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HOUSE . . . . . No. 2154

The Commonwealth of Massachusetts

In the Year Two Thousand Nine

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;

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

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

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

i. Name and strength of the medication;

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

iii. The date the product was prepackaged or repackaged;

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

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

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

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

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

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

(i) The drugs are not controlled drugs.

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

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

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

(c) Is not adulterated or misbranded;

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

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

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

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