HOUSE DOCKET, NO. 2916 FILED ON: 2/18/2011

HOUSE . . . . . No. 3602

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:
Carolyn C. Dykema	*8th Middlesex*
John V. Fernandes	*10th Worcester*
Kimberly N. Ferguson	*1st Worcester*
Angelo M. Scaccia	*14th Suffolk*
William N. Brownsberger	

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HOUSE . . . . . No. 3602

By Ms. Dykema of Holliston, a petition (accompanied by bill, House, No. 3602) 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:

Chapter 94C of the General Laws, as appearing in the 2008 Official Edition, is hereby amended by striking out section 27A, and inserting in place thereof the following two sections:

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

"Manufacturer", a person or entity that:

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

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

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

17 "Medical sharps", hypodermic needles, pen needles, intravenous needles, lancets, and
18 other 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
20 other manufacturers pursuant to this section for the collection, handling, transportation, treatment
21 and disposal of unwanted medical sharps.

22 "Residential source" includes single-family and multiple-family residences and other
23 locations where unwanted medical sharps are generated outside of the healthcare setting.
24 Residential source does not include a hospital, clinic, pharmacy or a business such as a
25 physician's or veterinary office, home health care service, or any other location identified by the
26 department 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
29 Safety and Health Administration and the federal Department of Transportation and is marked
30 with the 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
35 in suitable containers for placement in the collection container;

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

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

40

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) Effective July 1, 2012 a person shall not knowingly place a medical sharp in the solid
51 waste for disposal in 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) By January 1, 2012 a manufacturer shall submit to the department a plan to operate
61 the manufacturer's program, individually or in conjunction with other manufacturers through a
62 stewardship organization.

63 (e) Before initiating sales of medical sharps in the State after July 1, 2012, a manufacturer
64 shall 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, 2012, 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 of public health in the implementation and ongoing
77 oversight of the program. Effective January 1, 2012, a manufacturer or stewardship organization
78 shall submit an amount, to be determined annually by the department of public health, for
79 deposit into the Statewide Sharps Collection and Disposal Trust Fund established pursuant to
80 section 27A1/2 for the purpose of providing for the administration and ongoing oversight of a
81 program by the department of public health.

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

84 (k). A program shall:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

135

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

192 Section 27A1/2. There is hereby established upon the books of the commonwealth a
193 separate fund to be known as the Statewide Sharps Collection and Disposal Trust Fund to be

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