

**HOUSE . . . . . No. 1933**

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**The Commonwealth of Massachusetts**

PRESENTED BY:

*Carolyn C. Dykema*

*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 safe disposal of medical sharps.

PETITION OF:

NAME:	DISTRICT/ADDRESS:
<i>Carolyn C. Dykema</i>	<i>8th Middlesex</i>
<i>Brian M. Ashe</i>	<i>2nd Hampden</i>
<i>Denise Provost</i>	<i>27th Middlesex</i>
<i>William Smitty Pignatelli</i>	<i>4th Berkshire</i>
<i>Kimberly N. Ferguson</i>	<i>1st Worcester</i>

**HOUSE . . . . . No. 1933**

By Ms. Dykema of Holliston, a petition (accompanied by bill, House, No. 1933) of Carolyn C. Dykema and others relative to the safe disposal of syringes, injection devices and other medical sharps. Public Health.

[SIMILAR MATTER FILED IN PREVIOUS SESSION  
SEE HOUSE, NO. 1940 OF 2013-2014.]

**The Commonwealth of Massachusetts**

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

An Act relative to safe disposal of medical sharps.

*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. Chapter 94C of the General Laws, as appearing in the 2012 Official Edition,  
2 is hereby amended by striking out section 27A, and inserting in place thereof the following 2  
3 sections:

4           Section 27A. (a) As used in this section, unless the context otherwise indicates, the  
5 following terms shall have the following meanings:-

6           "Manufacturer", a person or entity that:

7           (1) has a physical presence in the United States and causes a medical sharp to be  
8 manufactured or has legal ownership of the brand, brand name or co-brand under which a  
9 medical sharp is sold;

10 (2) imports a medical sharp branded or manufactured by a person or entity that has no  
11 physical presence in the United States; or

12 (3) sells at wholesale a medical sharp and does not have legal ownership of the brand or  
13 brand name, but elects to fulfill the manufacturer's responsibilities for that medical sharp;  
14 provided, however that manufacturer does not include a compounding pharmacy or pharmacist  
15 who compounds a prescribed drug for an individual and uses a sharp as a delivery system or a  
16 retailer that puts its store label on a medical sharp unless the retailer imports the medical sharp  
17 directly from a person that has no physical presence in the United States.

18 "Medical sharps", hypodermic needles, pen needles, intravenous needles, lancets, and  
19 other devices that are used to penetrate the skin for the delivery of medications.

20 "Program", a stewardship program established by a manufacturer or in conjunction with  
21 other manufacturers pursuant to this section for the collection, handling, transportation, treatment  
22 and disposal of unwanted medical sharps.

23 "Residential source" includes single-family and multiple-family residences and other  
24 locations where unwanted medical sharps are generated outside of the healthcare setting.  
25 Residential source does not include a hospital, clinic, pharmacy or a business such as a  
26 physician's or veterinary office, home health care service, or any other location identified by the  
27 department that may generate sharps in the course of its business.

28 "Sharps collection center", a site which:

29 (1) uses only collection containers that meet the requirements of federal Occupational  
30 Safety and Health Administration and the federal Department of Transportation and is marked  
31 with the international biohazard symbol;

32 (2) provides secure and accessible collection containers on site;

33 (3) accepts sharps from sharps users that are in leak-proof, rigid, puncture-resistant and  
34 shatterproof containers;

35 (4) provides appropriate transfer containers for sharps users who fail to bring their sharps  
36 in suitable containers for placement in the collection container;

37 (5) has a written agreement with a medical waste transporter providing for regularly  
38 scheduled waste pickups; and

39 (6) stores, handles, transports and treats the collected waste in accordance with  
40 department regulations.

41 “Sharps collection containers”, a container specifically designed for holding waste  
42 sharps that meets the requirements of the federal Occupational Safety and Health Administration  
43 and the federal Department of Transportation and is marked with the international biohazard  
44 symbol.

45 “Stewardship organization”, a corporation, nonprofit organization, or other legal entity  
46 created or contracted by a manufacturer or group of manufacturers to implement the medical  
47 sharps stewardship program required under this section.

48 “Unwanted medical sharp”, a medical sharp that its user no longer wants or that has been  
49 abandoned or discarded or is intended to be discarded by the user.

50 (b) A person shall not knowingly place a medical sharp in the solid waste for disposal in  
51 a solid waste disposal facility.

52 (c) A manufacturer shall participate in a program, individually or in conjunction with  
53 other manufacturers, for the collection, handling, transportation, treatment and disposal of  
54 unwanted medical sharps generated by residential sources. A manufacturer that operates a  
55 program independently or that participates in a program with other manufacturers shall ensure  
56 that the program operates in compliance with the provisions of this section, in accordance with  
57 the approval issued by the department in consultation with the department of environmental  
58 protection under subsection (f) of this section, and in compliance with all applicable state and  
59 federal laws and regulations.

60 (d) A manufacturer shall submit to the department a plan to operate the manufacturer's  
61 program, individually or in conjunction with other manufacturers through a stewardship  
62 organization.

63 (e) Before initiating sales of medical sharps in the commonwealth, a manufacturer shall  
64 submit a plan to operate a program or join a program approved under subsection (l).

65 (f) A manufacturer or stewardship organization whose program plan has been approved  
66 under subsection (l) shall begin operating the program within 90 days of obtaining approval from  
67 the department or by July 1, whichever is sooner.

68 (g) At least every 4 years a manufacturer or stewardship organization shall update its  
69 program plan and submit the updated plan to the department for review and approval.

70 (h) A manufacturer or stewardship organization shall pay all the administrative and  
71 operational costs associated with implementation of a program, including the cost of the  
72 collection, transportation, management and disposal of the unwanted medical sharps and the  
73 related packaging. Sharps collection containers shall be considered part of program costs and  
74 shall be supplied on an ongoing basis and free of charge to individual sharps collection centers.

75 (i) A manufacturer or stewardship organization shall pay all the administrative and  
76 oversight costs incurred by the department in the implementation and ongoing oversight of the  
77 program. On or before January 1, each manufacturer or stewardship organization shall submit an  
78 amount, to be determined annually by the department, for deposit into the Statewide Sharps  
79 Collection and Disposal Trust Fund established pursuant to section 27B for the purpose of  
80 providing for the administration and ongoing oversight of a program by the department.

81 (j) A manufacturer or stewardship organization may not charge a fee at collection for the  
82 management of used medical sharps.

83 (k) A program shall:

84 (1) Collect unwanted medical sharps generated by residential sources. The collection  
85 system shall be convenient and adequate to serve the needs of residents in both urban and rural  
86 areas.

87 (2) Establish sharps collection centers in the following types of locations that volunteer  
88 to participate and agree to follow state guidelines and rules for sharps management including, but  
89 not limited to: (i) medical facilities and pharmacies; and (ii) municipal facilities such as fire  
90 stations, police stations and public health offices; provided that sharps collection centers may be

91 located at senior centers only for the purpose of disposing of medically necessary hypodermic  
92 needles.

93 (3) Transport, handle, treat and dispose of unwanted medical sharps from all  
94 manufacturers.

95 (4) Manage medical sharps as biomedical waste at a licensed biomedical waste treatment  
96 facility;

97 (5) The program shall include a public education and communications strategy that  
98 includes educational and outreach information and materials provided at no cost to consumers,  
99 pharmacies, health care facilities and other interested parties. The public education and  
100 communications strategy shall: (i) promote the use of the program and the proper disposal of  
101 unwanted medical sharps so that collection options are widely understood by consumers,  
102 pharmacists, retailers of medical sharps and health care practitioners including doctors and other  
103 prescribers; and (ii) provide a toll-free telephone number and publicly accessible website where  
104 information regarding collection options and locations is made available.

105 (6) The program shall identify performance metrics that include the number of collection  
106 locations and quantity collected and shall describe target goals for each component over the life  
107 of the plan.

108 (7) The program may include a medical waste mail-back program approved by the  
109 United States Postal Service.

110 (l) A program plan submitted to the department under subsection (d) shall:

111 (1) list all manufacturers participating in the program and the manufacturers' contact  
112 information;

113 (2) list the biomedical waste treatment and disposal facilities and transporters, and their  
114 contact information, to be used to collect and destroy the unwanted residential source medical  
115 sharps;

116 (3) describe how the collected medical sharps are tracked through to final disposal and  
117 the policies and procedures to be followed to ensure that safety and security are maintained;

118 (4) describe the financing mechanism for the program;

119 (5) annual target for volume of unwanted residential source medical sharps to be  
120 collected; and

121 (6) include a description of how the program's components required under this section  
122 will be met.

123 (m) The department, in consultation with the department of environmental protection,  
124 shall review each program plan submitted.

125 (n) If the department is satisfied that a plan is complete and that a program complies with  
126 the requirements of this section, the department shall issue an approval or an approval with  
127 conditions.

128 (o) If a program is rejected, the department shall provide the applicant with the reasons  
129 for rejecting the program in writing.



130 (p) The department, in consultation with the department of environmental protection,  
131 shall establish an appeals process for programs that are rejected.

132 (q) Except as provided in this subsection, a program shall be operated in compliance with  
133 the approval issued by the department under subsection (l).

134 A manufacturer or stewardship organization may make substantive changes to the  
135 manner in which the program is operated only upon submission of a written application for  
136 modification to the department and the issuance of a notice of written approval by the  
137 department. The manufacturer or stewardship organization operating the program may request a  
138 substantive change to the previously approved program at any time.

139 An additional manufacturer may join a stewardship organization and participate in their  
140 program if the manufacturer or stewardship organization operating the program provide the  
141 department with an updated manufacturer participant list within 15 days after an additional  
142 manufacturer begins participation in the program; provided, that if a manufacturer withdraws  
143 from a program operated by a stewardship organization or discontinues a program operated  
144 independently, the manufacturer shall provide notice to the department within 15 days prior to  
145 taking action and a statement explaining the manufacturer's plans for complying with this  
146 section.

147 (r) A manufacturer or stewardship organization shall annually report to the department  
148 the list of manufacturers participating in the program and their contact information; and a  
149 statement of annual targets for volume of unwanted residential source approved under subsection  
150 (l) and annual volumes actually collected.

151 A manufacturer or stewardship organization shall maintain the following information for  
152 a period of 5 years and shall provide it as requested by the department and the department of  
153 environmental protection:

154 (1) a list of manufacturers participating in the program and their contact information;

155 (2) a list of the biomedical treatment facilities used, the location of those facilities and the  
156 weight of unwanted medical sharps treated at each facility;

157 (3) documentation verifying collection and disposal of the unwanted medical sharps;

158 (4) a statement of whether policies and procedures for transporting and disposing of  
159 unwanted medical sharps, as established in the program plan, were followed and a description of  
160 noncompliance with those policies and procedures, if any;

161 (5) a statement of whether any safety or security problems occurred during collection,  
162 handling, transportation, treatment or disposal of unwanted medical sharps and, if so, what  
163 changes are proposed for policies, procedures or tracking mechanisms to improve safety and  
164 security in the future;

165 (6) a description of the public education effort and communications strategy required  
166 under clause (5) of subsection (j) implemented during the year;

167 (7) a list of active sharps collection centers and locations; and

168 (8) any other information that the department or the United States Department of Health  
169 and Human Services may reasonably require.

170 (s) The department shall impose penalties for manufacturers that are not in compliance  
171 with this section.

172 (t) A pharmacy that is part of a chain with 3 or more locations doing business in the  
173 commonwealth under the same name regardless of the form of ownership and licensed under  
174 chapter 112; that is authorized to sell sharps, shall operate a sharps collection center for  
175 residential sources on the premises and shall make available free of charge to its customers the  
176 educational information and materials provided by the department or the manufacturers.

177 (u) A hospital, medical clinic, municipal facility or other approved site may volunteer to  
178 be a sharps collection center for residential sources at any time.

179 (v) Any pharmacy under subsection (t) and any volunteer site shall abide by collection  
180 procedures issued by the department and any other general or special law applicable to sharps  
181 management. If the location is a hospital or medical facility it shall keep medical sharps  
182 accepted from residential sources separate from those generated in the course of business.  
183 Sharps collection centers shall be provided with free sharps collection containers by  
184 manufacturers with written information to give to sharps users.

185 (w) The department, in consultation with the department of environmental protection,  
186 shall adopt regulations to ensure the enforcement of this section.

187 (x) The department shall maintain on its publicly accessible website information about  
188 and links to manufacturers programs, collection events and collection sites. Inclusion on the  
189 state's website is not a determination by the state that the manufacturer's plan is in compliance  
190 with this section or other laws.

191           Section 27B. There is hereby established upon the books of the commonwealth a  
192 separate fund to be known as the Statewide Sharps Collection and Disposal Trust Fund to be  
193 expended without appropriation by the department for the purposes of section 27A. All monies  
194 deposited into the fund shall be expended exclusively for the purpose set forth in this section.  
195 The fund shall consist of the fee revenue collected in accordance with subsection (i) of said  
196 section 27A. The department shall expend such sums from the fund as it deems necessary to  
197 establish safe, secure and accessible sharps collection centers at retail pharmacies and other  
198 municipal locations. No expenditure from said fund shall cause said fund to be in deficiency at  
199 the close of a fiscal year. Moneys deposited in the fund that are unexpended at the end of the  
200 fiscal year shall revert to contributory manufacturers or stewardship organizations in a  
201 proportionate amount of the payment in section 27 to be determined by the commissioner.

202           SECTION 2. Subsection (b) of section 27A of chapter 94C of the General Laws, as  
203 inserted by section 1, shall take effect on July 1, 2016.

204           SECTION 3. The plan required by subsection (d) of section 27A of chapter 94C of the  
205 General Laws, as inserted by section 1, shall be submitted by January 1, 2016.

206           SECTION 4. Subsection (e) of section 27A of chapter 94C of the General Laws, as  
207 inserted by section 1, shall apply to all sales after July 1, 2016.

208           SECTION 5. Subsections (f) and (i) of section 27A of chapter 94C of the General Laws,  
209 as inserted by section 1, shall take effect on January 1, 2016.

210           SECTION 6. Subsection (s) of section 27A of chapter 94C of the General Laws, as  
211 inserted by section 1, shall take effect on July 1, 2016.

212           SECTION 7. Subsection (x) of section 27A of chapter 94C of the General Laws, as  
213 inserted by section 1, shall take effect on June 1, 2016.