

HOUSE No. 2156

The Commonwealth of Massachusetts

PRESENTED BY:
John W. Scibak

To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:

The undersigned legislators and/or citizens respectfully petition for the passage of the accompanying bill:
An Act providing for the establishment and operation of a cancer drug repository program.

PETITION OF:

NAME:	DISTRICT/ADDRESS:
John W. Scibak	2nd Hampshire
Steven J. D'Amico	4th Bristol
Denise Provost	27th Middlesex
Richard J. Ross	9th Norfolk
Kay Khan	11th Middlesex

[SIMILAR MATTER FILED IN PREVIOUS SESSION
SEE HOUSE, NO. 2240 OF .]

The Commonwealth of Massachusetts

—————
In the Year Two Thousand and Nine
—————

AN ACT PROVIDING FOR THE ESTABLISHMENT AND OPERATION OF A CANCER DRUG REPOSITORY PROGRAM..

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

SECTION 1. Chapter 111 of the General Laws, as appearing in the 2004 Official Edition, is hereby amended by adding the following section: Section 25J. Cancer drug repository program. Section 1. Definitions. The following words as used in this chapter, unless a different meaning is required by the context or is specifically prescribed, shall have the following meanings:

“Board”, the Board of Registration in Pharmacy.

“Cancer drug”, a prescription drug that is used to treat any of the following:

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

“Commissioner”, the Commissioner of the Department of Public Health.

“Department”, the Department of Public Health.

“Dispense”, has the meaning given to that term in Section 1 of Chapter 94 C of the General Laws.

“Medical facility” means any of the following:

- (1) An entity licensed by the Commonwealth to provide clinically related health services, including any hospital or clinic, nursing home or long-term care nursing facility, or hospice, as defined in Section 71 of Chapter 111 of the General Laws.
- (2) A cancer treatment center where radiation therapy and chemotherapy are administered on an ambulatory basis.
- (3) An office where a physician licensed to practice medicine in the Commonwealth conducts the practice of medicine.

“Pharmacy”, any pharmacy licensed by the Commonwealth for transacting retail drug business in accordance with Section 38 of Chapter 112 of the General Laws.

“Program”, the Cancer Drug Repository Program established in Section 2.

“Supplies”, any supplies used in the administration of a cancer drug.

Section 2. Establishment. The Department and the Board of Registration in Pharmacy shall establish a cancer drug repository program for the purpose of authorizing and facilitating the donation of cancer drugs or supplies and their dispensation to residents of the Commonwealth who meet the eligibility standards established in the administrative regulations promulgated by the Department and the Board pursuant to Section 5 of this Act. Under the program, donations may be made on the premises of a medical facility or pharmacy that elects to participate in the program and meets the requirements specified in Section 3 of this Act as well as those promulgated by the Department in regulations.

Section 3. Requirements for participation by pharmacies and medical facilities. (a) Participation in the program shall be voluntary.

(b) To be eligible for participation in the cancer drug repository program, a pharmacy or medical facility must be licensed and in compliance with all applicable federal and state laws and administrative rules and regulations.

(c) A pharmacy or medical facility may fully participate in the cancer drug repository program by accepting, storing, and dispensing donated drugs and supplies, or may limit its participation to only accepting and storing donated drugs and supplies. If a pharmacy or medical facility chooses to limit its participation, the pharmacy or facility shall distribute any donated drugs to a fully participating cancer drug repository in accordance with Section 3.

(d) A pharmacy or medical facility may withdraw from participation in the cancer drug repository program at any time upon notification in writing to the commissioner.

Section 3. Donation of cancer drugs. Any person or entity, including but not limited to, a cancer drug manufacturer, or medical facility, may donate cancer drugs or supplies to the program or to a participating pharmacy or medical facility. Cancer drugs or supplies may not be donated to a specific cancer patient, and donated drugs or supplies may not be resold by the program or a participating pharmacy or medical facility.

Section 4. Acceptance and dispensation of cancer drugs. A cancer drug or supplies needed to administer a cancer drug may be accepted and dispensed under the program if all of the following requirements are met:

(a) The cancer drug or supplies to administer a cancer drug is in its original, unopened, sealed and tamper-evident unit-dose packaging or, if packaged in single-unit doses, the single-unit-dose packaging is unopened.

(b) The cancer drug bears an expiration date that is later than 6 months after the date that the drug was donated.

(c) The cancer drug or supplies needed to administer a cancer drug are not adulterated or misbranded, as determined by a pharmacist who must inspect the drug or supplies before it can be dispensed.

The drugs accepted under the program may be distributed to another participating physician's office, pharmacy, hospital or health clinic for dispensing.

Nothing in this section shall be construed as prohibiting a pharmacy or medical facility from accepting drugs that are not eligible to be dispensed under the drug repository program for the proper disposal of those drugs.

Section 5. Storage, distribution and fees. (a) A pharmacy or medical facility that accepts donated cancer drugs under the program shall comply with all applicable provisions of Federal and State law relating to the storage, distribution and dispensing of cancer drugs.

(b) The cancer drugs dispensed through the program shall only be dispensed pursuant to a prescription issued by a prescribing practitioner.

(c) A pharmacy or medical facility may charge a handling fee for distributing or dispensing cancer drugs under the program. The fee shall be established in regulations promulgated by the Board.

Section 6. Immunity. (a) Unless a pharmaceutical manufacturer exercises bad faith, the manufacturer is not subject to criminal or civil liability for injury, death, or loss to a person or property for matters related to the donation, acceptance, or dispensing of a cancer drug or supply manufactured by the manufacturer that is donated by any person under this Act, including liability for failure to transfer or communicate product or consumer information or the expiration date of the donated cancer drug or supply.

(b) Except as provided in Section 6(c), a pharmacy or medical facility participating in the program, a pharmacist dispensing a drug or supply pursuant to the program, a practitioner administering a drug or supply pursuant to the program, or the donor of a cancer drug or supply is immune from civil liability for an act or omission that causes injury to or the death of an individual to whom the cancer drug is dispensed and no disciplinary action shall be taken against a pharmacist or practitioner so long as the drug or supply is donated, accepted, distributed, and dispensed in accordance with the requirements of this section.

(c) The immunity or the prohibition of a finding of guilty of unprofessional conduct under Section 6(b) does not extend to the donation, acceptance, distribution, or dispensation of a cancer drug or supply by a person whose act or omission involved reckless, wanton, or intentional misconduct, or malpractice unrelated to the quality of the cancer drug or supply.

SECTION 7. In consultation with the Department, the Board shall establish rules and regulations governing the drug repository program that establish all of the following:

- (a) Eligibility criteria for pharmacies and medical facilities to receive and dispense donated drugs under the program.
- (b) Standards and procedures for accepting, safely storing, and dispensing donated cancer drugs or supplies needed to administer cancer drugs.
- (c) Standards and procedures for inspecting donated cancer drugs or supplies needed to administer cancer drugs to determine whether the drugs or supplies are in their original, unopened sealed and tamper-evident unit-dose packaging or, if packaged in single-unit doses, the single-unit-dose packaging is unopened.
- (d) Standards and procedures for inspecting donated cancer drugs or supplies needed to administer cancer drugs to determine that the drugs or supplies are not adulterated or misbranded and are safe and suitable for dispensing;
- (e) Eligibility criteria for individuals to receive donated cancer drugs or supplies needed to administer cancer drugs. The standards shall include a method to determine priority of eligible patients under the program.
- (f) A means, such as an identification card, by which an individual who is eligible to receive donated cancer drugs or supplies needed to administer cancer drugs may demonstrate eligibility to the pharmacy, hospital, or nonprofit clinic dispensing the drugs;
- (g) A form that an individual receiving a drug from the repository must sign before receiving the drug to confirm that the individual understands the immunity provisions of the program;
- (h) A formula to determine the handling fee that pharmacies, hospitals, and nonprofit clinics may charge to drug recipients to cover restocking and dispensing costs;
- (i) A list of cancer drugs and supplies to administer cancer drugs, arranged either by category or by individual drug or supply, that the repository will accept for dispensing.
- (j) A list of cancer drugs and supplies to administer cancer drugs, arranged either by category or by individual drug or supply, that the repository will not accept for dispensing. The list must include a statement that specifies the reason that the drug or supplies are ineligible for donation.

Any other standards and procedures the Board considers appropriate.