

**New York State
Department of Health
Department of Environmental Conservation**

Proposal to Operate a New York State Drug Take Back Program

INTRODUCTION

Pursuant to Chapter 120 Laws of 2018, the New York State Drug Take Back Act (DTB) mandates that manufacturers of covered drugs establish, fund, and operate a New York State approved drug take back program for the safe collection and disposal of unused covered drugs. Any manufacturer or drug take back organization seeking to operate a drug take back program should use this form to submit a proposal to the Department of Health (DOH).

A proposed drug take back program shall be approved if it complies with Drug Take Back Regulations at 10 NYCRR §60-4, and includes the following:

1. contact information for the person submitting the planned drug take back program;
2. a certification that all covered drugs will be accepted regardless of who produced them;
3. details of a collection system to provide convenient, ongoing collection services to all persons seeking to dispose of covered drugs;
4. a description of other collection methods by authorized collectors;
5. an explanation of how covered drugs will be safely and securely tracked and handled from collection through final disposal and destruction;
6. a description of the public education and outreach activities that will be undertaken as part of the program;
7. details of how the costs of the pharmacy collection and other authorized collectors will be reimbursed by the manufacturer(s); and
8. further information deemed appropriate by DOH.

Approved drug take back programs must be updated at least every three years and submitted to DOH.

Please complete all sections of this proposal and submit along with any supporting attachments to the New York State Department of Health, Bureau of Narcotic Enforcement, by e-mail to dtb@health.ny.gov. Incomplete submissions will not be processed.

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I. OPERATOR CONTACT INFORMATION

Pursuant to 10 NYCRR §60-4.3(b)(1), this section must provide contact information for the responsible person submitting the proposal on behalf of the Operator of the proposed drug take back program, to whom New York State shall direct all inquiries.

Operator:

Manufacturer **Drug Take Back Organization (Please check one)**

Name of Operator: Click or tap here to enter text.

Contact First Name: Click or tap here to enter text.

Contact Last Name: Click or tap here to enter text.

Contact Phone: Click or tap here to enter text.

Contact E-mail: Click or tap here to enter text.

Mailing Address – Street Address 1: Click or tap here to enter text.

Mailing Address – Street Address 2: Click or tap here to enter text.

Mailing Address – City: Click or tap here to enter text.

Mailing Address – State: Click or tap here to enter text.

Mailing Address – Zip Code: Click or tap here to enter text.

Mailing Address – Country: Click or tap here to enter text.

II. CERTIFICATION

Pursuant to *10 NYCRR §60-4.3(b)(2)*, I certify that this proposed drug take back program will accept all covered drugs, regardless of who produced them.

III. COLLECTION SYSTEM

This section must detail a collection system to provide convenient, ongoing collection services to all persons seeking to dispose of covered drugs pursuant to Public Health Law §292 of Article 2-B and Drug Take Back Regulations at 10 NYCRR §60-4, that is geographically distributed in a way to ensure access in rural and underserved areas.

Pursuant to 10 NYCRR §60-4.3(b)(3-6) and (17), provide a detailed description of the proposed drug take back collection system that shall include the following:

- **information on geographic distribution (and specifically, how it ensures access in rural and underserved areas), convenience for all consumers across the state, ongoing services of the program;**
- **how pharmacies providing collection boxes for take back in areas outside of the counties with convenience standards will be included in the program;**
- **the name, address, phone, e-mail address, DEA number, and Bureau of Narcotic Enforcement license number, for any entity(ies) that will reverse distribute covered drugs for the drug take back program;**
- **a list of participating pharmacies and other authorized collectors, their DEA number, and their Education Department registration number (if applicable), their locations, and methods of collection, including collection receptacles, mail back programs, and other approved collection methods; and**
- **how authorized collectors that are currently providing collection receptacles will be included in the program.**

Click or tap here to enter text.

IV. OTHER COLLECTION METHODS

Pursuant to 10 NYCRR §60-4.3(b)(7), use this section to describe other approved collection methods, including drug take back events, that the proposed program will use to collect covered drugs.

Click or tap here to enter text.

V. HANDLING, COLLECTION, AND DISPOSAL OF COVERED DRUGS

This section must explain how covered drugs will be safely and securely tracked and handled from collection through final disposal and destruction, policies to ensure security and compliance with all applicable laws and regulations including disposal and destruction at a permitted waste disposal facility meeting federal requirements.

Pursuant to 10 NYCRR §60-4.3(b)(8), provide detailed policies and procedures on how the proposed drug take back program will safely and securely track and handle collection of covered drugs through final disposal and destruction, which includes information on policies to ensure security and compliance with all applicable laws and regulations including disposal and destruction at a permitted waste disposal facility that meets federal requirements.

Click or tap here to enter text.

Pursuant to 10 NYCRR §60-4.3(b)(16), provide detailed information on how the operator will identify and resolve safety and security issues arising from the collection, transportation or disposal of covered drugs.

Click or tap here to enter text.

VI. PUBLIC EDUCATION AND OUTREACH

This section must describe the public education and outreach activities that will be undertaken, which shall include advertising of collection locations on a website and through use of signage and other written materials, and how the program will evaluate the effectiveness of each method.

Pursuant to 10 NYCRR §60-4.3(b)(9), provide detailed information on the public education and outreach activities the drug take back program will undertake, which includes information on advertisement, website, signage, and other written materials.

Click or tap here to enter text.

Pursuant to 10 NYCRR §60-4.3(b)(10), provide detailed descriptions on how the program will evaluate the effectiveness of public education and outreach activities of the proposed drug take back program.

Click or tap here to enter text.

Pursuant to 10 NYCRR §60-4.3(b)(13), provide detailed information on the methods to be used for outreach and participation by pharmacies and other authorized collectors.

Click or tap here to enter text.

VII. FUNDING

This section must detail how the costs of pharmacy collection and other authorized collectors will be reimbursed, which costs shall include those retroactive to the effective date of Article 2-B, and where more than one manufacturer will be involved in the planned drug take back program, a plan for the fair and reasonable manner of allocated costs among the participants in such program such that the costs paid by each manufacturer is reasonably related to the volume or value of covered drugs sold in New York State. The proposal should also address how the program will pay costs incurred by the state in the administration and enforcement of the drug take back program.

Pursuant to 10 NYCRR §60-4.3(b)(11), provide detailed information on how costs of pharmacy collection and other authorized collectors of the proposed drug take back program will be paid or reimbursed by all manufacturers involved in the proposed program, including but not limited to the following: who pays for the purchase and installation of collection receptacles, the inner liners, mail back vouchers, envelopes, packages, postage, transportation and disposal costs, communications, and public education and outreach efforts, as well as how the costs are managed and by whom.

Click or tap here to enter text.

Please also provide detailed information on how the program will pay costs incurred by the state in the administration and enforcement of the drug take back program

Click or tap here to enter text.

Note: A manufacturer, individually or jointly, will be responsible for payment of all administrative and operational fees associated with the drug take back program, including the cost of collecting, transporting, disposing of covered drugs and the cost of recycling and/or disposing of the packing collected with the covered drug.

VIII. ADDITIONAL REQUIRED INFORMATION

Completion of this section is deemed appropriate by New York State for review of a proposed drug take back program.

Pursuant to 10 NYCRR §60-4.3(b)(12), provide a detailed drug take back program timeline for implementation, including the specific expected date(s) that the program will be operational.

Click or tap here to enter text.

Pursuant to 10 NYCRR §60-4.3(b)(14), provide a detailed description of the methods to be used to retain data and information necessary for reporting, pursuant to Article 2-B of the Public Health Law, as deemed necessary by the Department. At a minimum, reporting must include the weight of covered drugs collected, a description of collection activities, the names and locations of all collection sites with collection methods and weight collected by each method, and public education and outreach activities.

Click or tap here to enter text.

For proposals representing participation by more than one manufacturer:

Pursuant to 10 NYCRR §60-4.3(b)(15), provide a separate detailed list in Excel format of manufacturers participating in the proposed drug take back program, which includes the following for each:

- name of the manufacturer,
- name of the manufacturer's parent company and any subsidiaries,
- mailing address,
- FDA labeler code, if applicable,
- DEA number, if applicable,
- NYS Education Department Registration, if applicable,
- any additional identifiers as requested by the Department

Click or tap here to enter text.

IX. SIGNATURE

I the undersigned, hereby certify under penalties of perjury, that the information stated herein is true, complete, and accurate to the best of my knowledge. False statements made herein are punishable as a class A misdemeanor pursuant to §210.45 of the Penal Law.

Signature (Original)

Click or tap here to enter text.
Date

Click or tap here to enter text.
Title (Corporate Officer/Owner)