



FREQUENTLY ASKED QUESTIONS ABOUT THE DRUG TAKE BACK ACT



Department
of Health

NEW YORK STATE DEPARTMENT OF HEALTH

Bureau of Narcotic Enforcement

1-866-811-7957

www.health.ny.gov/professionals/narcotic

DEFINITIONS

Q1: What is the Drug Take Back Act definition of a Pharmacy?

A1: For the purposes of the Drug Take Back Act, pursuant to Public Health Law (PHL), §290.4), a pharmacy shall mean all pharmacies registered under section 6808 of the Education Law that are:

- (a) part of a group of ten or more pharmacies under common ownership or management, or
- (b) part of a group of ten or more pharmacies linked to the same company via franchise agreements; or
- (c) non-resident pharmacies registered pursuant to section 6808-b of the Education Law that provide covered drugs to state residents by mail.

Q2: Are all pharmacies required to participate in a drug take back program?

A2: No. All pharmacies as defined by the Drug Take Back Act are required to provide for the safe collection of covered drugs.

Q3: As the owner of an independent pharmacy, can I still participate in a drug take back program?

A3: Yes. Any pharmacy not meeting the drug take back definition of a pharmacy may voluntarily participate in a drug take back program.

Q4: What is a drug take back organization?

A4: A drug take back organization, pursuant to PHL, §290.5, means an organization designated by a manufacturer or a group of manufacturers to act as an agent on behalf of the manufacturer or group of manufacturers to operate and implement a drug take back program.

Q5: Can you clarify the definition of a “Covered drug”?

A5: “Covered drug” means any substance recognized as a drug under 21 USC § 321(g)(1), as amended, and any regulations promulgated thereunder that is sold, offered for sale, or dispensed in the state, whether directly or through a wholesaler, in any form including prescription and nonprescription drugs, drugs in medical devices and combination products, brand and generic drugs and drugs for veterinary use. It does not include used syringes, vitamins, or supplements, etc. For a full list of exclusions, please see drug take back regulations 10NYCRR §60-4.1(b).

Q6: What is a reverse distributor?

A6: A Reverse Distributor, pursuant to 10NYCRR, §60.4.1(k), means a person, company, corporation, or other entity that acquires controlled substances from another Drug Enforcement Administration (DEA) registrant or law enforcement agency for the purpose of destruction. Any person that reverse distributes a controlled substance shall be licensed by the New York State Department of Education and Department of Health as a distributor and registered with the DEA as a reverse distributor as defined in 21 CFR §1317.15.

OPERATIONS

Q7: Can interested pharmacies and/or authorized collectors still participate in a drug take back program?

A7: Yes, the drug take back operator/organization can add collection sites to its program at any time with notification to the Department.

Q8: Can a manufacturer or drug take back organization still submit a proposal to operate a drug take back program in accordance with drug take back regulations?

A8: Yes. A manufacturer or drug take back organization seeking approval to operate a drug take back program must submit a proposal to the Department utilizing the New York State Department of Health (NYSDOH) drug take back proposal template, which can be found at https://www.health.ny.gov/professionals/narcotic/docs/dtb_proposal.pdf. On June 8, 2022, the NYSDOH, in consultation with the Department of Environmental Conservation (NYSDEC), announced the approval of two drug take back programs by Inmar Rx Solutions and MED-Project, LLC. For more information on their programs, please visit: Inmar: www.safemedicinedrop.com and MED-Project: <https://med-project.org>.

Q9: How do manufacturers notify the Department upon contracting with a drug take back organization to operate a drug take back program on their behalf?

A9: A manufacturer who contracts with a drug take back organization must notify the Department by completing and submitting a Notification of Participation and Compliance which can be found on our Bureau's website located: [doh-5724.pdf \(ny.gov\)](#).

Q10: Will the Department have a list of NYSDOH-approved drug take back organizations for manufacturers who choose to enter into an agreement with an organization to operate a drug take back program on their behalf?

A10: Yes, there are currently two approved programs. For more information, please visit their websites directly:

Inmar: www.safemedicinedrop.com

MED-Project: <https://med-project.org>.

Q11: Will the Department have a list of manufacturers participating in the approved drug take back programs?

A11: Yes, please check the Bureau's website for updates: [Drug Take Back \(ny.gov\)](#)

Q12: Are Physicians' offices or Health Care Facilities required to dispose of expired samples through the drug take back program?

A12: No. Drug take back legislation does not require any individual or entity to utilize the drug take back program to dispose of unused or unwanted drugs. Other state and federal laws apply, and providers and facilities should consult their own legal counsel on compliance matters.

Q13: Are wholesalers required to provide the state with an ongoing list of manufacturers that produce covered drugs?

A13: Yes. The Department may request updated lists at its discretion.

Q14: For how long must drug take back operators maintain their records and reports?

A14: 5 years.

STANDARDS

- Q15:** What factors were considered in developing the convenience standards?
- A15:** The Department, in consultation with the NYSDEC, considered all relevant factors, including assessments of population and rural/underserved conditions, in developing the convenience standard, pursuant to §292.4 of the Public Health Law. In accordance with this legislation, the convenience standard applies to cities with a population of 125,000 or more.

MAIL BACK

- Q16:** Can a drug take back operator utilize a mail back program alone, without using collection receptacles, to meet the convenience standards?
- A16:** No. Mail back programs may be used as part of a drug take back operator's program, but not to satisfy the convenience standard.
- Q17:** Who can provide mail back supplies for the drug take back program?
- A17:** Any authorized collector may distribute mail back envelopes or vouchers as part of an approved drug take back program.
- Q18:** Are all pharmacies required to accept mail back packages/envelopes?
- A18:** No. Pharmacies are not permitted to accept mail-back envelopes that contain covered drugs unless it is registered as a collector with the DEA and uses an on-site method of destruction that complies with all applicable federal laws and regulations. Mail back envelopes are to be returned directly to the reverse distributor based on the terms of the contract/agreement and following the instructions that come with the envelope or voucher.

PHARMACIES

- Q19:** Who, in a participating pharmacy, may access the inner liner of a receptacle?
- A19:** Liners must be accessible only to employees of the pharmacy.
- Q20:** Pursuant to the Drug Take Back Act, will the costs associated with the receptacle be covered by drug manufacturers?
- A20:** If the pharmacy must be participating in the DTB program through an agreement with an approved operator. The Drug Take Back Act provides that all costs incurred by participating pharmacies and authorized collectors because of the drug take back programs required by the act must be paid or reimbursed by the manufacturers of covered drugs. A pharmacy or other authorized collector wishing to seek reimbursement must contract with an approved drug take back operator.
- Q21:** What is required for a pharmacy to begin offering on-site drug collection as part of the Drug Take Back Act?
- A21:** To offer on-site drug collection as part of the Drug Take Back Act, a pharmacy must be properly registered under section 6808 of the Education Law and must obtain a modified registration from the DEA to be a collector. Pharmacies must comply with all state and federal laws concerning the disposal of controlled substances. Finally, the pharmacy must join an approved Drug Take Back Program pursuant to an agreement with an operator.

For additional questions on the Drug Take Back Act, please email dtb@health.ny.gov.

For questions about approved programs, please contact the operators directly as they provide through their websites:

Inmar: www.safemedicinedrop.com

MED-Project: <https://med-project.org>