SENATE DOCKET, NO. 1739 FILED ON: 1/16/2015

SENATE . . . . . No. 1042

The Commonwealth of Massachusetts

PRESENTED BY:

John F. Keenan

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 relative to responsible stewardship by drug manufacturers.

PETITION OF:

NAME:	DISTRICT/ADDRESS:
John F. Keenan	*Norfolk and Plymouth*
James M. Cantwell	*4th Plymouth*
Daniel A. Wolf	*Cape and Islands*
Bruce E. Tarr	*First Essex and Middlesex*
Josh S. Cutler	*6th Plymouth*
Tackey Chan	*2nd Norfolk*
Robert M. Koczera	*11th Bristol*
Tricia Farley-Bouvier	*3rd Berkshire*
Carolyn C. Dykema	*8th Middlesex*
Elizabeth A. Malia	*11th Suffolk*
Angelo M. Scaccia	*14th Suffolk*
Jason M. Lewis	*Fifth Middlesex*
Denise C. Garlick	*13th Norfolk*
Eric P. Lesser	*First Hampden and Hampshire*
Brian M. Ashe	*2nd Hampden*
Joseph W. McGonagle, Jr.	*28th Middlesex*
Joan B. Lovely	*Second Essex*
Randy Hunt	*5th Barnstable*

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SENATE . . . . . No. 1042

By Mr. Keenan, a petition (accompanied by bill, Senate, No. 1042) of John F. Keenan, James M. Cantwell, Daniel A. Wolf, Bruce E. Tarr and other members of the General Court for legislation relative to responsible stewardship by drug manufacturers. Mental Health and Substance Abuse.

The Commonwealth of Massachusetts

In the One Hundred and Eighty-Ninth General Court
(2015-2016)

An Act relative to responsible stewardship by drug manufacturers.

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. Section 21 of Chapter 94C, as appearing in the 2014 Official Edition, is hereby amended by inserting after the first paragraph the following new paragraph:-

"If the dispensed substance has a recommended or required expiration date, the label affixed by the pharmacist shall have the expiration date displayed in a print size allowing no more than ten characters per inch."

SECTION 2. The Massachusetts General Laws are hereby amended by inserting the following new chapter:-

CHAPTER 94G.

PROVISIONS CONCERNING PHARMACEUTICAL PRODUCT MANUFACTURERS

Section 1. Definitions.

As used in this chapter, the following words shall have the following meanings:-

"Covered drug," shall mean any brand or generic drug placed in schedules II or III of section 3 of chapter 94C, and shall also mean benzodiazepines, but shall not include:

(a) drugs intended solely for use in veterinary care;

(b) substances that are regulated as cosmetic products under the federal Food, Drug, and Cosmetic Act;

(c) drugs that are compounded under a specialty license pursuant to sections 39G through 39J of chapter 112;

(d) hypodermic needles, lancets, or other sharps products subject to collection and disposal procedures established pursuant to section 27A of chapter 94C;

(e) drugs approved and used primarily for the purpose of medication assisted addiction treatment.

"Department" shall mean the department of public health.

"Drug stewardship program" shall mean a program that is financed by a pharmaceutical product manufacturer or group of manufacturers to collect, secure, transport, and safely dispose of unwanted drugs, and that complies with the requirements of this chapter.

"Pharmaceutical product manufacturer" or "manufacturer" shall mean any entity that engages in the manufacture of a controlled substance under a federal Food and Drug Administration manufacturer's license. "Pharmaceutical product manufacturer" or "manufacturer" shall not include a hospital pharmacy.

"Prescription drug" shall mean any drug product which, pursuant to chapter 94C, may be dispensed only pursuant to a written prescription by an authorized practitioner.

"Stewardship organization" shall mean an organization designated by a manufacturer, or a group of manufacturers, to act as an agent on behalf of the manufacturer or manufacturers to implement and operate a drug stewardship program.

"Unwanted drug" shall mean a covered drug that is no longer wanted, or no longer intended to be consumed, or that is abandoned, discarded, or surrendered by the person to whom it was prescribed or by any other person; provided however that this term shall not apply to waste or unused products from a pharmacy, hospital, or health clinic, nor to waste or unused products from other commercial sources that the department may determine by regulation to be a nonresidential source; and provided further that "unwanted product" shall include covered drugs that are voluntarily deposited at collection points co-located with a law enforcement agency, but shall not include drugs seized by law enforcement officers in the course of their law enforcement duties.

"Wholesaler" shall mean an entity licensed pursuant to section 36B of chapter 112.

Section 2. Stewardship program as requirement of selling or distributing; approval of stewardship plan; renewal and reporting requirements.

(a) Any pharmaceutical product manufacturer selling or distributing a covered drug to consumers within the Commonwealth, whether directly or through a wholesaler, retailer, or other agent, shall do one of the following:

(1) Operate, individually or jointly with other manufacturers, a drug stewardship plan approved by the department; or

(2) Enter into an agreement with a stewardship organization that shall operate a drug stewardship plan approved by the department.

(b) The department shall establish a process to review applications for approval and re-approval of a manufacturer's drug stewardship plan, and through this process shall ensure that the scope and extent of each approved stewardship program is reasonably related to the manufacturer's total sales of covered drugs in the Commonwealth.

(c) Each operator of a drug stewardship program shall provide an annual written report to the department describing the program's activities for the prior year and the volume and type of unwanted drugs collected.

(d) Each drug stewardship program, whether operated by a manufacturer, several manufacturers, or a stewardship organization, must be reviewed for re-approval by the department at least every 3 years.

(e) The department shall publish and make publicly available a list and description of each approved drug stewardship program, and shall update this list at least bi-monthly.

Section 3. Components of a stewardship program.

An applicant seeking approval for a drug stewardship program shall provide, in a manner and form determined by the department, information on how the program will meet the following minimum requirements:

(a) A collection system to provide convenient, ongoing collection services to all persons seeking to dispose of an unwanted drug. Said collection system must have the capacity to accept any covered drug and any other prescription drug in a pill formulation regardless of its brand or source of manufacture, must offer reasonably frequent access to persons across all geographic regions of the Commonwealth, and may include one or more of the following:

(i) Mail-back programs that provide prepaid and preaddressed packaging for pharmacies to distribute when filling a prescription for a covered drug, or upon request by a consumer.

(ii) Collection kiosks

(iii) Drop off day events at regional locations

(iv) Other methods recommended by the department or pursuant to federal Drug Enforcement Administration guidelines.

(b) Adequate provisions for the security of the unwanted drugs throughout the collection process and for the safety of any persons involved in monitoring, staffing or servicing the stewardship program.

(c) A program for public outreach and education about the drug stewardship program, which shall include a plan for communicating information about: the drug products that may be disposed of through the program; a listing of all available collection methods, participating collectors, and the locations, dates and hours of operation for all collection or drop-off locations; educational information on the environmental, health, and addiction risks posed by unused or improperly disposed prescription drugs, and; a means of communication to receive public comments and questions about the program.

(d) A plan for the manufacturer, or manufacturers, or stewardship organization operating the program to provide for the operational and administrative costs associated with the program; provided however that no point-of-sale, point-of-collection, processing fees or other drug cost increases may be charged to individual consumers for the purpose of recouping costs for the program.

(e) Provisions by the manufacturer, or manufacturers, or stewardship organization operating the program, that provide incentives to consumers to return unused drugs.

(f) An attestation that the program will comply with all applicable state and federal requirements for the collection, security, transport and disposal of drugs, including any requirements established by rule or regulation of the federal Drug Enforcement Administration or the federal Environmental Protection Agency.

(g) Other requirements as established in regulation by the department for the safe and effective administration of a drug stewardship program.

Section 4. Violations and Enforcement

(a) The department shall issue an initial notice to any pharmaceutical product manufacturer that is selling or distributing a covered drug in the Commonwealth and that has not submitted an application for approval under section 2, informing the manufacturer of the requirements to comply with this chapter. Any manufacturer in receipt of such initial notice shall submit such application within 180 calendar days.

(b) Upon knowledge that a pharmaceutical product manufacturer has discontinued its drug stewardship program, or has altered said program such that the program no longer fulfills

the requirements of this chapter, the department shall send a notice of noncompliance to the manufacturer. Any manufacturer in receipt of such notice of noncompliance shall within 30 days take all required corrective steps to reestablish compliance with the requirements of this chapter or submit a written appeal of the notice of noncompliance

(c) If, after consideration of an appeal or after the manufacturer submits no appeal in the prescribed time period, the department determines that the manufacturer continues to act in violation of this chapter, the department shall assess the manufacturer an initial penalty of not more than $150,000 and a further penalty of not more than $10,000 for each subsequent day that the violation continues.

(c) Assessments collected pursuant to this section shall be deposited in the Substance Abuse Services Fund established by section 2I of chapter 111.

(d) The department shall report any persistent violations of this chapter to the attorney general, who shall retain the authority to protect consumers in the health care market under this chapter or any other law.

Section 5. Application of provisions; limitations.

(a) The requirements established by the department pursuant to this chapter may exceed but shall not conflict with any obligations which may be imposed on a manufacturer by a federally approved Risk Evaluation and Mitigation Strategy.

(b) Nothing in this chapter shall require a retail pharmacy or a pharmacist practicing in a retail setting to participate in the collection, securing, transport or disposal of prescription drug products.

(c) No stewardship program developed by a manufacturer or stewardship organization may require a pharmacy in the Commonwealth to participate in the collection, securing, transport or disposal of unwanted drugs; or to provide a space for or maintain a collection kiosk within a retail pharmacy; except upon the consent of and pursuant to a written agreement with the pharmacy licensee.

(d) The department shall promulgate regulations to implement this chapter.