HOUSE DOCKET, NO. 2239 FILED ON: 1/15/2015

HOUSE . . . . . No. 1933

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*
Brian M. Ashe	*2nd Hampden*
Denise Provost	*27th Middlesex*
William Smitty Pignatelli	*4th Berkshire*
Kimberly N. Ferguson	*1st Worcester*

HOUSE DOCKET, NO. 2239 FILED ON: 1/15/2015

HOUSE . . . . . No. 1933

By Ms. Dykema of Holliston, a petition (accompanied by bill, House, No. 1933) of Carolyn C. Dykema and others relative to 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

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:

SECTION 1.Chapter 94C of the General Laws, as appearing in the 2012 Official Edition, is hereby amended by striking out section 27A, and inserting in place thereof the following 2 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

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

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

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

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

“Sharps collection center”, a site which:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(k) A program shall:

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

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

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

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

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

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

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

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

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

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

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

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

(4) describe the financing mechanism for the program;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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