



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](mailto:drugstewardship@massmail.state.ma.us)

For questions, please submit an email to [drugstewardship@massmail.state.ma.us](mailto:drugstewardship@massmail.state.ma.us).