

COUNTY OF ERIE
 LOCAL LAW NO. _____ - 2017
 LOCAL LAW INTRO NO. 1-2 -2017

A LOCAL LAW to prevent medical waste from entering the Great Lakes, also known as the Erie County Pharmaceutical Water Pollution Act

Legislative Intent

Recent studies across the nation have found trace amounts of prescription medication in drinking water due to the inadequate disposal of said medications. This Legislature has established its commitment to protecting our water supply; as well as the responsibility of protecting the Great Lakes. Negative effects of medication entering our water supply have been observed in wildlife, and the concern of their effect on humans is duly noted and poses a concern to this Legislature. The intent of this legislation is twofold: one, to ensure that facilities in Erie County that utilize large quantities of medications in providing health care are appropriately disposing of unused and/or expired medications, and two, to establish a “product stewardship program” requiring pharmaceutical producers whose covered drug is sold or distributed in Erie County to be held responsible for ensuring the proper and safe disposal of the drug at its end of life cycle.

Declaration of findings

The Erie County Legislature hereby finds and declares the following:

- A. Legal medicinal drugs are a necessary medical technology that successfully allows us to live longer, healthier, and more productive lives;
- B. The public, particularly children and the elderly, are at significant and unnecessary risk of poisoning due to improper or careless disposal of prescription and non-prescription drugs and the illegal re-sale of prescription drugs;
- C. Our groundwater and drinking water are being contaminated by unwanted, leftover or expired prescription and non-prescription drugs passing through our wastewater treatment centers;

There is no mandatory statewide drug stewardship program for unwanted drugs in New York, and drug manufacturers and producers have not offered any support for a permanent collection program to date.

Definitions

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

1. "Controlled Substance" for purposes of this Section shall be defined under New York State Public Health Law and Title 21 of the United States Code, Sections 812 and 813 or any successor legislation.
2. "Cosmetics" means (I) 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, (ii) articles intended for use as a component of any such articles, and (iii) cosmetics as defined above with expiration dates.
3. "Covered Drug" means a Drug sold, offered for sale or dispensed in Erie County in any form including prescription and nonprescription drugs, drugs in medical devices and combination products, brand name and generic drugs, and drugs for veterinary use.
Covered Drug" does not include:
(i) Vitamins or supplements; (ii) Herbal-based remedies and homeopathic drugs, products, or remedies; (iii) 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. Sec. 301 et seq. (2002)); (iv) Drugs for which Producers provide a take-back program as part of a Federal Food and Drug Administration managed risk evaluation and mitigation strategy (21 U.S.C. Sec. 355-1); (v) Drugs that are biological products as defined by 21 C.F.R. 600.3(h) as it exists on the effective date of this Section if the Producer already provides a take-back program; (vi)) medical devices or their component parts or accessories if it contains no Covered Drug.
4. "Department" means the Erie County Department of Health.
5. "Drug Wholesaler" means a Person that sells or distributes drugs and Covered Drugs for resale to an Entity other than a consumer.
6. "Drug" means: (i) any article 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; (ii) any substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; (iii) any substance, other than food, intended to affect the structure or any function of the body of humans or other animals; (iv) any substance intended for use as a component of any substance specified in (i), (ii), or (iii) of this definition.
7. "Entity" means a person other than an individual.
8. "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.

9. "Mail-Back Program" means a collection method for the return of Unwanted Products from Residential Generators, utilizing prepaid and preaddressed mailing envelopes, for shipment to an Entity that will dispose of them safely and legally.
10. "Manufacture" means the production, preparation, propagation, compounding, or processing of a Drug but does not include the activities of a re-packager, wholesaler or practitioner who distributes or dispense such substance or device in the course of his or her professional practice.
11. "Manufacturer" means a person engaged in the manufacture of drugs.
12. "Nonprescription Drug" means any drug that may be lawfully sold without a prescription.
13. "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.
14. "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.
15. "Prescription Drug" means any drug, including any Controlled Substance, that by federal or state law may be dispensed lawfully only on prescription, or is restricted to use by practitioners only.
16. "Producer" means a Manufacturer engaged in the Manufacture of a Covered Drug sold in the County. "Producer" does not include (i) a retailer that puts its store label on a Covered Drug and the retailer provides verification and contact information of the Producer; or (ii) a pharmacist who compounds a prescribed individual drug product for direct distribution to a consumer and the pharmacist provides verification and contact information of the Producer; or (iii) a wholesaler and the wholesaler provides verification and contact information of the Producer. For purposes of this section contact information must contain the following: each Producer's name, address, phone number, and email address, and the name, address, phone number, and email address of a human being to whom the Department may direct all inquiries regarding the Producer's participation in the Stewardship Program.
17. "Product Stewardship Program" or "Program" means a program for the collection, transportation, and disposal of Unwanted Products under this Law that is: (1) financed, developed, implemented, and participated in by one or more Producers; (2) operated by the participating Producers or a Stewardship Organization; (3) approved by the Department; and (4) meets the educational and other requirements set forth in this Law.

18. "Repackager" means a Person who owns or operates an establishment that repacks and relabels a product or package containing a Covered Drug for further sale or for distribution without a further transaction.
19. "Residential Generators" means single and multiple family residences and locations where household drugs are unused, unwanted, disposed of, or abandoned. "Residential Generators" do not include airport security, drug seizures by law enforcement, pharmacy waste, business waste, or any other source identified by the Department as a nonresidential source.
20. "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.
21. "Unwanted Product" means any Covered Drug no longer wanted by its owner or that has been abandoned, discarded, or is intended to be discarded by its owner.
22. "Facilities" are defined as hospitals, nursing homes, hospice care facilities, and long-term care facilities operating in Erie County.

Product Stewardship Program

A. Requirement for sale. This Chapter shall apply only to a Producer whose Covered Drug is sold or distributed in Erie County. This Chapter shall apply to all of Erie County including unincorporated and incorporated areas. This Chapter shall be administered and implemented by the Erie County Department of Health. 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. Product Stewardship Program costs:

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 Residential Generators

and the recycling or disposal, or both, of packaging collected with the Unwanted Product.

2. A Producer, group of Producers, or Stewardship Organization must pay for all fees associated with obtaining compliance with New York State regulations.
3. 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 Residential Generators or delivered for disposal.
4. A Producer, group of Producers, or Stewardship Organization must pay all costs incurred by the County of Erie, including but not limited to the Department of Health, in the administration and enforcement of their Product Stewardship Program. Exclusive of fines and penalties, the County of Erie shall only recover its actual costs of administration and enforcement under this Ordinance and shall not charge any amounts under this Ordinance in excess of its actual administrative and enforcement costs.

Product Stewardship Plan

- A. Plan content. Each Product Stewardship Program shall have a product stewardship plan that contains each of 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. Contact information for the individual and the Entity submitting the Plan and for each of the Producers participating in the Product Stewardship Program, including each Drug Producer's name, address, phone number, and email address, and the name, address, phone number, and email address of a human being to whom the Department may direct all inquiries regarding the Producer's participation in the Stewardship Program;
 3. A description of the methods by which Unwanted Products from Residential Generators will be collected in Erie County and an explanation of how the collection system will be convenient and adequate to serve the needs of Erie County residents;

4. A description of how the product stewardship Plan will provide collection services for Unwanted Products in all areas of Erie County that are convenient to the public and adequate to meet the needs of the population in the area being served.
5. The location of each collection site and locations where envelopes for a Mail-Back Program are available (if applicable);
6. 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 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 disposal and a description of the policies and procedures to be followed by Persons handling Unwanted Products collected under the Stewardship Program to ensure security;
8. A description of the public education and outreach activities required under this Chapter and how their effectiveness will be evaluated;
9. A description of how the scope and extent of the Product Stewardship Program are reasonably related to the amount of Covered Drugs that are sold in the County of Alameda by the Producer or group of Producers;
10. A starting date when collection of Unwanted Products will begin;
11. A description of how support will be provided to any law enforcement agencies within Erie County that have, or later agree to have, a collection program for collection of Unwanted Products including:
 - (i) the provision of a collection kiosk with appropriate accessories and signage,
 - (ii) an ability to accept Controlled Substances and other Covered Drugs,
 - (iii) technical support up to and including an appropriate Person to provide on-site assistance at no cost to a participating law enforcement agency;
12. A description of how collection sites for Unwanted Products may be placed at appropriate locations in Erie County including a description of the involvement of the retail store.; and
13. 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 amount of Covered Drugs that Producer sells in the County of Erie.

14. A certification that any patient information on Drug packaging will be promptly destroyed

B.. Department review and approval; updates

1. No Producer, group of Producers, or Stewardship Organization may begin collecting Unwanted Products to comply with this Ordinance until it has received written approval of its product stewardship Plan from the Commissioner of Health.
2. Product stewardship Plans must be submitted to the Department for approval. The initial Plans must be submitted by July 1, 2013, or at a later date as approved in writing by the Department.
3. Within 180 days after receipt and review of a Product Stewardship Plan, the Department shall conduct a noticed public hearing and determine whether the Plan complies with the requirements of this Chapter and of any regulations adopted pursuant to this Chapter.
 - 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 60 days after receiving notice of the rejection. The Department may require the submission of a further revised Plan or, in 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 Ordinance. The imposed Plan will be presented at the public hearing. The Department is not required, and nothing in this Ordinance 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 are subject to the enforcement provisions contained in this Chapter. If the Department imposes its own or another Plan the Producer(s) at issue shall not be considered out of compliance with this Chapter if they comply with that Plan. However, the Producers shall be subject to the enforcement provisions contained in this Chapter as they relate to compliance with an approved Plan.

4. 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.
5. A Producer who begins to offer a Prescription Covered Drug for sale in the County of Erie after July 1, 2017, must submit a product stewardship Plan to the Department or provide evidence of having joined an existing approved Product Stewardship Program within 180 days following the Producer's initial offer for sale of a Covered Drug.
 - a) For Producers selling only Non-prescription Covered Drugs, they must meet the requirements of this Ordinance for a Product Stewardship Program no later than February 1, 2017.
 - b) For Producers selling Prescription and Nonprescription Covered Drugs, they must come into compliance for all Nonprescription Covered Drugs no later than March 31, 2016.
 - c) Approved Product Stewardship Programs must immediately begin accepting Nonprescription Drugs.
6. Any proposed changes to a Product Stewardship Plan, other than collection of non-prescription Covered Drugs, must be submitted in writing to the Department and approved by the Department in writing prior to implementation of any change.

Disposal of Unwanted Products.

- A. 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 disposal of medical waste and Controlled Substances.
- B. Disposal at medical waste or hazardous waste facility. Each Product Stewardship Program must dispose of all Unwanted Products by incineration at a medical waste or hazardous waste facility. The medical waste or hazardous waste facility must be in possession of all required regulatory permits and licenses.
- C. Producers with Product Stewardship Programs may petition the Department for approval to use 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:

1. Monitoring of any emissions or waste;
 2. Worker health and safety;
 3. Reduction or elimination of air, water, or land emissions contributing to persistent, bioaccumulative, and toxic pollution; and,
 4. Overall impact on the environment and human health.
- D. Packaging separation. Each Product Stewardship Program shall encourage Residential Generators to separate Unwanted Products from their original containers, when appropriate, prior to collection or disposal.

Product Stewardship Program promotion and outreach.

- A. A Product Stewardship Program must promote the Product Stewardship Program to Residential Generators, pharmacists, retailers of Covered Drugs, health care practitioners, veterinarians, and veterinary hospitals as to the proper and safe method to dispose of Unwanted Products, so that collection options for Covered Drugs are widely understood and to promote the safe storage of Covered Drugs by Residential Generators.
- B. A Product Stewardship Program shall include, but is not limited to, developing, and updating as necessary, educational and other outreach materials aimed at retailers of Covered Drugs. These materials may include, but are not limited to, one or more of the following:
 1. Signage that is prominently displayed and easily visible to the consumer.
 2. 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.
 3. Advertising and/or other promotional materials related to the Product Stewardship Program.
- C. A Product Stewardship Program must prepare education and outreach materials that publicize the location and operation of collection locations in Erie 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 Residential Generators can call to find nearby collection locations and understand how the Program works.

- D. Product Stewardship Programs shall not require, conduct or allow any sorting of items brought to collection events or at drop off locations.
- E. A Product Stewardship Program shall provide a kiosk at any location in which a person requests or volunteers to have a kiosk if the following conditions are met:
 - 1. The approved Product Stewardship Plan includes having physical collection sites, such as kiosks (even if the approved number of sites have been accomplished by the Plan);
 - 2. The Person is a law enforcement agency or a registered manufacturer, distributor, reverse distributor or retail pharmacy that is authorized to receive a Controlled Substance for the purpose of destruction.

Report.

- A. Each year on or before the date set by the department every Producer, group of Producers or Stewardship Organization operating a Product Stewardship Program must prepare and submit to the Department an annual written report describing the Program's activities during the previous reporting period. The report must include the following:
 - 1. A list of Producers participating in the Product Stewardship Program;
 - 2. The amount, by weight, of Unwanted Products collected from Residential Generators collected at each drop-off site and in the entire County of Erie 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, locations where envelopes for a Mail-Back Program are provided;
 - 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. Whether policies and procedures for collecting, transporting, and disposing of Unwanted Products, as established in the Plan, were followed during the reporting period and a description of any noncompliance;

6. Whether any safety or security problems occurred during collection, transportation, or disposal of Unwanted Products during the reporting period and, if so, what changes have or will be made to policies, procedures, or tracking mechanisms to alleviate the problem and to improve safety and security;
7. A description of public education and outreach activities implemented during the reporting period, including the methodology used to evaluate the outreach and Program activities;
8. How the Product Stewardship Program complied with all other elements in the product stewardship Plan approved by the Department, including its degree of success in meeting any performance goals set by the Department as part of its approval of the Program; and
9. Any other information that the Department may reasonably require.

- B. For the purposes of this section, "reporting period" means the period beginning January 1 and ending December 31 of the same calendar year, or such other date as established at Plan approval or as may be amended by the Department in a written notice.

List of Producers

The Department shall provide on its website 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.

Facility Disposal Plan Required

- A. All hospitals, hospice facilities, nursing homes, and long-term care facilities located in the County of Erie shall file with the county Department of Health a written plan for the safe disposal of unused and/or expired covered drugs. Such plan must establish the means by which the facility will dispose of such medications in an environmentally safe manner to prevent medications from entering the County's drinking water supply and rivers, ponds, streams, the Erie Canal, and the Great Lakes.
- B. Beginning in 2018, each facility shall file its written uncovered drug disposal plan with the Department of Health shall constitute a violation and shall be punishable by a civil fine of \$500.

Regulations and fees

- A. The Commissioner of the Department of Health may, after a noticed public hearing, adopt such rules and regulations as necessary to implement, administer, and enforce this Chapter. The Director may revise the adopted regulations from time to time after posting on the Erie County website.

proposed revisions on the Department webpage for not less than ten (10) calendar days with a solicitation for public comments and considering any public comments received.

- B. As soon as practicable, the Department shall submit to the Legislature a proposed schedule of fees to be charged to the Producers to cover Erie County's costs of administering and enforcing this Law.

Enforcement

- A. The Department of Health shall administer the penalty provisions of this Chapter.
- B. The County Department of Health shall notify to the best of their abilities facilities operating in Erie County that this law affects.
- C. The Department of Health may issue an administrative citation to a Producer for violation of this chapter or any regulation adopted pursuant to this chapter. The Department shall first send a written warning to the Producer as well as a copy of this Chapter and any regulations adopted pursuant to this Chapter. The Producer shall have 30 days after receipt of the warning to comply and correct any violations.
- D. If the Producer 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.
- E. Any Person in violation of this Chapter or any regulation adopted pursuant to this Chapter shall be liable to the County of Erie for a civil penalty in an amount not to exceed one thousand dollars (\$1,000) per day per violation. Each day in which the violation continues shall constitute a separate and distinct violation.
- F. In determining the appropriate penalties, the Department of Health 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.
- G. Any Producer 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 of Erie holiday, then the deadline shall be extended until the next regular business day.

The request to appeal must:

1. Be in writing;

2. Be accompanied by a deposit of the total fine and any fees noted on the administrative citation;
 3. Specify the basis for the appeal in detail;
 4. Be postmarked within 21 days from the date the administrative citation was issued; and
 5. Be sent to the address as set forth on the administrative citation.
- G. 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 of Health. 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 appealing the citation. Service by first class mail, postage prepaid shall be effective on the date of mailing.
- H. Failure of any Producer to file an appeal in accordance with the provisions of this section shall constitute waiver of that Producer'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.
- I. The Producer requesting the appeal may request the Director of the Department of Health 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:
1. A valid administrative citation shall be prima facie evidence of the violation;
 2. Testimony shall be by declaration under penalty of perjury except to the extent the hearing officer permits or requires live testimony concerning the violation.
 3. 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.
 4. 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, unless a timely notice of appeal is filed for hearing by the Board of Supervisors of the County of Alameda.
- J. A second appeal may be filed with the Legislature within ten calendar days after the date of service of the Hearing Officer Decision.

- 1... The appeal may be taken by any Producer or the Department within said ten-day period, by filing with the clerk of the Legislature a notice of appeal specifying the grounds for such appeal. The Board of Supervisors shall not hear any appeal that is untimely filed
 2. Upon receiving an appeal, the Clerk of the Legislature shall indicate upon every notice of appeal received the date upon which it was filed. The Department shall immediately arrange for an administrative record to be made available to the Board of Supervisors of all of the documents constituting the record upon which the action appealed was taken.
 3. The Legislature shall give written notice of the time and place for a public hearing on any appeal filed pursuant to this section to the appellant and the Department.
 4. The Legislature may hear additional evidence in its sole discretion and may sustain, modify or overrule any order brought before it on appeal.
 5. The Legislature may make such findings and decisions as are consistent with state law and the County of Erie Code. If no motion relative to the Hearing Officer Decision appealed attains a majority vote of the Legislature within thirty (30) days from the date of the hearing by said board thereon, the Hearing Officer Decision shall stand sustained and be final.
- K. The Department of Health may establish appropriate administrative rules for implementing this Chapter, conducting hearings, and rendering decisions pursuant to this section.
- L. 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 Erie County Attorney's Office may petition any court having jurisdiction for injunctive relief, payment of civil penalties and any other appropriate remedy, including restraining such Person from continuing any prohibited activity and compelling compliance with lawful requirements. However, this subsection does not permit the County of Erie or any court of competent jurisdiction to restrain the sale of any Covered Drug in Erie County.
- M. Any Person who knowingly and willfully violates the requirements of this Chapter or any rule or regulation adopted pursuant to this Chapter is guilty of a misdemeanor and may be prosecuted by the Erie County District Attorney's Office. A conviction for a misdemeanor violation under this Chapter is punishable by a fine of not less than fifty dollars (\$50) and not more than five hundred (\$500) for each day per violation, or by imprisonment in the Erie County Holding Center or Erie County Detention Center for a period not to exceed six (6) months, or by both such fine and imprisonment.

- N. Failure of any facility to file a written covered drug disposal plan with the county Department of Health shall constitute a violation and shall be punishable by a civil fine of \$500.

Additional Provisions.

- A. Disclaimer. In adopting and implementing this Chapter, the County of Erie is assuming an undertaking only to promote the general welfare. Erie 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.
- B. 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 Erie 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. Erie County shall suspend enforcement of this Ordinance to the extent that said enforcement would conflict with any preemptive state or federal legislation subsequently adopted.
- C. 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.
- D. Nothing in this Law, or the Program of stewardship in which manufacturers of pharmaceutical products who sell Prescription Drugs in Erie County are required to participate, is intended to protect anticompetitive or collusive conduct nor shall this law 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.
- E. This Ordinance shall be construed in accordance with New York state law, and shall not be construed in a way that would result in conflict with, or preemption by, any such state law.
- F. Effective Date. This local law shall become effective upon filing with the Secretary of State.

Sponsor: Legislator Patrick B. Burke