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

(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) “Reverse Distributor” means a person, company, corporation or other entity that is licensed by the New York State Department of Education and Department of Health as a distributor, and registered with the DEA to acquire controlled substances from another DEA registrant or law enforcement agency for the purpose of destruction.

(l) "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 ninety 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 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;

(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 tack 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. If the discontinuance involves an authorized collector in a city or county described in §60-4.2(a), the report must state the resulting impact on the convenience standard.

(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

Notwithstanding any provision of section 60-4.1, for the purposes of this section, a pharmacy shall also include any pharmacy located in the state and that, though not required to by Article 2-B of the Public Health Law, voluntarily participates in an authorized drug take back program. 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) If maintaining an onsite collection receptacle, modify existing registration to obtain authorization from the DEA to be a collector.

(c) Comply with all federal laws and regulations concerning the disposal of controlled substances.

(d) Notify the Department and any contracted drug take back program operator, as applicable, within 30 days of drug take back program discontinuance or change of address of collection activity.

(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 regularly 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 arranging for delivery of sealed inner liners and their contents to a reverse distributor's registered location by common or contract carrier pickup or by reverse distributor pickup;

(4) Ensure that receptacle box liners that are removed are safely and securely stored until retrieved by the reverse distributor or by common or contract carrier;

(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. Collection Receptacles

(a) Every collection receptacle maintained at participating pharmacies and residential health care facilities shall comply with all applicable state and federal laws and regulations and:

1. Be securely fastened to a permanent structure so that it cannot be removed;
2. Be a securely-locked, substantially-constructed container with a permanent outer container and a removable inner liner;
3. 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; and
4. Display signage describing items eligible and not eligible for deposit in the collection receptacle.

(b) Inner liners shall meet the following requirements:

1. Be accessible only to employees of the pharmacy;

2. Be waterproof, tamper-evident, and tear-resistant;
3. Be removable and sealable immediately upon removal without emptying or touching the contents;
4. The contents of the inner liner shall not be viewable from the outside when sealed;
5. The size of the inner liner shall be clearly marked on the outside of the liner (e.g., 5-gallon, 10-gallon, etc.);
6. The inner liner shall bear a permanent, unique identification number that enables the inner liner to be tracked;
7. Immediately upon removal from the permanent outer container, be sealed by two pharmacy employees, except that in a residential health care facility it may be sealed by one pharmacy employee and one supervisory level New York State-licensed healthcare professional employed by the residential health care facility;
8. Shall not be opened, x-rayed, analyzed, or otherwise penetrated, and;
9. If at a pharmacy, be removed from a collection receptacle and retrieved by the reverse distributor or common or contract carrier on the same business day whenever possible. If not possible, it must be safely secured and stored at the pharmacy until retrieved by the reverse distributor or common or contract carrier; and
10. If at a residential healthcare facility, be removed from a collection receptacle and retrieved by the reverse distributor or common or contract carrier on the same business day whenever possible. If not possible, it must be safely secured and stored. Such storage shall not exceed three business days.

(c) Any pharmacy authorized by DEA to be a collector shall maintain a record that includes the date of sealing, the names of the two employees who performed the sealing, the date of removal, and the unique identification number of the liner.

(d) Pharmacy employees may not handle drugs for disposal, review contents of the collection receptacle, remove, count, weigh, consume, repurpose, restock, redispense, resell, or touch items placed in the collection receptacle.

(e) 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) Manufacturers, drug take back organizations, pharmacies and other authorized collectors shall maintain all records required by this Part for a period of five years.

(2) Records and invoices required by this Part 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 action.

(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.

SUMMARY OF ASSESSMENT OF PUBLIC COMMENT

The new Subpart 60-4 to Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, implements 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 covered drugs.

Following the assessment of public comments, the Department has determined that no substantive changes to the regulations were necessary, and no additional requirements were added or removed as a result of the comments received. Commenters included pharmacies, drug manufacturers and distributors, reverse distributors, drug take back program operators, waste collectors, nonprofit, environmental/trade organizations, local departments of health and other governmental agencies.

The Department responded to a large number of public comments received in the areas of convenience standards, pharmacy engagement and reporting requirements related to the creation of a drug take back program. The substance of each comment was reviewed, and comments were consolidated by topic.

The Department remains committed to the establishment of an accessible statewide program for the safe disposal of covered drugs at no cost to New York State consumers.

ASSESSMENT OF PUBLIC COMMENT

The New York State Department of Health (the Department) received ninety-seven comments from thirty-six entities and individuals regarding the proposed amendments to Title 10 of the New York Codes, Rules and Regulations and the addition of Subpart 60-4, Drug Take Back. The comments and the Department's responses are summarized below.

General Comments

Comment: Several commenters requested that the Department publish all comments received on the proposed regulations on its website.

Response: Pursuant to the State Administrative Procedure Act § 202(b), each agency shall publish and make available to the public an assessment of public comment. No changes were made to the proposed regulation as a result of this comment.

Comment: Several commenters requested that the Department expedite the timeline for program implementation.

Response: The Department must follow all rulemaking procedures governed by the State Administrative Procedure Act before program implementation. No changes were made to the proposed regulation as a result of this comment.

Comment: Several commenters requested that the state consider how it will share reporting data with local health departments and other agencies working on the opioid epidemic.

Response: The Department will collect information indicating the total weight of all covered drugs collected, by method of collection and by location address, as well as the aggregate weights for each of the 62 counties in New York State and the cities of Buffalo, Rochester, Syracuse, and Yonkers. The Department will share such data with counties and these cities as it becomes available. No changes were made to the proposed regulation as a result of this comment.

Comment: One commenter expressed concern that elements of the regulation have the effect of requiring participating entities to police each other for compliance and believes that each entity should be held accountable for its own activities.

Response: It is the responsibility of each entity to comply with all applicable state and federal laws and regulations. No changes were made to the proposed regulation as a result of this comment.

Comment: One commenter requested the Department include an exemption for non-resident pharmacies with sales under $10 million in the definition of pharmacy.

Response: The new subdivision at 10 NYCRR § 60-4.1(h) is consistent with Public Health Law § 290(4), which states all nonresident pharmacies providing covered drugs to NY residents by mail are included in the definition of a pharmacy, and does not allow for the exemption of certain non-resident pharmacies for any reason, including sales volume. No changes were made to the proposed regulation as a result of this comment.

Comment: Two commenters expressed concern that the proposed 10 NYCRR § 60-4.1(h)(4) definition of pharmacy differed substantially from § 290(4) of Article 2-B of the Public Health Law.

Response: The Department made a technical amendment to the proposed regulations to improve clarity. Specifically, the following provision was added to 10 NYCRR § 60-4.4:
"Notwithstanding any provision of section 60-4.1, for the purposes of this section, a pharmacy shall also include any pharmacy located in the State that, though not required to by Article 2-B of the Public Health Law, voluntarily participates in an authorized drug take back program."

Comment: One commenter expressed concern that the provision in proposed 10 NYCRR § 60-4.1(b)(10) stating that "drugs that are used solely in a clinical setting" may be misunderstood. This commenter also requested the addition of a definition of Residential Healthcare Facility.

Response: The Department finds proposed 10 NYCRR § 60-4.1(b)(10) consistent with Public Health Law § 290(2)(h). Guidance regarding covered drugs will be forthcoming. The definition of "residential health care facility" is contained in the Public Health Law. No changes were made to the proposed regulation as a result of this comment.

Comment: One commenter requested that the Department change the spelling of "marihuana" in proposed 10 NYCRR § 60-4.1 (b)(9) to "marijuana".

Response: The spelling of marihuana in proposed 10 NYCRR § 60-4.1(b)(9) is consistent with Title 5-A of Article 33 of the Public Health Law. No changes were made to the proposed regulation as a result of this comment.

Comment: One commenter requested clarification of the definitions of "Drug take back organization" and "Operator."

Response: The proposed 10 NYCRR § 60-4.1(d) definition of "Drug take back organization" consistent with Public Health Law § 290(5), and the proposed definition of "Operator" clear and concise. No changes were made to the proposed regulation as a result of this comment.

Comment: One commenter requested an explanation for the inclusion of the definition of "repackager" in proposed 10 NYCRR §60-4.1(j).

Response: The definition found in proposed 10 NYCRR § 60-4.1(j) is consistent with Public Health Law § 290(7). No changes were made to the proposed regulation as a result of this comment.

Comment: One commenter requested the Department add a definition of "collection receptacle" to proposed 10 NYCRR § 60-4.1.

Response: The use of "collection receptacle" throughout proposed Subpart 60-4 is in alignment with 21 CFR § 1317.75. To provide further clarification regarding collection receptacles, a technical amendment was made to 10 NYCRR § 60-4.5 as follows: "[Pharmacy] Collection Receptacles: (a) Every [pharmacy] collection receptacle maintained at participating pharmacies and residential healthcare facilities shall <u>comply with all applicable state and federal laws and regulations</u>…"

Comment: One commenter requested that the Department add a term to 10 NYCRR § 60-4.1 to define the entities that provide services for management of inner liners.

Response: The regulation, as proposed, outlines the requirements for the management of collection receptacles by the authorized collectors, as required by Article 2-B of the Public Health Law. These requirements are also consistent with that of 21 CFR §§ 1317.15 and 1317.55. No changes were made to the proposed regulation as a result of this comment.

Comment: One commenter requested the Department add a definition of "Reverse Distributor" to proposed 10 NYCRR §60-4.1.

Response: The Department made a technical amendment to the proposed 10 NYCRR § 60-4.1 to provide a definition of the term "Reverse Distributor."

Comment: One commenter requested the Department create an "Other Authorized Collector" definition that would apply to a non-mandated pharmacy voluntarily participating as an authorized collector. The commenter also requested the Department mandate manufacturers to pay for collection costs incurred by these establishments.

Response: Proposed 10 NYCRR § 60-4.1(h) (revised as described above) is consistent with PHL §§ 290(4) and 292(3). No changes were made to the proposed regulation as a result of this comment.

Comment: One commenter requested the Department add limitations on subcontracting in proposed 10 NYCRR § 60-4.1(d) such that at least fifty percent of the cost of program performance incurred for personnel shall be expended for employees of the organization.

Response: This comment is beyond the scope of the proposed regulations. No changes were made to the proposed regulation as a result of this comment.

Comment: Several commenters requested the Department add definitions of "Commissioner" and "Department" to proposed 10 NYCRR § 60-4.1.

Response: The Department notes that these terms are defined in 10 NYCRR 60-1.1. No changes were made to the proposed regulation as a result of this comment.

Comment: Several commenters stated that there should be a statewide convenience standard including a collection receptacle in all pharmacies (as defined in the Drug Take Back Act) and at least one collection receptacle in every village, town, city (regardless of population size), island and unincorporated community, in every county.

Response: Pursuant to PHL § 292(4), a convenience standard is only required for cities with a population over 125,000. Furthermore, the standards proposed in 10 NYCRR § 60-4.2 are intended to reflect local conditions, which would not be achieved by the use of a statewide standard. No changes were made to the proposed regulation as a result of this comment.

Comment: Several commenters proposed a much more relaxed convenience standard, while others expressed that the convenience standard should be more expansive. One commenter stressed the importance of requiring a convenience standard to ensure that collection services are made available to rural and underserved areas.

Response: The Department considered all relevant factors in developing the convenience standard, in consultation with DEC, pursuant to § 292(4) of the Public Health Law. The standard developed provides that receptacles are reasonably accessible to all residents while providing for program cost efficiency, consistent with Public Health Law §292(4). The convenience standard applies to cities with a population of 125,000 or more, yet program operators are required to demonstrate how their program provides convenient, ongoing collection services to all persons.

Comment: One commenter stated requirements for adding and removing collection receptacles are unnecessary and burdensome and that thirty days (stated in proposed regulation 10 NYCRR § 60-4.2(c)(2) is insufficient time to replace a kiosk (collection receptacle) and recommends extending that time restriction.

Response: A technical amendment was made to 10 NYCRR § 60-4.2(c)(2) to allow an operator ninety days to meet the convenience standard after a discontinuance of a collection receptacle.

Comment: One commenter interpreted the regulations to mean the Commissioner's approval is required for the method of distributing collection receptacles but not the addition or removal of individual receptacles (10 NYCRR § 60-4.2(b)).

Response: The regulation does not require the Commissioner's approval for the addition or removal of collection receptacles. No changes were made to the proposed regulation as a result of this comment.

Comment: One commenter stated that it would be overly burdensome for any drug take back program to identify and track programs being implemented by law enforcement.

Response: Program operators may, but are not required to, include collection receptacles maintained by law enforcement agencies to meet the applicable convenience standard. No changes were made to the proposed regulation as a result of this comment.

Comment: One commenter stated that drug take back organizations should cooperate in good faith to develop cost-efficient plans for covered drugs in the county or counties in which they operate and to minimize, where possible, operational redundancies.

Response: The Department acknowledges the comment. No changes were made to the proposed regulation as a result of this comment.

Comment: Two commenters stated that the federal Drug Enforcement Agency (DEA) must be notified of the physical locations of receptacles and recommended that the regulations be changed to require collectors to update their DEA Registration to state new locations of receptacles.

Response: Pharmacies and any authorized collectors are required to follow all applicable federal, state, and local laws and regulations. Revisions to 10 NYCRR § 60-4.4 were made to require pharmacies participating in drug take back programs and maintaining an onsite collection receptacle to modify their existing DEA registration to obtain authorization from the DEA to be a collector.

Comment: The Department received two comments that recommended program operators include a list of interested collectors in their proposals, in lieu of participating pharmacies, and to allow for the list to be changed at any time.

Response: PHL Article 2-B requires the Department to approve proposed collection programs based, in part, upon the list of *participating* locations. A Drug Take Back operator may request to modify its approved program to include additional participating pharmacies and authorized collectors. No changes were made to the proposed regulation as a result of these comments.

Comment: One commenter supported the limiting of reimbursement to certain collection and disposal costs as cited in 10 NYCRR § 60-4.3(b)(11), and favored pharmacies covering their own costs outlined in the Regulatory Impact Statement.

Response: The Department will evaluate each operator's proposal, which includes a description cost allocation. No changes were made to the proposed regulation as a result of these comments.

Comment: One commenter stated that the requirements in 10 NYCRR § 60-4.3(f)(9), pertaining to the evaluation of program costs, collection method costs and suggestions for program improvement were overly burdensome.

Response: The Department reviewed the proposed regulations and has limited the requirements to only those relevant factors necessary to operate and to evaluate the efficacy of the program and each collection method, as required by Public Health Law §291(7), and that the regulations were not overly burdensome. No changes were made to the proposed regulation as a result of this comment.

Comment: One commenter requested that any additional requirements imposed by the Department be established by new regulations. The commenter cited 10 NYCRR §60-4.3(b)(17) and §60-4.3(f)(11) which allow the Department to request "additional information."

Response: Under PHL Article 2-B the Department has the discretion to request additional information if deemed necessary. If additional information is required, the Department will exercise its discretion. No changes were made to the proposed regulation as a result of this comment.

Comment: One commenter expressed concern that information reported to the Department, pursuant 10 NYCRR § 60-4.3(f), stating the number of times each collection receptacle liner was replaced could be used to divert material from collection receptacles with frequent liner changes.

Response: The Department is sensitive to the publication of any information that could increase diversion and will treat such information accordingly, consistent with its mission to protect public health and safety. No changes were made to the proposed regulation as a result of this comment.

Comment: One commenter requested the removal of all requirements to list the manufacturers DEA number and replace that with information clarifying the scope of what is required, and the underlying reasons for such requirement(s).

Response: The Department is sensitive to the publication of any information that could increase diversion and will treat such information accordingly, consistent with its mission to protect public health and safety. All available corporate identifiers are requested to ensure compliance

among manufacturers. No changes were made to the proposed regulation as a result of this comment.

Comment: Two commenters inquired on the availability of Drug Take Back program forms.

Response: Further guidance regarding proposal requirements and forms will be forthcoming. No changes were made to the proposed regulation as a result of these comments.

Comment: One commenter stated that pharmacies will not want to participate in the program if they have to pay all costs up front and wait for reimbursement. The commenter recommended striking "reimbursement" from 10 NYCRR §60-4.3(b)(11) or providing a timeframe for when pharmacy reimbursements will be made.

Response: Public Health Law §292(3) provides that all pharmacy costs shall be paid or reimbursed by the manufacturer, jointly or individually, as part of the drug take back programs. The regulation gives the program operators the authority to decide how costs will be covered. No changes were made to the proposed regulation as a result of this comment.

Comment: One commenter expressed concern about having to supply the Department with detailed information on the operator's safety and security issues/plans under proposed regulation 10 NYCRR § 60-4.3(b)(16).

Response: The Department is sensitive to the publication of any information that could increase diversion and will treat such information accordingly, consistent with its mission to protect public health and safety. No changes were made to the proposed regulation as a result of this comment.

Comment: One commenter stated that a separate approval of a Drug Take Back program by the Department of Environmental Conservation (DEC) should not be required.

Response: Drug Take Back programs do not require a separate approval by DEC. Rather, PHL § 291(5) requires the Department to consult with DEC prior to issuing approvals. No changes were made to the proposed regulation as a result of this comment.

Comment: One commenter viewed the regulations as requiring the Drug Take Back organization to take on the obligation of other regulated entities. In addition, the commenter suggested replacing the word "Certification" with "Acknowledgement" in proposed regulation 10 NYCRR §60-4.3(b)(2).

Response: PHL § 291(2)(a) specifically requires proposed drug take back programs to certify that they will accept all covered drugs. No changes were made to the proposed regulation as a result of this comment.

Comment: One commenter recommended requiring proposed drug take back programs to include their "reverse distributor or 3PL license number" in their proposals submitted to the Department.

Response: Drug take back programs will be required to provide their Bureau of Narcotic Enforcement license number, which already captures the suggested information. No changes were made to the proposed regulation as a result of this comment.

Comment: One commenter wanted to know if pharmacies that sell covered drugs online were included in the proposed regulation.

Response: Yes, all covered drugs sold or dispensed in the state are included. Participating pharmacies can include resident and non-resident pharmacies.

Comment: One commenter suggested several additional forms of education and outreach activities that should be included in each drug take back program proposal.

Response: The regulations place no limit on education and outreach activities. The Department will evaluate the methods proposed by each program proposal. No changes were made to the proposed regulation as a result of this comment.

Comment: One commenter recommended the use of Generally Accepted Accounting Principles and Generally Accepted Auditing Standards, with respect to the requirements to include cost of pharmacy collection in drug take back program proposals.

Response: This comment is beyond of the scope of the proposed rule. No changes were made to the proposed regulation as a result of this comment.

Comment: One commenter expressed concern with the possibility that certain records submitted as part of a drug take back program proposal may be subject to public disclosure under the Freedom of Information Law.

Response: The Department is sensitive to the publication of any information that could increase diversion or is confidential or proprietary in nature, and will treat such information accordingly,

consistent with its mission to protect public health and safety, while complying with applicable laws. No changes were made to the proposed regulation as a result of this comment.

Comment: One commenter suggested the Department clarify that operators will ensure the Drug Take Back program allows for alternatives for participants; widespread public engagement; and back-up coverage; in addition, the operators will work together to lower costs through distribution and allocation of program expenses.

Response: The requirements in the proposed regulations will ensure robust and ongoing Drug Take Back collection activity. Manufacturers of covered drugs may work collectively to ensure cost efficient program operations. No changes were made to the proposed regulation as a result of this comment.

Comment: One commenter recommended including safety and security issues in each drug take back program's required annual reporting.

Response: Program operators are required to immediately report to the Department any tampering with, or damage to, a collection receptacle, or diversion or theft of deposited materials. No changes were made to the proposed regulation as a result of this comment.

Comment: One commenter recommended grammatical changes and clarifying language regarding the phrase "bags of waste collected" used in 10 NYCRR §60-4.3(b)(11).

Response: The Department has made a technical amendment to the proposed regulation, replacing the phrase "bags of waste collected" with the phrase "inner liners" to better reflect the

intent of the regulation. No other changes were made to the proposed regulation as a result of this comment.

Comment: One commenter requested that the Department add notification of potential authorized collectors to the Drug Take Back proposal requirements under 10 NYCRR §60-4.3(b).

Response: The Department made technical changes in 10 NYCRR 60-4.3 in response to this comment which require program operators to propose how they will notify other authorized collectors how to participate in the program and to report such efforts annually.

Comment: Several commenters requested clarification regarding the requirement for participating pharmacies to obtain a registration for Disposal of Controlled Substances from the DEA.

Response: The Department made technical amendments in 10 NYCRR 60-4.4(b) to clarify that pharmacies maintaining an onsite collection receptacle must modify their existing registration to obtain authorization from the DEA to be a collector.

Comment: One commenter expressed concern regarding the use of the term "secured area" in 10 NYCRR §60.4-4(e)(2)(ii) because it might limit ultimate users' access to collection receptacles in a residential health care facility.

Response: Proposed regulation 10 NYCRR §60.4-4(e)(2)(ii) is consistent with federal requirements for the use of collection receptacles in "secured areas" of residential health care

facilities. *See* 21 CFR §1317.75. No changes were made to the proposed regulation as a result of this comment.

Comment: One commenter stated that under proposed regulation 10 NYCRR § 60-4.4(e)(3), periodic monitoring of the collection receptacles' fullness would be considered "access" by the DEA, thus requiring the activity to be performed only by authorized personnel.

Response: The Department agrees that access to the inner liner shall be restricted to employees of the collector in accordance with state and federal laws and regulations, which is consistent with proposed regulations under 10 NYCRR §60.4-4.5. No changes were made to the proposed regulation as a result of this comment.

Comment: One commenter suggested, under proposed regulation 10 NYCRR §60-4.4(e)(2)(i), that the monitoring requirement of collection receptacles be changed from "continuously" to "regularly".

Response: The Department made a technical amendment as proposed by this comment.

Comment: Two commenters requested clarification regarding operation of collection receptacles and the roles of common carriers and reverse distributors.

Response: The Department made a technical amendment at 10 NYCRR §§ 60-4.4(e)(3) and (4) to provide clarification that pharmacies participating in drug take back programs must arrange for delivery of sealed inner liners and their contents to a reverse distributor's registered location by common or contract carrier pickup, as an alternative to pick up by the reverse distributor, and

must ensure that liners are secure until pick up either by the reverse distributor or a common or contract carrier.

Comment: One commenter requested the Department clarify the threshold for pharmacies reporting damage to a collection receptacle under 10 NYCRR § 60-4.4(f).

Response: The Department believes a threshold of damage to be reported would be impractical and subjective. No changes were made to the proposed regulation as a result of this comment.

Comment: Several commenters requested that proposed regulations 10 NYCRR § 60-4 specify compliance with the Secure and Responsible Drug Disposal Act of 2010, and the 2014 Final Rule for the Disposal of Controlled Substances.

Response: The proposed regulations require compliance with all relevant federal laws and regulations currently in effect, as well as any applicable laws or regulations that may be promulgated in the future. The CFR is updated annually and contains all federal rules in effect at the time of its publication. As such, referencing specific rules is unnecessary. No changes were made to the proposed regulation as a result of these comments.

Comment: Several commenters expressed concerns with proposed regulations regarding the physical requirements of collection receptacles, storage, security, and access to their inner liners, and the records associated with inner liners. Specifically, these commenters requested that the language under 10 NYCRR § 60-4.5 align more closely with the DEA regulations at 21 CFR Part 1317.

Response: The Department made technical amendments to § 60-4.5 to more clearly align the regulation with 21 CFR Part 1317.

Comment: Several commenters expressed concern regarding the convenience of, and access to mail back supplies for ultimate users, particularly in rural and underserved areas, under proposed regulation 10 NYCRR § 60-4.6(a).

Response: Nothing in the proposed regulations would prohibit an organization, including authorized collectors, from providing mail back supplies. Drug Take Back program operators' proposed programs must comply with all applicable state and federal laws and regulations. Mail-back programs must be described in detail and will be reviewed and assessed by the Department for compliance, functionality and convenience. No changes were made to the proposed regulation as a result of these comments.

Comment: One commenter requested that the Department clarify proposed regulations under 10 NYCRR § 60-4.6(a)(2) and (b) regarding the roles, responsibilities, and costs of the provision of vouchers and mail back envelopes and packages.

Response: The proposed regulations are consistent with the requirements pertaining to vouchers and mail back envelopes in PHL§ 292(1)(a)(ii) and § 292(5). In addition, pursuant to proposed regulation 10 NYCRR § 60-4.3(b)(11), costs of pharmacy collection must be described in detail in the Drug Take Back program operator's proposal, which will be reviewed and assessed by the Department for compliance with all applicable regulations. No changes were made to the proposed regulation as a result of this comment.

Comment: One commenter suggested that the term "voucher" be removed under proposed regulation at 10 NYCRR § 60-4.6(a)(2), stating that the distribution of mail back envelopes being dependent upon a voucher system would put an additional burden on the ultimate user to coordinate the disposal of pharmaceutical waste.

Response: PHL § 292(5) which requires the distribution of vouchers for pre-paid envelopes. No changes were made to the proposed regulation as a result of this comment.

Comment: One commenter expressed concerned with the term "packages" under proposed regulation 10 NYCRR § 60-4.3(f)(4), stating that "packages" could be interpreted to include products that are not traceable to final destruction.

Response: The terminology used in this regulation, including the term "package," is consistent with those used in the DEA's regulations at 21 CFR § 1317.70. No changes were made to the proposed regulation as a result of this comment.

Comment: Two commenters expressed concern regarding restrictions on the acceptance of mail back envelopes and packages by pharmacies.

Response: The proposed regulations at 10 NYCRR § 60-4.6(c) are consistent with federal regulations at 21 CFR §§ 1317.40 and 1317.70, which similarly restrict the ability of pharmacies to accept mail back envelopes. No changes were made to the proposed regulation as a result of these comments.

Comment: One commenter suggested that the term "pharmacy" be replaced with "authorized collector" under 10 NYCRR § 60-4.6(c), and that the regulation should include language mandating compliance with local laws.

Response: PHL § 294 preempts all local laws and regulations on drug disposal. The Department finds proposed regulation 10 NYCRR § 60-4.6(c) consistent with federal regulations at 21 CFR §1317.40 and §1317.70. No changes were made to the proposed regulation as a result of this comment.

Comment: One commenter suggested that the Department remove the term "mail back envelopes and/or packages" throughout proposed regulations 10 NYCRR 60-4 to more closely align with the voucher requirements under PHL Article 2-B. This revision would allow for vouchers to be the only option for mail back collection.

Response: The Department finds that the option (not requirement) to provide a physical mail-back envelope or package, upon the request of an ultimate user, will improve convenience and ultimately increase utilization of the drug take back program and is in keeping with the intent of the legislation. No changes were made to the proposed regulation as a result of these comments.

Comment: One commenter requested clarification on record-keeping and documentation requirements of 10 NYCRR § 60-4.7(a)(1) and (2) to ensure they are not overly burdensome, and suggested records to be kept for the period of time required by federal and state regulations.

Response: To align with PHL Article 33 controlled substance record-keeping requirements, the Department requires holding records on controlled substances for 5 years. The Department made technical amendments to 10 NYCRR § 60-4.7(a)(1) to clarify this requirement.

Comment: One commenter expressed that drug take back organizations may not enter into contracts with drug manufacturers, or that such contracts may be cumbersome as ownership and manufacturing roles change, prompting for multiple levels of departmental review. The commentor also suggested the use of "action" instead of "incident" in 10 NYCRR § 60-4.7(c).

Response: The use of the term "contract" is consistent with the requirements of the Drug Take Back Act. The Department finds 15 days is a reasonable time for notification. However, the Department made a technical amendment to change the word "incident" to "action."

Comment: Several commenters requested that all authorized collectors, including current operators of the DEC Pilot Program, be allowed to participate in the program at the covered drug manufacturers' expense.

Response: The Department will evaluate how the proposals submitted by the Drug Take Back program operators will account for the authorized collectors that are currently providing collection receptacles. No changes were made to the regulation in response to this comment.

Comment: Several commenters noted that the Act requires that manufacturers of covered drugs must pay all administration costs and that the State should not incur any costs to administer the program, including initial costs and the additional 5-10 personnel the Department of Health anticipates needing to hire for implementation and enforcement.

Response: While the Act requires the manufacturers to cover the costs incurred by the State in the administration and enforcement of the Drug Take Back program, it does not require

manufacturers to cover the cost of collection receptacles outside the manufacturer's own program. No changes were made to the regulation in response to this comment.