

HOUSE No. 2240

By Mr. Scibak of South Hadley, petition of John W. Scibak and others that the Board of Registration in Pharmacy be authorized to provide for the establishment and operation of a cancer drug repository program. Public Health.

The Commonwealth of Massachusetts

PETITION OF:

John W. Scibak	Stephen R. Canessa
David Paul Linsky	Kay Khan
Patricia D. Jehlen	Jennifer M. Callahan
Peter V. Kocot	

In the Year Two Thousand and Seven.

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:

1 Chapter 111 of the General Laws, as appearing in the 2004 Offi-
2 cial Edition, is hereby amended by adding the following section:—

3 SECTION 25J. Cancer drug repository program.

4 Section 1. Definitions. The following words as used in this
5 chapter, unless a different meaning is required by the context or is
6 specifically prescribed, shall have the following meanings:—

7 “Board”, the Board of Registration in Pharmacy.

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

10 (1) Cancer or the side effects of cancer.

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

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

15 “Department”, the Department of Public Health.

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

18 “Medical facility” means any of the following:—

19 (1) An entity licensed by the Commonwealth to provide clinically
20 related health services, including any hospital or clinic, nursing
21 home or long-term care nursing facility, or hospice, as defined in
22 Section 71 of Chapter 111 of the; General Laws.

23 (2) A cancer treatment center where radiation therapy and
24 chemotherapy are administered on an ambulatory basis.

25 (3) An office where a physician licensed to practice medicine in
26 the Commonwealth conducts the practice of medicine.

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

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

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

34 Section 2. Establishment. The Department and the Board of Reg-
35 istration in Pharmacy shall establish a cancer drug repository pro-
36 gram for the purpose of authorizing and facilitating the donation of
37 cancer drugs or supplies and their dispensation to residents of the
38 Commonwealth who meet the eligibility standards established in the
39 administrative regulations promulgated by the Department and the
40 Board pursuant to Section 5 of this Act. Under the program, dona-
41 tions may be made on the premises of a medical facility or pharmacy
42 that elects to participate in the program and meets the requirements
43 specified in Section 3 of this Act as well as those promulgated by the
44 Department in regulations.

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

47 (b) To be eligible for participation in the cancer drug repository
48 program, a pharmacy of medical facility must be licensed and in
49 compliance with all applicable federal and state laws and administra-
50 tive rules and regulations.

51 (c) A pharmacy or medical facility may fully participate in the
52 cancer drug repository program by accepting, storing, and dis-
53 pensing donated drugs and supplies, or may limit its participation to
54 only accepting and storing donated drugs and supplies. If a phar-

55 macy or medical facility chooses to limit its participation, the
56 pharmacy or facility shall distribute any donated drugs to a fully
57 participating cancer drug repository in accordance with Section 3.

58 (d) A pharmacy or medical facility may withdraw from partici-
59 pation in the cancer drug repository program at any time upon
60 notification in writing to the commissioner.

61 Section 3. Donation of cancer drugs. Any person or entity,
62 including but not limited to, a cancer drug manufacturer, or med-
63 ical facility, may donate cancer drugs or supplies to the program
64 or to a participating pharmacy or medical facility. Cancer drugs
65 or supplies may not be donated to a specific cancer patient, and
66 donated drugs or supplies may not be resold by the program or a
67 participating pharmacy or medical facility.

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

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

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

78 (c) The cancer drug or supplies needed to administer a cancer
79 drug are not adulterated or misbranded, as determined by a phar-
80 macist who must inspect the drug or supplies before it can be dis-
81 pensed.

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

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

89 Section 5. Storage, distribution and fees. (a) A pharmacy or
90 medical facility that accepts donated cancer drugs under the pro-
91 gram shall comply with all applicable provisions of Federal and

92 State law relating to the storage, distribution and dispensing of
93 cancer drugs.

94 (b) The cancer drugs dispensed through the program shall only be
95 dispensed pursuant to a prescription issued by a prescribing practi-
96 tioner.

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

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

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

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

124 Section 7. In consultation with the Department, the Board shall
125 establish rules and regulations governing the drug repository pro-
126 gram that establish all of the following:—

127 (a) Eligibility criteria for pharmacies and medical facilities to
128 receive and dispense donated drugs under the program.

129 (b) Standards and procedures for accepting, safely storing, and
130 dispensing donated cancer drugs or supplies needed to administer
131 cancer drugs.

132 (c) Standards and procedures for inspecting donated cancer drugs
133 or supplies needed to administer cancer drugs to determine whether
134 the drugs or supplies are in their original, unopened sealed and
135 tamper-evident unit-dose packaging or, if packaged in single-unit
136 doses, the single-unit-dose packaging is unopened.

137 (d) Standards and procedures for inspecting donated cancer drugs
138 or supplies needed to administer cancer drugs to determine that the
139 drugs or supplies are not adulterated or misbranded and are safe and
140 suitable for dispensing;

141 (e) Eligibility criteria for individuals to receive donated cancer
142 drugs or supplies needed to administer cancer drugs. The standards
143 shall include a method to determine priority of eligible patients
144 under the program.

145 (f) A means, such as an identification card, by which an indi-
146 vidual who is eligible to receive donated cancer drugs or supplies
147 needed to administer cancer drugs may demonstrate eligibility to the
148 pharmacy, hospital, or nonprofit clinic dispensing the drugs;

149 (g) A form that an individual receiving a drug from the repository
150 must sign before receiving the drug to confirm that the individual
151 understands the immunity provisions of the program;

152 (h) A formula to determine the handling fee that pharmacies, hos-
153 pitals, and nonprofit clinics may charge to drug recipients to cover
154 restocking and dispensing costs;

155 (i) A list of cancer drugs and supplies to administer cancer drugs,
156 arranged either by category or by individual drug or supply, that the
157 repository will accept for dispensing.

158 (j) A list of cancer drugs and supplies to administer cancer drugs,
159 arranged either by category or by individual drug or supply, that the
160 repository will not accept for dispensing. The list must include a
161 statement that specifies the reason that the drug or supplies are ineli-
162 gible for donation.

163 (k) Any other standards and procedures the Board considers
164 appropriate.