HOUSE DOCKET, NO. 183 FILED ON: 1/11/2011

HOUSE . . . . . No. 619

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 adoption of the accompanying bill:

An Act providing for the establishment and operation of a drug repository program.

PETITION OF:

NAME:	DISTRICT/ADDRESS:
John W. Scibak	*2nd Hampshire*

HOUSE DOCKET, NO. 183 FILED ON: 1/11/2011

HOUSE . . . . . No. 619

By Mr. Scibak of South Hadley, a petition (accompanied by bill, House, No. 619) of John W. Scibak relative to establishing a drug repository program. Public Health.

[SIMILAR MATTER FILED IN PREVIOUS SESSION
SEE HOUSE, NO. *2155* OF 2009-2010.]

The Commonwealth of Massachusetts

In the Year Two Thousand Eleven

An Act providing for the establishment and operation of a 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. Notwithstanding any general or special law to the contrary, the Department of Public Health and the Board of Registration in Pharmacy shall establish a drug repository program to accept and dispense prescription drugs donated for the purpose of being dispensed to individuals who are residents of the Commonwealth and meet the eligibility standards established in the administrative regulations promulgated by the Department and the Board pursuant to Section 5 of this Act.

SECTION 2. Only drugs in their original sealed and tamper-evident unit dose packaging may be accepted and dispensed. The packaging must be unopened, except that drugs packaged in single unit doses may be accepted and dispensed when the outside packaging is opened if the single unit dose packaging is undisturbed. Drugs donated by individuals bearing an expiration date that is less than six months from the date the drug is donated shall not be accepted or

12 dispensed. A drug shall not be accepted or dispensed if there is reason to believe that it is
13 adulterated pursuant to section 186 of chapter 94 of the General Laws, as appearing in the 2004
14 Official Edition. Nothing in this section shall be construed as prohibiting a pharmacy from
15 accepting drugs that are not eligible to be dispensed under the drug repository program for the
16 proper disposal of those drugs.

17 SECTION 3. (a) Any person, including a drug manufacturer, health care facility, or
18 government entity, may donate prescription drugs to the drug repository program. The drugs
19 must be donated at a pharmacy, hospital, or a nonprofit clinic that elects to participate in the drug
20 repository program and meets the criteria for participation established by rule of the
21 Department. Participation in the program by pharmacies, hospitals and nonprofit clinics shall be
22 voluntary. Nothing in this Act shall require a pharmacy, hospital or nonprofit clinic to
23 participate in the program.

24 (b) A pharmacy, hospital, or nonprofit clinic that participates in the program shall
25 dispense drugs to individuals who meet the eligibility standards established, or to other
26 government entities and nonprofit private entities to be dispensed to individuals who meet the
27 eligibility standards. A drug may be dispensed only pursuant to a valid drug order. A pharmacy,
28 hospital or nonprofit clinic that accepts donated drugs shall comply with all applicable federal
29 laws and laws of the Commonwealth dealing with storage and distribution of dangerous drugs
30 and shall inspect all drugs before dispensing them to determine that they are not adulterated. The
31 pharmacy, hospital, or nonprofit clinic may charge individuals receiving donated drugs a
32 handling fee established in accordance with the administrative regulations promulgated by the
33 Department and the Board under Section 5 of this Act.

34 (c) Drugs donated to the repository shall not be resold.

35 SECTION 4. (a) The Department of Public Health; the Board of Registration in
36 Pharmacy, any person, including a drug manufacturer, health care facility, or government entity
37 that donates drugs to the repository program; any pharmacy, hospital, nonprofit clinic or health
38 care professional that accepts or dispenses drugs under the program; and any pharmacy, hospital,
39 or nonprofit clinic that employs a health care professional who accepts or dispenses drugs under
40 the program shall not, in the absence of bad faith, be subject to any criminal prosecution, liability
41 in tort or other civil action for injury, death, or loss to person or property; or professional
42 disciplinary action, relating to donating, accepting, or dispensing drugs under the drug repository
43 program.

44 (b) A drug manufacturer shall not, in the absence of bad faith, be subject to criminal
45 prosecution or liability in tort or other civil action for injury, death, or loss to person or property
46 for matters related to the donation, acceptance, or dispensing of a drug manufactured by the drug
47 manufacturer that is donated under the program, including but not limited to liability for failure
48 to transfer or communicate product or consumer information or the expiration date of the
49 donated drug.

50 SECTION 5. In consultation with the Department of Public Health, the Board of
51 Registration in Pharmacy shall establish rules and regulations governing the drug repository
52 program that establish all of the following:

53 (a) Eligibility criteria for pharmacies, hospitals, and nonprofit clinics to receive and
54 dispense donated drugs under the program;

55 (b) Standards and procedures for accepting, safely storing, and dispensing donated
56 drugs;

57 (c) Standards and procedures for inspecting donated drugs to determine that the original
58 unit dose packaging is sealed and tamper-evident and that the drugs are unadulterated, safe and
59 suitable for dispensing;

60 (d) Eligibility standards based on economic need for individuals to receive drugs;

61 (e) A means, such as an identification card, by which an individual who is eligible to
62 receive donated drugs may demonstrate eligibility to the pharmacy, hospital, or nonprofit clinic
63 dispensing the drugs;

64 (f) A form that an individual receiving a drug from the repository must sign before
65 receiving the drug to confirm that the individual understands the immunity provisions of the
66 program;

67 (g) A formula to determine the handling fee that pharmacies, hospitals, and nonprofit
68 clinics may charge to drug recipients to cover restocking and dispensing costs;

69 (h) For drugs donated to the repository by individuals:

70 1. A list of drugs, arranged either by category or
71 by individual drug, that the repository will accept from individuals;

72 2. A list of drugs, arranged either by category or
73 by individual drug, that the repository will not accept from individuals, including a statement as
74 to why the drug is ineligible for donation; and

75 3. A form each donor must sign stating that the

76 donor is the owner of the drugs and intends to voluntarily donate them to the repository;

77 (i) For drugs donated to the repository by health care facilities or governmental

78 entities:

79 1. A list of drugs, arranged either by category or

80 by individual drug, that the repository will accept from health care facilities or governmental

81 entities;

82 2. A list of drugs, arranged either by category or

83 by individual drug, that the repository will not accept from health care facilities or governmental

84 entities, including a statement as to why the drug is ineligible for donation; and

85 (j) Any other standards and procedures the Board considers appropriate.