

THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 638 Session of
2007

INTRODUCED BY WONDERLING, ERICKSON, KITCHEN, BOSCOLA,
TARTAGLIONE, FONTANA, GORDNER, MUSTO, STOUT, PUNT, CORMAN,
STACK, TOMLINSON, RAFFERTY, FERLO, ORIE, COSTA, O'PAKE,
GREENLEAF, REGOLA, WOZNIAK, BROWNE, MELLOW, EARLL, RHOADES,
M. WHITE, WAUGH, C. WILLIAMS AND WASHINGTON, MARCH 21, 2007

AS REPORTED FROM COMMITTEE ON HEALTH AND HUMAN SERVICES, HOUSE
OF REPRESENTATIVES, AS AMENDED, SEPTEMBER 24, 2007

AN ACT

1 Establishing the Cancer Drug Repository Program for accepting
2 donated cancer drugs and dispensing cancer drugs; and
3 providing for the powers and duties of the State Board of
4 Pharmacy.

5 The General Assembly of the Commonwealth of Pennsylvania
6 hereby enacts as follows:

7 Section 1. Short title.

8 This act shall be known and may be cited as the Cancer Drug
9 Repository Program Act.

10 Section 2. Definitions.

11 The following words and phrases when used in this act shall
12 have the meanings given to them in this section unless the
13 context clearly indicates otherwise:

14 "APPROVED PARTICIPATING PHARMACY." A PHARMACY APPROVED BY
15 THE STATE BOARD OF PHARMACY FOR THE PURPOSE OF DISPENSING UNUSED
16 CANCER DRUGS TO PARTICIPATING ENTITIES AND TO PATIENTS WHO ARE

<—

1 INDIGENT.

2 "Board." The State Board of Pharmacy.

3 "Cancer drug." A prescription drug used to treat any of the
4 following:

5 (1) Cancer or its side effects.

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

8 "Closed drug delivery system." A system in which the actual
9 control of a unit dose medication is maintained by a health care
10 facility, health clinic, hospital, pharmacy or physician's
11 office rather than an individual patient.

12 "Health care facility." A for-profit or nonprofit entity
13 providing clinically related health services, including those
14 operated by the Commonwealth or its political subdivisions and
15 including a general or special hospital, including psychiatric
16 hospitals, rehabilitation hospitals, ambulatory surgical
17 facilities, long-term care nursing facilities, a hospice, cancer
18 treatment center using radiation therapy on an ambulatory basis
19 and inpatient drug and alcohol treatment facility.

20 "Health clinic." A for-profit or nonprofit clinic providing
21 health services.

22 ~~"Hospital." An entity licensed as a hospital under:~~ <—

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

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

27 "HOSPITAL." AN ENTITY LICENSED AS A HOSPITAL UNDER THE ACT <—
28 OF JULY 19, 1979 (P.L.130, NO.48), KNOWN AS THE HEALTH CARE
29 FACILITIES ACT.

30 "Pharmacist." A pharmacist licensed by the Commonwealth.

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

2 "Physician's office." The office of a person licensed to
3 practice medicine and surgery or osteopathic medicine and
4 surgery.

5 "Prescribing practitioner." A health care practitioner
6 licensed under the laws of this Commonwealth who is authorized
7 to prescribe cancer drugs.

8 "Prescription drug." A drug requiring a prescription in this
9 Commonwealth.

10 "Program." The Cancer Drug Repository Program established in
11 section 3.

12 "Unit dose system." A system wherein all individually sealed
13 unit doses are physically connected as a unit.

14 Section 3. Establishment.

15 The board shall establish a Cancer Drug Repository Program
16 consistent with public health and safety standards through which
17 unused cancer drugs may be redispensed to cancer patients by
18 pharmacies approved by the board for the purpose of dispensing
19 unused cancer drugs to residents who are indigent. The board
20 shall develop and promulgate rules and regulations to establish
21 procedures necessary to implement the program. Participation in
22 the program shall be voluntary.

23 Section 4. Restocking and dispensing of cancer drugs.

24 An entity that is part of a closed drug delivery system may
25 return to an approved participating pharmacy an unused cancer
26 drug under the following conditions:

27 (1) If the cancer drug is in its original unopened,
28 sealed and tamper-evident unit dose packaging. A cancer drug
29 packaged in single-unit doses may be accepted and dispensed
30 if the outside packaging is opened but the single-unit-dose

1 packaging is unopened.

2 (2) The cancer drug may not be accepted or dispensed by
3 the approved participating pharmacy if the cancer drug bears
4 an expiration date that is earlier than six months after the
5 date the cancer drug was restocked or the cancer drug is
6 adulterated or misbranded.

7 (3) Except as provided in this subsection, an unused
8 cancer drug dispensed under a State medical assistance
9 program may be accepted and dispensed by the approved
10 participating pharmacy.

11 (4) In the case of controlled substances, as it is
12 allowed by Federal law.

13 Section 5. Storage, distribution and fees.

14 (a) General rule.--An entity that accepts donated cancer
15 drugs under the Cancer Drug Repository Program shall comply with
16 all applicable provisions of Federal and State law relating to
17 the storage, distribution and dispensing of cancer drugs and
18 shall inspect all cancer drugs prior to dispensing to determine
19 if they are adulterated or misbranded. The cancer drugs shall
20 only be dispensed by a pharmacist according to State law
21 pursuant to a prescription issued by a prescribing practitioner.
22 The cancer drugs may be distributed to another participating
23 physician's office, pharmacy, hospital or health clinic for
24 dispensing by a pharmacist as allowed by Federal or State law.

25 (b) Handling fee.--A participating entity may charge a
26 handling fee for distributing or dispensing cancer drugs under
27 the program. The fee shall be established in regulations
28 promulgated by the board. Cancer drugs donated under the program
29 shall not be resold.

30 (c) No compensation for returned or redispensed drugs.--

1 (1) No participating health care facility, health
2 clinic, hospital, pharmacist, pharmacy or physician's office
3 that provides unused prescription drugs to the program in
4 accordance with this act shall be required to compensate
5 another entity for the cost of any drug returned and
6 redispensed under this act.

7 (2) This subsection shall not apply to drugs dispensed
8 under any Federal prescription drug program.

9 (D) RECORDKEEPING.--A PARTICIPATING ENTITY SHALL RECORD AND <—
10 LOG THE EXACT QUANTITY, NAME AND STRENGTH OF DRUG PRIOR TO
11 RETURNING THE DRUGS TO AN APPROVED PARTICIPATING PHARMACY. THE
12 APPROVED PARTICIPATING PHARMACY THAT RECEIVES THE DRUG SHALL
13 RECORD RECEIPT AND VERIFY THE QUANTITY OF DRUGS.

14 Section 6. Immunity.

15 Any person or entity, acting in good faith, who exercises
16 reasonable care in donating, accepting, distributing, dispensing
17 or manufacturing cancer drugs donated and utilized under the
18 program shall be immune from civil or criminal liability or
19 professional disciplinary action for any injury, death or loss
20 to a person or property relating to activities under the
21 program. Immunity granted under this paragraph is solely
22 applicable to the donation, acceptance, distribution, dispensing
23 or manufacture of the actual medications donated to the program
24 and is explicitly not a general waiver of liability.

25 Section 7. Regulations.

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

29 (1) Eligibility criteria and other standards and
30 procedures for entities participating in the program that

1 restock and distribute or dispense donated cancer drugs.

2 (2) Necessary forms for administration of the program,
3 including forms for use by entities permitted to accept,
4 distribute or dispense cancer drugs under the program.

5 (3) The maximum handling fee that may be charged by
6 entities permitted to restock and distribute or dispense
7 donated cancer drugs.

8 (4) Categories of cancer drugs that the program will
9 accept for dispensing and categories of cancer drugs that the
10 program will not accept for dispensing and the reason that
11 the cancer drugs will not be accepted.

12 (5) Informed consent provision for patients
13 participating in the program indicating that the cancer drug
14 has been restocked and redistributed.

15 (6) Provisions for recalls of the drug if necessary.

16 (7) PROCEDURES FOR ENTITIES PARTICIPATING IN THE PROGRAM <—
17 TO MINIMIZE THEFT AND DIVERSION.

18 Section 25. Effective date.

19 This act shall take effect in 60 days.