

SUMMARY OF EXPRESS TERMS

These regulations add a new Subpart 60-4 to Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, implementing the requirements of Article 2-B of the Public Health Law regarding the creation of a statewide drug take back program for the safe disposal of drugs.

Section 60-4.1 defines the terms used in the Subpart, including “authorized collector,” “covered drug,” and “drug take back organization.”

Section 60-4.2 establishes a convenience standard for cities with a population of 125,000 or more.

Section 60-4.3 requires operators of drug take back programs to submit proposals to the Department of Health which include enumerated requirements, and to update such proposals every three years. It also requires the operators to maintain records and to submit an annual report as required by the Department.

Section 60-4.4 imposes certain requirements on pharmacies that maintain a drug collection receptacle.

Section 60-4.5 establishes security requirements for drug collection receptacles.

Section 60-4.6 establishes requirements for pharmacies that participate in a drug mail back program.

Section 60-4.7 establishes general requirements, including notifying the Department of any change to a drug take back program as well as the requirement that upon request, wholesalers of covered drugs must provide the Department with updated lists of manufacturers whose covered drugs they sell.

Subparagraph (6) is added to paragraph (c) of section 80.51 to clarify the requirements for the transfer of controlled substances by a residential health care facility to an authorized collection receptacle.

Pursuant to the authority vested in the Commissioner of Health by sections 291 and 3308 of the Public Health Law, Subpart 60-4 of Part 60 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is added, and sections 80.51 is amended, to be effective upon publication of a Notice of Adoption in the State Register, to read as follows:

Subpart 60-4 DRUG TAKE BACK

Section 60-4.1. Definitions

For purposes of this Subpart, the following terms shall have the following meanings.

(a) “Authorized collector” means

- (1) a person, company, corporation or other entity that is registered with the DEA to collect controlled substances for the purposes of safe disposal and destruction; or
- (2) a law enforcement agency; or
- (3) a person, company, corporation or other entity authorized by the Department to provide alternative collection methods for covered drugs that are not controlled substances.

(b) “Covered drug” shall have the same meaning as defined in section 290 of the Public Health Law; provided, however, that “covered drug” shall not include the following:

- (1) vitamins or supplements;
- (2) herbal-based remedies and homeopathic drugs, products or remedies;
- (3) cosmetics, soap (with or without germicidal agents), laundry detergent, bleach, household cleaning products, shampoos, sunscreens, toothpaste, lip balm, antiperspirants or other personal care products that are regulated as both cosmetics and drugs by the FDA;

- (4) pet pesticide products contained in pet collars, powders, shampoos, topical applications, or other forms;
 - (5) drugs that are biological products as defined in subdivision twenty-seven of section 6802 of the Education Law if the manufacturer already provides a take back program;
 - (6) veterinary biological products regulated by the United States Department of Agriculture;
 - (7) drugs for which a manufacturer provides a take back program as part of a FDA managed risk evaluation and mitigation strategy;
 - (8) emptied injector products, emptied medical devices, including dialysis bags and solutions, and their component parts or accessories;
 - (9) medical marihuana as defined in section 3360 of the Public Health Law; and
 - (10) drugs that are used solely in a clinical setting.
- (c) “DEA” means the Drug Enforcement Administration of the United States Department of Justice, or its successor agency.
- (d) “Drug take back organization” 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.
- (e) “FDA” means the Food and Drug Administration of the United States Department of Health and Human Services, or its successor agency.
- (f) “Manufacturer” means a person, company, corporation or other entity engaged in the manufacture of covered drugs, or, a person, company, corporation, or other entity using a contract manufacturing organization for the manufacture of covered drugs, sold in the

state. “Manufacturer” includes a virtual manufacturer but does not include a repackager or wholesaler.

(g) “Operator” means any manufacturer, individually or jointly, or a drug take back organization, that implements or operates an authorized drug take back program.

(h) “Pharmacies” means all pharmacies registered under section 6808 of the Education Law that are:

(1) part of a group of ten or more pharmacies under common ownership or management, or

(2) part of a group of ten or more pharmacies linked to the same company via franchise agreements; or

(3) non-resident pharmacies registered pursuant to section 6808-b of the Education Law that provide covered drugs to state residents by mail; or

(4) located in the State and that, though not required to by Article 2-B of the Public Health Law, voluntarily participate in an authorized drug take back program.

(i) “Population” means the total population of a given city, or a given county in the City of New York, according to the most recent decennial United States Census.

(j) “Repackager” means an entity that owns or operates an establishment that repacks and relabels a product or package containing a covered drug for further sale or for distribution without further transaction.

(k) “Wholesaler” means any person, company, corporation or other entity that sells or distributes drugs and covered drugs for resale to an entity in the state other than a consumer.

Section 60-4.2. Convenience Standards for Certain Cities and Counties

- (a) Authorized drug take back programs must offer a minimum number of collection receptacles in cities and certain counties with a population of 125,000 or more, according to the following convenience standards:
- (1) For the City of Buffalo: at least one on-site collection receptacle per 10,000 population.
 - (2) For the City of Rochester: at least one on-site collection receptacle per 10,000 population.
 - (3) For the City of Syracuse: at least one on-site collection receptacle per 10,000 population.
 - (4) For the City of Yonkers: at least one on-site collection receptacle per 10,000 population.
 - (5) For New York County: at least one on-site collection receptacle per 10,000 population.
 - (6) For Richmond County: at least one on-site collection receptacle per 10,000 population.
 - (7) For Queens County: at least one on-site collection receptacle per 15,000 population.
 - (8) For Kings County: at least one on-site collection receptacle per 20,000 population.
 - (9) For Bronx County: at least one on-site collection receptacle per 20,000 population.
- (b) On-site collection receptacles shall be evenly distributed throughout the above cities and counties with regard to geography and population density, as approved by the Commissioner. Collection receptacles maintained by law enforcement agencies in each of the above jurisdictions shall be eligible for inclusion to meet the applicable convenience standard.
- (c) (1) If a pharmacy with an on-site collection receptacle permanently closes or relocates, or if a law enforcement agency relocates or discontinues its maintenance of a collection receptacle, such that a convenience standard is no longer met, the operator of the drug take back program responsible for the relocated or discontinued collection receptacle shall be required to add an on-site collection receptacle to another pharmacy or law enforcement agency in a

manner consistent with this Subpart and appropriate to ensure the applicable convenience standard continues to be met.

(2) The operator shall have thirty days from the date of discontinuance or relocation of the collection receptacle to meet the convenience standard by adding the new collection receptacle.

(3) The operator shall have 15 days from the addition of the new collection receptacle to provide written notice to the Department of the change. Such notice shall provide the location of the original collection receptacle and the date of its discontinuance or relocation; the location of the new collection receptacle and the date of its availability to the public; and an affirmation that the operator's drug take back program continues to meet the applicable convenience standard.

Section 60-4.3. Drug Take Back Programs

Operators of Drug Take Back Program.

- (a) Before implementing or modifying a drug take back program, an operator must submit a proposal to, and obtain approval of such program from, the Department, in consultation with the Department of Environmental Conservation. Drug take back program proposals shall be submitted to the Department in such a manner and form as determined by the Department.
- (b) A drug take back program proposal shall include, but is not limited to, the following:
 - (1) The name, address, phone, e-mail address, and any additional contact information requested by the Department for the responsible person submitting the planned drug take back program and to whom the Department may direct all inquiries;

- (2) Certification that the drug take back program will accept all covered drugs regardless of who produced them;
- (3) A detailed description of the drug take back collection system which includes:
information on geographic distribution (and specifically how it ensures access in rural and underserved areas), convenience for all consumers across the state, and ongoing services of the program;
- (4) A detailed description of how pharmacies providing collection boxes for take back in areas outside of the counties with convenience standards will be included in the program.
- (5) The name, address, phone, e-mail address, DEA number, and Bureau of Narcotic Enforcement license number, for any entity that will reverse distribute covered drugs for the drug take back program;
- (6) 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;
- (7) A description of other approved collection methods, including drug take back events, that will be utilized to collect covered drugs;
- (8) Detailed policies and procedures on how the 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 meeting federal requirements;

- (9) 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;
- (10) Detailed descriptions of how the effectiveness of public education and outreach activities of the drug take back program will be evaluated;
- (11) Detailed information on how the costs of pharmacy collection and other authorized collectors of the 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 bags of waste collected, 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;
- (12) A detailed drug take back program timeline for implementation, including specific expected dates;
- (13) Detailed information on the methods to be used for outreach and participation by pharmacies and other authorized collectors;
- (14) 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, this must include the weight of covered drugs collected, a description of collection activities, the names and locations of all collection sites with collection method and weight collected by method, and the public education and outreach activities;

- (15) A detailed list of manufacturers that are partners in the proposed drug take back program which includes: 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, and any additional identifiers as requested by the Department;
- (16) Detailed information on how the operator will identify and resolve safety and security issues arising from the collection, transportation or disposal of covered drugs; and
- (17) Any additional information as required by the Department to evaluate the proposal.
- (c) A drug take back program operator must update its proposal and submit it to the Department at least every 3 years, from the date of the previous Department approval, in such a manner and form as determined by the Department.
- (d) An operator of a drug take back program shall maintain records of program details that include participating manufacturers, authorized collectors, and functions performed in accordance with such program, including but not limited to the following:
- (1) The name of the manufacturer, name of the manufacturer's parent company and any subsidiaries, mailing address, FDA labeler code and DEA number, as applicable, for each manufacturer of covered drug(s) contracted with the drug take back program and the date enrolled,
- (2) The name, address, phone, e-mail address, DEA number, and Bureau of Narcotic Enforcement license number, for any entity that will reverse distribute covered drugs for the drug take back program;
- (3) The name and address of each location in which a collection receptacle is installed and the date of its installation, as well as the dates of its discontinuance, removal, or relocation;

- (4) The name and address of each location providing mail back packages, and the date initiated;
 - (5) The total weight of covered drugs collected by each collection method annually; and
 - (6) Any other details as the Department may direct.
- (e) A report shall be made within 30 days to the Department upon the discontinuance of participation in the program by any manufacturer of covered drug(s) or authorized collector.
- (f) A report in such form as the Department directs shall be made annually to the Department, on or before August 1, detailing for the preceding calendar year all program activities, including but not limited to the following:
- (1) A list of manufacturers that participated during the reporting period that includes: name of parent company and/or subsidiary(ies), address, FDA labeler code and DEA number, as applicable, for each manufacturer of covered drug(s) contracted with the drug take back program and the date enrolled;
 - (2) The name, address, phone, e-mail address, DEA number, and Bureau of Narcotic Enforcement license number, for any entity that reverse distribute covered drugs for the drug take back program;
 - (3) A list of all pharmacies and other authorized collectors that maintained collection receptacles across the state during the reporting period that includes: DEA number, Education Department registration number (if applicable), name, address, total weight collected by method of collection, and the number of times each collection receptacle liner was replaced;
 - (4) A list of pharmacies and other authorized collectors that provided mail back envelopes and/or packages during the reporting period that includes: DEA number, Education

Department registration number (if applicable), name, address, process for patient accessing mail back envelopes or packages, number of vouchers and/or mail back envelopes and/or packages utilized, and total weight collected by mail back envelope and/or package;

- (5) A list of drug take back events held during the reporting period that includes: date of event, name of authorized collector, address, and total weight collected per event;
- (6) Total weight of covered drugs collected by method of collection, and by location address, as well as aggregate weights for each of the 62 counties of New York State and the cities of Buffalo, Rochester, Syracuse, and Yonkers;
- (7) Description of collection activities, including policies and procedures for methods of collection;
- (8) Description of program's statewide outreach and public education activities, including marketing materials, public service messages, and website information;
- (9) Evaluation of the program and of each collection method, including an evaluation of education and outreach, an evaluation of program costs and of costs involved for each method and suggestions for overall program improvement;
- (10) A list of manufacturers and authorized collectors that have discontinued participation; and
- (11) Additional information as determined by the Department.

Section 60-4.4. Pharmacies Engaged in Drug Take Back

Pharmacies participating in drug take back shall:

- (a) Be properly registered under section 6808 of the Education Law or, in the case of non-resident pharmacies, be registered under section 6808-b of the Education Law.
- (b) Obtain a registration for Disposal of Controlled Substances for a collection receptacle, or mail back program, or both collection receptacle and mail back program from the DEA.
- (c) Comply with all federal laws and regulations concerning the disposal of controlled substances.
- (d) Notify the Department within 30 days of drug take back program discontinuance.
- (e) If maintaining a collection receptacle:
 - (1) Utilize a collection receptacle that meets the requirements of section 60-4.5 of this Subpart and all applicable federal laws and regulations.;
 - (2) Collection receptacle placement:
 - i. Receptacles accessible to the public, shall be located in the immediate proximity of the registered pharmacy area where prescription drugs are stored and be easily and continuously monitored by the pharmacist or pharmacy staff; or
 - ii. receptacles located in a residential health care facility shall be located in a secured area regularly monitored by residential health care facility employees.
 - (3) Ensure proper operation of the collection receptacle, which includes but is not limited to periodic monitoring to determine when it is full; removing and replacing the inner liner when it is full; and contacting the reverse distributor to arrange for liner pickup;
 - (4) Ensure that receptacle box liners that are removed are safely and securely stored until retrieved by the reverse distributor;

- (5) Ensure that pharmacy employees do not handle drugs for disposal, review the contents of the collection receptacle, remove, count, weigh, consume, repurpose, restock, redispense, resell, or touch items placed in the collection receptacle;
- (6) Ensure the sealed inner liners and their contents are shipped to a reverse distributor's registered location by common or contract carrier or by licensed reverse distributor pick-up at the licensed pharmacy's or residential health care facility's premises;
- (f) Report to the Department immediately, and in any event within 24 hours of discovery of tampering with, or damage to, a collection receptacle, or diversion or theft of deposited contents, or any tampering with, damage to, or theft of a removed liner.

Section 60-4.5. Pharmacy Collection Receptacles

Every pharmacy collection receptacle maintained at participating pharmacies and residential health care facilities shall:

- (a) Be securely fastened to a permanent structure so that it cannot be removed without authorization;
- (b) Be a securely-locked, substantially-constructed container with a permanent outer container and a removable inner liner;
- (c) Feature an outer container which shall include a small opening that allows contents to be deposited into the inner liner, but which does not allow removal of the inner liner's contents;
- (d) Display signage describing items eligible and not eligible for deposit in the collection receptacle;
- (e) Use inner liners which shall meet the following requirements:
 - (1) Be waterproof, tamper-evident, and tear-resistant;

- (2) Be removable and sealable immediately upon removal without emptying or touching the contents;
 - (3) The contents of the inner liner shall not be viewable from the outside when sealed;
 - (4) The size of the inner liner shall be clearly marked on the outside of the liner (e.g., 5-gallon, 10-gallon, etc.); and
 - (5) The inner liner shall bear a permanent, unique identification number that enables the inner liner to be tracked.
- (f) Only employees of the pharmacy may access the inner liner.
 - (g) The inner liner, immediately upon removal from the permanent outer container, shall be sealed by two pharmacy employees, except that in a residential health care facility it may be sealed by one pharmacy employee and one New York State licensed healthcare professional employed by the residential health care facility. The sealed inner liner shall not be opened, x-rayed, analyzed, or otherwise penetrated. If the inner liner is not removed from collection receptacle and released to common or contract carrier on the same day, the collection receptacle liner must be safely secured and stored.
 - (h) Pharmacies shall maintain a record that includes the date of sealing, the names of the two pharmacy employees who performed the sealing, the date of removal, and the unique identification number of the liner.
 - (i) Pharmacy employees may not handle drugs for disposal, review contents of collection receptacle, remove, count, weigh, consume, repurpose, restock, redispense, resell, or touch items placed in collection receptacle.
 - (j) Installation, removal, transfer, and storage of inner liners must be performed in compliance with all applicable state and federal laws and regulations.

Section 60-4.6. Mail back envelopes and packages

- (a) Pharmacies that provide a mail back option as part of a drug take back program and all non-resident pharmacies that distribute covered drugs to residents by mail shall:
 - (1) provide a prepaid package or envelope, or
 - (2) provide a voucher for a prepaid package or envelope, which includes patient education regarding the drug take back program and safe drug disposal methods, upon dispensing a covered drug. Patients shall be directed to mail their unused drugs using the packages or envelopes.
- (b) Mail back packages and envelopes shall be preaddressed with the address of a collector registered with the DEA, or its successor agency, and the cost of shipping must be prepaid. The exterior of the package must be nondescript; water- and spill-proof; tamper-evident; tear-resistant; sealable; and have a unique identification number that enables each package to be tracked.
- (c) A pharmacy shall not accept any mail back packages or envelopes that contain covered drugs unless it is registered as a collector with the DEA, or its successor agency, and uses an on-site method of destruction that complies with all applicable federal laws and regulations.

Section 60-4.7. General Requirements

- (a) Recordkeeping requirements.
 - (1) Records of all transactions concerning the disposal of covered drugs required to be kept by manufacturers, drug take back organizations, pharmacies and other authorized collectors shall be kept for a period of five years from the date of the transaction.

- (2) Records and invoices required by this Subpart shall be readily available and promptly produced for inspection and copying upon request by authorized representatives of the Department's Bureau of Narcotic Enforcement, or the Department of Environmental Conservation.
- (b) Upon request by the Department, a wholesaler shall provide the Department with a list of manufacturers that produce the covered drugs it sells or distributes for resale in New York State.
- (c) A manufacturer must notify the Department upon contracting with an organization to operate a drug take back program on its behalf, in a manner and in such form as determined by the Department; upon the manufacturer's discontinuance of participation in a drug take back program; upon the manufacturer's changing of participation from one drug take back program to another; and upon discontinuance of the sale of the manufacturer's covered drugs in the state. Such notices to the Department shall be in writing and may be electronic, and shall occur within 15 days of the date of the applicable incident.
- (d) A manufacturer who begins to offer a covered drug must notify the Department of its joining an existing approved drug take back program, or submit a proposal for a drug take back program within ninety days following the initial offer for sale of a covered drug.

Subparagraph (5) of Paragraph (c) of section 80.51 is amended and a new subparagraph (6) of Paragraph (c) of section 80.51 is added to read as follows:

- (5) surrender the controlled substances to the federal Drug Enforcement Administration, or its successor agency[.]; or

(6) transfer such controlled substances into an authorized collection receptacle, located at the residential health care facility and maintained by a properly licensed and registered pharmacy, no longer than three business days after discontinuation.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (PHL) Article 2-B and Chapter 120 of the Laws of 2018 require and authorize the Commissioner of Health to adopt rules and regulations implementing a statewide drug take back program for the safe disposal of drugs. Further, the Commissioner is authorized by section 3308 of the Public Health Law to make any regulations necessary or proper to supplement the provisions of PHL Article 33, or to effectuate the purposes and intent thereof or to clarify its provisions.

Legislative Objectives:

The legislative objective of PHL Article 2-B and Chapter 120 of the Laws of 2018, otherwise known as the Drug Take Back Act, is to promote the safe disposal of drugs, remove excess medication from households to avoid abuse, and to reduce the amount of drugs entering the State's water supply, by making drug take back programs more accessible.

The purpose of PHL Article 33 is to prevent the illegal use of and trade in controlled substances and to provide for the legitimate use of controlled substances in health care.

Needs and Benefits:

Prescription drug abuse has become an epidemic in New York State and across the nation. It is well known that the first supply of opioids is often leftover medication a family member or friend received and did not use. Drug-related deaths in New York increased by 40% to 2,175 deaths between 2009 and 2013. In 2016, approximately 64,000 Americans died of drug overdoses, with more than half of those involving prescription drugs. Recent literature reports

that removing unneeded pharmaceuticals from homes can reduce the risk of both intentional and accidental nonmedical use, overdose, and poisoning.

Further, the lack of an easily accessible, proper disposal method for pharmaceuticals has also affected our environment. Pharmaceuticals have been detected in bodies of water across the United States, with recent studies finding pharmaceuticals in both the Niagara and Hudson Rivers. The environmental effects of this contamination include changes to the spawning ability of fish and the evolution of antibiotic resistant strains of bacteria. In addition, the long-term effects on humans of drinking water containing low levels of pharmaceuticals are not fully understood.

To address these issues, Governor Cuomo signed the Drug Take Back Act, which creates a statewide drug take back program to ensure these and other drugs are not diverted for misuse or improperly disposed by flushing or other means that results in harm to our water supply and harms aquatic life. This program will provide for a unified, statewide drug take back program, to be paid for by manufacturers, and require participation of chain and mail-order pharmacies. Manufacturers are responsible for all costs from public education and awareness, to collection, transport and destruction. Pharmacies will provide methods for convenient drop-off and collection.

The Drug Take Back Act also requires the Department to establish a statewide on-site collection receptacle distribution plan, otherwise known as a “convenience standard,” for any city with a population of 125,000 or more, to ensure on-site collection receptacle placement is reasonably accessible to all residents and provides for program cost efficiency. New York State is extremely diverse geographically and population numbers differ significantly across these cities. The number of chain pharmacies located in these cities is also not uniform, so some areas

may have a greater number of chain pharmacies and therefore potentially offer greater accessibility to on-site collection receptacles than others.

For example, Queens County has a population of 2,230,545 and has 156 chain pharmacies, while Syracuse has a population of 145,170 and has 20 chain pharmacies. Therefore, Queens County has a pharmacy to population ratio of 1:14,298, whereas Syracuse has a ratio of 1:7,286. Based on this analysis, Syracuse residents have access to nearly twice as many chain pharmacies as residents in Queens.

To address this variability and complexity, the Department determined that a statewide, universal convenience standard would not be effective, nor would it ensure the goals of the Act are fully achieved. Thus, these regulations create a convenience standard specific to the city or county's population and geography.

Costs:

Costs to Regulated Parties:

In accordance with PHL Article 2-B, the proposed regulations would require that drug manufacturers, individually or jointly, enter into an agreement to operate a drug take back program. Manufacturers shall bear all administrative and operational fees associated with the drug take back program, including the cost of collecting, transporting and disposing of covered drugs from pharmacies and other authorized collectors and the recycling or disposal, or both, of packing collected with the covered drug. Manufacturers shall also pay costs incurred by the state in the administration and enforcement of the drug take back program.

The drug take back program operates in pharmacies, which must either maintain a collection receptacle to receive covered drugs for disposal from the public, or offer a mail-back solution. There will be costs to pharmacy owners in the forms of lost retail or advertising space occupied by the collection receptacle and signage required by the Drug Take Back Act, as well as costs in staff time and resources to maintain, secure, and monitor collection receptacles. Pharmacies not required by the Drug Take Back Act to participate in a drug take back program, but who currently voluntarily participate in the Department of Environmental Conservation's Pilot Pharmaceutical Take-Back Program, may face similar additional costs. Pharmacies may also incur a cost to obtain or modify a Drug Enforcement Administration registration.

Costs to State Government:

The State will incur the initial costs of administration and enforcement of the Drug Take Back program.

Costs to Local Governments:

There will be no additional costs to local government as a result of the proposed amendment.

Costs to the Department of Health:

The Department is increasing staff and equipment to implement and enforce the Drug Take Back Act in coordination with the Department of Environmental Conservation. These staff and equipment are necessary to perform numerous activities including but not limited to communicating with wholesalers, manufacturers, pharmacies, drug take back program

organizations and operators, and the public, evaluating program applications, maintaining the Department's drug take back program website, reviewing program data, preparing the annual report, and coordinating enforcement activities. In total, the Department anticipates incurring costs for approximately 5-10 FTE's in total for implementation and enforcement.

Local Government Mandates:

This amendment will not impose any program, service, duty, additional cost, or responsibility on any county, city, town, village, school district, fire district, or other special district.

Paperwork:

The proposed regulations will require operators of drug take back programs to submit a proposal to the Department for drug take back to be approved every three years, maintain records, and submit annual reports on the operation of their plans, under Article 2-B of the Public Health Law as described above. The reporting may be electronic; no paper reports will be required. Pharmacies will be required to maintain records of their administration of the collection receptacles and mail-back solutions. Upon request of the Department, wholesalers must provide updated lists of the manufacturers whose covered drugs they sell in New York State. The Department must produce an annual report to the Governor and State Legislature about the Drug Take Back program.

Duplication:

There are no duplicative or conflicting rules identified.

Alternatives:

The Department is required by the Drug Take Back Act to issue regulations creating a distribution plan establishing convenience standards for collection receptacles in cities with populations of 125,000 or more. The Department considered distribution plans with fewer collection receptacles but determined, in consultation with the Department of Environmental Conservation, that they were not sufficient to address the needs of the impacted communities. The Department has limited this rulemaking to address the convenience standards of each jurisdiction by population and geography, thereby maximizing the freedom of drug take back programs to operate as effectively and efficiently as possible.

The Department is further authorized to adopt regulations as necessary to implement and enforce the Drug Take Back Act. Because the remaining regulations provide definitional clarity, establish standards of compliance for various aspects of drug take back programs, and help to prevent the diversion, theft and misuse of drugs disposed in accordance with the Drug Take Back Act, they are necessary to implement and enforce the Drug Take Back Act.

Federal Standards:

The regulatory amendment does not exceed any minimum standards of the federal government.

Compliance Schedule:

The proposed regulation will take effect upon a Notice of Adoption in the New York State Register.

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**STATEMENT IN LIEU OF
REGULATORY FLEXIBILITY ANALYSIS**

No regulatory flexibility analysis is required pursuant to section 202-(b)(3)(a) of the State Administrative Procedure Act. The proposed amendment applies only to pharmacies within a chain of ten or more locations and thus does not impose an adverse economic impact on small businesses or local governments, and it does not impose reporting, record keeping or other compliance requirements on small businesses or local governments. While not mandated under these regulations, pharmacies that are not part of a chain may choose to operate a drug take back program and would incur any associated costs with that program.

RURAL AREA FLEXIBILITY ANALYSIS

Effect on Rural Areas:

Rural areas are defined as counties with populations less than 200,000 and, for counties with populations greater than 200,000, include towns with population densities of 150 persons or less per square mile. The following 43 counties have populations of less than 200,000:

Allegany	Hamilton	Schenectady
Cattaraugus	Herkimer	Schoharie
Cayuga	Jefferson	Schuyler
Chautauqua	Lewis	Seneca
Chemung	Livingston	Steuben
Chenango	Madison	Sullivan
Clinton	Montgomery	Tioga
Columbia	Ontario	Tompkins
Cortland	Orleans	Ulster
Delaware	Oswego	Warren
Essex	Otsego	Washington
Franklin	Putnam	Wayne
Fulton	Rensselaer	Wyoming
Genesee	St. Lawrence	Yates
Greene		

The following eleven counties have certain townships with population densities of 150 persons or less per square mile:

Albany	Monroe	Orange
Broome	Niagara	Saratoga
Dutchess	Oneida	Suffolk
Erie	Onondaga	

The proposed regulation affects three cities located in rural counties of the State. The City of Rochester is located in Monroe County. Operators of drug take back programs will be required to offer one collection receptacle per 10,000 population in these cities. There are currently 6 collection receptacles available in the city. Under the proposed regulations, the city shall have 21 receptacles, for a total of 15 new receptacles to be added. The City of Syracuse is located in Onondaga County. There are currently 4 collection receptacles available in the city. Under the proposed regulations, the city shall have 15 receptacles, for a total of 11 new receptacles to be added. The City of Buffalo is located in Erie County. There are currently 17 collection receptacles available in the city. Under the proposed regulations, the city shall have 26 receptacles, for a total of 9 new receptacles to be added.

While not mandated under these regulations, pharmacies in rural areas that are not part of a chain may choose to operate a drug take back program and would incur any associated costs with that program.

Reporting, Recordkeeping and Other Compliance Requirements; and Professional Services:

The proposed regulations will require operators of drug take back programs to submit a proposal to the Department for drug take back to be approved every three years, maintain records, and submit annual reports on the operation of their plans, under Article 2-B of the Public Health Law as described above. The reporting may be electronic; no paper reports will be required. Pharmacies will be required to maintain records of their administration of the collection receptacles and mail-back solutions. Upon request of the Department, wholesalers must provide updated lists of the manufacturers whose covered drugs they sell in New York State. The Department must produce an annual report to the Governor and State Legislature about the Drug Take Back program.

Costs:

The drug take back program operates in pharmacies, which must either maintain a collection receptacle to receive covered drugs for disposal from the public, or offer a mail-back solution. There will be costs to pharmacy owners in the forms of lost retail or advertising space occupied by the collection receptacle and signage required by the drug take back act, as well as costs in staff time and resources to maintain, secure, and monitor collection receptacles. Pharmacies not required by the Drug Take Back Act to participate in a drug take back program, but who currently voluntarily participate in the Department of Environmental Conservation's Pilot Pharmaceutical Take-Back Program, may face similar additional costs. Pharmacies may also incur a cost to obtain or modify a DEA registration. The proposed regulation may result in

minimal costs to pharmacies in rural areas, which will be the same as the costs expected in non-rural areas.

Minimizing Adverse Impact:

The impact of this proposal is expected to be minimal. It is designed to encourage efficiency for regulated entities by permitting operators to submit drug take back proposals consistent with their own business needs and scope, so long as they meet the statutory and regulatory requirements. Costs are statutorily imposed upon drug manufacturers. The Department has proposed a convenience standard for each city with a population of 125,000 or more, but the Drug Take Back Act does not require one for rural areas and the Department does not propose one. The option of a mail-back solution will help patients in rural areas to dispose of medications in a convenient and cost-effective manner. Finally, a DEC pilot project already in effect has helped to familiarize many participants with the concepts of drug take back programs. Many regulated entities are already participating in drug take back on a voluntary basis through the DEC pilot project.

Rural Area Participation:

The Department conducted various forms of outreach about the Drug Take Back Act, including presentations, meetings and conference calls, some of which were attended by rural participants. The Department also conducted interagency discussions with the Department of Environmental Conservation. As a result of these efforts, the Department received and considered comments and feedback from pharmacy owners who operate in rural areas as well as environmental advocates active on behalf of rural areas, and drug take back program operators

with experience in rural areas of other states. Finally, the proposed regulation will have a 60-day public comment period.

**STATEMENT IN LIEU OF
JOB IMPACT STATEMENT**

A Job Impact Statement for these amendments is not being submitted because it is apparent from the nature and purposes of the amendments that they will not have a substantial adverse impact on jobs and/or employment opportunities.