

THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 934 Session of
2003

INTRODUCED BY WONDERLING, MOWERY, KUKOVICH, ERICKSON, ORIE,
LOGAN, COSTA, KITCHEN, O'PAKE, RAFFERTY, WENGER, STOUT,
EARLL, GREENLEAF, MELLOW, CORMAN, KASUNIC, STACK, BOSCOLA,
RHOADES, M. WHITE, LEMMOND, TARTAGLIONE, LAVALLE AND
THOMPSON, OCTOBER 23, 2003

REFERRED TO PUBLIC HEALTH AND WELFARE, OCTOBER 23, 2003

AN ACT

1 Establishing the Cancer Drug Repository Program for accepting
2 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 "Cancer drug." A prescription drug used to treat any of the
13 following:

14 (1) Cancer or its side effects.

15 (2) The side effects of a prescription drug used to
16 treat cancer or its side effects.

1 "Department." The Department of Health of the Commonwealth.

2 "Health care facility." A for-profit or nonprofit entity
3 providing clinically related health services, including those
4 operated by the Commonwealth or its political subdivisions and
5 including a general or special hospital, including psychiatric
6 hospitals, rehabilitation hospitals, ambulatory surgical
7 facilities, long-term care nursing facilities, a hospice, cancer
8 treatment center using radiation therapy on an ambulatory basis
9 and inpatient drug and alcohol treatment facility.

10 "Health clinic." A for-profit or nonprofit clinic providing
11 health services.

12 "Hospital." An entity licensed as a hospital under:

13 (1) the act of June 13, 1967 (P.L.31, No.21), known as
14 the Public Welfare Code; or

15 (2) the act of July 19, 1979 (P.L.130, No.48), known as
16 the Health Care Facilities Act.

17 "Pharmacy." A pharmacy licensed by the Commonwealth.

18 "Physician's office." The office of a person licensed to
19 practice medicine and surgery or osteopathic medicine and
20 surgery.

21 "Prescribing practitioner." A health care practitioner
22 licensed under the laws of this Commonwealth who is authorized
23 to prescribe cancer drugs.

24 "Prescription drug." All drugs requiring a prescription in
25 this Commonwealth.

26 "Program." The Cancer Drug Repository Program established in
27 section 3.

28 Section 3. Establishment.

29 The department shall establish a Cancer Drug Repository
30 Program for accepting donated cancer drugs and dispensing cancer

1 drugs to residents of this Commonwealth. Participation in the
2 program shall be voluntary.

3 Section 4. Donation of cancer drugs.

4 Any person or entity, including, but not limited to, a cancer
5 drug manufacturer or health care facility, may donate cancer
6 drugs to the program. Cancer drugs may be donated at a
7 physician's office, pharmacy, hospital or health clinic that
8 elects to participate in the program and meets the criteria
9 established by the department for participation.

10 Section 5. Acceptance and dispensation of cancer drugs.

11 (1) A cancer drug shall only be accepted or dispensed
12 under the program if the drug is in its original unopened,
13 sealed and tamper-evident unit dose packaging. A cancer drug
14 packaged in single-unit doses may be accepted and dispensed
15 if the outside packaging is opened but the single-unit-dose
16 packaging is unopened.

17 (2) A cancer drug shall not be accepted or dispensed
18 under the program if the drug bears an expiration date that
19 is earlier than six months after the date the drug was
20 donated or the drug is adulterated or misbranded.

21 (3) Except as provided in this subsection, unused cancer
22 drugs dispensed under a State medical assistance program may
23 be accepted and dispensed under the program.

24 Section 6. Storage, distribution and fees.

25 (1) A physician's office, pharmacy, hospital or health
26 clinic that accepts donated cancer drugs under the Cancer
27 Drug Repository Program shall comply with all applicable
28 provisions of Federal and State law relating to the storage,
29 distribution and dispensing of cancer drugs and shall inspect
30 all cancer drugs prior to dispensing to determine if they are

1 adulterated or misbranded. The drugs shall only be dispensed
2 pursuant to a prescription issued by a prescribing
3 practitioner. The drugs may be distributed to another
4 participating physician's office, pharmacy, hospital or
5 health clinic for dispensing.

6 (2) A physician's office, pharmacy, hospital or health
7 clinic may charge a handling fee for distributing or
8 dispensing cancer drugs under the program. The fee shall be
9 established in regulations promulgated by the department.

10 Cancer drugs donated under the program shall not be resold.

11 Section 7. Immunity.

12 (1) Any person or entity, including a cancer drug
13 manufacturer, which exercises reasonable care in donating,
14 accepting, distributing or dispensing cancer drugs under the
15 program shall be immune from civil or criminal liability or
16 professional disciplinary action for any injury, death or
17 loss to a person or property relating to such activities.

18 (2) Notwithstanding paragraph (1), the donation of a
19 cancer drug by a cancer drug manufacturer shall not:

20 (i) Absolve the manufacturer of any criminal or
21 civil liability that would have existed except for the
22 donation.

23 (ii) Increase the liability of the cancer drug
24 manufacturer that would have existed except for the
25 donation.

26 Section 8. Regulations.

27 The department shall promulgate regulations to carry out the
28 purposes of this act within 90 days of the effective date of
29 this act. The regulations shall include:

30 (1) Eligibility criteria and other standards and

1 procedures for physician's offices, pharmacies, hospitals and
2 health clinics that accept and distribute or dispense donated
3 cancer drugs.

4 (2) Necessary forms for administration of the program,
5 including forms for use by persons or entities that donate,
6 accept, distribute or dispense cancer drugs under the
7 program.

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

11 (4) Categories of cancer drugs that the program will
12 accept for dispensing and categories of cancer drugs that the
13 program will not accept for dispensing and the reason that
14 the drugs will not be accepted.

15 Section 25. Effective date.

16 This act shall take effect in 60 days.