

**HOUSE . . . . . No. 03602**

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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 passage 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>John V. Fernandes</i>	<i>10th Worcester</i>
<i>Kimberly Ferguson</i>	<i>1st Worcester</i>
<i>Angelo M. Scaccia</i>	<i>14th Suffolk</i>
<i>William N. Brownsberger</i>	<i>24th Middlesex</i>

# HOUSE . . . . . No. 03602

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

## The Commonwealth of Massachusetts

In the Year Two Thousand Eleven

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 Chapter 94C of the General Laws, as appearing in the 2008 Official Edition, is hereby amended
- 2 by striking out section 27A, and inserting in place thereof the following two sections:
- 3 Section 27A. (a). As used in this section, unless the context otherwise indicates, the following
- 4 terms shall have the following meanings:-
- 5 "Manufacturer", a person or entity that:
- 6 (1) has a physical presence in the United States and causes a medical sharp to be manufactured
- 7 or has legal ownership of the brand, brand name or co-brand under which a medical sharp is
- 8 sold;
- 9 (2) imports a medical sharp branded or manufactured by a person or entity that has no physical
- 10 presence in the United States; or

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

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

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

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

27 “Sharps collection center”, a site which:

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

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

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

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

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

38 (6) stores, handles, transports and treats the collected waste in accordance with department of  
39 public health regulations.

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

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

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

49 (b) Effective July 1, 2012 a person shall not knowingly place a medical sharp in the solid waste  
50 for disposal in a solid waste disposal facility.

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

59 (d) By January 1, 2012 a manufacturer shall submit to the department a plan to operate the  
60 manufacturer's program, individually or in conjunction with other manufacturers through a  
61 stewardship organization.

62 (e) Before initiating sales of medical sharps in the State after July 1, 2012, a manufacturer shall  
63 submit a plan to operate a program or join a program approved under subsection (l).

64 (f) A manufacturer or stewardship organization whose program plan has been approved under  
65 subsection (l) shall begin operating the program within 90 days of obtaining approval from the  
66 department or by July 1, 2012, whichever is sooner.

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

69 (h) A manufacturer or stewardship organization shall pay all the administrative and operational  
70 costs associated with implementation of a program, including the cost of the collection,  
71 transportation, management and disposal of the unwanted medical sharps and the related

72 packaging. Sharps collection containers shall be considered part of program costs and shall be  
73 supplied on an ongoing basis and free of charge to individual sharps collection centers.

74 (i) A manufacturer or stewardship organization shall pay all the administrative and oversight  
75 costs incurred by the department of public health in the implementation and ongoing oversight of  
76 the program. Effective January 1, 2012, a manufacturer or stewardship organization shall submit  
77 an amount, to be determined annually by the department of public health, for deposit into the  
78 Statewide Sharps Collection and Disposal Trust Fund established pursuant to section 27A1/2 for  
79 the purpose of providing for the administration and ongoing oversight of a program by the  
80 department of public health.

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 system  
85 shall be convenient and adequate to serve the needs of residents in both urban and rural areas.

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

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

93 (4) Manage medical sharps as biomedical waste at a licensed biomedical waste treatment  
94 facility;

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

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

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

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

109 (1) list all manufacturers participating in the program and the manufacturers' contact  
110 information;

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

113 (3) describe how the collected medical sharps are tracked through to final disposal and the  
114 policies and procedures to be followed to ensure that safety and security are maintained;  
115 (4) describe the financing mechanism for the program;  
116 (5) annual target for volume of unwanted residential source medical sharps to be collected; and  
117 (6) include a description of how the program's components required under this section will be  
118 met.

119 (m) The department of public health, in consultation with the department of environmental  
120 protection, shall review each program plan submitted.

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

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

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

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

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131 A manufacturer or stewardship organization may make substantive changes to the  
132 manner in which the program is operated only upon submission of a written application for



133 modification to the department and the issuance of a notice of written approval by the  
134 department. The manufacturer or stewardship organization operating the program may request a  
135 substantive change to the previously approved program at any time.

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

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

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

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

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

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

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

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

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

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

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

166 (s) The department shall develop penalties for manufacturers that are not in compliance with this  
167 subsection by July 1, 2012. By June 1, 2012 the department shall maintain on its publicly  
168 accessible website information about and links to manufacturers programs, collection events and  
169 collection sites. Inclusion on the state's website is not a determination by the state that the  
170 manufacturer's plan is in compliance with this Act or other laws.

171 (t)A pharmacy that is part of a chain with 3 or more locations doing business in the  
172 commonwealth under the same name regardless of the form of ownership and licensed under  
173 chapter 112; that is authorized to sell sharps, shall operate a sharps collection center for

174 residential sources on the premises and shall make available free of charge to its customers the  
175 educational information and materials provided by the department or the manufacturers.

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

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

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

186 Section 27A1/2. There is hereby established upon the books of the commonwealth a separate  
187 fund to be known as the Statewide Sharps Collection and Disposal Trust Fund to be expended  
188 without appropriation by the department for the purposes of section 27A. All monies deposited  
189 into the fund shall be expended exclusively for the purpose set forth in this section. The fund  
190 shall consist of the fee revenue collected in accordance with subsection (i) of said section 27A.

191 The department shall expend such sums from the fund as it deems necessary to establish safe,  
192 secure and accessible sharps collection centers at retail pharmacies and other municipal  
193 locations. No expenditure from said fund shall cause said fund to be in deficiency at the close of  
194 a fiscal year. Moneys deposited in the fund that are unexpended at the end of the fiscal year shall

195 revert to contributory manufacturers or stewardship organizations in a proportionate amount of  
196 the payment in section 27 to be determined by the commissioner.