HOUSE No.

The Commonwealth of Massachusetts

PRESENTED BY:

Carole A. Fiola

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 medical sharps stewardship.

PETITION OF:

NAME:	DISTRICT/ADDRESS:	DATE ADDED:
Carole A. Fiola	6th Bristol	1/15/2025

HOUSE No.

[Pin Slip]

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The Commonwealth of Alassachusetts

In the One Hundred and Ninety-Fourth General Court (2025-2026)

An Act relative to medical sharps stewardship.

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. Section 1 of chapter 94H of the General Laws, as appearing in the 2022

Official Edition, is hereby amended by striking out the second paragraph and inserting in place

thereof the following paragraph:-

4 "Covered drug", any brand name or generic opioid drug placed in Schedule II or

Schedule III of section 3 of chapter 94C; provided, however, that "covered drug" shall also

include "(i) benzodiazepines, and (ii) sharps subject to collection and disposal procedures

established in section 27A of chapter 94C; provided, further, that "covered drug" shall not

8 include (i) drugs intended for use solely in veterinary care; (ii) substances that are regulated as

cosmetic products under the United States Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq;

(iii) drugs that are compound under a specialty license pursuant to sections 39G to 39J, inclusive,

of chapter 112; or (iv) drugs approved and used primarily for medication-assisted substance use

12 disorder treatment.

SECTION 2. Said section 1 of chapter 94H, is hereby further amended by inserting the following definition:-

"Sharps", objects with sharp points or edges that can puncture or cut skin, which shall include but are not limited to hypodermic needles, syringes, lancets, auto injectors, infusion sets, and connection needles.

SECTION 3. Said section 1 of chapter 94H, is hereby further amended by inserting the following definition:-

"Sharps disposal containers", containers made from rigid puncture-resistant plastic or metal with leak-resistant sides and bottom, and a tight-fitting, puncture-resistant lid with an opening to accommodate depositing a sharp but not large enough for a hand to enter.

SECTION 4. Section 3 of chapter 94H, as so appearing, is hereby amended by striking out the section in its entirety and inserting in place thereof the following section:-

Section 3. A manufacturer or stewardship organization seeking approval for a drug stewardship program shall submit, in a manner and form determined by the department, a plan that meets, but is not limited to, the following requirements:

(i) for all covered drugs not including sharps, a collection system to provide convenient, ongoing collection services to all persons seeking to dispose of unwanted drugs; provided, however, that the collection system may accept any covered drug and any other prescription drug in a pill formulation regardless of its schedule, brand or source of manufacture; provided further, that the collection system shall include 2 methods as recommended by the department, which may include, but not be limited to: (A) a mail-back program that provides prepaid and

preaddressed packaging for a pharmacy to distribute when filling a prescription for a covered drug or upon request by a consumer; (B) collection kiosks; (C) drop-off day events at regional locations; (D) in-home disposal methods that render a product safe from misuse and that comply with applicable controlled substance regulations and environmental safety regulations; or (E) any other method recommended pursuant to United States Drug Enforcement Administration guidelines;

- (ii) for sharps, a mail-back collection system that provides prepaid and preaddressed packaging for a pharmacy to distribute when filling a prescription that includes sharps or upon request by a consumer that shall include but not be limited to: (a) the contact information for the operator of the program and for each entity participating in the program; (b) the list of sharps sold or offered by sale by each participating entity covered by the stewardship program; (c) the name and contact information of the service provider to be used to transport, process, or dispose of sharps collected through the stewardship program; (d) safe and secure processes that collect, track, and properly manage sharps waste from collection through final disposal; (e) sufficient amounts of sharps disposal containers to accommodate the volume of sharps purchased by the consumer over a selected time period; (f) all necessary information for the consumer on the proper disposal of sharps; (g) a label affixed to the sharps disposal container or packaging or on a separate sheet with the program operator's internet website and toll-free telephone number; (h) all necessary prepaid postage and mail-back packaging;
- (iii) adequate provisions for the security of unwanted drugs throughout the collection process and the safety of any person involved in monitoring, staffing, or servicing the stewardship program;

(iv) a plan for the manufacturer or stewardship organization that provides the operational and administrative costs associated with the program; provided, however that no point-of-sale, point-of-collection, processing fees or other drug cost increases may be charged to individual consumers to recoup program costs;

- (v) an attestation that the program shall comply with all applicable state and federal requirements for the collection, security, transport and disposal of drug products, including any requirements established by the rule or regulation of either the United States Drug Enforcement Administration or the United States Environmental Protection Agency; and
- (vi) any other requirements established by the department for the sale and effective administration of a drug stewardship program.