

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

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:

1 SECTION 1. Section 21 of Chapter 94C, as appearing in the 2014 Official Edition, is
2 hereby amended by inserting after the first paragraph the following new paragraph:-

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

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

8 CHAPTER 94G.

9 PROVISIONS CONCERNING PHARMACEUTICAL PRODUCT
10 MANUFACTURERS

11 Section 1. Definitions.

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

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

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

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

18 (c) drugs that are compounded under a specialty license pursuant to sections 39G through
19 39J of chapter 112;

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

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

24 “Department” shall mean the department of public health.

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

28 “Pharmaceutical product manufacturer” or “manufacturer” shall mean any entity that
29 engages in the manufacture of a controlled substance under a federal Food and Drug
30 Administration manufacturer’s license. “Pharmaceutical product manufacturer” or
31 “manufacturer” shall not include a hospital pharmacy.

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

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

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

46 “Wholesaler” shall mean an entity licensed pursuant to section 36B of chapter 112.

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

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

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

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

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

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

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

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

68 Section 3. Components of a stewardship program.

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

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

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

79 (ii) Collection kiosks

80 (iii) Drop off day events at regional locations

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

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

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

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

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

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

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

106 Section 4. Violations and Enforcement

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

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

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

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

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

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

128 Section 5. Application of provisions; limitations.

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

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

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

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