

New York State Drug Take Back Act

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Drug Take Back Act

Article 2-B

Public Health Law (PHL) §§290-294

Implemented and Administered by the Bureau of Narcotic Enforcement, with DEC

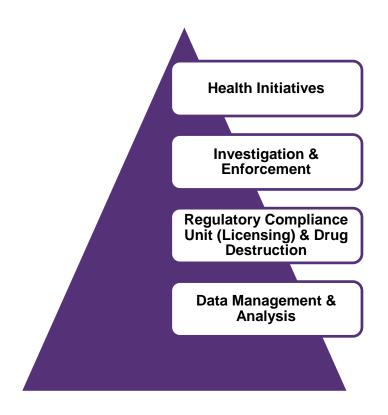
Effective Date: January 6, 2019



BNE Safe Disposal Program

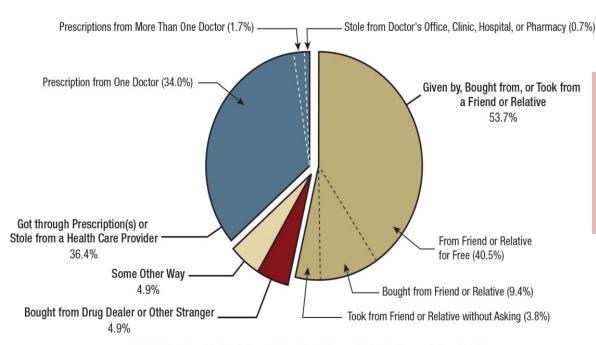


Bureau of Narcotic Enforcement (BNE)





Sources for Nonmedical Use of Prescription Drugs United States, 2015



Consumers need a means to safely dispose of prescription medications including controlled substances.

12.5 Million People Aged 12 or Older Who Misused Pain Relievers in the Past Year



Safe Disposal

- Consumers need a means to safely dispose of prescription medications including controlled substances
- Safe disposal sites established with local police departments/law enforcement agencies
- Public Health Law §3343-b: disposal must be in accordance with federal law



Safe Disposal



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Medication Drop Boxes by County

Abuse of prescription drugs is a major public health problem in New York State. Studies show that a majority of abused prescription drugs are obtained from family and friends, including the home medicine cabinet.

To help address this problem, the New York State Department of Health has established a permanent medication drop box program through the state, county, and local law enforcement agencies. The program will expand the options currently available for households to dispose of discontinued, expired or unwanted medications in a manner that considers public health, as well as the environment. The following agencies expressed interest and are participating in the New York State Medication Drop Box Program. The map below lists by county the participating law enforcement agencies.

Please note some localities began their own drop box program before this was established. These too are located on the map below.

Select a county from the map below, or from a list of counties in New York State



http://www.health.ny.gov/ professionals/narcotic/me dication_drop_boxes/

Map Key

Color	Definition
	Drop box available
	Dron how not available



Drug Take Back Act



Drug Take Back Act – PHL §§290-294

§290 Definitions

§291 Drug Take Back

§292 Collection

§293 Violations

§294 Jurisdiction



Drug Take Back Act – PHL §290 Definitions

- (1) Authorized collector
- (2) Covered drug
- (3) Manufacturer
- (4) Pharmacies
- (5) Drug take back organization
- (6) Wholesaler
- (7) Repackager



By 2/5/19: Wholesalers who sell covered drugs in NY must provide DOH with a list of manufacturers that produce them.

DOH may request updated lists at its discretion.



Manufacturers of covered drugs must either:

- (a) operate a drug take back program approved by DOH individually or jointly with other manufacturers;
- (b) enter into an agreement with a drug take back organization which shall operate a drug take back program approved by DOH; or
- (c) enter into an agreement with DOH to operate a drug take back program on its behalf.



Whatever of those 3 courses of action they choose, they must submit a proposal to DOH by July 5, 2019 (within 180 days of the effective date of January 6, 2019).

DOH then has 60 days to review, with DEC.



If DOH and DEC reject the proposal, the manufacturer has 30 days to resubmit or it is out of compliance, and the penalty provisions kick in.

DOH shall provide, and update annually, on its website a list of all manufacturers participating in an approved drug take back program.



Minimum Requirements §291(a)-(h)

- (a) Certifies the drug take back program will accept all covered drugs regardless of who produced them;
- (b) Provides contact information for the person submitting the planned drug take back program with whom the Department shall direct all inquiries;
- (c) Details a collection system to provide convenient, ongoing collection services to all persons seeking to dispose of covered drugs pursuant to section two hundred ninety-two of this article that is geographically distributed in a way to ensure access in rural and underserved areas;



Minimum Requirements

- (d) Describes other collection methods by which covered drugs will be collected by authorized collectors;
- (e) Explains 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;
- (f) Describes 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 effectiveness will be evaluated;



Minimum Requirements

(g) Details how the costs of pharmacy collection and other authorized collectors will be reimbursed which shall include costs retroactive to the effective date of this article, 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 are reasonably related to the volume or value of covered drugs sold in the state; and

(h) Provides any further information deemed appropriate by the Department.



Minimum Requirements

Manufacturers bear all costs – collection, transportation, disposal.

Manufacturers bear all state costs – administration, enforcement.

Manufacturers must update plans at least every 3 years.



Reporting Requirements

 Each approved drug take back program must report to DOH at a date and manner set by DOH.

 DOH must submit an annual report to the Governor, speaker of the Assembly and temporary president of the Senate by January 1.



Reporting Requirements

The DOH report will describe

- 1. all program activities,
- 2. weight collected by each program,
- 3. description of the collection activities,
- 4. name and location of all collection sites,
- 5. public education and outreach activities,
- 6. evaluation of the efficacy of the program and each collection method, and
- 7. any manufacturer out of compliance or subject to penalties.



Drug Take Back Act – PHL §292 Collection

Pharmacies must provide for safe collection of drugs by 1 or more of the following:

- On-Site Collection/Drop boxes
- 2. Mail-back envelopes
- 3. Other DEA-approved methods

Also must have signage prominently displayed advertising drug collection to consumers.



Drug Take Back Act – PHL §292 Collection

Pharmacies that choose to offer mail-back collection must provide a voucher for a prepaid envelope upon dispensing a covered drug.

The voucher must include information on drug take back and safe drug disposal methods.



Other Requirements

All drug take back program operators shall <u>notify other potential</u> <u>authorized collectors of the opportunity</u> to serve as an authorized collector for the drug take back program.

Participation of authorized collectors besides pharmacies is voluntary.

All costs of pharmacies and other authorized collectors shall be paid or reimbursed by the manufacturer, jointly or individually, as part of the drug take back programs required by this article.



Convenience Standard

For any city with a population of 125,000 or more as of the last census, the commissioner shall establish by regulation a distribution plan that ensures that on-site collection receptacle or dropbox placement shall be reasonably accessible to all residents and that provides for program cost efficiency.

NYC, Yonkers, Syracuse, Rochester, and Buffalo.



Drug Take Back Act – PHL §293 Violations

Violations are subject to fines pursuant to PHL §12.

Each day the violation continues is a separate violation.



Drug Take Back Act – PHL §293 Violations

PHL §12 fines:

- Up to \$2,000 per violation;
- Up to \$5,000 if
 - o committed within 12 months of the 1st one, AND
 - a serious threat to health and safety;
- Up to \$10,000 if the violation directly results in serious physical harm to a patient.



Drug Take Back Act – PHL §294 Jurisdiction

New York State has exclusive jurisdiction over all drug disposal matters in the DTBA.

All conflicting county and local laws, rules, and regulations are preempted.



Drug Take Back Act – Timeline

- Jan, 6, 2019: effective date
- **Feb. 5, 2019** (30 days after effective date): all wholesalers that sell in or into the state must provide DOH with a list of manufacturers that produce covered drugs
- July 5, 2019 (180 days after effective date): manufacturers' proposed drug take back programs must be submitted to DOH



Drug Take Back Act – Timeline

- **Sept. 3, 2019** (60 days after submission): DOH must approve or deny proposed plan, in consultation with DEC
- Oct. 3, 2019 (30 days after declination): If the proposed plan is not approved by DOH, a revised plan must be submitted by this date

No defined date for when collection must be up and running.

