HOUSE DOCKET, NO. 184 FILED ON: 1/11/2011

HOUSE . . . . . No. 620

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:

An Act providing for health care facilities and hospice programs to return certain unused pharmaceutical drugs.

PETITION OF:

NAME:	DISTRICT/ADDRESS:
John W. Scibak	*2nd Hampshire*
David B. Sullivan	*6th Bristol*
Anne M. Gobi	*5th Worcester*

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HOUSE . . . . . No. 620

By Mr. Scibak of South Hadley, a petition (accompanied by bill, House, No. 620) of John W. Scibak, David B. Sullivan and Anne M. Gobi relative to returning unused pharmaceutical drugs by a health care facility or hospice program to a pharmacy. Public Health.

[SIMILAR MATTER FILED IN PREVIOUS SESSION
SEE
HOUSE
, NO. *2154* OF 2009-2010.]

The Commonwealth of Massachusetts

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:

Chapter 111 of the General Laws is hereby amended by striking out section 25I, as appearing in the 2004 Official Edition, and inserting in place thereof the following section:–

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

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

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

15 (c) The drugs are provided in the manufacturer's unit dose packaging or are repackaged
16 by the pharmacy in a hermetically sealed single unit dose container that meets Class A or Class
17 B standards on pages 1937 and 1938 of the United States Pharmacopeia;

18 (d) The unit dose package is labeled by the manufacturer with the drug lot number and
19 expiration date;

20 (e) If the drug is repackaged by the pharmacy, each single unit dose prepackaged or
21 repackaged container must be labeled in accordance with this regulation. Labeling must include
22 the following:

23 i. Name and strength of the medication;

24 ii. A suitable expiration date which shall not be later than the expiration date on the
25 manufacturer's container, or one year maximum from the date the drug is prepackaged or
26 repackaged;

27 iii. The date the product was prepackaged or repackaged;

28 iv. The manufacturer's lot number, expiration date, and identity;

29 v. The identity of the pharmacist responsible for prepackaging or repackaging;

30 If the requirements of subsections (e)(iv) and (e)(v) are maintained in the internal records

31 of the drug outlet, those requirements may be omitted from the labeling.

32 (f) The drug's packaging is tamper resistant and shows no evidence of contamination,
33 such as an opened or stained container;

34 (g) The unit dose drugs have not reached the expiration date;

35 (h) The drugs have not been dispensed in packaging that intermingles different drugs in a
36 single compartment; and

37 (i) The drugs are not controlled drugs.

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

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

43 (b) Has remained at all times under the control or direction of a person in the institutional
44 facility or the pharmacy trained and knowledgeable in the storage of drugs, including periods in
45 transit by any carrier for hire or person or entity hired solely to transport prescription drugs;

46 (c) Is not adulterated or misbranded;

47 (d) Has been stored under conditions meeting United States Pharmacopoeia standards;

48 (e) Is returned and redispensed or redistributed before the expiration date or use by date
49 on the multiple dose container or single user unit;

50 (f) Has not been in the possession of an individual member of the public; and

51 (g) Is not included within the classification of controlled substances, as defined in
52 applicable federal and state laws.