

HOUSE No.

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 health care facilities and hospice programs to return certain unused pharmaceutical drugs.

PETITION OF:

NAME:

John W. Scibak

DISTRICT/ADDRESS:

2nd Hampshire

[SIMILAR MATTER FILED IN PREVIOUS SESSION
SEE HOUSE, NO. 2242 OF .]

The Commonwealth of Massachusetts

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In the Year Two Thousand and Nine
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AN ACT PROVIDING FOR HEALTH CARE FACILITIES AND HOSPICE PROGRAMS TO RETURN CERTAIN UNUSED PHARMACEUTICAL DRUGS..

*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 is hereby amended by striking out section 25I, as appearing in
2 the 2004 Official Edition, and inserting in place thereof the following section:—

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4 SECTION 25I. Notwithstanding any general or special law to the contrary, prescription drugs previously
5 dispensed or distributed by a pharmacy for administration to patients in hospice programs, nursing
6 homes, or assisted living facilities may be returned to the pharmacy that dispensed the drugs for credit
7 and redispensing if the following requirements are met:

8 (a) The facility or hospice program consults with a licensed pharmacist to oversee the drug
9 distribution to ensure that a person trained and knowledgeable in the storage, use and
10 administration of the drug has been in control of any unit dose drug being returned to the
11 pharmacy and that the unit dose drug has not come into the physical possession of the person
12 for whom it was prescribed;

13 (b) The pharmacy's manager has received written approval from the Board of Registration in
14 Pharmacy of a protocol detailing the procedure used to repackage, label, transfer, restock,
15 redispense, and credit any unit dose drugs returned to the pharmacy;

- 16 (c) The drugs are provided in the manufacturer's unit dose packaging or are repackaged by the
17 pharmacy in a hermetically sealed single unit dose container that meets Class A or Class B
18 standards on pages 1937 and 1938 of the United States Pharmacopeia;
- 19 (d) The unit dose package is labeled by the manufacturer with the drug lot number and expiration
20 date;
- 21 (e) If the drug is repackaged by the pharmacy, each single unit dose prepackaged or repackaged
22 container must be labeled in accordance with this regulation. Labeling must include the
23 following:
- 24 i. Name and strength of the medication;
 - 25 ii. A suitable expiration date which shall not be later than the expiration date on
26 the manufacturer's container, or one year maximum from the date the drug is
27 prepackaged or repackaged;
 - 28 iii. The date the product was prepackaged or repackaged;
 - 29 iv. The manufacturer's lot number, expiration date, and identity;
 - 30 v. The identity of the pharmacist responsible for prepackaging or repackaging;

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32 If the requirements of subsections (e)(iv) and (e)(v) are maintained in the internal records
33 of the drug outlet, those requirements may be omitted from the labeling.

- 34 (f) The drug's packaging is tamper resistant and shows no evidence of contamination, such as an
35 opened or stained container;
- 36 (g) The unit dose drugs have not reached the expiration date;
- 37 (h) The drugs have not been dispensed in packaging that intermingles different drugs in a single
38 compartment; and
- 39 (i) The drugs are not controlled drugs.

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41 SECTION 2. Unused unit dose drugs that are returned under this section may be redispensed if the
42 drug is in:

- 43 (a) Its original dispensed, unopened, untampered multiple dose container or unopened,
44 untampered single user unit; or an in-use multiple dose container subject to appropriate
45 safeguards as defined in rules for public health or operational considerations;

- 46 (b) Has remained at all times under the control or direction of a person in the institutional facility or
47 the pharmacy trained and knowledgeable in the storage of drugs, including periods in transit by
48 any carrier for hire or person or entity hired solely to transport prescription drugs;
- 49 (c) Is not adulterated or misbranded;
- 50 (d) Has been stored under conditions meeting United States Pharmacopoeia standards;
- 51 (e) Is returned and redispensed or redistributed before the expiration date or use by date on the
52 multiple dose container or single user unit;
- 53 (f) Has not been in the possession of an individual member of the public; and
- 54 (g) Is not included within the classification of controlled substances, as defined in applicable federal
55 and state laws.

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