



## Committee on Infrastructure

~AGENDA~

Tuesday, May, 23, 2017

11:00 AM

Committee Chair: MaryJane Shimsky

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Committee Room, 148 Martine Avenue, 8th Floor, White Plains, NY 10601

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## CALL TO ORDER

## MINUTES APPROVAL

## I. ITEMS FOR DISCUSSION

1. **(ID # 10179) Resolution – PH-Establishing a Pharmaceutical Product Stewardship Program:**

A RESOLUTION to set a public hearing on "LOCAL LAW amending the Laws of Westchester County by adding a new Chapter 538 establishing a Pharmaceutical Product Stewardship Program." [Public Hearing set for \_\_\_\_\_; 2017 at \_\_\_\_\_; LOCAL LAW INTRO No.10035-2017]

2. **(ID # 10035) Local Law – LEGISLATORS SHIMSKY, BORGIA, BOYKIN, JENKINS, A. WILLIAMS, PARKER AND L. WILLIAMS: Local Law-Establishing a Pharmaceutical Product Stewardship Program:**

A proposed "LOCAL LAW" amending the Laws of Westchester County by adding a new Chapter 538 establishing a Pharmaceutical Product Stewardship Program.

## II. OTHER BUSINESS

Unfinished Business and any other agenda items to come before the Committee.

## III. RECEIVE & FILE

## ADJOURNMENT

**RESOLUTION NO. \_\_\_\_ – 2017**

RESOLVED, that this Board hold a public hearing pursuant to Section 209.141(4) of the Laws of Westchester County on Local Law Intro. No. \_\_\_\_ - 2017, entitled “A LOCAL LAW amending the Laws of Westchester County by adding a new Chapter 538 establishing a Pharmaceutical Product Stewardship Program.” The public hearing will be held at \_\_.m. on the \_\_\_\_ day of \_\_\_\_\_, 2017 in the Chambers of the Board of Legislators, 8th Floor, Michaelian Office Building, White Plains, New York. The Clerk of the Board shall cause notice of the time and date of such hearing to be published at least once in one or more newspapers published in the County of Westchester and selected by the Clerk of the Board for that purpose in the manner and time required by law.

TO: HONORABLE BOARD OF LEGISLATORS  
COUNTY OF WESTCHESTER

Your Committee has reviewed “A LOCAL LAW amending the Laws of Westchester County by adding a new Chapter 538 establishing a Pharmaceutical Product Stewardship Program.”

Your Committee is informed that Westchester County has seen a scourge of prescription drug abuse. In the year 2015 alone, 107 Westchester residents died from overdoses. According to the County Medical Examiner’s report, one family of drugs, opioids and opiates which includes heroin, were the cause of 83% of these deaths.

Your Committee is also informed that in 2011 the United States Department of Health and Human Services, Centers for Disease Control and Prevention stated that unintentional prescription opioid overdose kills more Americans than cocaine and heroin combined. The cycle of addiction too frequently begins with extra painkillers lying around someone’s medicine cabinet. People are often prescribed large quantities of serious drugs to deal with short-term pain which can quickly lead to dependence, which turns into abuse of leftover pills and escalation to illegal narcotics. Another path to addiction results from extra, unused pain medications ending up in the possession of others – stolen from medicine cabinets by people who are already addicted or by teenagers experimenting with drugs recreationally.

Your Committee is aware of the serious environmental repercussions the practice of dumping unwanted medications down the drain or in the garbage. These disposed pills often find a way into our waterways and landfills harming our drinking water supply. Even if they enter the sewage system first, pharmaceutical compounds reach wastewater treatment plants that are not designed to remove them before being released into the environment. A 2002 study conducted by the U.S. Geological Survey found that 80 percent of streams tested across the country were contaminated with at least one pharmaceutical, personal care product or other organic wastewater contaminants.

This proposed Local Law which increases the number of places where people can return unused drugs, will help reduce the number of unused prescriptions left in people's homes, cutting off a major source of the first pill that gets a victim hooked. In addition the alarming cocktail of pharmaceuticals contaminating our water, increasing the opportunities for people to safely rid their medicine cabinets of prescription drugs they no longer need will benefit our ecological system. Sound practices like these can make a difference in preserving our environment and help to save lives.

Your Committee notes that the purpose of this proposed Local Law is to protect the health, safety and welfare of the public and our environment by providing for the safe and orderly collection and disposal of unused drugs; and by placing responsibility for end-of-life management of drug products on the manufacturers of

the products, while encouraging product design that minimizes negative impacts on human health and the environment at every stage of the product's lifecycle.

Your Committee notes that that this proposed Local Law will require pharmacy chains with more than three stores in Westchester County to become locations to dispose of unused medications. This Product Stewardship Program, which was recently adopted into law in Rockland County, is intended to help stem the tide of widespread drug abuse, particularly of opioids. Signage about the program near the retail establishment's entrance, as well as the creation of a hotline and a website for county residents to locate drop-off sites is required. Fines of up to \$1,000 can be imposed on companies failing to comply with this measure.

As you know, this Honorable Board must comply with the requirements of the State Environmental Quality Review Act ("SEQRA"). Your Committee is advised that the Department of Planning has reviewed the applicable SEQRA regulations, and has concluded that this proposed Local Law "will not 'change the use, appearance or condition of any natural resource or structure' or otherwise affect the environment, other than to facilitate the proper disposal of unused drugs." Therefore, the proposed local law does not constitute an action as defined in section 617.2(b) of 6 NYCRR Part 617 and, as such, no environmental review is required. Your Committee concurs with that conclusion.

Your Committee, after careful consideration, recommends the adoption of this

Local Law.

Dated: \_\_\_\_\_, 2017  
White Plains, New York

COMMITTEE ON

A/5-17-17



Memorandum  
Department of Planning

TO: Thomas Gardiner  
Senior Assistant County Attorney

FROM: Eileen Mildenberger   
Acting Commissioner

DATE: May 5, 2017

SUBJECT: **SEQR DOCUMENTATION FOR PHARMACEUTICAL PRODUCT STEWARDSHIP PROGRAM**

Pursuant to your request for an environmental review of the above referenced action, the Planning Department has determined that no environmental review is necessary.

The action involves a local law that would add a new chapter, Chapter 538, to the Laws of Westchester County, which would require producers of certain drugs that are sold or distributed in Westchester County to establish a program to accept and dispose of unwanted drugs from the public. Collection sites are to be provided at retail stores and public health facilities. The Department of Consumer Protection will be responsible for administering and implementing the requirements of this law.

Since the action will not “change the use, appearance or condition of any natural resource or structure,” or otherwise affect the environment, other than to facilitate the proper disposal of unused drugs, with respect to the State Environmental Quality Review (SEQR) Act, the proposed local law does not constitute an action as defined in section 617.2(b) of 6NYCRR Part 617. As such, no environmental review is required.

Please contact my office if you need any additional information on this matter.

EMM/cnm

cc: Mark Fang, Director of Consumer Protection  
Robert Alberty, Deputy Chief of Staff  
Paula Friedman, Assistant to the County Executive  
David Kvinge, Director of Environmental Planning

**LOCAL LAW INTRO. NO. -2017**

A LOCAL LAW amending the Laws of Westchester County by adding a new Chapter 538 establishing a Pharmaceutical Product Stewardship Program.

BE IT ENACTED by the County Board of the County of Westchester as follows:

Section 1. A new Chapter 538 is hereby added to the Laws of Westchester

County to read as follows:

**CHAPTER 538**

**PHARMACEUTICAL PRODUCT STEWARDSHIP PROGRAM**

**Sec. 538.01. Definitions.**

**Sec. 538.11. Product stewardship program.**

**Sec. 538.21. Product stewardship plan.**

**Sec. 538.31. Disposal of unwanted products.**

**Sec. 538.41. Product stewardship program promotion and outreach.**

**Sec. 538.51. Retailer participation.**

**Sec. 538.61. List of producers.**

**Sec. 538.71. Regulations and fees.**

**Sec. 538.81. Enforcement.**

**Sec. 538.91. Additional provisions.**

**Sec. 538.01. Definitions.**

For the purposes of this Chapter, the following terms have the meanings given below.

1. LEGISLATURE refers to the Westchester County Board of Legislators.
2. CONSUMER GENERATORS means residents of single and multiple family residences or other locations, who possess, dispose of or abandon household drugs. "Consumer generators" does not include drug seizures by law enforcement, pharmacy waste, business waste, or any other source identified by the Department as a non-consumer source.

3. CONTROLLED SUBSTANCE for purposes of this Chapter shall mean any substance listed under New York Public Health Law Section 3306 or Title 21 of the United States Code, Sections 812 and 813 or any successor legislation.

4. COSMETICS means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to, the human body, or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, (2) articles intended for use as a component of any such articles, and (3) cosmetics as defined above with expiration dates.

5. COVERED DRUG means all drugs as defined in 21 U.S.C. Section 321(g)(1) of the Federal Food, Drug and Cosmetic Act (FFDCA) covered under 21 U.S.C. Section 353(b)(1) of the FFDCA, including both brand name and generic drugs, and nonprescription drugs. "Covered drug" does not include: (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 nonprescription drugs under the Federal Food, Drug, and Cosmetic Act ("FFDCA") (21 U.S.C. Section 301 et seq. [2002]); (4) drugs for which producers provide a takeback program as part of a Federal Food and Drug Administration managed risk evaluation and mitigation strategy (21 U.S.C. Section 3551); (5) drugs that are biological products as defined by 21 CFR 600.3(h) as it exists on the effective date of this section if the producer already provides a takeback program; and (6) pet pesticide products contained in pet collars, powders, shampoos, topical applications.

or other delivery systems.

6. COUNTY means the County of Westchester, New York.

7. DEPARTMENT means the Westchester County Department of Consumer Protection.

8. DRUG WHOLESALER means a business that sells or distributes drugs and covered drugs for resale to an entity other than a consumer.

9. DRUGS means: (1) articles recognized in the official United States pharmacopoeia, the official national formulary, the official homeopathic pharmacopoeia of the United States, or any supplement of the formulary or those pharmacopoeias; (2) substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; (3) substances, other than food, intended to affect the structure or any function of the body of humans or other animals. "Drugs" does not mean medical devices, their component parts or accessories.

10. ENTITY means a person other than an individual.

11. GENERIC DRUG means a drug that is chemically identical or bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use, though inactive ingredients may vary.

12. HAZARDOUS WASTE means pharmaceutical waste that falls under the Federal Resource Conservation and Recovery Act (RCRA) of 1976, as amended (42 U.S.C.A. Section 6901 et seq.). This waste includes bulk chemotherapy drugs, P-listed waste, U-listed waste and characteristic hazardous waste.

13. MANUFACTURE means the production, preparation, propagation, compounding, or processing of drugs but does not include the activities of a repackager, wholesaler or medical practitioner.

14. MANUFACTURER means a person, company, corporation or other entity engaged in the manufacture of drugs.

15. MAIL-BACK PROGRAM means a system whereby consumer generators of unwanted products obtain prepaid and preaddressed mailing envelopes in which to place unwanted products for shipment to an entity that will dispose of them safely and legally.

16. MEDICAL WASTE means any biohazardous, pathology, pharmaceutical, or trace chemotherapy waste not regulated by the Federal Resource Conservation and Recovery Act (RCRA) of 1976, as amended; sharps and trace chemotherapy wastes generated in a health care setting in the diagnosis, treatment, immunization, or care of humans or animals; waste generated in autopsy or necropsy; waste generated during preparation of a body for final disposition such as cremation or interment; waste generated in research pertaining to the production or testing of microbiologicals; waste generated in research using human or animal pathogens; sharps and laboratory waste that poses a potential risk of infection to humans generated in the inoculation of animals in commercial farming operations; waste generated from the consolidation of home-generated sharps; and waste generated in the cleanup of trauma scenes.

17. NONPRESCRIPTION DRUG means any drug that may be lawfully sold without a prescription.

18. PERSON means an individual, firm, sole proprietorship, corporation,

limited liability corporation, general partnership, limited partnership, limited liability partnership, association, cooperative, or other legal entity, however organized.

19. PHARMACY means any place registered as a pharmacy pursuant to Section 6802 of New York Education Law where the practice of pharmacy is conducted.

20. PLAN or PRODUCT STEWARDSHIP PLAN means a product stewardship plan required under this Chapter that describes the manner in which a product stewardship program will be provided.

21. PLAN OPERATOR means the person, company or organization that develops, implements and operates a product stewardship plan, including but not limited to a producer or stewardship organization.

22. PRESCRIPTION DRUG means any drug that by Federal or State law may be dispensed lawfully only on prescription.

23. PRODUCER shall be determined, with regard to covered drugs that are sold, offered for sale, or distributed in Westchester County as meaning one of the following:

(i). The person who manufactures covered drugs and who sells, offers for sale, or distributes covered drugs in Westchester County under that person's own name or brand.

(ii). If there is no person who sells, offers for sale, or distributes covered drugs in Westchester County under the person's own name or brand, the producer of covered drugs is the owner or licensee of a trademark or brand under which the covered drugs are sold or distributed in Westchester County, whether or not the

trademark is registered.

(iii). If there is no person who is a producer of covered drugs for purposes of subsections “i” and “ii” of this subdivision, the producer of covered drugs is the person who brings the covered drug into Westchester County for sale or distribution. "Producer" does not include (1) a retailer that puts its store label on a covered drug, or (2) a pharmacist who dispenses prescription drugs to, or compounds a prescribed individual drug product for a consumer.

24. PRODUCT STEWARDSHIP PROGRAM or PROGRAM means a program financed and operated by producers.

25. PROVIDER means any person or entity that sells or otherwise furnishes drugs to consumers at a medical or veterinary office, clinic, hospital or approved needle exchange program located in the County.

26. PUBLIC HEARING means any hearing held by the Department or the County which is open to the public for the purposes of collecting public comment. It does not necessarily refer to meetings of the Legislature.

27. RETAILER means any person or entity that sells drugs directly to consumers at a business located in the County. To be subject to this law, a retailer must belong to a chain of three or more retail establishments, whether operating inside or outside of Westchester County, that are engaged in the same general field of business and: (1) conduct business under the same business name; or (2) operate under common ownership or management or pursuant to a franchise agreement with the same franchisor.

28. STEWARDSHIP ORGANIZATION means an organization designated by

a group of producers to act as an agent on behalf of each producer to operate a product stewardship program.

29. UNWANTED PRODUCTS means covered drugs no longer wanted by the owner or that have been abandoned, discarded, or are intended to be discarded by the owner.

**Sec 538.11. Product stewardship program.**

1. Requirement for Sale. This Chapter shall apply only to producers whose covered drugs are sold or distributed in Westchester County and to retailers who sell covered drugs in Westchester County. This Chapter shall be administered and implemented by the Westchester County Department of Consumer Protection.

Each producer must:

- i. Operate, individually or jointly with other producers, a product stewardship program approved by the Department in consultation with the Westchester County Department of Health; or
- ii. Enter into an agreement with a stewardship organization to operate, on the producer's behalf, a product stewardship program approved by the Department in consultation with the Westchester County Department of Health.

2. Product Stewardship Program Costs.

- i. A producer, group of producers, or stewardship organization must pay all administrative and operational fees associated with their product stewardship program, including the cost of collecting, transporting, and disposing of unwanted products collected from consumer generators and the recycling or disposal, or both, of packaging collected with the unwanted product.

ii. A producer, group of producers, or stewardship organization must pay for all fees and expenses associated with obtaining compliance with the New York State Environmental Quality Review (6 NYCRR Part 617), if required, for a specific product stewardship program and product stewardship plan.

iii. No person or producer may charge a specific point of sale fee to consumers to recoup the costs of their product stewardship program, nor may they charge a specific point of collection fee at the time the unwanted products are collected from consumer generators or delivered for disposal.

iv. A producer, group of producers, or stewardship organization must pay all costs incurred by the County of Westchester, including but not limited to the Department, in the administration and enforcement of their product stewardship program. Exclusive of fines and penalties, the County of Westchester shall only recover its actual costs of administration and enforcement under this Chapter and shall not charge any amounts under this Chapter in excess of its actual administrative and enforcement costs.

v. A producer, group of producers, or stewardship organization must pay all collection and disposal costs as of the date that the ordinance codified in this Chapter becomes effective. If the County incurs any costs due to delays in establishment of an approved stewardship plan, the producer, group of producers, or stewardship organization must reimburse the County in full for such costs.

**Sec. 538.21. Product stewardship plan.**

1. Plan Content. Each product stewardship program shall have a product stewardship plan that contains each of the following:

- i. Certification that the product stewardship program will accept all unwanted products regardless of who produced them, unless excused from this requirement by the Department as part of the approval of the plan;
- ii. Contact information for the individual and the entity submitting the plan and for each of the producers participating in the product stewardship program;
- iii. A description of the methods by which unwanted products from consumer generators will be collected at all retail sale facilities of drugs in the County, including a description of bins to be used and collection methods;
- iv. A description of the methods by which unwanted products from consumer generators will be collected at all public health facilities in Westchester County, as well as at such other locations as designated by the Department, including a description of bins to be used and collection methods;
- v. The location of each collection site and locations where envelopes for a mail-back program are available (if applicable);
- vi. A list containing the name, location, permit status, and record of any penalties, violations, or regulatory orders received in the previous five years by each person that will be involved in transporting unwanted products and each medical waste or hazardous waste disposal facility proposed to participate in the product stewardship program;
- vii. A description of how the unwanted products will be safely and securely tracked and handled from collection through final disposal and the policies and procedures to be followed to ensure security;
- viii. A description of the public education and outreach activities required

under this Chapter and how their effectiveness will be evaluated;

ix. A description of how the scope and extent of the product stewardship program are reasonably related to the number of covered drugs that are sold in the County of Westchester, by the producer or group of producers;

x. A starting date when collection of unwanted products will begin;

xi. A description of how support will be provided to any law enforcement agencies within Westchester County that have, or later agree to have, a collection program for controlled substances, including: (a) the provision of a collection kiosk with appropriate accessories and signage, (b) an ability to accept controlled substances and other covered drugs, (c) technical support up to and including an appropriate person to provide onsite assistance with the sorting and separation of controlled substances at no cost to a participating law enforcement agency;

xii. If more than one producer will be involved in a proposed product stewardship program, then the product stewardship plan for that program must include a fair and reasonable manner for allocating the costs of the program among the participants in that program, such that the portion of costs paid by each producer is reasonably related to the number of covered drugs that producer sells in the County of Westchester.

## 2. Department Review and Approval-Updates.

i. No producer, group of producers, or stewardship organization may begin collecting unwanted products to comply with this Chapter until it has received written approval of its product stewardship plan from the Department. The County may continue collection on an interim basis if there is any delay in establishing a

stewardship program as required.

ii. Product stewardship plans must be submitted to the Department for approval. The initial plans must be submitted by December 31, 2017, or at a later date as approved in writing by the Department.

iii. Within 60 days after receipt and review of a product stewardship plan, the Department will determine whether the plan complies with the requirements of this Chapter and of any regulations adopted pursuant to this Chapter. The Department may at its sole discretion conduct a noticed public hearing as part of this process.

a. As part of its approval, the Department may set reasonable performance goals for the program.

b. If the Department approves a plan, it shall notify the applicant of its approval in writing.

c. If the Department rejects a plan, it shall notify the applicant in writing of its reasons for rejecting the plan. The Department may reject a plan without conducting a public hearing.

d. An applicant whose plan has been rejected by the Department must submit a revised plan to the Department within 30 days after receiving notice of the rejection. The Department may require the submission of a further revised plan or, at its sole discretion, the Department may develop, approve and impose its own product stewardship plan or an approved plan submitted by other producer(s) pursuant to this Chapter. The imposed plan will be presented at a public hearing. The Department is not required, and nothing in this Chapter shall be interpreted as requiring, the Department to create or impose a product stewardship plan.

e. If the Department rejects a revised product stewardship plan or any other subsequently revised plan, the producer(s) at issue shall be out of compliance with this Chapter and shall be subject to the enforcement provisions contained in this Chapter.

iv. At least every three years, a producer, group of producers or stewardship organization operating a product stewardship program shall update its product stewardship plan and submit the updated plan to the Department for review and approval.

v. A producer who begins to offer a covered drug for sale in the County of Westchester after December 31, 2017, must submit a product stewardship plan to the Department or provide evidence of having joined an existing approved product stewardship program within 60 days following the producer's initial offer for sale of a covered drug.

vi. Any proposed changes to a product stewardship plan must be submitted in writing to the Department and approved by the Department in writing prior to implementation of any change.

vii. Required Plan Amendment. Within 60 days of the final promulgation of any rules by the New York State Board of Pharmacy regarding collection of controlled substances by retail pharmacies in conformity with the U.S. Drug Enforcement Agency regulations resulting from the Secure and Responsible Drug Disposal Act of 2010, each producer, group of producers or stewardship organization operating a product stewardship program shall submit to the Department for review and approval an update to its product stewardship plan that describes how the plan will, within 120 days, include collection of controlled substances at all collection locations on the

premises of retailers and providers of covered drugs.

**Sec. 538.31. Disposal of unwanted products.**

1. Compliance with Applicable Law. Each product stewardship program must comply with all local, State, and Federal laws and regulations applicable to its operations, including laws and regulations governing the treatment and disposal of unwanted products.

2. Treatment and Disposal. Each product stewardship program must dispose of all unwanted covered drugs by incineration at a medical waste or hazardous waste facility. Each treatment or disposal facility utilized must be in possession of all required regulatory permits and licenses.

3. New Technologies. Producers with product stewardship programs may petition the Department for approval to use treatment and final disposal technologies, where lawful, that provide superior environmental and human health protection than provided by current medical waste disposal technologies for covered drugs if and when those technologies are proven and available. The proposed technology must provide equivalent protection in each, and superior protection in one or more, of the following areas:

- i. Monitoring of any emissions or waste;
- ii. Worker health and safety;
- iii. Air, water, or land emissions contributing to persistent, bioaccumulative, and toxic pollution; and
- iv. Overall impact on the environment and human health.

4. Packaging Separation. Each product stewardship program shall encourage

consumer generators to separate unwanted products from their original containers and packaging, when appropriate, prior to collection or disposal.

**Sec. 538.41. Product stewardship program promotion and outreach.**

1. A product stewardship program must promote the program to consumer generators, pharmacists, retailers of covered drugs, and health care practitioners as to the proper and safe method to dispose of unwanted products.

2 A product stewardship program shall include, but is not limited to, developing, and updating as necessary, educational and other outreach materials for use by retailers of covered drugs. These materials may include, but are not limited to, two or more of the following:

- i. Signage that is prominently displayed and easily visible to the consumer.
- ii. Written materials and templates of materials for reproduction by retailers to be provided to the consumer at the time of purchase or delivery, or both.
- iii. Advertising and/or other promotional materials related to the product stewardship program.

3. A product stewardship program must prepare education and outreach materials that publicize the location and operation of collection locations in Westchester County and disseminate the materials to health care facilities, pharmacies, and other interested parties. The program also must establish a website publicizing collection locations and program operations and a toll- free telephone number that consumer generators can call to find nearby collection locations and understand how the program works.

**Sec. 538.51. Retailer participation.**

1. Every retailer and every provider of covered drugs in the County shall establish a system consistent with the requirements of this Chapter for the collection of discarded consumer generated covered drugs for proper disposal during the retailer's or provider's normal hours of operation, except that a retailer or provider who does not sell or provide covered drugs to consumers is not required to establish a collection system for discarded covered drugs.

2. Each system established by a retailer or provider for the collection and disposal of discarded consumer generated covered drugs shall include, at a minimum, the following elements:

i. Each retailer or provider shall provide one of the following:

a. On-Site Collection System. Receptacles for the collection of discarded consumer-generated covered drugs within the retailer or provider establishment. The receptacle shall meet applicable State and Federal standards for safe disposal of drugs. The retailer or provider shall provide for the management and disposal of all discarded consumer-generated covered drugs that is collected at the retailer or provider establishment in a safe manner consistent with all State and Federal laws and regulations; or

b. Mail-Back Collection System. Prepaid mail-back envelopes in sufficient capacity for safe disposal of discarded covered drugs, as required by a consumer.

ii. Signage prominently displayed within five feet of every public entrance to the retailer or provider establishment and easily visible to the consumer, indicating that the retailer or provider establishment collects consumer-generated covered drugs

from consumers.

3. All costs of participation by retailers and providers shall be paid or reimbursed by the producer, group of producers, or stewardship organization as part of its program as provided in this Chapter. Retailers and providers shall not be expected to incur any costs for participation.

**Sec. 538.61. List of producers.**

The Department of Consumer Protection and the Department of Health shall provide on their respective websites a list of all producers participating in product stewardship programs approved by the Department and a list of all producers the Department has identified as noncompliant with this Chapter or any regulations adopted pursuant to this Chapter.

**Sec. 538.71. Regulations and fees.**

1. The Director of the Department of Consumer Protection may, after a noticed public hearing, adopt such rules and regulations as necessary to implement, administer, and enforce this Chapter.

2. As soon as practicable, the Department shall submit to the Legislature a proposed schedule of fees to be charged to producers to cover Westchester County's costs of administering and enforcing this Chapter.

**Sec. 538.81. Enforcement.**

1. The Department shall administer the penalty provisions of this Chapter.

2. The Department may issue an administrative citation to a producer, plan operator or product stewardship organization for violation of this Chapter or any regulation adopted pursuant to this Chapter. The Department shall first send a written

warning to the producer, plan operator or product stewardship organization as well as a copy of this Chapter and any regulations adopted pursuant to this Chapter. The producer, plan operator or product stewardship organization shall have 30 days after receipt of the warning to comply and correct any violations.

3. If the producer, plan operator or product stewardship organization fails to comply and correct any violations, the Department may impose administrative fines for violations of this Chapter or of any regulations adopted pursuant to this Chapter. Each day shall constitute a separate violation for these purposes. .

4. Any person in violation of this Chapter or any regulation adopted pursuant to this Chapter shall be liable to the County of Westchester for a civil penalty in an amount not to exceed \$1,000 per day per violation. Each day in which the violation continues shall constitute a separate and distinct violation.

5. In determining the appropriate penalties, the Department shall consider the extent of harm caused by the violation, the nature and persistence of the violation, the frequency of past violations, any action taken to mitigate the violation, and the financial burden to the violator.

6. Any producer, plan operator or product stewardship organization receiving an administrative citation under this Chapter or any regulation adopted pursuant to this Chapter may appeal it within 21 calendar days from the date the administrative citation was issued. The administrative citation is deemed issued on the day it is sent by first class mail or personal service. The administrative citation shall state the date of issuance. If the deadline falls on a weekend or County holiday, then the deadline shall be extended until the next regular business day. The request to appeal must:

- i. Be in writing;
  - ii. Be accompanied by a deposit of the total fine and any fees noted on the administrative citation;
  - iii. Specify the basis for the appeal in detail;
  - iv. Be postmarked within 21 days from the date the administrative citation was issued; and
  - v. Be sent to the address as set forth on the administrative citation.
7. The written request to appeal will be reviewed and, if found to be complete, a date, time and place shall be set for a hearing before a Hearing Officer designated by the Director of the Department. Written notice of the time and place for the hearing will be served by first class mail or personal service at least 21 days prior to the date of the hearing to the producer, plan operator or product stewardship organization appealing the citation. Service by first class mail, postage prepaid, shall be effective on the date of mailing.
8. Failure of any producer, plan operator or product stewardship organization to file an appeal in accordance with the provisions of this section shall constitute waiver of that producer's, plan operator's or product stewardship organization's rights to administrative determination of the merits of the administrative citation and the amount of the fine and any fees and shall constitute a failure by that producer to exhaust administrative remedies.
9. The producer, plan operator or product stewardship organization requesting the appeal may request the Director of the Department to recuse a Hearing Officer for reasons of actual prejudice against the party's cause. The Hearing Officer

shall conduct an orderly, fair hearing and accept evidence as follows:

- i. A valid administrative citation shall be prima facie evidence of the violation.
- ii. Testimony shall be by declaration under penalty of perjury except to the extent the Hearing Officer permits or requires live testimony concerning the violation.
- iii. The Hearing Officer may reduce, waive or conditionally reduce the fines and any fees stated in the administrative citation. The Hearing Officer may impose deadlines or a schedule for payment of the fine and any fees due in excess of the deposit.
- iv. The Hearing Officer shall make findings based on the record of the hearing and make a written decision based on the findings ("Hearing Officer decision"). The Hearing Officer decision shall be served by first class mail on the producer appealing and the Department. The Hearing Officer decision affirming or dismissing the administrative citation is final.

10. The Department may establish appropriate administrative rules for implementing this Chapter, conducting hearings, and rendering decisions pursuant to this section.

11. Upon the failure of any producer to comply with any requirement of this Chapter and any rule or regulation adopted pursuant to this Chapter, the County Attorney of Westchester County may petition any court having jurisdiction for injunctive relief, payment of civil penalties and any other appropriate remedy, including restraining such person or entity from continuing any prohibited activity and compelling compliance with lawful requirements. However, this subsection does not

permit the County of Westchester or any court of competent jurisdiction to restrain the sale of any covered drug in Westchester County.

**Sec. 538.91. Additional provisions.**

1. Disclaimer. In adopting and implementing this Chapter, the County of Westchester is assuming an undertaking only to promote the general welfare. Westchester County is not assuming or imposing on its officers and employees an obligation by which they could be liable in money damages to any person or entity who claims that a breach proximately caused injury.

2. Conflict with State or Federal Law. This Chapter shall be construed so as not to conflict with applicable Federal or State laws, rules or regulations. Nothing in this Chapter shall authorize any Westchester County agency or Department to impose any duties or obligations in conflict with limitations on municipal authority established by State or Federal law at the time such agency or Department action is taken. Westchester County shall suspend enforcement of this Chapter to the extent that said enforcement would conflict with any preemptive State or Federal legislation subsequently adopted.

3. Severability. If any of the provisions of this Chapter or the application thereof to any person or circumstance is held invalid, the remainder of those provisions, including the application of such part or provisions to persons or circumstances other than those to which it is held invalid shall not be affected thereby and shall continue in full force and effect. To this end, the provisions of this Chapter are severable.

4. Nothing in this Chapter, or the program of stewardship in which

manufacturers of pharmaceutical products who sell drugs in Westchester County are required to participate, is intended to protect anticompetitive or collusive conduct nor shall this Chapter be construed to modify, impair, or supersede the operation of any of the antitrust laws or unfair competition laws of the State of New York or of the United States.

5. This Chapter shall be construed in accordance with New York State law, including but not limited to New York Public Health Law, Article 13, Title 13 (Storage, Treatment and Disposal of Regulated Medical Waste) and New York Environmental Conservation Law, Article 27, Title 15 (Storage, Treatment, Disposal and Transportation of Regulated Medical Waste) and shall not be construed in a way that would result in conflict with, or preemption by, any such State law.

§2. This Local Law shall take effect 30 days after its adoption.

TO: HONORABLE BOARD OF LEGISLATORS  
COUNTY OF WESTCHESTER

Your Committee has reviewed “A LOCAL LAW amending the Laws of Westchester County by adding a new Chapter 538 establishing a Pharmaceutical Product Stewardship Program.”

Your Committee is informed that the purpose of this proposed Local Law is to protect the health, safety and welfare of the public and of the environment by providing for the safe and orderly collection and disposal of unused drugs; and by placing responsibility for end-of-life management of drug products on the manufacturers of the products, while encouraging product design that minimizes negative impacts on human health and the environment at every stage of the product’s lifecycle.

As you know, this Honorable Board must comply with the requirements of the State Environmental Quality Review Act (“SEQRA”). Your Committee is advised that the Department of Planning has reviewed the applicable SEQRA regulations, and has concluded that this proposed Local Law \_\_\_\_\_  
\_\_\_\_\_. Your Committee concurs with that conclusion.

Your Committee, after careful consideration, recommends the adoption of this

Local Law.

Dated: \_\_\_\_\_, 2017  
White Plains, New York

COMMITTEE ON

A/tgg/3-23-17

**RESOLUTION NO. \_\_\_\_ – 2017**

RESOLVED, that this Board hold a public hearing pursuant to Section 209.141(4) of the Laws of Westchester County on Local Law Intro. No. \_\_\_\_ - 2017, entitled “A LOCAL LAW amending the Laws of Westchester County by adding a new Chapter 538 establishing a Pharmaceutical Product Stewardship Program.” The public hearing will be held at \_\_.m. on the \_\_\_\_ day of \_\_\_\_\_, 2017 in the Chambers of the Board of Legislators, 8th Floor, Michaelian Office Building, White Plains, New York. The Clerk of the Board shall cause notice of the time and date of such hearing to be published at least once in one or more newspapers published in the County of Westchester and selected by the Clerk of the Board for that purpose in the manner and time required by law.

**LOCAL LAW INTRO. NO. -2017**

A LOCAL LAW amending the Laws of Westchester County by adding a new Chapter 538 establishing a Pharmaceutical Product Stewardship Program.

BE IT ENACTED by the County Board of the County of Westchester as follows:

Section 1. A new Chapter 538 is hereby added to the Laws of Westchester

County to read as follows:

**CHAPTER 538****PHARMACEUTICAL PRODUCT STEWARDSHIP PROGRAM****Sec. 538.01. Definitions.****Sec. 538.11. Product stewardship program.****Sec. 538.21. Product stewardship plan.****Sec. 538.31. Disposal of unwanted products.****Sec. 538.41. Product stewardship program promotion and outreach.****Sec. 538.51. Retailer participation.****Sec. 538.61. List of producers.****Sec. 538.71. Regulations and fees.****Sec. 538.81. Enforcement.****Sec. 538.91. Additional provisions.****Sec. 538.01. Definitions.**

For the purposes of this Chapter, the following terms have the meanings given below.

1. LEGISLATURE refers to the Westchester County Board of Legislators.
2. CONSUMER GENERATORS means residents of single and multiple family residences or other locations, who possess, dispose of or abandon household drugs. "Consumer generators" does not include drug seizures by law enforcement, pharmacy waste, business waste, or any other source identified by the Department as a non-consumer source.

3. CONTROLLED SUBSTANCE for purposes of this Chapter shall mean any substance listed under New York Public Health Law Section 3306 or Title 21 of the United States Code, Sections 812 and 813 or any successor legislation.

4. COSMETICS means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to, the human body, or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, (2) articles intended for use as a component of any such articles, and (3) cosmetics as defined above with expiration dates.

5. COVERED DRUG means all drugs as defined in 21 U.S.C. Section 321(g)(1) of the Federal Food, Drug and Cosmetic Act (FFDCA) covered under 21 U.S.C. Section 353(b)(1) of the FFDCA, including both brand name and generic drugs, and nonprescription drugs. "Covered drug" does not include: (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 nonprescription drugs under the Federal Food, Drug, and Cosmetic Act ("FFDCA") (21 U.S.C. Section 301 et seq. [2002]); (4) drugs for which producers provide a takeback program as part of a Federal Food and Drug Administration managed risk evaluation and mitigation strategy (21 U.S.C. Section 3551); (5) drugs that are biological products as defined by 21 CFR 600.3(h) as it exists on the effective date of this section if the producer already provides a takeback program; and (6) pet pesticide products contained in pet collars, powders, shampoos, topical applications,

or other delivery systems.

6. COUNTY means the County of Westchester, New York.

7. DEPARTMENT means the Westchester County Department of Consumer Protection.

8. DRUG WHOLESALER means a business that sells or distributes drugs and covered drugs for resale to an entity other than a consumer.

9. DRUGS means: (1) articles recognized in the official United States pharmacopoeia, the official national formulary, the official homeopathic pharmacopoeia of the United States, or any supplement of the formulary or those pharmacopoeias; (2) substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; (3) substances, other than food, intended to affect the structure or any function of the body of humans or other animals. "Drugs" does not mean medical devices, their component parts or accessories.

10. ENTITY means a person other than an individual.

11. GENERIC DRUG means a drug that is chemically identical or bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use, though inactive ingredients may vary.

12. HAZARDOUS WASTE means pharmaceutical waste that falls under the Federal Resource Conservation and Recovery Act (RCRA) of 1976, as amended (42 U.S.C.A. Section 6901 et seq.). This waste includes bulk chemotherapy drugs, P-listed waste, U-listed waste and characteristic hazardous waste.

13. MANUFACTURE means the production, preparation, propagation, compounding, or processing of drugs but does not include the activities of a repackager, wholesaler or medical practitioner.

14. MANUFACTURER means a person, company, corporation or other entity engaged in the manufacture of drugs.

15. MAIL-BACK PROGRAM means a system whereby consumer generators of unwanted products obtain prepaid and preaddressed mailing envelopes in which to place unwanted products for shipment to an entity that will dispose of them safely and legally.

16. MEDICAL WASTE means any biohazardous, pathology, pharmaceutical, or trace chemotherapy waste not regulated by the Federal Resource Conservation and Recovery Act (RCRA) of 1976, as amended; sharps and trace chemotherapy wastes generated in a health care setting in the diagnosis, treatment, immunization, or care of humans or animals; waste generated in autopsy or necropsy; waste generated during preparation of a body for final disposition such as cremation or interment; waste generated in research pertaining to the production or testing of microbiologicals; waste generated in research using human or animal pathogens; sharps and laboratory waste that poses a potential risk of infection to humans generated in the inoculation of animals in commercial farming operations; waste generated from the consolidation of home-generated sharps; and waste generated in the cleanup of trauma scenes.

17. NONPRESCRIPTION DRUG means any drug that may be lawfully sold without a prescription.

18. PERSON means an individual, firm, sole proprietorship, corporation,

limited liability corporation, general partnership, limited partnership, limited liability partnership, association, cooperative, or other legal entity, however organized.

19. PHARMACY means any place registered as a pharmacy pursuant to Section 6802 of New York Education Law where the practice of pharmacy is conducted.

20. PLAN or PRODUCT STEWARDSHIP PLAN means a product stewardship plan required under this Chapter that describes the manner in which a product stewardship program will be provided.

21. PLAN OPERATOR means the person, company or organization that develops, implements and operates a product stewardship plan, including but not limited to a producer or stewardship organization.

22. PRESCRIPTION DRUG means any drug that by Federal or State law may be dispensed lawfully only on prescription.

23. PRODUCER shall be determined, with regard to covered drugs that are sold, offered for sale, or distributed in Westchester County as meaning one of the following:

(i). The person who manufactures covered drugs and who sells, offers for sale, or distributes covered drugs in Westchester County under that person's own name or brand.

(ii). If there is no person who sells, offers for sale, or distributes covered drugs in Westchester County under the person's own name or brand, the producer of covered drugs is the owner or licensee of a trademark or brand under which the covered drugs are sold or distributed in Westchester County, whether or not the

trademark is registered.

(iii). If there is no person who is a producer of covered drugs for purposes of subsections “i” and “ii” of this subdivision, the producer of covered drugs is the person who brings the covered drug into Westchester County for sale or distribution. "Producer" does not include (1) a retailer that puts its store label on a covered drug, or (2) a pharmacist who dispenses prescription drugs to, or compounds a prescribed individual drug product for a consumer.

24. PRODUCT STEWARDSHIP PROGRAM or PROGRAM means a program financed and operated by producers.

25. PROVIDER means any person or entity that sells or otherwise furnishes drugs to consumers at a medical or veterinary office, clinic, hospital or approved needle exchange program located in the County.

26. PUBLIC HEARING means any hearing held by the Department or the County which is open to the public for the purposes of collecting public comment. It does not necessarily refer to meetings of the Legislature.

27. RETAILER means any person or entity that sells drugs directly to consumers at a business located in the County. To be subject to this law, a retailer must belong to a chain of three or more retail establishments, whether operating inside or outside of Westchester County, that are engaged in the same general field of business and: (1) conduct business under the same business name; or (2) operate under common ownership or management or pursuant to a franchise agreement with the same franchisor.

28. STEWARDSHIP ORGANIZATION means an organization designated by

a group of producers to act as an agent on behalf of each producer to operate a product stewardship program.

29. UNWANTED PRODUCTS means covered drugs no longer wanted by the owner or that have been abandoned, discarded, or are intended to be discarded by the owner.

**Sec 538.11. Product stewardship program.**

1. Requirement for Sale. This Chapter shall apply only to producers whose covered drugs are sold or distributed in Westchester County and to retailers who sell covered drugs in Westchester County. This Chapter shall be administered and implemented by the Westchester County Department of Consumer Protection.

Each producer must:

- i. Operate, individually or jointly with other producers, a product stewardship program approved by the Department in consultation with the Westchester County Department of Health; or
- ii. Enter into an agreement with a stewardship organization to operate, on the producer's behalf, a product stewardship program approved by the Department in consultation with the Westchester County Department of Health.

2. Product Stewardship Program Costs.

- i. A producer, group of producers, or stewardship organization must pay all administrative and operational fees associated with their product stewardship program, including the cost of collecting, transporting, and disposing of unwanted products collected from consumer generators and the recycling or disposal, or both, of packaging collected with the unwanted product.

ii. A producer, group of producers, or stewardship organization must pay for all fees and expenses associated with obtaining compliance with the New York State Environmental Quality Review (6 NYCRR Part 617), if required, for a specific product stewardship program and product stewardship plan.

iii. No person or producer may charge a specific point of sale fee to consumers to recoup the costs of their product stewardship program, nor may they charge a specific point of collection fee at the time the unwanted products are collected from consumer generators or delivered for disposal.

iv. A producer, group of producers, or stewardship organization must pay all costs incurred by the County of Westchester, including but not limited to the Department, in the administration and enforcement of their product stewardship program. Exclusive of fines and penalties, the County of Westchester shall only recover its actual costs of administration and enforcement under this Chapter and shall not charge any amounts under this Chapter in excess of its actual administrative and enforcement costs.

v. A producer, group of producers, or stewardship organization must pay all collection and disposal costs as of the date that the ordinance codified in this Chapter becomes effective. If the County incurs any costs due to delays in establishment of an approved stewardship plan, the producer, group of producers, or stewardship organization must reimburse the County in full for such costs.

**Sec. 538.21. Product stewardship plan.**

1. Plan Content. Each product stewardship program shall have a product stewardship plan that contains each of the following:

- i. Certification that the product stewardship program will accept all unwanted products regardless of who produced them, unless excused from this requirement by the Department as part of the approval of the plan;
- ii. Contact information for the individual and the entity submitting the plan and for each of the producers participating in the product stewardship program;
- iii. A description of the methods by which unwanted products from consumer generators will be collected at all retail sale facilities of drugs in the County, including a description of bins to be used and collection methods;
- iv. A description of the methods by which unwanted products from consumer generators will be collected at all public health facilities in Westchester County, as well as at such other locations as designated by the Department, including a description of bins to be used and collection methods;
- v. The location of each collection site and locations where envelopes for a mail-back program are available (if applicable);
- vi. A list containing the name, location, permit status, and record of any penalties, violations, or regulatory orders received in the previous five years by each person that will be involved in transporting unwanted products and each medical waste or hazardous waste disposal facility proposed to participate in the product stewardship program;
- vii. A description of how the unwanted products will be safely and securely tracked and handled from collection through final disposal and the policies and procedures to be followed to ensure security;
- viii. A description of the public education and outreach activities required

under this Chapter and how their effectiveness will be evaluated;

ix. A description of how the scope and extent of the product stewardship program are reasonably related to the number of covered drugs that are sold in the County of Westchester, by the producer or group of producers;

x. A starting date when collection of unwanted products will begin;

xi. A description of how support will be provided to any law enforcement agencies within Westchester County that have, or later agree to have, a collection program for controlled substances, including: (a) the provision of a collection kiosk with appropriate accessories and signage, (b) an ability to accept controlled substances and other covered drugs, (c) technical support up to and including an appropriate person to provide onsite assistance with the sorting and separation of controlled substances at no cost to a participating law enforcement agency;

xii. If more than one producer will be involved in a proposed product stewardship program, then the product stewardship plan for that program must include a fair and reasonable manner for allocating the costs of the program among the participants in that program, such that the portion of costs paid by each producer is reasonably related to the number of covered drugs that producer sells in the County of Westchester.

## 2. Department Review and Approval-Updates.

i. No producer, group of producers, or stewardship organization may begin collecting unwanted products to comply with this Chapter until it has received written approval of its product stewardship plan from the Department. The County may continue collection on an interim basis if there is any delay in establishing a

stewardship program as required.

ii. Product stewardship plans must be submitted to the Department for approval. The initial plans must be submitted by December 31, 2017, or at a later date as approved in writing by the Department.

iii. Within 60 days after receipt and review of a product stewardship plan, the Department will determine whether the plan complies with the requirements of this Chapter and of any regulations adopted pursuant to this Chapter. The Department may at its sole discretion conduct a noticed public hearing as part of this process.

a. As part of its approval, the Department may set reasonable performance goals for the program.

b. If the Department approves a plan, it shall notify the applicant of its approval in writing.

c. If the Department rejects a plan, it shall notify the applicant in writing of its reasons for rejecting the plan. The Department may reject a plan without conducting a public hearing.

d. An applicant whose plan has been rejected by the Department must submit a revised plan to the Department within 30 days after receiving notice of the rejection. The Department may require the submission of a further revised plan or, at its sole discretion, the Department may develop, approve and impose its own product stewardship plan or an approved plan submitted by other producer(s) pursuant to this Chapter. The imposed plan will be presented at a public hearing. The Department is not required, and nothing in this Chapter shall be interpreted as requiring, the Department to create or impose a product stewardship plan.

e. If the Department rejects a revised product stewardship plan or any other subsequently revised plan, the producer(s) at issue shall be out of compliance with this Chapter and shall be subject to the enforcement provisions contained in this Chapter.

iv. At least every three years, a producer, group of producers or stewardship organization operating a product stewardship program shall update its product stewardship plan and submit the updated plan to the Department for review and approval.

v. A producer who begins to offer a covered drug for sale in the County of Westchester after December 31, 2017, must submit a product stewardship plan to the Department or provide evidence of having joined an existing approved product stewardship program within 60 days following the producer's initial offer for sale of a covered drug.

vi. Any proposed changes to a product stewardship plan must be submitted in writing to the Department and approved by the Department in writing prior to implementation of any change.

vii. Required Plan Amendment. Within 60 days of the final promulgation of any rules by the New York State Board of Pharmacy regarding collection of controlled substances by retail pharmacies in conformity with the U.S. Drug Enforcement Agency regulations resulting from the Secure and Responsible Drug Disposal Act of 2010, each producer, group of producers or stewardship organization operating a product stewardship program shall submit to the Department for review and approval an update to its product stewardship plan that describes how the plan will, within 120 days, include collection of controlled substances at all collection locations on the

premises of retailers and providers of covered drugs.

**Sec. 538.31. Disposal of unwanted products.**

1. Compliance with Applicable Law. Each product stewardship program must comply with all local, State, and Federal laws and regulations applicable to its operations, including laws and regulations governing the treatment and disposal of unwanted products.

2. Treatment and Disposal. Each product stewardship program must dispose of all unwanted covered drugs by incineration at a medical waste or hazardous waste facility. Each treatment or disposal facility utilized must be in possession of all required regulatory permits and licenses.

3. New Technologies. Producers with product stewardship programs may petition the Department for approval to use treatment and final disposal technologies, where lawful, that provide superior environmental and human health protection than provided by current medical waste disposal technologies for covered drugs if and when those technologies are proven and available. The proposed technology must provide equivalent protection in each, and superior protection in one or more, of the following areas:

- i. Monitoring of any emissions or waste;
- ii. Worker health and safety;
- iii. Air, water, or land emissions contributing to persistent, bioaccumulative, and toxic pollution; and
- iv. Overall impact on the environment and human health.

4. Packaging Separation. Each product stewardship program shall encourage

consumer generators to separate unwanted products from their original containers and packaging, when appropriate, prior to collection or disposal.

**Sec. 538.41. Product stewardship program promotion and outreach.**

1. A product stewardship program must promote the program to consumer generators, pharmacists, retailers of covered drugs, and health care practitioners as to the proper and safe method to dispose of unwanted products.

2 A product stewardship program shall include, but is not limited to, developing, and updating as necessary, educational and other outreach materials for use by retailers of covered drugs. These materials may include, but are not limited to, two or more of the following:

- i. Signage that is prominently displayed and easily visible to the consumer.
- ii. Written materials and templates of materials for reproduction by retailers to be provided to the consumer at the time of purchase or delivery, or both.
- iii. Advertising and/or other promotional materials related to the product stewardship program.

3. A product stewardship program must prepare education and outreach materials that publicize the location and operation of collection locations in Westchester County and disseminate the materials to health care facilities, pharmacies, and other interested parties. The program also must establish a website publicizing collection locations and program operations and a toll- free telephone number that consumer generators can call to find nearby collection locations and understand how the program works.

**Sec. 538.51. Retailer participation.**

1. Every retailer and every provider of covered drugs in the County shall establish a system consistent with the requirements of this Chapter for the collection of discarded consumer generated covered drugs for proper disposal during the retailer's or provider's normal hours of operation, except that a retailer or provider who does not sell or provide covered drugs to consumers is not required to establish a collection system for discarded covered drugs.

2. Each system established by a retailer or provider for the collection and disposal of discarded consumer generated covered drugs shall include, at a minimum, the following elements:

i. Each retailer or provider shall provide one of the following:

a. On-Site Collection System. Receptacles for the collection of discarded consumer-generated covered drugs within the retailer or provider establishment. The receptacle shall meet applicable State and Federal standards for safe disposal of drugs. The retailer or provider shall provide for the management and disposal of all discarded consumer-generated covered drugs that is collected at the retailer or provider establishment in a safe manner consistent with all State and Federal laws and regulations; or

b. Mail-Back Collection System. Prepaid mail-back envelopes in sufficient capacity for safe disposal of discarded covered drugs, as required by a consumer.

ii. Signage prominently displayed within five feet of every public entrance to the retailer or provider establishment and easily visible to the consumer, indicating that the retailer or provider establishment collects consumer-generated covered drugs

from consumers.

3. All costs of participation by retailers and providers shall be paid or reimbursed by the producer, group of producers, or stewardship organization as part of its program as provided in this Chapter. Retailers and providers shall not be expected to incur any costs for participation.

**Sec. 538.61. List of producers.**

The Department of Consumer Protection and the Department of Health shall provide on their respective websites a list of all producers participating in product stewardship programs approved by the Department and a list of all producers the Department has identified as noncompliant with this Chapter or any regulations adopted pursuant to this Chapter.

**Sec. 538.71. Regulations and fees.**

1. The Director of the Department of Consumer Protection may, after a noticed public hearing, adopt such rules and regulations as necessary to implement, administer, and enforce this Chapter.

2. As soon as practicable, the Department shall submit to the Legislature a proposed schedule of fees to be charged to producers to cover Westchester County's costs of administering and enforcing this Chapter.

**Sec. 538.81. Enforcement.**

1. The Department shall administer the penalty provisions of this Chapter.

2. The Department may issue an administrative citation to a producer, plan operator or product stewardship organization for violation of this Chapter or any regulation adopted pursuant to this Chapter. The Department shall first send a written

warning to the producer, plan operator or product stewardship organization as well as a copy of this Chapter and any regulations adopted pursuant to this Chapter. The producer, plan operator or product stewardship organization shall have 30 days after receipt of the warning to comply and correct any violations.

3. If the producer, plan operator or product stewardship organization fails to comply and correct any violations, the Department may impose administrative fines for violations of this Chapter or of any regulations adopted pursuant to this Chapter. Each day shall constitute a separate violation for these purposes. .

4. Any person in violation of this Chapter or any regulation adopted pursuant to this Chapter shall be liable to the County of Westchester for a civil penalty in an amount not to exceed \$1,000 per day per violation. Each day in which the violation continues shall constitute a separate and distinct violation.

5. In determining the appropriate penalties, the Department shall consider the extent of harm caused by the violation, the nature and persistence of the violation, the frequency of past violations, any action taken to mitigate the violation, and the financial burden to the violator.

6. Any producer, plan operator or product stewardship organization receiving an administrative citation under this Chapter or any regulation adopted pursuant to this Chapter may appeal it within 21 calendar days from the date the administrative citation was issued. The administrative citation is deemed issued on the day it is sent by first class mail or personal service. The administrative citation shall state the date of issuance. If the deadline falls on a weekend or County holiday, then the deadline shall be extended until the next regular business day. The request to appeal must:

- i. Be in writing;
  - ii. Be accompanied by a deposit of the total fine and any fees noted on the administrative citation;
  - iii. Specify the basis for the appeal in detail;
  - iv. Be postmarked within 21 days from the date the administrative citation was issued; and
  - v. Be sent to the address as set forth on the administrative citation.
7. The written request to appeal will be reviewed and, if found to be complete, a date, time and place shall be set for a hearing before a Hearing Officer designated by the Director of the Department. Written notice of the time and place for the hearing will be served by first class mail or personal service at least 21 days prior to the date of the hearing to the producer, plan operator or product stewardship organization appealing the citation. Service by first class mail, postage prepaid, shall be effective on the date of mailing.
8. Failure of any producer, plan operator or product stewardship organization to file an appeal in accordance with the provisions of this section shall constitute waiver of that producer's, plan operator's or product stewardship organization's rights to administrative determination of the merits of the administrative citation and the amount of the fine and any fees and shall constitute a failure by that producer to exhaust administrative remedies.
9. The producer, plan operator or product stewardship organization requesting the appeal may request the Director of the Department to recuse a Hearing Officer for reasons of actual prejudice against the party's cause. The Hearing Officer

shall conduct an orderly, fair hearing and accept evidence as follows:

- i. A valid administrative citation shall be prima facie evidence of the violation.
- ii. Testimony shall be by declaration under penalty of perjury except to the extent the Hearing Officer permits or requires live testimony concerning the violation.
- iii. The Hearing Officer may reduce, waive or conditionally reduce the fines and any fees stated in the administrative citation. The Hearing Officer may impose deadlines or a schedule for payment of the fine and any fees due in excess of the deposit.
- iv. The Hearing Officer shall make findings based on the record of the hearing and make a written decision based on the findings ("Hearing Officer decision"). The Hearing Officer decision shall be served by first class mail on the producer appealing and the Department. The Hearing Officer decision affirming or dismissing the administrative citation is final.

10. The Department may establish appropriate administrative rules for implementing this Chapter, conducting hearings, and rendering decisions pursuant to this section.

11. Upon the failure of any producer to comply with any requirement of this Chapter and any rule or regulation adopted pursuant to this Chapter, the County Attorney of Westchester County may petition any court having jurisdiction for injunctive relief, payment of civil penalties and any other appropriate remedy, including restraining such person or entity from continuing any prohibited activity and compelling compliance with lawful requirements. However, this subsection does not

permit the County of Westchester or any court of competent jurisdiction to restrain the sale of any covered drug in Westchester County.

**Sec. 538.91. Additional provisions.**

1. Disclaimer. In adopting and implementing this Chapter, the County of Westchester is assuming an undertaking only to promote the general welfare. Westchester County is not assuming or imposing on its officers and employees an obligation by which they could be liable in money damages to any person or entity who claims that a breach proximately caused injury.

2. Conflict with State or Federal Law. This Chapter shall be construed so as not to conflict with applicable Federal or State laws, rules or regulations. Nothing in this Chapter shall authorize any Westchester County agency or Department to impose any duties or obligations in conflict with limitations on municipal authority established by State or Federal law at the time such agency or Department action is taken. Westchester County shall suspend enforcement of this Chapter to the extent that said enforcement would conflict with any preemptive State or Federal legislation subsequently adopted.

3. Severability. If any of the provisions of this Chapter or the application thereof to any person or circumstance is held invalid, the remainder of those provisions, including the application of such part or provisions to persons or circumstances other than those to which it is held invalid shall not be affected thereby and shall continue in full force and effect. To this end, the provisions of this Chapter are severable.

4. Nothing in this Chapter, or the program of stewardship in which

manufacturers of pharmaceutical products who sell drugs in Westchester County are required to participate, is intended to protect anticompetitive or collusive conduct nor shall this Chapter be construed to modify, impair, or supersede the operation of any of the antitrust laws or unfair competition laws of the State of New York or of the United States.

5. This Chapter shall be construed in accordance with New York State law, including but not limited to New York Public Health Law, Article 13, Title 13 (Storage, Treatment and Disposal of Regulated Medical Waste) and New York Environmental Conservation Law, Article 27, Title 15 (Storage, Treatment, Disposal and Transportation of Regulated Medical Waste) and shall not be construed in a way that would result in conflict with, or preemption by, any such State law.

§2. This Local Law shall take effect 30 days after its adoption.

TO: HONORABLE BOARD OF LEGISLATORS  
COUNTY OF WESTCHESTER

Your Committee has reviewed “A LOCAL LAW amending the Laws of Westchester County by adding a new Chapter 538 establishing a Pharmaceutical Product Stewardship Program.”

Your Committee is informed that Westchester County has seen a scourge of prescription drug abuse. In the year 2015 alone, 107 Westchester residents died from overdoses. According to the County Medical Examiner’s report, one family of drugs, opioids and opiates which includes heroin, were the cause of 83% of these deaths.

Your Committee is also informed that in 2011 the United States Department of Health and Human Services, Centers for Disease Control and Prevention stated that unintentional prescription opioid overdose kills more Americans than cocaine and heroin combined. The cycle of addiction too frequently begins with extra painkillers lying around someone’s medicine cabinet. People are often prescribed large quantities of serious drugs to deal with short-term pain which can quickly lead to dependence, which turns into abuse of leftover pills and escalation to illegal narcotics. Another path to addiction results from extra, unused pain medications ending up in the possession of others – stolen from medicine cabinets by people who are already addicted or by teenagers experimenting with drugs recreationally.

Your Committee is aware of the serious environmental repercussions the practice of dumping unwanted medications down the drain or in the garbage. These disposed pills often find a way into our waterways and landfills harming our drinking water supply. Even if they enter the sewage system first, pharmaceutical compounds reach wastewater treatment plants that are not designed to remove them before being released into the environment. A 2002 study conducted by the U.S. Geological Survey found that 80 percent of streams tested across the country were contaminated with at least one pharmaceutical, personal care product or other organic wastewater contaminants.

This proposed Local Law which increases the number of places where people can return unused drugs, will help reduce the number of unused prescriptions left in people's homes, cutting off a major source of the first pill that gets a victim hooked. In addition the alarming cocktail of pharmaceuticals contaminating our water, increasing the opportunities for people to safely rid their medicine cabinets of prescription drugs they no longer need will benefit our ecological system. Sound practices like these can make a difference in preserving our environment and help to save lives.

Your Committee notes that the purpose of this proposed Local Law is to protect the health, safety and welfare of the public and our environment by providing for the safe and orderly collection and disposal of unused drugs; and by placing responsibility for end-of-life management of drug products on the manufacturers of

the products, while encouraging product design that minimizes negative impacts on human health and the environment at every stage of the product's lifecycle.

Your Committee notes that that this proposed Local Law will require pharmacy chains with more than three stores in Westchester County to become locations to dispose of unused medications. This Product Stewardship Program, which was recently adopted into law in Rockland County, is intended to help stem the tide of widespread drug abuse, particularly of opioids. Signage about the program near the retail establishment's entrance, as well as the creation of a hotline and a website for county residents to locate drop-off sites is required. Fines of up to \$1,000 can be imposed on companies failing to comply with this measure.

As you know, this Honorable Board must comply with the requirements of the State Environmental Quality Review Act ("SEQRA"). Your Committee is advised that the Department of Planning has reviewed the applicable SEQRA regulations, and has concluded that this proposed Local Law "will not 'change the use, appearance or condition of any natural resource or structure' or otherwise affect the environment, other than to facilitate the proper disposal of unused drugs." Therefore, the proposed local law does not constitute an action as defined in section 617.2(b) of 6 NYCRR Part 617 and, as such, no environmental review is required. Your Committee concurs with that conclusion.

Your Committee, after careful consideration, recommends the adoption of this

Local Law.

Dated: \_\_\_\_\_, 2017  
White Plains, New York

COMMITTEE ON

A/5-17-17

Attachment: Local Law-Establishing a Pharmaceutical Product Stewardship Program - DRAFT2 (10035 : Local Law-Establishing a

**RESOLUTION NO. \_\_\_\_ – 2017**

RESOLVED, that this Board hold a public hearing pursuant to Section 209.141(4) of the Laws of Westchester County on Local Law Intro. No. \_\_\_\_ - 2017, entitled “A LOCAL LAW amending the Laws of Westchester County by adding a new Chapter 538 establishing a Pharmaceutical Product Stewardship Program.” The public hearing will be held at \_\_.m. on the \_\_\_\_ day of \_\_\_\_\_, 2017 in the Chambers of the Board of Legislators, 8th Floor, Michaelian Office Building, White Plains, New York. The Clerk of the Board shall cause notice of the time and date of such hearing to be published at least once in one or more newspapers published in the County of Westchester and selected by the Clerk of the Board for that purpose in the manner and time required by law.



Memorandum  
Department of Planning

TO: Thomas Gardiner  
Senior Assistant County Attorney

FROM: Eileen Mildenberger   
Acting Commissioner

DATE: May 5, 2017

SUBJECT: **SEQR DOCUMENTATION FOR PHARMACEUTICAL PRODUCT STEWARDSHIP PROGRAM**

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Pursuant to your request for an environmental review of the above referenced action, the Planning Department has determined that no environmental review is necessary.

The action involves a local law that would add a new chapter, Chapter 538, to the Laws of Westchester County, which would require producers of certain drugs that are sold or distributed in Westchester County to establish a program to accept and dispose of unwanted drugs from the public. Collection sites are to be provided at retail stores and public health facilities. The Department of Consumer Protection will be responsible for administering and implementing the requirements of this law.

Since the action will not “change the use, appearance or condition of any natural resource or structure,” or otherwise affect the environment, other than to facilitate the proper disposal of unused drugs, with respect to the State Environmental Quality Review (SEQR) Act, the proposed local law does not constitute an action as defined in section 617.2(b) of 6NYCRR Part 617. As such, no environmental review is required.

Please contact my office if you need any additional information on this matter.

EMM/cnm

cc: Mark Fang, Director of Consumer Protection  
Robert Alberty, Deputy Chief of Staff  
Paula Friedman, Assistant to the County Executive  
David Kvinge, Director of Environmental Planning

**LOCAL LAW INTRO. NO. -2017**

A LOCAL LAW amending the Laws of Westchester County by adding a new Chapter 538 establishing a Pharmaceutical Product Stewardship Program.

BE IT ENACTED by the County Board of the County of Westchester as follows:

Section 1. A new Chapter 538 is hereby added to the Laws of Westchester

County to read as follows:

**CHAPTER 538****PHARMACEUTICAL PRODUCT STEWARDSHIP PROGRAM**

**Sec. 538.01. Definitions.**

**Sec. 538.11. Product stewardship program.**

**Sec. 538.21. Product stewardship plan.**

**Sec. 583.31. Disposal of unwanted products.**

**Sec. 538.41. Product stewardship program promotion and outreach.**

**Sec. 538.51. Retailer participation.**

**Sec. 538.61. List of producers.**

**Sec. 538.71. Regulations and fees.**

**Sec. 538.81. Enforcement.**

**Sec. 538.91. Additional provisions.**

**Sec. 538.01. Definitions.**

For the purposes of this Chapter, the following terms have the meanings given below.

1. LEGISLATURE refers to the Westchester County Board of Legislators.
2. CONSUMER GENERATORS means residents of single and multiple family residences or other locations, who possess, dispose of or abandon household drugs. "Consumer generators" does not include drug seizures by law enforcement, pharmacy waste, business waste, or any other source identified by the Department as a non-consumer source.

3. CONTROLLED SUBSTANCE for purposes of this Chapter shall mean any substance listed under New York Public Health Law Section 3306 or Title 21 of the United States Code, Sections 812 and 813 or any successor legislation.

4. COSMETICS means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to, the human body, or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, (2) articles intended for use as a component of any such articles, and (3) cosmetics as defined above with expiration dates.

5. COVERED DRUG means all drugs as defined in 21 U.S.C. Section 321(g)(1) of the Federal Food, Drug and Cosmetic Act (FFDCA) covered under 21 U.S.C. Section 353(b)(1) of the FFDCA, including both brand name and generic drugs, and nonprescription drugs. "Covered drug" does not include: (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 nonprescription drugs under the Federal Food, Drug, and Cosmetic Act ("FFDCA") (21 U.S.C. Section 301 et seq. [2002]); (4) drugs for which producers provide a takeback program as part of a Federal Food and Drug Administration managed risk evaluation and mitigation strategy (21 U.S.C. Section 3551); (5) drugs that are biological products as defined by 21 CFR 600.3(h) as it exists on the effective date of this section if the producer already provides a takeback program; and (6) pet pesticide products contained in pet collars, powders, shampoos, topical applications.

or other delivery systems.

6. COUNTY means the County of Westchester, New York.

7. DEPARTMENT means the Westchester County Department of Consumer Protection.

8. DRUG WHOLESALER means a business that sells or distributes drugs and covered drugs for resale to an entity other than a consumer.

9. DRUGS means: (1) articles recognized in the official United States pharmacopoeia, the official national formulary, the official homeopathic pharmacopoeia of the United States, or any supplement of the formulary or those pharmacopoeias; (2) substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; (3) substances, other than food, intended to affect the structure or any function of the body of humans or other animals. "Drugs" does not mean medical devices, their component parts or accessories.

10. ENTITY means a person other than an individual.

11. GENERIC DRUG means a drug that is chemically identical or bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use, though inactive ingredients may vary.

12. HAZARDOUS WASTE means pharmaceutical waste that falls under the Federal Resource Conservation and Recovery Act (RCRA) of 1976, as amended (42 U.S.C.A. Section 6901 et seq.). This waste includes bulk chemotherapy drugs, P-listed waste, U-listed waste and characteristic hazardous waste.

13. MANUFACTURE means the production, preparation, propagation, compounding, or processing of drugs but does not include the activities of a repackager, wholesaler or medical practitioner.

14. MANUFACTURER means a person, company, corporation or other entity engaged in the manufacture of drugs.

15. MAIL-BACK PROGRAM means a system whereby consumer generators of unwanted products obtain prepaid and preaddressed mailing envelopes in which to place unwanted products for shipment to an entity that will dispose of them safely and legally.

16. MEDICAL WASTE means any biohazardous, pathology, pharmaceutical, or trace chemotherapy waste not regulated by the Federal Resource Conservation and Recovery Act (RCRA) of 1976, as amended; sharps and trace chemotherapy wastes generated in a health care setting in the diagnosis, treatment, immunization, or care of humans or animals; waste generated in autopsy or necropsy; waste generated during preparation of a body for final disposition such as cremation or interment; waste generated in research pertaining to the production or testing of microbiologicals; waste generated in research using human or animal pathogens; sharps and laboratory waste that poses a potential risk of infection to humans generated in the inoculation of animals in commercial farming operations; waste generated from the consolidation of home-generated sharps; and waste generated in the cleanup of trauma scenes.

17. NONPRESCRIPTION DRUG means any drug that may be lawfully sold without a prescription.

18. PERSON means an individual, firm, sole proprietorship, corporation,

limited liability corporation, general partnership, limited partnership, limited liability partnership, association, cooperative, or other legal entity, however organized.

19. PHARMACY means any place registered as a pharmacy pursuant to Section 6802 of New York Education Law where the practice of pharmacy is conducted.

20. PLAN or PRODUCT STEWARDSHIP PLAN means a product stewardship plan required under this Chapter that describes the manner in which a product stewardship program will be provided.

21. PLAN OPERATOR means the person, company or organization that develops, implements and operates a product stewardship plan, including but not limited to a producer or stewardship organization.

22. PRESCRIPTION DRUG means any drug that by Federal or State law may be dispensed lawfully only on prescription.

23. PRODUCER shall be determined, with regard to covered drugs that are sold, offered for sale, or distributed in Westchester County as meaning one of the following:

(i). The person who manufactures covered drugs and who sells, offers for sale, or distributes covered drugs in Westchester County under that person's own name or brand.

(ii). If there is no person who sells, offers for sale, or distributes covered drugs in Westchester County under the person's own name or brand, the producer of covered drugs is the owner or licensee of a trademark or brand under which the covered drugs are sold or distributed in Westchester County, whether or not the

trademark is registered.

(iii). If there is no person who is a producer of covered drugs for purposes of subsections “i” and “ii” of this subdivision, the producer of covered drugs is the person who brings the covered drug into Westchester County for sale or distribution. "Producer" does not include (1) a retailer that puts its store label on a covered drug, or (2) a pharmacist who dispenses prescription drugs to, or compounds a prescribed individual drug product for a consumer.

24. PRODUCT STEWARDSHIP PROGRAM or PROGRAM means a program financed and operated by producers.

25. PROVIDER means any person or entity that sells or otherwise furnishes drugs to consumers at a medical or veterinary office, clinic, hospital or approved needle exchange program located in the County.

26. PUBLIC HEARING means any hearing held by the Department or the County which is open to the public for the purposes of collecting public comment. It does not necessarily refer to meetings of the Legislature.

27. RETAILER means any person or entity that sells drugs directly to consumers at a business located in the County. To be subject to this law, a retailer must belong to a chain of three or more retail establishments, whether operating inside or outside of Westchester County, that are engaged in the same general field of business and: (1) conduct business under the same business name; or (2) operate under common ownership or management or pursuant to a franchise agreement with the same franchisor.

28. STEWARDSHIP ORGANIZATION means an organization designated by

a group of producers to act as an agent on behalf of each producer to operate a product stewardship program.

29. UNWANTED PRODUCTS means covered drugs no longer wanted by the owner or that have been abandoned, discarded, or are intended to be discarded by the owner.

**Sec 538.11. Product stewardship program.**

1. Requirement for Sale. This Chapter shall apply only to producers whose covered drugs are sold or distributed in Westchester County and to retailers who sell covered drugs in Westchester County. This Chapter shall be administered and implemented by the Westchester County Department of Consumer Protection.

Each producer must:

- i. Operate, individually or jointly with other producers, a product stewardship program approved by the Department in consultation with the Westchester County Department of Health; or
- ii. Enter into an agreement with a stewardship organization to operate, on the producer's behalf, a product stewardship program approved by the Department in consultation with the Westchester County Department of Health.

2. Product Stewardship Program Costs.

- i. A producer, group of producers, or stewardship organization must pay all administrative and operational fees associated with their product stewardship program, including the cost of collecting, transporting, and disposing of unwanted products collected from consumer generators and the recycling or disposal, or both, of packaging collected with the unwanted product.

ii. A producer, group of producers, or stewardship organization must pay for all fees and expenses associated with obtaining compliance with the New York State Environmental Quality Review (6 NYCRR Part 617), if required, for a specific product stewardship program and product stewardship plan.

iii. No person or producer may charge a specific point of sale fee to consumers to recoup the costs of their product stewardship program, nor may they charge a specific point of collection fee at the time the unwanted products are collected from consumer generators or delivered for disposal.

iv. A producer, group of producers, or stewardship organization must pay all costs incurred by the County of Westchester, including but not limited to the Department, in the administration and enforcement of their product stewardship program. Exclusive of fines and penalties, the County of Westchester shall only recover its actual costs of administration and enforcement under this Chapter and shall not charge any amounts under this Chapter in excess of its actual administrative and enforcement costs.

v. A producer, group of producers, or stewardship organization must pay all collection and disposal costs as of the date that the ordinance codified in this Chapter becomes effective. If the County incurs any costs due to delays in establishment of an approved stewardship plan, the producer, group of producers, or stewardship organization must reimburse the County in full for such costs.

**Sec. 538.21. Product stewardship plan.**

1. Plan Content. Each product stewardship program shall have a product stewardship plan that contains each of the following:

- i. Certification that the product stewardship program will accept all unwanted products regardless of who produced them, unless excused from this requirement by the Department as part of the approval of the plan;
- ii. Contact information for the individual and the entity submitting the plan and for each of the producers participating in the product stewardship program;
- iii. A description of the methods by which unwanted products from consumer generators will be collected at all retail sale facilities of drugs in the County, including a description of bins to be used and collection methods;
- iv. A description of the methods by which unwanted products from consumer generators will be collected at all public health facilities in Westchester County, as well as at such other locations as designated by the Department, including a description of bins to be used and collection methods;
- v. The location of each collection site and locations where envelopes for a mail-back program are available (if applicable);
- vi. A list containing the name, location, permit status, and record of any penalties, violations, or regulatory orders received in the previous five years by each person that will be involved in transporting unwanted products and each medical waste or hazardous waste disposal facility proposed to participate in the product stewardship program;
- vii. A description of how the unwanted products will be safely and securely tracked and handled from collection through final disposal and the policies and procedures to be followed to ensure security;
- viii. A description of the public education and outreach activities required

under this Chapter and how their effectiveness will be evaluated;

ix. A description of how the scope and extent of the product stewardship program are reasonably related to the number of covered drugs that are sold in the County of Westchester, by the producer or group of producers;

x. A starting date when collection of unwanted products will begin;

xi. A description of how support will be provided to any law enforcement agencies within Westchester County that have, or later agree to have, a collection program for controlled substances, including: (a) the provision of a collection kiosk with appropriate accessories and signage, (b) an ability to accept controlled substances and other covered drugs, (c) technical support up to and including an appropriate person to provide onsite assistance with the sorting and separation of controlled substances at no cost to a participating law enforcement agency;

xii. If more than one producer will be involved in a proposed product stewardship program, then the product stewardship plan for that program must include a fair and reasonable manner for allocating the costs of the program among the participants in that program, such that the portion of costs paid by each producer is reasonably related to the number of covered drugs that producer sells in the County of Westchester.

## 2. Department Review and Approval-Updates.

i. No producer, group of producers, or stewardship organization may begin collecting unwanted products to comply with this Chapter until it has received written approval of its product stewardship plan from the Department. The County may continue collection on an interim basis if there is any delay in establishing a

stewardship program as required.

ii. Product stewardship plans must be submitted to the Department for approval. The initial plans must be submitted by December 31, 2017, or at a later date as approved in writing by the Department.

iii. Within 60 days after receipt and review of a product stewardship plan, the Department will determine whether the plan complies with the requirements of this Chapter and of any regulations adopted pursuant to this Chapter. The Department may at its sole discretion conduct a noticed public hearing as part of this process.

a. As part of its approval, the Department may set reasonable performance goals for the program.

b. If the Department approves a plan, it shall notify the applicant of its approval in writing.

c. If the Department rejects a plan, it shall notify the applicant in writing of its reasons for rejecting the plan. The Department may reject a plan without conducting a public hearing.

d. An applicant whose plan has been rejected by the Department must submit a revised plan to the Department within 30 days after receiving notice of the rejection. The Department may require the submission of a further revised plan or, at its sole discretion, the Department may develop, approve and impose its own product stewardship plan or an approved plan submitted by other producer(s) pursuant to this Chapter. The imposed plan will be presented at a public hearing. The Department is not required, and nothing in this Chapter shall be interpreted as requiring, the Department to create or impose a product stewardship plan.

e. If the Department rejects a revised product stewardship plan or any other subsequently revised plan, the producer(s) at issue shall be out of compliance with this Chapter and shall be subject to the enforcement provisions contained in this Chapter.

iv. At least every three years, a producer, group of producers or stewardship organization operating a product stewardship program shall update its product stewardship plan and submit the updated plan to the Department for review and approval.

v. A producer who begins to offer a covered drug for sale in the County of Westchester after December 31, 2017, must submit a product stewardship plan to the Department or provide evidence of having joined an existing approved product stewardship program within 60 days following the producer's initial offer for sale of a covered drug.

vi. Any proposed changes to a product stewardship plan must be submitted in writing to the Department and approved by the Department in writing prior to implementation of any change.

vii. Required Plan Amendment. Within 60 days of the final promulgation of any rules by the New York State Board of Pharmacy regarding collection of controlled substances by retail pharmacies in conformity with the U.S. Drug Enforcement Agency regulations resulting from the Secure and Responsible Drug Disposal Act of 2010, each producer, group of producers or stewardship organization operating a product stewardship program shall submit to the Department for review and approval an update to its product stewardship plan that describes how the plan will, within 120 days, include collection of controlled substances at all collection locations on the

premises of retailers and providers of covered drugs.

**Sec. 538.31. Disposal of unwanted products.**

1. Compliance with Applicable Law. Each product stewardship program must comply with all local, State, and Federal laws and regulations applicable to its operations, including laws and regulations governing the treatment and disposal of unwanted products.

2. Treatment and Disposal. Each product stewardship program must dispose of all unwanted covered drugs by incineration at a medical waste or hazardous waste facility. Each treatment or disposal facility utilized must be in possession of all required regulatory permits and licenses.

3. New Technologies. Producers with product stewardship programs may petition the Department for approval to use treatment and final disposal technologies, where lawful, that provide superior environmental and human health protection than provided by current medical waste disposal technologies for covered drugs if and when those technologies are proven and available. The proposed technology must provide equivalent protection in each, and superior protection in one or more, of the following areas:

- i. Monitoring of any emissions or waste;
- ii. Worker health and safety;
- iii. Air, water, or land emissions contributing to persistent, bioaccumulative, and toxic pollution; and
- iv. Overall impact on the environment and human health.

4. Packaging Separation. Each product stewardship program shall encourage

consumer generators to separate unwanted products from their original containers and packaging, when appropriate, prior to collection or disposal.

**Sec. 538.41. Product stewardship program promotion and outreach.**

1. A product stewardship program must promote the program to consumer generators, pharmacists, retailers of covered drugs, and health care practitioners as to the proper and safe method to dispose of unwanted products.

2 A product stewardship program shall include, but is not limited to, developing, and updating as necessary, educational and other outreach materials for use by retailers of covered drugs. These materials may include, but are not limited to, two or more of the following:

- i. Signage that is prominently displayed and easily visible to the consumer.
- ii. Written materials and templates of materials for reproduction by retailers to be provided to the consumer at the time of purchase or delivery, or both.
- iii. Advertising and/or other promotional materials related to the product stewardship program.

3. A product stewardship program must prepare education and outreach materials that publicize the location and operation of collection locations in Westchester County and disseminate the materials to health care facilities, pharmacies, and other interested parties. The program also must establish a website publicizing collection locations and program operations and a toll- free telephone number that consumer generators can call to find nearby collection locations and understand how the program works.

**Sec. 538.51. Retailer participation.**

1. Every retailer and every provider of covered drugs in the County shall establish a system consistent with the requirements of this Chapter for the collection of discarded consumer generated covered drugs for proper disposal during the retailer's or provider's normal hours of operation, except that a retailer or provider who does not sell or provide covered drugs to consumers is not required to establish a collection system for discarded covered drugs.

2. Each system established by a retailer or provider for the collection and disposal of discarded consumer generated covered drugs shall include, at a minimum, the following elements:

i. Each retailer or provider shall provide one of the following:

a. On-Site Collection System. Receptacles for the collection of discarded consumer-generated covered drugs within the retailer or provider establishment. The receptacle shall meet applicable State and Federal standards for safe disposal of drugs. The retailer or provider shall provide for the management and disposal of all discarded consumer-generated covered drugs that is collected at the retailer or provider establishment in a safe manner consistent with all State and Federal laws and regulations; or

b. Mail-Back Collection System. Prepaid mail-back envelopes in sufficient capacity for safe disposal of discarded covered drugs, as required by a consumer.

ii. Signage prominently displayed within five feet of every public entrance to the retailer or provider establishment and easily visible to the consumer, indicating that the retailer or provider establishment collects consumer-generated covered drugs

from consumers.

3. All costs of participation by retailers and providers shall be paid or reimbursed by the producer, group of producers, or stewardship organization as part of its program as provided in this Chapter. Retailers and providers shall not be expected to incur any costs for participation.

**Sec. 538.61. List of producers.**

The Department of Consumer Protection and the Department of Health shall provide on their respective websites a list of all producers participating in product stewardship programs approved by the Department and a list of all producers the Department has identified as noncompliant with this Chapter or any regulations adopted pursuant to this Chapter.

**Sec. 538.71. Regulations and fees.**

1. The Director of the Department of Consumer Protection may, after a noticed public hearing, adopt such rules and regulations as necessary to implement, administer, and enforce this Chapter.

2. As soon as practicable, the Department shall submit to the Legislature a proposed schedule of fees to be charged to producers to cover Westchester County's costs of administering and enforcing this Chapter.

**Sec. 538.81. Enforcement.**

1. The Department shall administer the penalty provisions of this Chapter.

2. The Department may issue an administrative citation to a producer, plan operator or product stewardship organization for violation of this Chapter or any regulation adopted pursuant to this Chapter. The Department shall first send a written

warning to the producer, plan operator or product stewardship organization as well as a copy of this Chapter and any regulations adopted pursuant to this Chapter. The producer, plan operator or product stewardship organization shall have 30 days after receipt of the warning to comply and correct any violations.

3. If the producer, plan operator or product stewardship organization fails to comply and correct any violations, the Department may impose administrative fines for violations of this Chapter or of any regulations adopted pursuant to this Chapter. Each day shall constitute a separate violation for these purposes. .

4. Any person in violation of this Chapter or any regulation adopted pursuant to this Chapter shall be liable to the County of Westchester for a civil penalty in an amount not to exceed \$1,000 per day per violation. Each day in which the violation continues shall constitute a separate and distinct violation.

5. In determining the appropriate penalties, the Department shall consider the extent of harm caused by the violation, the nature and persistence of the violation, the frequency of past violations, any action taken to mitigate the violation, and the financial burden to the violator.

6. Any producer, plan operator or product stewardship organization receiving an administrative citation under this Chapter or any regulation adopted pursuant to this Chapter may appeal it within 21 calendar days from the date the administrative citation was issued. The administrative citation is deemed issued on the day it is sent by first class mail or personal service. The administrative citation shall state the date of issuance. If the deadline falls on a weekend or County holiday, then the deadline shall be extended until the next regular business day. The request to appeal must:

- i. Be in writing;
  - ii. Be accompanied by a deposit of the total fine and any fees noted on the administrative citation;
  - iii. Specify the basis for the appeal in detail;
  - iv. Be postmarked within 21 days from the date the administrative citation was issued; and
  - v. Be sent to the address as set forth on the administrative citation.
7. The written request to appeal will be reviewed and, if found to be complete, a date, time and place shall be set for a hearing before a Hearing Officer designated by the Director of the Department. Written notice of the time and place for the hearing will be served by first class mail or personal service at least 21 days prior to the date of the hearing to the producer, plan operator or product stewardship organization appealing the citation. Service by first class mail, postage prepaid, shall be effective on the date of mailing.
8. Failure of any producer, plan operator or product stewardship organization to file an appeal in accordance with the provisions of this section shall constitute waiver of that producer's, plan operator's or product stewardship organization's rights to administrative determination of the merits of the administrative citation and the amount of the fine and any fees and shall constitute a failure by that producer to exhaust administrative remedies.
9. The producer, plan operator or product stewardship organization requesting the appeal may request the Director of the Department to recuse a Hearing Officer for reasons of actual prejudice against the party's cause. The Hearing Officer

shall conduct an orderly, fair hearing and accept evidence as follows:

- i. A valid administrative citation shall be prima facie evidence of the violation.
- ii. Testimony shall be by declaration under penalty of perjury except to the extent the Hearing Officer permits or requires live testimony concerning the violation.
- iii. The Hearing Officer may reduce, waive or conditionally reduce the fines and any fees stated in the administrative citation. The Hearing Officer may impose deadlines or a schedule for payment of the fine and any fees due in excess of the deposit.
- iv. The Hearing Officer shall make findings based on the record of the hearing and make a written decision based on the findings ("Hearing Officer decision"). The Hearing Officer decision shall be served by first class mail on the producer appealing and the Department. The Hearing Officer decision affirming or dismissing the administrative citation is final.

10. The Department may establish appropriate administrative rules for implementing this Chapter, conducting hearings, and rendering decisions pursuant to this section.

11. Upon the failure of any producer to comply with any requirement of this Chapter and any rule or regulation adopted pursuant to this Chapter, the County Attorney of Westchester County may petition any court having jurisdiction for injunctive relief, payment of civil penalties and any other appropriate remedy, including restraining such person or entity from continuing any prohibited activity and compelling compliance with lawful requirements. However, this subsection does not

permit the County of Westchester or any court of competent jurisdiction to restrain the sale of any covered drug in Westchester County.

**Sec. 538.91. Additional provisions.**

1. Disclaimer. In adopting and implementing this Chapter, the County of Westchester is assuming an undertaking only to promote the general welfare. Westchester County is not assuming or imposing on its officers and employees an obligation by which they could be liable in money damages to any person or entity who claims that a breach proximately caused injury.

2. Conflict with State or Federal Law. This Chapter shall be construed so as not to conflict with applicable Federal or State laws, rules or regulations. Nothing in this Chapter shall authorize any Westchester County agency or Department to impose any duties or obligations in conflict with limitations on municipal authority established by State or Federal law at the time such agency or Department action is taken. Westchester County shall suspend enforcement of this Chapter to the extent that said enforcement would conflict with any preemptive State or Federal legislation subsequently adopted.

3. Severability. If any of the provisions of this Chapter or the application thereof to any person or circumstance is held invalid, the remainder of those provisions, including the application of such part or provisions to persons or circumstances other than those to which it is held invalid shall not be affected thereby and shall continue in full force and effect. To this end, the provisions of this Chapter are severable.

4. Nothing in this Chapter, or the program of stewardship in which

manufacturers of pharmaceutical products who sell drugs in Westchester County are required to participate, is intended to protect anticompetitive or collusive conduct nor shall this Chapter be construed to modify, impair, or supersede the operation of any of the antitrust laws or unfair competition laws of the State of New York or of the United States.

5. This Chapter shall be construed in accordance with New York State law, including but not limited to New York Public Health Law, Article 13, Title 13 (Storage, Treatment and Disposal of Regulated Medical Waste) and New York Environmental Conservation Law, Article 27, Title 15 (Storage, Treatment, Disposal and Transportation of Regulated Medical Waste) and shall not be construed in a way that would result in conflict with, or preemption by, any such State law.

§2. This Local Law shall take effect 30 days after its adoption.