

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

SENATOR ARMSTRONG, APPROPRIATIONS, RE-REPORTED AS AMENDED,
JUNE 25, 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 ~~and the Department of Health.~~ <—

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 "Board." The State Board of Pharmacy.

15 "Cancer drug." A prescription drug used to treat any of the
16 following:

17 (1) Cancer or its side effects.

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

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

~~"Department." The Department of Health of the Commonwealth.~~ <—

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

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

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

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

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

"Pharmacist." A pharmacist licensed by the Commonwealth.

"Pharmacy." A pharmacy licensed by the Commonwealth.

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

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

1 "Prescription drug." A drug requiring a prescription in this
2 Commonwealth.

3 "Program." The Cancer Drug Repository Program established in
4 section 3.

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

7 Section 3. Establishment.

8 The board shall establish a Cancer Drug Repository Program
9 consistent with public health and safety standards through which
10 unused cancer drugs may be redispensed to cancer patients by
11 pharmacies approved by the board for the purpose of dispensing
12 unused cancer drugs to residents who are indigent. The board
13 shall develop and promulgate rules and regulations to establish
14 procedures necessary to implement the program. Participation in
15 the program shall be voluntary.

16 Section 4. Restocking and dispensing of cancer drugs.

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

20 (1) If the cancer drug is in its original unopened,
21 sealed and tamper-evident unit dose packaging. A cancer drug
22 packaged in single-unit doses may be accepted and dispensed
23 if the outside packaging is opened but the single-unit-dose
24 packaging is unopened.

25 (2) The cancer drug may not be accepted or dispensed by
26 the approved participating pharmacy if the cancer drug bears
27 an expiration date that is earlier than six months after the
28 date the cancer drug was restocked or the cancer drug is
29 adulterated or misbranded.

30 (3) Except as provided in this subsection, an unused

1 cancer drug dispensed under a State medical assistance
2 program may be accepted and dispensed by the approved
3 participating pharmacy.

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

6 Section 5. Storage, distribution and fees.

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

18 (b) Handling fee.--A participating entity may charge a
19 handling fee for distributing or dispensing cancer drugs under
20 the program. The fee shall be established in regulations
21 promulgated by the board. Cancer drugs donated under the program
22 shall not be resold.

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

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

30 (2) This subsection shall not apply to drugs dispensed

1 under any Federal prescription drug program.

2 Section 7 6. Immunity. <—

3 Any person or entity, acting in good faith, who exercises
4 reasonable care in donating, accepting, distributing, dispensing
5 or manufacturing cancer drugs donated and utilized under the
6 program shall be immune from civil or criminal liability or
7 professional disciplinary action for any injury, death or loss
8 to a person or property relating to activities under the
9 program. Immunity granted under this paragraph is solely
10 applicable to the donation, acceptance, distribution, dispensing
11 or manufacture of the actual medications donated to the program
12 and is explicitly not a general waiver of liability.

13 Section 8 7. Regulations. <—

14 The board shall promulgate regulations to carry out the
15 purposes of this act within 90 days of the effective date of
16 this section. The regulations shall include:

17 (1) Eligibility criteria and other standards and
18 procedures for entities participating in the program that
19 restock and distribute or dispense donated cancer drugs.

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

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

26 (4) Categories of cancer drugs that the program will
27 accept for dispensing and categories of cancer drugs that the
28 program will not accept for dispensing and the reason that
29 the cancer drugs will not be accepted.

30 (5) Informed consent provision for patients

1 participating in the program indicating that the cancer drug
2 has been restocked and redistributed.

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

4 Section 25. Effective date.

5 This act shall take effect in 60 days.