



The Commonwealth of Massachusetts
 Executive Office of Health and Human Services
 Department of Public Health
 Bureau of Health Professions Licensure
 Drug Control Program

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Drug Stewardship Program Non-Participation Form

M.G.L. c. 94H requires that every pharmaceutical product manufacturer who sells or distributes a brand name or generic Schedule II or Schedule III opioid drug or benzodiazepine in the Commonwealth must file a plan to operate a Drug Stewardship Program with the Department of Public Health (“Department”).

If a pharmaceutical product manufacturer believes that they are not required to file a Drug Stewardship Plan with the Department, this form must be filled out and provided to the Department.

Section 1: Contact Info

Company Name: _____

Address: _____

City, State, Zip Code: _____

Contact Name: _____

Phone: _____

Email: _____

Compliance Officer Name: _____

Phone: _____

Email: _____

Section 2: Attestation and Signature

By selecting one or more of the following, the Entity attests that it is not required to file a Drug Stewardship Plan with the Department because: (please check all that apply)

- The Entity does not manufacture controlled substances under a U.S. Food and Drug Administration manufacturer's license.
- The Entity does not sell or distribute to consumers in the Commonwealth of Massachusetts, whether directly or through a wholesaler, retailer, or other agent.
- The Entity does not sell or distribute brand name or generic Schedule II or Schedule III opioid drugs, or benzodiazepines.
- The only drugs which the Entity sells or distributes, whether directly or through a wholesaler, retailer, or other agent, are (please check all that apply):
 - Drugs intended for use solely in veterinary care;
 - Cosmetic products as defined in 21 U.S.C. § 301 et seq., the U.S. Food, Drug & Cosmetic Act;
 - Drugs compounded under a specialty license pursuant to M.G.L. c. 112, §§ 39G through 39J;
 - Hypodermic needles, lancets or other sharps products subject to collection and disposal procedures established in accordance with M.G.L. c. 94C, § 27A through 39J; or
 - Drugs approved and used primarily for medication-assisted substance use disorder treatment.
- The only drugs which the Entity sells or distributes to consumers in the Commonwealth of Massachusetts, whether directly or through a wholesaler, retailer, or other agent, are (please check all that apply):
 - Drugs intended for use solely in veterinary care;
 - Cosmetic products as defined in 21 U.S.C. § 301 et seq., the U.S. Food, Drug & Cosmetic Act;
 - Drugs compounded under a specialty license pursuant to M.G.L. c. 112, §§ 39G through 39J;
 - Hypodermic needles, lancets or other sharps products subject to collection and disposal procedures established in accordance with M.G.L. c. 94C, § 27A through 39J; or
 - Drugs approved and used primarily for medication-assisted substance use disorder treatment.

**I hereby certify to the Massachusetts Department of Public Health
to the best of the company's knowledge, information, and belief that**

_____ (Company Name)

is not required to participate in the Drug Stewardship Program under M.G.L. c. 94H.

Signed under the pains and penalties of perjury:

Signature of Compliance Officer _____

Name of Compliance Officer (Print): _____

Date _____

Section 3: Submission

Please submit this completed non-participation form to the following contact:

Drug Stewardship Program
MA Bureau of Health Professions Licensure
239 Causeway St., 5th floor – Suite 500
Boston, MA 02114

Or, email a scanned copy to: drugstewardship@massmail.state.ma.us

For questions, please submit an email to drugstewardship@massmail.state.ma.us.