LEGISLATURE OF NEBRASKA

ONE HUNDREDTH LEGISLATURE

SECOND SESSION

LEGISLATIVE BILL 866

Introduced by McDonald, 41; Hudkins, 21.

Read first time January 11, 2008

Committee: Health and Human Services

A BILL

FOR AN ACT relating to public health and welfare; to adopt the Chronic Disease Drug Repository Program Act; and to declare an emergency.

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

Section 1. Sections 1 to 9 of this act shall be known and may be cited as the Chronic Disease Drug Repository Program Act.

Sec. 2. For purposes of the Chronic Disease Drug Repository Program Act:

(1) Chronic disease means a disease that is long-lasting or recurrent. Chronic disease includes, but is not limited to, Alzheimer's disease, arthritis, cardiovascular disease, stroke, all cancers, chronic obstructive pulmonary disease, chronic lower respiratory disease, diabetes mellitus, cirrhosis, hepatitis C, and kidney disease;

(2) Chronic disease drug means a prescription drug used to treat (a) a chronic disease or its side effects or (b) the side effects of a prescription drug used to treat a chronic disease or its side effects;

(3) Department means the Department of Health and Human Services;

(4) Health care facility has the definition found in section 71-413;

(5) Health clinic has the definition found in section 71-416;

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

(7) Participant means a physician's office, pharmacy, hospital, or health clinic that has elected to voluntarily participate in the program and that accepts donated chronic disease drugs under the rules and regulations adopted and promulgated by

the department for the program;

(8) Pharmacy has the definition found in section 71-425;

(9) Physician's office means the office of a person licensed to practice medicine and surgery or osteopathic medicine and surgery;

(10) Prescribing practitioner means a health care practitioner licensed to practice in Nebraska who is authorized to prescribe chronic disease drugs;

(11) Prescription drug means:

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

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

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

(iii) Rx Only; or

(b) A drug 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; and

(12) Program means the chronic disease drug repository program established pursuant to the Chronic Disease Drug Repository Program Act.

Sec. 3. The department shall establish a chronic disease drug repository program for accepting donated chronic disease drugs

and dispensing such drugs to Nebraska residents. Participation in the program shall be voluntary.

Sec. 4. Any person or entity, including, but not limited to, a chronic disease drug manufacturer or health care facility, may donate chronic disease drugs to the program. Chronic disease drugs may be donated to a participant.

Sec. 5. (1) A chronic disease drug shall only be accepted or dispensed under the program if such drug is in its original, unopened, sealed, and tamper-evident packaging. A chronic disease drug packaged in single unit doses may be accepted and dispensed if the outside packaging is opened but the single-unit-dose packaging is unopened. There shall be no limitation on the number of doses that can be donated to the program as long as the donated drugs meet the requirements of this section. An injectable chronic disease drug may be accepted if it does not have temperature requirements other than controlled room temperature.

(2) A chronic disease drug shall not be accepted or dispensed under the program if (a) such drug bears an expiration date prior to the date of donation, (b) such drug is adulterated or misbranded as described in section 71-2401 or 71-2402, or (c) such drug has expired while in the repository.

(3) Subject to limitations provided in this section, unused chronic disease drugs dispensed under the medical assistance program established pursuant to the Medical Assistance Act may be accepted and dispensed under the chronic disease drug repository

program.

Sec. 6. (1) A participant shall comply with all applicable provisions of state and federal law relating to the storage, distribution, and dispensing of donated chronic disease drugs and shall inspect all such drugs prior to dispensing to determine if they are adulterated or misbranded as described in section 71-2401 or 71-2402. Such drugs shall only be dispensed pursuant to a prescription issued by a prescribing practitioner. Such drugs may be distributed to another participant for dispensing.

(2) A participant may charge a handling fee for distributing or dispensing chronic disease drugs under the program. Such fee shall be established in rules and regulations adopted and promulgated by the department. Chronic disease drugs donated under the program shall not be resold.

Sec. 7. (1) Any person or entity, including a chronic disease drug manufacturer, which exercises reasonable care in donating, accepting, distributing, or dispensing chronic disease drugs under the Chronic Disease Drug Repository Program Act or rules and regulations adopted and promulgated under the act 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.

(2) Notwithstanding subsection (1) of this section, the donation of a chronic disease drug by a chronic disease drug

manufacturer does not absolve the manufacturer of any criminal or civil liability that would have existed but for the donation, nor shall such donation increase the liability of such chronic disease drug manufacturer that would have existed but for the donation.

Sec. 8. The department shall establish and maintain a participant registry for the program. The participant registry shall include the participant's name, address, and telephone number and shall identify whether the participant is a physician's office, a pharmacy, a hospital, or a health clinic. The department shall make the participant registry available to any person or entity wishing to donate chronic disease drugs to the program.

Sec. 9. The department, upon the recommendation of the Board of Pharmacy, shall adopt and promulgate rules and regulations to carry out the Chronic Disease Drug Repository Program Act. Such rules and regulations shall include, but not be limited to:

(1) Eligibility criteria and other standards and procedures for participants that accept and distribute or dispense donated chronic disease drugs;

(2) Necessary forms for administration of the program, including, but not limited to, forms for use by persons or entities that donate, accept, distribute, or dispense chronic disease drugs under the program. The forms shall include the name of the person to whom the drug was originally prescribed;

(3) The maximum handling fee that may be charged by participants that accept and distribute or dispense donated chronic

disease drugs;

(4)(a) Categories of chronic disease drugs that the program will accept for dispensing and (b) categories of chronic disease drugs that the program will not accept for dispensing and the reason that such drugs will not be accepted; and

(5) Maintenance and distribution of the participant registry established by the act.

Sec. 10. Since an emergency exists, this act takes effect when passed and approved according to law.