An Act To Promote the Proper Disposal of Used Medical Sharps

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 38 MRSA §1319-O, sub-§3, ¶F is enacted to read:

F. A generator of sharps is not required to dispose of them by shredding. As used in this paragraph, "sharps" has the same meaning as in paragraph E.

Sec. 2. 38 MRSA §1611 is enacted to read:

§ 1611. Medical sharps

1. Definitions. As used in this section, unless the context otherwise indicates, the following terms have the following meanings.

A. "Manufacturer" means 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 cobrand 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.

"Manufacturer" does not include a compounding pharmacy or pharmacist who compounds a prescribed drug for an individual and uses a medical 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.

B. "Medical sharp" means a hypodermic needle, pen needle, intravenous needle, lancet and other device that is used to penetrate the skin for the delivery of medications.

C. "Program" means 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.

D. "Program plan" means a plan developed by a manufacturer to operate a program.

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

F. "Sharps collection center" means a site that provides medical sharps users with secure collection containers and accepts unwanted medical sharps from a residential source for proper disposal.

G. "Sharps collection container" means a container specifically designed for holding unwanted medical 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.

H. "Stewardship organization" means a corporation, nonprofit organization or other legal entity created or contracted by a manufacturer or group of manufacturers to implement a program.

I. "Unwanted medical sharp" means 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.

J. "Wholesaler" means a person or entity that buys a medical sharp for resale and distribution to a person or entity other than a consumer but that does not have legal ownership of the brand or brand name.

2. Disposal ban. After July 1, 2013, a person may not knowingly place a medical sharp in the solid waste for disposal in a solid waste disposal facility as defined in section 1303-C, subsection 30.

3. Manufacturer responsibility. 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. 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 under subsection 6 and in compliance with all applicable state and federal law, rules and regulations.

A. By July 1, 2012, a manufacturer shall submit to the department a program plan individually or in conjunction with other manufacturers through a stewardship organization.

B. Before initiating sales of medical sharps in the State after July 1, 2012, a manufacturer shall submit a program plan or join a program approved under subsection 6.

C. A manufacturer or stewardship organization whose program plan has been approved under subsection 6 shall begin operating the program within 90 days of obtaining approval from the department or by January 1, 2013, whichever is sooner.

D. At least every 4 years, a manufacturer or stewardship organization must update its program plan and submit the updated plan to the department for review and approval.

E. For each program plan submitted under paragraph A and annual report submitted under subsection 8, a manufacturer or stewardship organization shall pay the department a processing fee as follows:

(1) A fee of $1,000 for each manufacturer represented in a program plan and report; or

(2) A fee of $10,000 for a program plan and report submitted on behalf of 10 or more manufacturers.

Processing fees collected by the department pursuant to this paragraph must be deposited in the Maine Environmental Protection Fund established in section 351.

F. 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 must be considered part of program costs and must be supplied on an ongoing basis and free of charge to sharps collection centers.

G. A manufacturer or stewardship organization may not charge a fee at the time of collection for the management of unwanted medical sharps.

4. Program requirements. A program must:

A. Provide for collection of unwanted medical sharps generated by residential sources. The collection system must be convenient and adequate to serve the needs of residents in both urban and rural areas;

B. 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: medical facilities such as hospitals and community clinics, pharmacies, locations that provide public transportation, public parks and municipal facilities such as fire or police stations;

C. Provide for transporting, handling, treatment and disposal of unwanted medical sharps from all manufacturers;

D. Provide for management of medical sharps as biomedical waste at a licensed biomedical waste disposal or treatment facility;

E. 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 must:

(1) 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

(2) Provide a toll-free telephone number and publicly accessible website where information regarding collection options and locations is made available; and

F. Identify performance standards that include the number of collection locations and the amount by weight of unwanted medical sharps collected and describe target goals for each component of the program under this subsection over the life of the program.

5. Plan requirements. A program plan submitted to the department under subsection 3 must:

A. List all manufacturers participating in the program and the manufacturers' contact information;

B. List the biomedical waste disposal or treatment facilities and transporters, and their contact information, to be used to collect and destroy the unwanted medical sharps;

C. Describe how the unwanted medical sharps are tracked from collection to final disposal and the policies and procedures to be followed to ensure that safety and security are maintained;

D. Describe the financing mechanism for the program and delineate any activities necessary to implement the program that are not funded by the program and identify who will be responsible for those costs. If the manufacturer is financing the program through payment to a stewardship organization, any assessment imposed by the manufacturer through its sales chain must reflect the manufacturer's actual program costs and must not be described at wholesale or retail as a tax or government-imposed fee. Any information provided to the consumer about the assessment must clearly state that it is imposed by the manufacturer and may not identify the assessment as, or imply that the assessment is, a tax or government-imposed fee or mandate; and

E. Include a description of how the program will meet the requirements under subsection 4.

6. Program review and approval. The department shall review each program plan submitted pursuant to subsection 3 in consultation with the Department of Health and Human Services.

A. If the department is satisfied that a program 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.

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

C. The department shall provide expedited review and approval for a program plan submitted by a manufacturer or a stewardship organization if it has entered into a contractual agreement with a statewide hospital association for dissemination of sharps collection containers and the collection and disposal of medical sharps from residential sources using the infrastructure of a statewide hospital association.

D. The decision of the department under this subsection is a final decision and may be appealed to the board pursuant to section 341-D, subsection 4.

7. Program modification. Except as provided in this subsection, a program must be operated in compliance with the approval issued by the department under subsection 6.

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

B. An additional manufacturer may join a stewardship organization and participate in its program if the manufacturer or stewardship organization operating the program provides the department with an updated manufacturer participant list within 15 days after the additional manufacturer begins participation in the program.

C. 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.

8. Program reports. A manufacturer or stewardship organization shall provide program reports as follows.

A. By February 1, 2014, and annually thereafter, the manufacturer or stewardship organization shall submit to the department 2 copies of a written annual report in a format prescribed by the department and covering the previous calendar year. The program report must include:

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

(2) A list of the biomedical waste disposal or 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 subsection 4, paragraph E;

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

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

B. By August 1, 2014, and annually thereafter, the manufacturer or stewardship organization shall submit to the department a midyear data report of the amount, by weight, of unwanted medical sharps collected during the 6-month period covering January to June.

9. Enforcement. If the department determines that a program is not being managed in accordance with this section or other applicable state rules or if the department determines that there is an imminent danger to the public or the environment:

A. The department may amend the approval of the program by clarifying terms or conditions to ensure full implementation of the program or suspend or cancel the approval of the program. Except as provided in paragraph B, at least 15 days prior to amending, suspending or canceling an approval, the department shall inform the manufacturer or stewardship organization of the action and provide the manufacturer or stewardship organization an opportunity to respond; and

B. If the department determines that it is necessary in order to protect the public or the environment from imminent danger, the department may immediately amend, suspend or cancel the approval of a program without giving the manufacturer or stewardship organization an opportunity to be heard, but shall provide an opportunity to be heard through proceedings consistent with Title 5, chapter 375, subchapter 4 within 15 days after the date on which the department takes action.

10. Penalties. After January 1, 2013, a manufacturer that is not in compliance with this section is subject to civil penalties under section 349. By June 1, 2013, the department shall list on its publicly accessible website manufacturers that are participating in approved programs and manufacturers that have been identified as being not in compliance with this section. All penalties collected for violations of this section must be deposited into the Maine Environmental Protection Fund established in section 351.

11. Wholesaler responsibility. By February 1, 2013, and annually thereafter, a wholesaler of medical sharps sold in the State shall report to the department the name and contact information for each manufacturer whose medical sharps the wholesaler sold or distributed within the State during the previous

calendar year. Information reported under this subsection is confidential and may not be disclosed by the department except that the department may share that information with the Department of Health and Human Services.

12. Pharmacy responsibility. A pharmacy licensed to operate in the State under Title 32, chapter 117 shall make available to its customers the educational information and materials provided free of charge by the Department of Health and Human Services, the manufacturers or the stewardship programs.

13. Voluntary participation. A hospital, medical clinic, pharmacy, public transportation location, public park, municipal facility or other approved site may volunteer to be a sharps collection center at any time. Volunteer sites must agree to abide by collection procedures issued by the department as well as state rules applicable to medical sharps management. If the location is a hospital or medical facility, it must keep medical sharps accepted from residential sources separate from those generated in the course of business. Sharps collection centers must be provided with free sharps collection containers and written information to give to medical sharps users.

14. Anticompetitive conduct. A stewardship organization that manages a program pursuant to this section is immune from state laws relating to antitrust, restraint of trade, unfair trade practices and other regulation of trade and commerce for the limited purpose of establishing and operating a program for residential sources. The activities of the organization that comply with the provisions of this section may not be considered to be in restraint of trade, a conspiracy or a combination thereof or any other unlawful activity in violation of any provision of Title 10.

15. Rules. The department may establish rules to implement this section. Rules adopted pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

SUMMARY

This bill requires a manufacturer of medical sharps to participate in a program, individually or in conjunction with other manufacturers, for the collection, handling, transportation, treatment and disposal of unwanted medical sharps. It also provides that an entity that uses medical sharps is not required to dispose of them by shredding.