

STRICKEN AS OF END OF YEAR
AMENDED COPY AS OF 9/30/2015

Intro. Res. No. 1564-2015
Introduced by Legislator Hahn

Laid on Table 7/28/2015

**RESOLUTION NO. -2015, ADOPTING LOCAL
LAW NO. -2015, A LOCAL LAW ESTABLISHING A DRUG
STEWARDSHIP PROGRAM FOR SUFFOLK COUNTY**

WHEREAS, there was duly presented and introduced to this County Legislature at a meeting held on _____, 2015, a proposed local law entitled, "**A LOCAL LAW ESTABLISHING A DRUG STEWARDSHIP PROGRAM FOR SUFFOLK COUNTY**"; now, therefore be it

RESOLVED, that said local law be enacted in form as follows:

LOCAL LAW NO. -2015, SUFFOLK COUNTY, NEW YORK

**A LOCAL LAW ESTABLISHING A DRUG STEWARDSHIP
PROGRAM FOR SUFFOLK COUNTY**

**BE IT ENACTED BY THE COUNTY LEGISLATURE OF THE COUNTY OF
SUFFOLK**, as follows:

Section 1. Legislative Intent.

This Legislature hereby finds and determines that pharmaceuticals are essential to the treatment of illnesses and long term conditions, allowing us to live longer, healthier lives.

This Legislature also finds and determines that prescription and over-the-counter drugs are often disposed of improperly, entering public drinking water supplies and causing harm to the environment.

This Legislature further finds and determines that Suffolk County sits atop a sole source aquifer which provides residents with necessary drinking water. Protection of the aquifer is critical to the health and safety of Long Island residents.

This Legislature finds that when medications are improperly disposed of, by flushing pills down the drain, water treatment plants do not remove medications from the potable water supply, exposing residents to trace or higher amounts of medications like benzodiazepines, steroids, pain killers, anti-epileptics and anti-depressants.

This Legislature determines that the failure to properly dispose of unused prescription pain killers can lead to abuse of these addictive medications. Research conducted by the Partnership for Drug Free Kids finds that the majority of teens who abuse prescription medications obtain them at the homes of their friends and family.

This Legislature also finds that prescription and over-the-counter medications are best disposed of through drug take back programs.

This Legislature further finds that Suffolk County operates a limited drug take back program at police precincts within the County Police Department and supports similar programs outside of the County Police District. These programs do not meet the needs of all County residents, particularly those in the environmentally sensitive east end. The program locations are also limited, which significantly reduces widespread participation.

This Legislature also determines that product stewardship is a strategy that allocates responsibility for drug disposal between consumers and manufacturers when products reach the end of their useful life.

This Legislature further determines that several counties in the United States, including Alameda County in California, have established drug product stewardship policies which require drug manufacturers to design and fund comprehensive collection programs for unwanted, unused and expired prescription and over-the counter medications. The program established by Alameda County was upheld by the courts upon challenge.

This Legislature also determines that manufacturer-funded drug product stewardship programs have been successfully established in France, Spain and Portugal, as well as in many provinces throughout Canada.

This Legislature further determines that New York does not have statewide stewardship program for unwanted medications. Drug manufacturers and producers have not offered to establish a collection program independently.

This Legislature also finds that Suffolk County should establish a manufacturer sponsored drug collection system to protect the health and welfare of County residents and the environment.

Therefore, the purpose of this local law is to establish a drug stewardship program that is fully funded and operated by drug manufacturers.

Section 2. Definitions.

As used in this law, the following terms shall have the meanings indicated:

“Cosmetics” – any product or component of a product intended to be applied on the human body, or any part thereof, for the purpose of cleansing, beautifying, or altering the appearance.

“Covered Product” – all prescription and non-prescription drugs, including brand name and generic drugs, that do not fall within the definition of “cosmetics”.

“Department” – the Suffolk County Department of Health Services.

“Drug Wholesaler” – a business that sells or distributes drugs for resale to an entity other than a consumer.

“Drugs” – any brand name or generic product recognized and regulated by the federal Food and Drug Administration as a prescription or non-prescription substance used to: (a) diagnose, cure, mitigate, treat or prevent disease or (b) affect the structure or function of the human body. This definition shall not include medical devices or their component parts or accessories.

“Generic Drug” – a drug that is chemically identical or bioequivalent to a brand name drug in dosage form, safety, strength, mode of administration, quality, performance characteristics and intended use. Inactive ingredients in generic drugs may vary from brand name drugs.

“Mail-Back Program” – a system where residential generators of unwanted products obtain preaddressed and prepaid mailing envelopes in which to place unwanted products for shipment to an entity that will dispose of them safely and legally.

“Non-Prescription Drug” – any drug that may be lawfully sold without a prescription.

“Person” – any natural individual, firm, proprietorship, corporation, unincorporated association, firm, partnership, joint venture, joint stock association, or other entity or business of any kind.

“Plan” – a product stewardship plan required under this law that describes the manner in which a product stewardship program will be provided.

“Prescription Drug” – any drug that by federal or state law may only be dispensed on prescription.

“Producer” – a person that (a) has a physical presence in the United States and causes a covered drug to be manufactured or has legal ownership of the brand, brand name, or co-brand under which a covered drug is sold; or (b) imports a covered drug branded or manufactured by a person or entity without a physical presence in the United States. This term shall not include retailers that put a store label on a covered drug, unless the retailer imports the drug from a producer outside of the United States, nor shall it include individual prescribed drug products compounded by a pharmacist for a patient.

“Product Stewardship Program” – a program financed and operated by producers to collect, transport and recycle unwanted products.

“Residential Generators” – single and multiple family residences and locations within Suffolk County where household drugs are unused, unwanted, disposed of or abandoned. This term shall include hospice services, nursing homes, boarding care homes, schools, foster care, day care, and any other locations where people reside on a temporary or permanent basis. This term shall not include airport security, drug seizures made by law enforcement, pharmacy or other business waste, or any other source identified by the Department as a non-residential source.

“Stewardship Organization” – an organization designated by a group of producers to act as an agent on behalf of each producer to operate a product stewardship program.

“Unwanted Product” – any covered product no longer wanted by its owner or that has been or is intended to be discarded or abandoned by its owner.

Section 3. Product Stewardship Program.

A. On and after January 1, 2016, all producers of covered products sold in the County of Suffolk shall participate in a product stewardship program to collect and dispose of unwanted products from residential generators. Each producer must:

1. operate, individually or jointly with other producers, a product stewardship program approved by the Department; or
2. enter into an agreement with a stewardship organization to operate, on the producer's behalf, a product stewardship program approved by the Department.

B. Program costs.

1. A producer, group of producers or stewardship organization must pay all administrative and operational costs associated with their product stewardship program, including the cost of collecting, transporting and disposing of unwanted products collected from residential generators and the recycling and/or disposal of packages collected with the unwanted product.
2. A producer, group of producers, or stewardship organization must pay for all costs associated with obtaining and maintaining compliance with the New York State Environmental Quality Review Law (NYS Environmental Conservation Law § 8-0101 et seq.) and State Safe Prescription Disposal Laws (NYS Public Health Law § 3343-b), if required, for a specific product stewardship program and product stewardship plan.
3. No person or producer may charge a fee to cover the costs of a product stewardship program at the time of sale of the covered product or when unwanted products are collected from residential generators or delivered for disposal.

Section 4. Product Stewardship Plan.

A. Each product stewardship program shall have a product stewardship plan that must contain the following:

1. 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;
2. the name, address and contact information for the producer, group of producers or stewardship program submitting the plan, including contact information for the individual overseeing the program, and a list of the producer participating in the proposed product stewardship program and plan;
3. a description of the methods by which unwanted products from residential generators will be collected in the County and an explanation of how the collection process will be convenient and sufficient to serve the needs of County residents;
4. provide collection services for covered products in all areas of the County that are reasonably convenient to the public and sufficient to meet the needs of the population in the area being served;

5. if applicable, include the location of each collection site and locations where envelopes for a mail-back program are available;
6. a list containing the name, location, permit status, and record of any penalties, violations or regulatory orders received in the previous five (5) years by each transporter and each medical waste disposal facility proposed to participate in the product stewardship program;
7. a description of how the unwanted products will be safely and securely tracked and handled from collection through final disposition and the policies and procedures to be followed to ensure security;
8. a description of the public education effort and outreach activities required under this law and how their effectiveness will be evaluated;
9. a description of how the scope and extent of the stewardship program are consistent with the scope and extent of the sales of covered products within the County by the producers or group of producers; and
10. a start date when collection of unwanted products will begin. For producers or groups of producers currently offering covered products for sale in the County, that date shall be no later than July 1, 2016.

B. Department review and approval of plan.

1. No producer, group of producers, or stewardship organization may begin collecting unwanted products until it has received written approval of its product stewardship plan from the Department.
2. Product stewardship plans must be submitted to the Department for approval. The initial plans must be submitted by January 1, 2016.
3. Within ninety (90) days of receiving a plan, the Department shall determine whether the plan complies with the requirements of this law and of any regulations adopted pursuant thereto. As part of its approval, the Department may establish reasonable performance goals for the program. The Department shall notify the applicant in writing of the plan's approval or rejection. If a plan is rejected, the Department shall provide the reasoning for its rejection. An applicant whose plan is rejected must submit to the Department a revised plan within sixty (60) days of receiving notice of the rejection.
4. Every three (3) years, a producer, group of producers or stewardship organization operating a product stewardship program must update its product stewardship plan and submit the updated plan to the Department for review and approval.
5. A producer who begins to offer covered products for sale in the County of Suffolk after June, 2016 must submit a product stewardship plan to the Department or provide proof of having joined an existing approved plan at

least ninety (90) days prior to the producer's initial offer of sale of covered products.

6. Any proposed changes to a product stewardship plan must be approved in writing by the Department.

Section 5. Disposal of Unwanted Products.

A. 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 disposal of medical waste and controlled substances.

B. Each product stewardship program must dispose of all unwanted products from residential generators at a medical waste facility that possesses all necessary regulatory permits and licenses for operation.

C. Product stewardship programs may petition the Department for approval to use disposal technologies, where lawful, that provide superior environmental and human health protection than provided by current medical waste disposal technologies for covered products once 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:

1. monitoring of any emissions or waste;
2. worker health and safety;
3. air, water or land emissions contributing to persistent, bioaccumulative, and toxic pollution; and
4. overall impact on the environment and human health.

D. Each product stewardship program is encouraged to separate unwanted products from their original containers, where appropriate, prior to collection or disposal.

Section 6. Program Promotion.

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

B. A product stewardship program shall develop and distribute educational and other outreach materials aimed at retailers of covered products, updating the materials as needed. Those materials may include, but are not limited to, the following:

1. signage that is prominently displayed and easily visible to the consumer;
2. written materials and templates for materials that can be reproduced by retailers and are provided to the consumer at the time of purchase or delivery; and
3. advertising or other promotional materials.

C. A product stewardship program must prepare and distribute education and outreach materials that publicize the location and operation of collection locations in the County and distribute these materials to health care facilities, pharmacies and other interested parties. The program must also establish a website publicizing collection locations, program operations and

provide a toll-free telephone number that residential generators can call to find nearby collection locations and understand how the program works.

Section 7. Report.

Beginning on July 1, 2017 and continuing every July 1st thereafter, every producer, group of producers, or stewardship organization operating a product stewardship program must prepare and submit to the Department an annual report describing the program's activities during the preceding calendar year. The report must include:

1. a list of participating producers in the program;
2. the amount, by weight, of unwanted products collected from residential generators at each collection site, in the entire County, and, if applicable, the total amount by weight collected by a mail-back program;
3. a description of the collection system, including the location of each collection site and, if applicable, all locations where envelopes for a mail-back program are available;
4. the name and location of disposal facilities at which unwanted products were disposed of and the weight of unwanted products collected from residential generators disposed of at each facility;
5. a statement regarding adherence to the plan's policies and procedures for collecting, transporting and disposing of unwanted products during the reporting period and a description of any incidents of non-compliance, if applicable;
6. a statement regarding safety and security problems during collection, transportation, or disposal of unwanted products during the reporting period. If any problem occurred, the report shall detail any changes that have been or will be made to policies, procedures or tracking mechanisms to alleviate the problem and improve safety and security;
7. a description of public education and outreach activities implemented during the reporting period, including the methods used to evaluate the effectiveness of outreach and program activities;
8. how the program complied with all additional elements set forth in its approved product stewardship plan, including the level of success in meeting performance goals set by the Department upon approving the program; and
9. any additional information the Department may require.

Section 8. Drug Wholesalers.

A. The Department shall post on its website a list of all producers participating in approved product stewardship programs, as well as a list of producers the Department has identified as non-compliant with this law.

B. Beginning forty-five (45) days after the effective date of this law, any drug wholesaler offering covered products for sale in the County must provide a list of the producer or producers of such products to the Department. Beginning in 2017, drug wholesalers shall provide the Department with an updated list by January 15th of each year.

Section 9. Enforcement.

This law shall be enforced by the Department of Health Services.

Section 10. Penalties.

A. Violation of this law shall be punishable by a civil penalty of up to \$1,000 per day. Each day a violation continues shall constitute a separate and distinct violation.

B. Any civil penalty may only be assessed by the Commissioner following a hearing and opportunity for an alleged violator to be heard.

Section 11. Rules and Regulations.

The Commissioner of the Department of Health Services is hereby authorized and empowered to issue and promulgate such rules and regulations as he or she may deem necessary for the implementation and enforcement of this law.

Section 12. Applicability.

This law shall apply to all actions occurring on or after the effective date of this law.

Section 13. Severability.

If any clause, sentence, paragraph, subdivision, section, or part of this law or the application thereof to any person, individual, corporation, firm, partnership, entity, or circumstance shall be adjudged by any court of competent jurisdiction to be invalid or unconstitutional, such order or judgment shall not affect, impair, or invalidate the remainder thereof, but shall be confined in its operation to the clause, sentence, paragraph, subdivision, section, or part of this law, or in its application to the person, individual, corporation, firm, partnership, entity, or circumstance directly involved in the controversy in which such order or judgment shall be rendered.

Section 14. SEQRA Determination.

This Legislature, being the State Environmental Quality Review Act (SEQRA) lead agency, hereby finds and determines that this law constitutes a Type II action pursuant to Section 617.5(c)(20), (21), and/or (27) of Title 6 of the NEW YORK CODE OF RULES AND REGULATIONS (6 NYCRR) and within the meaning of Section 8-0109(2) of the NEW YORK ENVIRONMENTAL CONSERVATION LAW as a promulgation of regulations, rules, policies, procedures, and legislative decisions in connection with continuing agency administration, management and information collection. The Suffolk County Council on Environmental Quality (CEQ) is hereby directed to circulate any appropriate SEQRA notices of determination of non-applicability or non-significance in accordance with this law.

Section 15. Effective Date.

This law shall take effect immediately upon its filing in the Office of the Secretary of State.

DATED:

APPROVED BY:

County Executive of Suffolk County

Date: