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## LEGISLATIVE BILL 274

## Approved by the Governor March $10,\ 2011$

- Introduced by Gloor, 35; Bloomfield, 17; Campbell, 25; Dubas, 34; Fulton, 29;
  Hadley, 37; Krist, 10; Schumacher, 22; Wallman, 30.
- FOR AN ACT relating to dispensed drugs and devices; to amend sections 71-2421 and 71-2453, Reissue Revised Statutes of Nebraska; to change provisions relating to return of dispensed drugs and devices; to harmonize provisions; and to repeal the original sections.
- Be it enacted by the people of the State of Nebraska,
- Section 1. Section 71-2421, Reissue Revised Statutes of Nebraska, is amended to read:
- 71-2421 (1) To protect the public safety, dispensed drugs or devices: may be returned to the dispensing pharmacy only under the following conditions:
- (a) For immediate destruction by a pharmacist, except that drugs and devices dispensed to residents of a long-term care facility shall be destroyed on the site of the long-term care facility;
- (b) In response to a recall by the manufacturer, packager, or distributor;
  - (c) If a device is defective or malfunctioning; or
- (d) Return from a long-term care facility for credit, (a) May be collected in a pharmacy for disposal;
- (b) May be returned to a pharmacy in response to a recall by the manufacturer, packager, or distributor or if a device is defective or malfunctioning;
- (c) Shall not be returned to saleable inventory nor made available for subsequent relabeling and redispensing, except as provided in subdivision (1)(d) of this section; or
- (d) May be returned from a long-term care facility to the pharmacy from which they were dispensed for credit or for relabeling and redispensing, except that:
  - (i) No controlled substance may be returned;
- (ii) The decision to accept the return of the dispensed drug or device shall rest solely with the pharmacist;
- (iii) The dispensed drug or device shall have been in the control of the long-term care facility at all times;
- (iv) The dispensed drug or device shall be in the original and unopened labeled container with a tamper-evident seal intact, as dispensed by the pharmacy. pharmacist. Such container shall bear the expiration date or calculated expiration date and lot number; and
- (v) Tablets or capsules shall have been dispensed in a unit dose with a tamper-evident container which is impermeable to moisture and approved by the Board of Pharmacy.
- (2) Returned dispensed drugs or devices shall not be retained in inventory nor made available for subsequent dispensing, except as provided in subdivision (1)(d) of this section.
- (2) Pharmacies may charge a fee for collecting dispensed drugs or devices for disposal or from a long-term care facility for credit or for relabeling and redispensing.
- (3) Any person or entity which exercises reasonable care in collecting dispensed drugs or devices for disposal or from a long-term care facility for credit or for relabeling and redispensing pursuant to this section shall be immune from civil or criminal liability or professional disciplinary action of any kind for any injury, death, or loss to person or property relating to such activities.
- (4) A drug manufacturer which exercises reasonable care shall be immune from civil or criminal liability for any injury, death, or loss to persons or property relating to the relabeling and redispensing of drugs returned from a long-term care facility.
- (5) Notwithstanding subsection (4) of this section, the relabeling and redispensing of drugs returned from a long-term care facility does not absolve a drug manufacturer of any criminal or civil liability that would have existed but for the relabeling and redispensing and such relabeling and redispensing does not increase the liability of such drug manufacturer that would have existed but for the relabeling and redispensing.
  - (3) (6) For purposes of this section:
- (a) Calculated expiration date means an expiration date on the prepackaged product which is not greater than twenty-five percent of the time

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between the date of repackaging and the expiration date of the bulk container nor greater than six months from the date of repackaging; the expiration date on the manufacturer's, packager's, or distributor's container or one year from the date the drug or device is repackaged, whichever is earlier;

- (b) Dispense, drugs, and devices are defined in the Pharmacy Practice Act; and
- (c) Long-term care facility does not include an assisted-living facility as defined in section 71-406.
- Sec. 2. Section 71-2453, Reissue Revised Statutes of Nebraska, is amended to read:
- 71-2453 (1) Prescription drugs or devices which have been dispensed pursuant to a valid prescription and delivered to a Department of Correctional Services facility, a criminal detention facility, a juvenile detention facility, or a jail for administration to a prisoner or detainee held at such facility or jail, but which are not administered to such prisoner or detainee, may be returned to the dispensing pharmacy from which they were dispensed under contract with the facility or jail for credit or for relabeling and redispensing and administration to another prisoner or detainee held at such facility or jail pursuant to a valid prescription as provided in this section.
- (2)(a) The decision to accept return of a dispensed prescription drug or device for credit or for relabeling and redispensing rests solely with the pharmacist at the contracting pharmacy.
- (b) A dispensed prescription drug or device shall be properly stored and in the control of the facility or jail at all times prior to the return of the drug or device for credit or for relabeling and redispensing. The drug or device shall be returned in the original and unopened labeled container dispensed by the pharmacist with the tamper-evident seal intact, and the container shall bear the expiration date or calculated expiration date and lot number of the drug or device.
- (c) A prescription drug or device shall not be returned or relabeled and redispensed under this section if the drug or device is a controlled substance or if the relabeling and redispensing is otherwise prohibited by
  - (3) For purposes of this section:
  - (a) Administration has the definition found in section 38-2807;
- (b) Calculated expiration date has the definition found in subdivision (3) (a) of section 71-2421;
- (c) Criminal detention facility has the definition found in section 83-4,125;
- (d) Department of Correctional Services facility has the definition of facility found in section 83-170;
- (e) Dispense or dispensing has the definition found in section 38-2817;
  - (f) Jail has the definition found in section 47-117;
- (g) Juvenile detention facility has the definition found in section 83-4,125;
  - (h) Prescription has the definition found in section 38-2840; and
- (i) Prescription drug or device has the definition found in section 38-2841.
- (4) The Jail Standards Board, in consultation with the Board of Pharmacy, shall adopt and promulgate rules and regulations relating to the return of dispensed prescription drugs or devices for credit, relabeling, or redispensing under this section, including, but not limited to, rules and regulations relating to (a) education and training of persons authorized to administer the prescription drug or device to a prisoner or detainee, (b) the proper storage and protection of the drug or device consistent with the directions contained on the label or written drug information provided by the pharmacist for the drug or device, (c) limits on quantity to be dispensed, (d) transferability of drugs or devices for prisoners or detainees between facilities, (e) container requirements, (f) establishment of a drug formulary, and (g) fees for the dispensing pharmacy to accept the returned drug or device
- (5) Any person or entity which exercises reasonable care in accepting, distributing, or dispensing prescription drugs or devices under this section or rules and regulations adopted and promulgated under this section shall be immune from civil or criminal liability or professional disciplinary action of any kind for any injury, death, or loss to person or property relating to such activities.
- Sec. 3. Original sections 71-2421 and 71-2453, Reissue Revised Statutes of Nebraska, are repealed.