The Commonwealth of Massachusetts

Executive Office of Health and Human Services

Department of Public Health

Bureau of Health Professions Licensure

Drug Control Program

MARYLOU SUDDERS

Secretary

MONICA BHAREL, MD, MPH Commissioner

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[www.mass.gov/dph/boards](http://www.mass.gov/dph/boards)



**Drug Stewardship Program Non-Participation Form**

CHARLES D. BAKER

Governor

KARYN E. POLITO

Lieutenant Governor

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)**.**