HOUSE BILL 466

46TH LEGISLATURE - STATE OF NEW MEXICO - SECOND SESSION, 2004

INTRODUCED BY

Al Park

AN ACT

RELATING TO PRESCRIPTION DRUGS; CREATING THE CANCER DRUG REPOSITORY PROGRAM; ALLOWING UNUSED AND UNADULTERATED CANCER DRUGS TO BE DONATED FOR USE BY AN ELIGIBLE INDIVIDUAL OR ENTITY; ENACTING THE CANCER DRUG REPOSITORY ACT.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF NEW MEXICO:

Section 1. SHORT TITLE.--This act may be cited as the "Cancer Drug Repository Act".

Section 2. DEFINITIONS.--As used in the Cancer Drug Repository Act:

A. "adulterated" means a drug that has been tampered or made impure;

B. "cancer drug" means a prescription drug used in the treatment of cancer;

C. "department" means the department of health;

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D. "hospital" means an institution that is licensed as a hospital by the department;

E. "nonprofit clinic" means a community-based nonprofit primary care clinic that operates in a rural or other underserved health care area of the state and that is a 501(c)(3) nonprofit corporation for federal income tax purposes;

F. "pharmacy" means a licensed place of business where drugs are compounded or dispensed and pharmaceutical care is provided; and

G. "prescription drug" means a drug for which an order has been given individually for the person for whom prescribed, either directly from a licensed practitioner or his agent to the pharmacist, including electronic transmission or indirectly by means of a written order signed by the prescriber, that bears the name and address of the prescriber, his license classification, the name and address of the patient, the name and quantity of the drug prescribed, directions for use and the date of issue.

Section 3. CANCER DRUG REPOSITORY PROGRAM CREATED.--

A. The department shall establish a cancer drug repository program to accept and dispense donated cancer drugs to individuals who are residents of the state and meet eligibility standards established in rules adopted pursuant to Section 6 of the Cancer Drug Repository Act.

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B. Only cancer drugs in their original sealed and tamper-evident single-unit-dose packaging shall be accepted and dispensed.

C. The packaging of a cancer drug shall be unopened to be accepted and dispensed; provided that cancer drugs packaged in single-unit doses may be accepted and dispensed when the outside packaging is opened if the single-unit-dose packaging is undisturbed.

D. Cancer drugs donated by individuals bearing an expiration date that is less than six months from the date the cancer drug is donated shall not be accepted or dispensed.

E. A cancer drug shall not be accepted or dispensed if there is reason to believe that the drug is adulterated.

F. A cancer drug dispensed pursuant to the medicaid program may be accepted and dispensed.

Section 4. DONATIONS TO THE CANCER DRUG REPOSITORY PROGRAM.--

A. Any person, including a prescription drug manufacturer or licensed health care facility, may donate cancer drugs to the cancer drug repository program. The drugs shall be donated at a pharmacy, hospital or nonprofit clinic that elects to participate in the cancer drug repository program and that meets the criteria for participation established by rule of the department. Participation in the program by pharmacies, hospitals and nonprofit clinics shall be

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voluntary.

B. A pharmacy, hospital or nonprofit clinic that meets the eligibility requirements may dispense cancer drugs donated under the program to persons who are residents of the state and who meet the eligibility requirements of the program or to other governmental entities and nonprofit private entities to be dispensed to persons who meet the eligibility requirements of the program. A cancer drug shall be dispensed only pursuant to a prescription issued by a health care professional authorized to prescribe drugs.

C. A pharmacy, hospital or nonprofit clinic that accepts donated cancer drugs shall comply with all applicable federal and state laws dealing with the storage and distribution of prescription drugs and shall inspect all cancer drugs prior to dispensing them to ensure that they are not adulterated.

D. The pharmacy, hospital or nonprofit clinic may charge persons receiving donated cancer drugs a dispsensing fee not to exceed three dollars ($3.00) per transaction. Cancer drugs donated to the program shall not be resold.

Section 5. LIMITED LIABILITY.--

A. The following persons, when acting in good faith, shall not be subject to civil or criminal liability for injury, death or loss to person or property or to professional disciplinary action for matters related to donating, accepting

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or dispensing cancer drugs under the cancer drug repository program:

(1) a cancer drug manufacturer, state agency or person donating cancer drugs to the program; and

(2) a pharmacy, hospital, nonprofit clinic or health care professional that accepts or dispenses cancer drugs under the program.

B. A prescription drug manufacturer shall not, in the absence of bad faith, be subject to criminal or civil liability for injury, death or loss to a person or property for matters related to donating, accepting or dispensing a cancer drug manufactured by the manufacturer that is donated by any person under the program, including liability for failure to transfer or communicate product or consumer information or the expiration date of the donated cancer drug.

Section 6. RULEMAKING.--The department, in consultation with the board of pharmacy, shall adopt and promulgate rules to implement the cancer drug repository program, including:

A. eligibility criteria for pharmacies, hospitals and nonprofit clinics to receive and dispense donated cancer drugs;

B. standards and procedures for accepting, storing and dispensing donated cancer drugs;

C. standards and procedures for inspecting donated cancer drugs to determine that the original single-unit-dose

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packaging is sealed and tamper-evident and that the cancer drugs are unadulterated and suitable for dispensing;

D. eligibility requirements for recipients in the program based on economic need for persons to receive cancer drugs through the program;

E. an identification card by which a person who is eligible to receive cancer drugs through the program may demonstrate eligibility to the pharmacy, hospital or nonprofit clinic;

F. a form that a person receiving a cancer drug from the program must sign before receiving the drug to confirm that such person understands the criminal and civil immunity from liability provisions of the program; and

G. for cancer drugs donated to the program:

(1) a list of cancer drugs, arranged by category or by individual drug, that are acceptable or unacceptable, including a statement that provides the reason why a drug is unacceptable for donation; and

(2) a form for each donor to sign stating that the donor is the owner of the cancer drugs or an authorized representative of a deceased owner; and

H. other standards and procedures that the department deems appropriate or necessary to implement the provisions of the Cancer Drug Repository Act.