Offered by Councilor Annissa Essaibi-George

CITY OF BOSTON

IN THE YEAR TWO THOUSAND TWENTY

AN ORDINANCE TO PROVIDE FOR SAFE DISPOSAL OF SHARPS THROUGH THE ESTABLISHMENT OF A PRODUCT STEWARDSHIP PROGRAM

WHEREAS: Under 105 CMR 480.000: minimum requirements for the disposal of medical or biological waste (State Sanitary Code Chapter VIII) there is a statewide ban on the disposal of needles, syringes and lancets collectively referred to as sharps in the household trash; and,

WHEREAS: There is a great volume of residents who use sharps, syringes, or needles legally for medical treatments and/or illegally for illicit drug use; and

WHEREAS: The insufficient number of safe drop-off sites for sharps has caused improper disposal of needles in household trash, parks, and public spaces; and

WHEREAS: Improper disposal of sharps poses a risk to public health and safety and our waste management system; and,

WHEREAS: Creation of additional safe collection sites and increased public awareness will aid in the City of Boston's efforts to curb this public health crisis; and

WHEREAS: It is necessary to establish a product stewardship program to ensure the safe and environmentally sound disposal of sharps and to ensure the costs associated with sharps disposal are the responsibility of those who produce and retail pharmaceuticals requiring the use of sharps in their administration.

NOW THEREFORE,

Be it ordained by the City Council of Boston, as follows:

Section 1.
The City of Boston Code, Ordinances, Chapter XII shall be amended by adding at the end thereof, the following new section and subsections:

12-16 Product Stewardship Program for Personal Use Sharps Waste Management.

12-16.1 Purpose.
The purpose of this ordinance is to protect the health, safety and welfare of the public and of the environment by providing for the safe and orderly collection and disposal of sharps by placing the responsibility on the manufacturers of the products through the creation of a product stewardship program. The purpose of this ordinance is to require manufacturers to collaborate with retailers that sell sharps for personal use in the City of Boston to take back sharps at the end of life at no additional cost to the consumer at the time of return. The intent of this ordinance is to provide consumers with more convenient ways to return and ensure the safe and environmentally sound disposal of personal use sharps.

12-16.2 Definitions.
"Department" means the Inspectional Services Department for the City of Boston.

"Manufacture" means the production, preparation, propagation, compounding, or processing of sharps.

"Manufacturer" means a person, company, corporation or other entity engaged in the manufacture of sharps, except for an institutional pharmacy, as defined in section 39D of chapter 112 of the General Laws or a wholesaler.

"Personal Use Sharps" means all spent non-commercially generated, hypodermic needles and lancets that have been used or are not in their original, intact and sealed packaging and that result from personal use by humans or animals at a residence or outside the home. Personal use sharps do not include needles or lancets generated by home health aides, visiting nurses, or any other person providing a professional service in a private residence.

"Pharmacy" means a facility under the direction or supervision of a registered pharmacist licensed by the Massachusetts Board of Registration in Pharmacy which is authorized to dispense controlled substances. The term "pharmacy" shall not include institutional pharmacies or pharmacy departments or any independent community pharmacies with fewer than two retail locations within the city of Boston.

"Proper disposal" means the lawful disposal of personal use sharps waste in compliance with the applicable provisions of state law and the State Sanitary Code.

"Retailer" means any person or entity that sells sharps directly to consumers at a business located in Boston; provided that for purposes of these sections and subsections, a retailer must belong to a chain of three or more retail establishments operating inside or outside the City of Boston, must conduct business under the same business name or operate under common ownership or management pursuant to a franchise agreement with the same franchisor.

"Sharps" means hypodermic needles, pen needles, intravenous needles, lancets, and other devices that are used to penetrate the skin for the delivery of medications, to humans or animals.

"Plan" or "Product Stewardship Plan" means a department-approved plan that is financed and implemented by a sharps manufacturer or a group of manufacturers to collect, secure, transport, and safely dispose of unwanted sharps.

12-16.3 Mandatory participation in sharps stewardship plan.
Any manufacturer selling or distributing sharps in the City of Boston, whether directly or indirectly through a wholesaler, retailer or other agent, shall

a. (i) Operate a product stewardship plan, individually or jointly with other manufacturers, approved by the department; or (ii) enter into an agreement with a stewardship organization to operate, on the manufacturer's behalf, a product stewardship plan approved by the department.
b. Each product stewardship plan must be approved by the department before the person administering the plan starts collecting and disposing of sharps for compliance with this Ordinance. Once approved, each product stewardship plan must have prior written approval of the department for proposed changes as described under Section 12-16.6
c. A manufacturer must submit a product stewardship plan within 90 days of the effective date of this Ordinance or commencement of sales or distribution within the City of Boston.
d. Each operator of a product stewardship plan shall file an annual written report to the department describing the program's activities for the prior year and the volume of collection.
e. Pay all administrative and operational costs and fees associated with its product stewardship plan.

12-16.4 Product Stewardship Plan Requirements
A manufacturer seeking approval for a product stewardship plan shall submit, in a manner and form determined by the department, a plan that must include the following requirements:

a. A description of a collection system the provides at least two methods of convenient, ongoing collection services to all persons seeking to dispose of unwanted sharps; provided further, that the collection system shall include a collection kiosk or other collection system at each pharmacy, as defined in this section, and at least one of the following: (A) a mail-back program that provides prepaid and pre-addressed packaging for a retailer to distribute at the point of sale of sharps; (B) drop-off day events at locations in the City of Boston; (C) in-home disposal methods that render a product safe from misuse and that comply with applicable city, state, and federal laws and regulations; or (D) any other method recommended pursuant to US DEA guidelines and subject to department approval;
b. A description of the policies and procedures to be followed by persons handling sharps collected under the product stewardship plan, including a description of how all collectors, transporters and waste disposal facilities used will ensure that the collected sharps are safely and securely tracked from collection through final disposal, and how all entities participating in the product stewardship plan will operate under and comply with all applicable federal and state laws, rules and guidelines, including but not limited to those of the United States Food and Drug Administration and Occupational Safety and

Health Administration, and how any pharmacy collection site will operate under applicable laws, regulations, rules, and guidelines related to the sale and disposal of sharps;

c. Adequate provisions for the security of sharps throughout the collection process and the safety of any person involved in monitoring, staffing, or servicing the stewardship plan are included in the product stewardship plan;
d. A plan that provides for the operational and administrative costs associated with the program; provided, however, that no point-of-sale or point-of-collection, processing fees or other sharps cost increases may be charged to the individual consumers to recoup program costs;
e. A plan for public outreach and education about the product stewardship plan;
f. A certification that any patient information on sharps packaging will be promptly destroyed;
g. A certification that the product stewardship plan will accept all sharps regardless of who produced them or their compatibility with producer's drugs;
h. Contact information for all manufacturers participating in the product stewardship plan, including each manufacturer's name, address, phone number, and email address, and the name, address, phone number, and email address of the person to whom the department may direct all inquiries regarding the manufacturer's participation in the product stewardship plan;
i. An attestation that the program shall comply with all applicable state and federal requirements.

The provisions of this Chapter shall be interpreted and applied at all times consistently with the provisions of Chapter 94C, section 27A of the General Laws; all provisions of any relevant general or special act; and, 105 CMR 480.00, Minimum Requirements for the Management of Medical or Biological Waste (State Sanitary Code Chapter VIII).

12-16.5 Container and Signage Requirements.

Collection and transfer containers must meet the requirements of the federal Occupational Safety and Health Administration and the federal Department of Transportation and is marked with the international biohazard symbol. Any containers provided for the stewardship plan will include the name and contact information for the person to direct all inquiries regarding the manufacturer's participation in the product stewardship plan.

12-16.6 Review of the product stewardship plan.

a. The department shall establish a process to review applications for approval and renewal of a manufacturer's product stewardship plan.
b. After the review of this section and within ninety (90) days after receipt of the proposed product stewardship plan, the department shall either approve or reject the proposed product stewardship plan in writing and, if rejected, provide reasons for the rejection.
c. If the department rejects a proposed product stewardship plan, the submitting producer, group of producers, or stewardship organization must submit a revised product stewardship plan to the department within thirty (30) days after receiving written notice of the rejection. The department shall review and approve or reject the revised product stewardship plan.

d. If the department rejects a revised product stewardship plan, or any subsequently revised plan, the department may deem the submitting producer or group of producers out of compliance with this Ordinance and subject to the enforcement provisions in this chapter until a plan is approved.
e. The department shall review for renewal each product stewardship plan at a frequency to be determined by the department. It is recommended that the product stewardship plan is reviewed as part of the regular inspection process of pharmacies.
f. The department may audit the records of a producer, group of producers, or stewardship organization related to a product stewardship plan or request that the producer, group of producers, or stewardship organization arrange for the department to inspect at reasonable times a product stewardship plan or a collector's facilities, vehicles, and equipment used in carrying out the plan.
g. The department shall make all product stewardship plans and proposed plans submitted under this section available to the public and shall update this list at a frequency determined by the department.
h. The department may promulgate regulations to implement this chapter.

12-16.7 Enforcement.
The Commissioner of Inspectional Services, or designee, shall have jurisdiction and authority to enforce the provisions of 12-16.

The department shall send a notice to a pharmaceutical product manufacturer that sells or distributes sharps in the Commonwealth that has not submitted an application for approval under Section 12-16.3, informing the manufacturer of the requirements to comply with this chapter. Any manufacturer in receipt of said notice must submit an application for approval within 45 calendar days of receipt of such initial notice before the department may deem them in violation of this Ordinance.

Any manufacturer or retailer found to be in violation of any provision of 12-16, or who fails to comply with any of its requirements, shall be punished by a fine of three hundred dollars ($300.00). Each day such violation continues shall be considered a separate offense. All revenue received from such fines shall be delegated to the city's Office of Recovery Services.

The provisions of this section may be enforced in accordance with the non-criminal disposition process of M.G.L. c. 40, s. 21D, provided that this section shall not preclude the City of Boston from proceeding to restrain a violation by injunction.

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