records, and electronic records must be either easily readable or easily rendered into a readable format.

(4) Records of electronic prescriptions for controlled substances shall be maintained in an application pursuant to 21 C.F.R. 1311. These must be readily retrievable at the registered location on request of an agent of the administration or

law enforcement agent and must be in a format those personnel can readily understand.

In Section 7, (1) is added to require that paper prescriptions for all Schedule II controlled substances shall be kept in a separate file by the dispensing practitioner, maintained for a minimum of five years, and made readily available to the department and law enforcement for inspection without a search warrant.

(2) All Schedule III, IV, or V controlled substance prescriptions shall be maintained either separately from other prescriptions or in a form in which their information can be readily retrieved from ordinary business records of the dispensing practitioner, and shall be maintained for a minimum of five years. These too shall be made readily available to the department and law enforcement for inspection without a search warrant.

(3) is added to require that, prior to dispensing any Schedule II, III, IV, or V controlled substance, the dispensing practitioner shall affix a label to its container bearing the name and address of the pharmacy or dispensing practitioner, the name of the patient, the date of filling, the serial number of the prescription under which it is recorded in the practitioner's prescription records, the name of the prescribing practitioner, and the directions for use of the controlled substance. Unless the prescribing practitioner writes "do not label" or words of similar import on the original paper, electronic, or oral prescription, the label shall also bear the name of the controlled substance.

Section 8 adds (1) and (2) to permit a registrant who is the owner of a controlled substance may transfer any Schedule I or II controlled substance to another registrant as provided by law or by rule or any Schedule III, IV, or V substance to another person if such owner complies with 28-411 (4).

Section 9 (1) adds that the owner of any stock of controlled substances may cause those controlled substances to be destroyed pursuant to this section when they are no longer needed. Complete records of the destruction shall be maintained by the registrant for five years after the date of destruction.

(2) If the owner is a registrant, (a) Schedule II, III, IV, or V controlled substances may be destroyed by a pharmacy inspector, a reverse distributor, or the administration. Upon their destruction, the required forms must be completed. (b) allows that liquid controlled substances in opened containers originally containing fifty milliliters or less or compounded liquid controlled substances within the facility where they were compounded may be destroyed if witnessed by two individuals credentialed under the Uniform Credentialing Act and properly designated and recorded by the facility. (c) Solid controlled substances in opened unit-dosed containers or which have been adulterated within a hospital where they were to be administered to patients in such hospital may be destroyed if witnessed by two individuals credentialed under the Uniform Credentialing Act and designated by the hospital and recorded in accordance 28-411 (4).

(3) clarifies that a patient-owner may utilize a medication take-back program or other lawfully recognized disposal program to dispose of his or her prescribed controlled substances.

(4) clarifies that Schedule II, III, IV, or V controlled substances owned by a resident of a long-term care facility or hospital shall be destroyed by two individuals credentialed under the Uniform Credentialing Act and designated by the facility or hospital.

Section 10 amends 28-1438.01 and transfers it to the Uniform Controlled Substances Act. (1) is the liability immunity provision re giving information to law enforcement or professional board. It is amended to clarify that the professional board is the board appointed pursuant to the Uniform Credentialing Act.

Section 11 transfers 28-1439 to the Uniform Credentialing Act.

Section 12, 13, 15, 16, and 17 Updates the correct statutory citations; makes revisor language changes and repeals language.

Sections 14 Changes the date of federal statue recognition to those in effect on January 1, 2014 and adds correct statutory citations.

Kathy Campbell, Chairperson