THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 2482 Session of 2006

INTRODUCED BY SOLOBAY, DeWEESE, COHEN, BEBKO-JONES, BEYER, BUNT, CALTAGIRONE, CAPPELLI, CORNELL, CRAHALLA, DENLINGER, DONATUCCI, J. EVANS, FABRIZIO, FRANKEL, FREEMAN, GEORGE, GINGRICH, GODSHALL, GOODMAN, GRUCELA, HENNESSEY, HERSHEY, HESS, JAMES, LaGROTTA, LEACH, LEDERER, MANN, MILLARD, MUNDY, MYERS, PALLONE, PHILLIPS, PISTELLA, READSHAW, REICHLEY, SCHRODER, SIPTROTH, STABACK, THOMAS, TIGUE, WALKO, WANSACZ, WOJNAROSKI, YOUNGBLOOD AND GEIST, MARCH 6, 2006

AS REPORTED FROM COMMITTEE ON HEALTH AND HUMAN SERVICES, HOUSE OF REPRESENTATIVES, AS AMENDED, OCTOBER 3, 2006

AN ACT

- 1 Establishing the Cancer Drug Repository Program for accepting donated cancer drugs and dispensing cancer drugs.
- 3 The General Assembly of the Commonwealth of Pennsylvania
- 4 hereby enacts as follows:
- 5 Section 1. Short title.
- 6 This act shall be known and may be cited as the Cancer Drug
- 7 Repository Program Act.
- 8 Section 2. Definitions.
- 9 The following words and phrases when used in this act shall
- 10 have the meanings given to them in this section unless the
- 11 context clearly indicates otherwise:
- 12 "BOARD." THE STATE BOARD OF PHARMACY.
- "Cancer drug." A prescription drug used to treat any of the
- 14 following:

- 1 (1) Cancer or its side effects.
- 2 (2) The side effects of a prescription drug used to
- 3 treat cancer or its side effects.
- 4 "Department." The Department of Health of the Commonwealth.
- 5 "Health care facility." A for-profit or nonprofit entity
- 6 providing clinically related health services, including those
- 7 operated by the Commonwealth or its political subdivisions and
- 8 including a general or special hospital, including psychiatric
- 9 hospitals, rehabilitation hospitals, ambulatory surgical
- 10 facilities, long-term care nursing facilities, a hospice, cancer
- 11 treatment center using radiation therapy on an ambulatory basis
- 12 and inpatient drug and alcohol treatment facility.
- 13 "Health clinic." A for-profit or nonprofit clinic providing
- 14 health services.
- 15 "Hospital." An entity licensed as a hospital under:
- 16 (1) the act of June 13, 1967 (P.L.31, No.21), known as
- 17 the Public Welfare Code; or
- 18 (2) the act of July 19, 1979 (P.L.130, No.48), known as
- 19 the Health Care Facilities Act.
- 20 "Pharmacy." A pharmacy licensed by the Commonwealth.
- 21 "Physician's office." The office of a person licensed to
- 22 practice medicine and surgery or osteopathic medicine and
- 23 surgery.
- 24 "Prescribing practitioner." A health care practitioner
- 25 licensed under the laws of this Commonwealth who is authorized
- 26 to prescribe cancer drugs.
- 27 "Prescription drug." All drugs requiring a prescription in
- 28 this Commonwealth.
- 29 "Program." The Cancer Drug Repository Program established in
- 30 section 3.

- 1 Section 3. Establishment.
- 2 The department BOARD shall establish a Cancer Drug Repository <
- 3 Program for accepting donated cancer drugs and dispensing cancer
- 4 drugs to residents of this Commonwealth. Participation in the
- 5 program shall be voluntary.
- 6 Section 4. Donation of cancer drugs.
- 7 Any person or entity, including, but not limited to, a cancer
- 8 drug manufacturer or health care facility, may donate cancer
- 9 drugs to the program. Cancer drugs may be donated at a
- 10 physician's office, pharmacy, hospital or health clinic that
- 11 elects to participate in the program and meets the criteria
- 12 established by the department BOARD for participation.
- 13 Section 5. Acceptance and dispensation of cancer drugs.
- 14 (1) A cancer drug shall only be accepted or dispensed
- under the program if the drug is in its original unopened,
- sealed and tamper-evident unit dose packaging. A cancer drug
- 17 packaged in single-unit doses may be accepted and dispensed
- if the outside packaging is opened but the single-unit-dose
- 19 packaging is unopened.
- 20 (2) A cancer drug shall not be accepted or dispensed
- 21 under the program if the drug bears an expiration date that
- 22 is earlier than six months after the date the drug was
- donated or the drug is adulterated or misbranded.
- 24 (3) Except as provided in this subsection, unused cancer
- 25 drugs dispensed under a State medical assistance program may
- be accepted and dispensed under the program.
- 27 Section 6. Storage, distribution and fees.
- 28 (1) A physician's office, pharmacy, hospital or health
- 29 clinic that accepts donated cancer drugs under the program
- 30 shall comply with all applicable provisions of Federal and

- 1 State law relating to the storage, distribution and
- 2 dispensing of cancer drugs and shall inspect all cancer drugs
- 3 prior to dispensing to determine if they are adulterated or
- 4 misbranded. The drugs shall only be dispensed pursuant to a
- 5 prescription issued by a prescribing practitioner. The drugs
- 6 may be distributed to another participating physician's
- office, pharmacy, hospital or health clinic for dispensing.
- 8 (2) A physician's office, pharmacy, hospital or health
- 9 clinic may charge a handling fee for distributing or
- 10 dispensing cancer drugs under the program. The fee shall be
- 11 established in regulations promulgated by the department
- BOARD. Cancer drugs donated under the program shall not be
- 13 resold.
- 14 Section 7. Immunity.
- 15 (1) Any person or entity, including a cancer drug
- manufacturer, which exercises reasonable care in donating,
- accepting, distributing or dispensing cancer drugs under the
- 18 program shall be immune from civil or criminal liability or
- 19 professional disciplinary action for any injury, death or
- loss to a person or property relating to such activities.
- 21 (2) Notwithstanding paragraph (1), the donation of a
- 22 cancer drug by a cancer drug manufacturer shall not:
- 23 (i) Absolve the manufacturer of any criminal or
- 24 civil liability that would have existed except for the
- donation.
- 26 (ii) Increase the liability of the cancer drug
- 27 manufacturer that would have existed except for the
- donation.
- 29 Section 8. Regulations.
- The department BOARD shall promulgate regulations to carry

<---

- 1 out the purposes of this act within 90 days of the effective
- 2 date of this act. The regulations shall include:
- 3 (1) Eligibility criteria and other standards and
- 4 procedures for physician's offices, pharmacies, PHARMACISTS, <-
- 5 hospitals and health clinics that accept and distribute or
- 6 dispense donated cancer drugs.
- 7 (2) Necessary forms for administration of the program,
- 8 including forms for use by persons or entities that donate,
- 9 accept, distribute or dispense cancer drugs under the
- 10 program.
- 11 (3) The maximum handling fee that may be charged by
- 12 physician's offices, pharmacies, hospitals or health clinics
- that accept and distribute or dispense donated cancer drugs.
- 14 (4) Categories of cancer drugs that the program will
- accept for dispensing and categories of cancer drugs that the
- 16 program will not accept for dispensing and the reason that
- the drugs will not be accepted.
- 18 Section 25. Effective date.
- 19 This act shall take effect in 60 days.