ONE HUNDRED FOURTH LEGISLATURE - FIRST SESSION - 2015
COMMITTEE STATEMENT
LB37

Hearing Date: Wednesday January 21, 2015
Committee On: Health and Human Services
Introducer: Krist
One Liner: Adopt the Prescription Drug Safety Act and change and transfer pharmacy, prescription, and drug provisions

Roll Call Vote - Final Committee Action:
Advanced to General File with amendment(s)

Vote Results:

Aye:	6	Senators Baker, Crawford, Howard, Kolterman, Riepe, Campbell
Nay:		
Absent:	1	Senator Cook
Present Not Voting:		

Verbal Testimony:

Proponents:	**Representing:**
Senator Bob Krist	District 10
Jennifer Tilleman	Nebraska Pharmacists Association
Kevin Borcher	Nebraska Pharmacists Association
Opponents:	**Representing:**
Kent Forney	Self
Neutral:	**Representing:**

Summary of purpose and/or changes:
LB 37 creates a Prescription Drug Safety Act to provide rules for the prescribing, storage, dispensing, and record keeping of non-controlled prescription drugs. Statutes regarding adulteration and misbranding of drugs and devices are moved into the Prescription Drug Safety Act.

LB 37 updates and amends many provisions and definitions within the Pharmacy Practice Act, and deletes outdated language and unnecessary references. This bill transfers language from the Drug Product Selection Act provisions into the Pharmacy Practice Act. The bill also adds sections relating to hospital pharmacy, compounding requirements and standards, prescription and chart orders, radiopharmaceuticals, and pharmacist supervision of technicians and pharmacist interns. Additionally, the bill removes the requirements for written control procedures for pharmacy technicians and harmonizes statutes found throughout the various pharmacy acts.

LB 37 names the statute pertaining to poisons as the Poison Control Act and adds provisions to the act that are being transferred from other acts.

Section-by-section description:
Section (1): Creates the Prescription Drug Safety Act (PSDA) in Sections 1-27.
Section (2): Definitions in the PDSA found in Sections 3-20.
Section (3): Defines "administer"- to directly apply a drug or device by injection, inhalation, ingestion, or other means to

the body of a patient or research subject.
Section (4): Defines "administration"- the act of administering, keeping a record of such activity, and observing, monitoring, reporting, and otherwise taking appropriate action regarding desired effect, side effect, interaction, and contraindication associated with administering the drug or device.
Section (5): Moves the definition of adulteration into the PSDA and updates the references to the United States Pharmacopeia and the National Formulary (used to be located in 71-2401- and last updated in 1943)
Section (6): Defines "chart order" as it is found in 38-2810
Section (7): Defines "compounding"- the preparation of components into a drug product
Section (8): Defines "controlled substance"- as found in 28-401
Section (9): Defines "dispense" or "dispensing"
Section (10): Defines "distribute"
Section (11): Defines "drugs", "medicines", and "medicinal substances"
Section (12): Defines "labeling"
Section (13): Defines "medical order"
Section (14): Moves and updates the definition of misbranding into the PSDA (used to be located at 71-2402- and last updated in 1943)
Section (15): Defines "pharmacist"
Section (16): Defines "pharmacy"
Section (17): Defines "practitioner"- a certified registered nurse anesthetist, a certified nurse midwife, a dentist, an optometrist, a nurse practitioner, a pharmacist, a physician assistant, a physician, a podiatrist, or a veterinarian credentialed under the Uniform Credentialing Act.
Section (18): Defines "prescribe"
Section (19): Defines "prescription"
Section (20): Defines "prescription drug" or "device" or "legend drug" or "device"
Section (21): Adds language- Nothing in the PDSA shall be construed as authority for a practitioner to perform any activity he or she is not otherwise authorized to perform by another law of this state. A practitioner that stores, dispenses incident to practice, administers, or otherwise provides any drug to a patient shall comply with the PDSA. A practitioner or authorized person that compounds or reconstitutes any drug shall comply with Section 45 of this act.
Section (22): Moves the legend drug statute (28-1437) into the PDSA.
Adds the requirements for a prescription and transmission of a prescription.
Updates the secton to recognize and allow electronic prescriptions for non-controlled substance legend drugs.
Updates the references to the federal Food, Drug and Cosmetic Act to January 1, 2015.
Deletes references to the Controlled Substance Act, due to the cleanup language in LB 869 that passed in 2014.
Updates the penalty section (which used to be 28-1438)
Section (23): Adds the requirements for labeling a non-controlled substance prescription drug and for recordkeeping.
Section (24): Moves into the PDSA the adulterated and misbranded statute (71-2404- last updated in 1943) that outlines that adulterated and misbranded drugs may be confiscated and the seller criminally prosecuted.
Section (25): Moves into the PDSA the adulterated and misbranded statute (71-2405- last updated in 1943) that states it is illegal to sell or have intent to sell adulterated and misbranded drugs.
Section (26): Creates a penalty section for violation of the adulteration and misbranding provisions of the PDSA of a Class III misdemeanor for a first violation and a CLass II misdemeanor for a second violation.
Section (27): States that an employee or agent of a prescribing practitioner may communicate a prescription, chart order or refill authorization to a pharmacist or pharmacist intern, except for an emergency oral authorization for a controlled substance listed in Schedule II of section 28-405.
Section (28): Amends 38-2801 to recognize statutes within the Pharmacy Practice Act.
Section (29): Amends 38-2802 to recognize all of the definitions that are applicable within the Pharmacy Practice Act.
Section (30): Adds and updates the definition of "calculated expiration date"- the expiration date on the manufacturer's, package's, or distributor's container or one year from the date the drug or device is repackaged, whichever is earlier.
Section (31): Amends the definition of "chart order" (38-2810) to allow chart orders to be used for dispensing purposed for long-term care facility patients (not controlled substances, though)
Section (32): Amends definition of "compounding" (38-2811). Most of the language in this statute is being deleted and moved to section 45 of the bill.
Section (33): Updates the official United States Pharmacopeia and the National Formulary reference in the "drugs,

medicines, and medicinal substances" definition (38-2819).
Section (34): Adds definition of"hospital pharmacy"- each facility licensed as a hospital in which the compounding, preparation for administration, or dispensing of drugs or devices pursuant to a chart order occurs for patients within the confines of the hospital with oversight by a pharmacist in charge.
Section (35): Updates the definition of "pharmaceutical care" (38-2831) to explicitly state that it must be provided by a pharmacist.
Section (36):
Updates definition of "pharmacist in charge" (38-2833) to include that a pharmacist in charge must also be designated in a hospital pharmacy.
Removes requirement that a pharmacist in charge work in the physical confines of such pharmacy "for a majority of the hours per week that the pharmacy is opened for business averaged over a twelve month period or thirty hours per week, whichever is less."
Section (37): Updates the definition of "the practice of pharmacy" (38-2837) to also include medication therapy management.
Section (38): Updates definition of "public health clinic worker" to remove the word "oral" for contraceptives allowed to be dispensed pursuant to a prescription.
Section (39): Adds definition of "telepharmacy"- 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.
Section (40):
Updates the exceptions to the practice of pharmacy statutes (38-2850). Adds PAs to the list of practitioners who cannot dispense drugs. Adds PAs to the list for authority to dispense samples. Deletes "regularly" to determine when a pharmacy license is needed by a practitioner for dispensing drugs. Adds LPNs to the section that specifies hospital medication administration pursuant to a chart order.
Removes language: persons who sell, offer, or expose for sale completely denatured alcohol or concentrated lye, insecticides, and fungicides in original packages- since pharmacists do not sell these items.
Deletes the hospital exception to the practice of pharmacy. Hospitals do not practice pharmacy; pharmacists in hospitals do practice pharmacy and must follow pharmacy practice laws which conflict with this statutory reference. The requirement for a license for dispensing out-patient medications can be found in Sections 69 & 70 on page 35 & 36.
Updates a reference to prepackaged drugs- which can also include repackaged drugs
Deletes references to a pharmacy or a business who sells, delivers, etc. medical gases- those are functions performed by people not entities.
Section (41):
Deletes a statutory reference that is eliminated due to the definition being added to the Pharmacy Practice Act definitions (see Section 39 on page 11)
Adds "repackaging, or educational use in an accredited pharmacy program" to the list of purposes for which a pharmacist may possess prescription medications.
Updates the credentials that pharmacists may use to identify themselves as pharmacists.
Adds that pharmacists may supervise pharmacy technician and pharmacist interns (language that is currently in regulation but being moved into statute).
Section (42): Adds to the Pharmacy Practice Act that a pharmacist may supervise any combination of pharmacy technicians and pharmacist interns for a total of three, but does not apply to pharmacist interns in training. The current pharmacist/technician ratio is 1 to 3, but no more than 2 technicians at any time. That provision is in pharmacy regulations.
Section (43): Updates statutory references for who can practice pharmacy.
Section (44): Adds new language (some of which came from 38-2811) and requirements to compounding drug products. Recognizes USP 795 and 797 compounding standards for compliance, as well as for office use compounding. Clarifies that reconstituting is not compounding and when compounding is not allowed. All who compound or reconstitute will be required to comply with this section.
Section (45): Adds new provisions for a pharmacist in charge of a hospital pharmacy, that by January 1, 2017, to develop and implement policies and procedures to ensure that the pharmacist reviews all medical orders prior to the first dose being administered to a patient in a hospital. Several exceptions are listed when a review by a pharmacist is not necessary.

Section (46):
Updates the statutes to reflect that the refusal of the verbal offer to counsel must be documented prior to dispensing.
Updates the words "telephone service" to "telepharmacy" as an option for providing patient counseling.
Corrects a reference to physician assistant.
Deletes the requirement when no patient counseling is indicated by a practitioner.
Deletes a reference to "a business."
Section (47):
Updates 38-2870 to reflect that medical orders can be oral, written, or electronic
Adds language that pharmacists and pharmacists interns are not required to dispense, compound, administer, or prepare for administration any drug or device pursuant to a medical order.
Adds language that allows electronic orders or faxing of written medical orders as a way to transmit them to a pharmacy.
Clarifies that an unsigned medical order shall be verified with the practitioners.
Clarifies requirements for use of electronic and digital signatures.
Section (48):
Updates the delegated dispensing statute (38-2884) reference of calculated expiration date to mirror the definition found in Section 32 on page 12.
Deletes "oral" in regards to contraceptives within 38-2884.
Updates references to repackaging, packager, and distributor for consistency.
Section (49): Deletes "oral" in regards to contraceptives within 38-2884, the delegated dispensing statute.
Section (50):
Eliminates the 30 day grace period for pharmacy technicians to become registered with the state once hired as pharmacy technicians.
Mandates that pharmacy technicians must be registered with the state prior to and during employment as a pharmacy technician.
Adds a requirement that beginning January 1, 2017, pharmacy technicians will have to be certified by a state or national certifying entity approved by the Board.
Section (51):
States that the pharmacist in charge of the pharmacy or the hospital pharmacy shall be responsible for the supervision and performance of the pharmacy technicians.
Deletes the requirement for the written control procedures and guidelines of the training and employment of pharmacy technicians, and the requirement to submit these materials to the Board of Pharmacy.
The supervision of the pharmacy technicians as a hospital pharmacy shall be performed by the licensed pharmacist assigned by the pharmacist in charge to be responsible for the supervision and verification of activities of the pharmacy technician.
Section (52): Deletes a reference to the pharmacy technician written control procedures that were stricken in Section 51, and adds verification to the list for which technicians and the pharmacists can be reprimanded when a technician works with no supervision and verification.
Section (53): Strikes statutory references for which the Nebraska Department of Health and Human Services may promulgate rules- those statutes will be deleted by the passage of this bill.
Section (54): Adds requirements of a prescription to the Pharmacy Practice Act.
Section (55): Adds requirements of a chart order to the Pharmacy Practice Act.
Section (56): Adds the same requirement found in Section 27 to the Pharmacy Practice Act.
Section (57):
Removes the statutory reference and adds the disposal, repackaging, and returns language from 71-2421 into the Pharmacy Practice Act
Also clarifies that an assisted living facility is not considered a long-term care facility for purposes of returns (the definition that made this distinction was stricken).
Adds a statement that no drugs can be returned if so restricted by the FDA.
Strikes the definitions that are already found in the Pharmacy Act.
Section (58)-(66):
Moves the Drug Product Selection Act into the Pharmacy Practice Act, and deletes duplicative definitions
Updates the sections to recognize electronic prescribing.
Section (67): Updates statutory references to the Health Care Facility Licensure Act (71-401)

Section (68): Updates the definition references to the Health Care Facility Licensure Act, which will not include Section (69).
Section (69): Adds definition of "hospital pharmacy"- means each facility licensed as a hospital in which the compounding, preparation for administration, or dispensing of drugs or devices pursuant to a chart order occurs for patients within the confines of the hospital with oversight by a pharmacist in charge.
Section (70):
States that a hospital is not required to obtain a separate license for a hospital pharmacy unless compounding or dispensing of drugs or devices is done in the pharmacy at the hospital for persons not registered as patients within the confines of the hospital; then a pharmacy license is required.
By Janurage 1, 2016 each hospital shall designate a licensed pharmacist as the pharmacist in charge of the hospital pharmacy.
Adds requirements for compounding for patients in a hospital, health system, or affiliated or network hospital.
States that a pharmacist in charge of a hospital pharmacy shall establish and implement policies and procedures for the practice of pharmacy and medication use in the hospital.
Section (71): Creates an exception for obtaining licensure as outlined in the Health Care Facilities Licensure Act as noted above for hospital pharmacy.
Section (72): Adds the Pharmacy Practice Act to the list of Acts for disciplinary purposes of the Health Care Licensure Act.
Section (73)- (76): Creates references to the Prescription Drug Safety Act within the Cancer Drug Repository Act and the Immunosuppressant Drug Act. Adds language that prohibits the return of drugs if restricted by the FDA.
Section (77): Updates the calculated expiration date reference in 71-2453, and adds language that prohibits the return of drugs if restricted by the FDA.
Section (78): This section, sections 71-2501 to 71-2512, and section 86 of this act are the Poison Control Act.
Section (79): Updates the definition of Poison (71-2501) and strikes outdated statutory references.
Section (80): Updates the statutory references in the Poison Control Act.
Section (81): Adds to the list of exceptions to the Poison Control Act the sale of patent or proprietary medicines in the original package of the manufacturer when labeled in conformity with 71-2502.
Section (82): Revisor language updates.
Section (83): Adds a statutory reference to 71-2507.
Section (84)- (85): Revisor language updates
Section (86): Adds 28-425 to the Poison Control Act.
Section (87): Updates the penalty provisions of the Poison Control Act and updates the statutory references within the Poison Control Act.
Section (88): Revises "emergency medical reasons" to allow regular and systematic sales of prescription drugs to be used by practitioners for routine office use.
Section (89): Updates a reference that sales of drugs to practitioners for office use cannot exceed 5 percent of sales (or it becomes wholesaling).
Section (90): Updates a reference number in 71-7447 (wholesale drugs)
Section (91): Lists section that have been modified.
Section (92): Repeal list.

Explanation of amendments:
makes corrections referencing section 45 instead of 44. Allows the pharmacy, alternatively or in addition to the pharmacist, to keep records. Clarifies that a pharmacist must be present for a pharmacy to be open. Removes veterinarians, who were not intended to be covered when written, from the bill.

Kathy Campbell, Chairperson