LEGISLATIVE BILL 756

Approved by the Governor April 16, 2003

Introduced by McDonald, 41; Aguilar, 35; Baker, 44; Bourne, 8; Burling, 33; Byars, 30; Combs, 32; Connealy, 16; Cudaback, 36; Cunningham, 40; Erdman, 47; Hudkins, 21; Jensen, 20; Johnson, 37; Jones, 43; Kremer, 34; Kruse, 13; Mines, 18; Mossey, 3; Dw. Pedersen, 39; D. Pederson, 42; Preister, 5; Price, 26; Redield, 12; Schimek, 27; Smith, 48; Stuhr, 24; Stuthman, 22; Synowiecki, 7; Thompson, 14; Tyson, 19; Vrtiska, 1; Wehrbein, 2; Foley, 29; Maxwell, 9

AN ACT relating to health; to adopt the Cancer Drug Repository Program Act; and to provide an operative date.

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

Section 1. Sections 1 to 8 of this act shall be known and may be cited as the Cancer Drug Repository Program Act.

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

(1) Cancer drug means a prescription drug used to treat (a) cancer or its side effects or (b) the side effects of a prescription drug used to treat cancer or its side effects;

(2) Department means the Department of Health and Human Services Regulation and Licensure;

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

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

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

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

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

(8) Prescribing practitioner means a health care practitioner licensed under the Uniform Licensing Law who is authorized to prescribe cancer drugs; and

(9) Prescription drug has the definition found in section 71-1,142.

Sec. 3. The department shall establish a cancer drug repository program for accepting donated cancer 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 cancer drug manufacturer or health care facility, may donate cancer drugs to the cancer drug repository program. Cancer drugs may be donated at a physician's office, pharmacy, hospital, or health clinic that elects to participate in the program and meets criteria established by the department for such participation.

Sec. 5. (1) A cancer drug shall only be accepted or dispensed under the cancer drug repository program if such drug is in its original, unopened, sealed, and tamper-evident unit dose packaging, except that a cancer 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.

(2) A cancer drug shall not be accepted or dispensed under the cancer drug repository program if (a) such drug bears an expiration date that is earlier than six months after the date the drug was donated or (b) such drug is adulterated or misbranded as described in section 71-2401 or 71-2402.

(3) Subject to limitations provided in this section, unused cancer drugs dispensed under the medical assistance program established in section 68-1018 may be accepted and dispensed under the cancer drug repository program.

Sec. 6. (1) A physician's office, pharmacy, hospital, or health clinic that accepts donated cancer drugs under the cancer drug repository program shall comply with all applicable provisions of state and federal law relating to the storage, distribution, and dispensing of such 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 participating physician's office, pharmacy, hospital, or health clinic for dispensing.

(2) A physician's office, pharmacy, hospital, or health clinic may charge a handling fee for distributing or dispensing cancer drugs under the cancer drug repository program. Such fee shall be established in rules and regulations adopted and promulgated by the department. Cancer drugs donated

under the program shall not be resold.

Sec. 7. (1) Any person or entity, including a cancer drug manufacturer, which exercises reasonable care in donating, accepting, distributing, or dispensing cancer drugs under the Cancer 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 cancer drug by a cancer 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 cancer drug manufacturer that would have existed but for the donation.

Sec. 8. The department, upon the recommendation of the Board of Pharmacy, shall adopt and promulgate rules and regulations to carry out the Cancer Drug Repository Program Act. Initial rules and regulations under the act shall be adopted and promulgated no later than ninety days after the operative date of this act. Such rules and regulations shall include, but not be limited to:

(1) Eligibility criteria and other standards and procedures for physician's offices, pharmacies, hospitals, and health clinics that accept and distribute or dispense donated cancer drugs;

(2) Necessary forms for administration of the cancer drug repository program, including, but not limited to, forms for use by persons or entities that donate, accept, distribute, or dispense cancer drugs under the program;

(3) The maximum handling fee that may be charged by physician's offices, pharmacies, hospitals, or health clinics that accept and distribute or dispense donated cancer drugs; and

(4)(a) Categories of cancer drugs that the cancer drug repository program will accept for dispensing and (b) categories of cancer drugs that the program will not accept for dispensing and the reason that such drugs will not be accepted.

Sec. 9. This act becomes operative on September 15, 2003.