

# **Proposed Local Law Number 4 Of 2022**

## **County Of Ulster**

### **A Local Law Enacting A Drug Take Back Program in Ulster County**

**BE IT ENACTED**, by the Legislature of the County of Ulster, as follows:

#### **SECTION 1. LEGISLATIVE INTENT AND FINDINGS.**

Ulster County continues to be a leader in environmental management and desires to take action to reduce contamination of its natural resources by eliminating improper disposal of pharmaceuticals. The Ulster County Legislature recognizes that in addition to protecting its water, proper disposal of pharmaceuticals will reduce unintentional access of drugs by individuals who were not initially prescribed the medication which may lead to substance abuse, addiction and/or overdose.

#### **SECTION 2. DEFINITIONS.**

1. "AUTHORIZED COLLECTOR" shall mean: (a) a person, company, corporation, or other entity that is registered with the United States Drug Enforcement Administration to collect controlled substances for the purposes of safe disposal and destruction; (b) a law enforcement agency; or (c) a person, company, corporation or other entity authorized by the department to provide alternative collection methods for covered drugs that are not controlled substances.

2. "COVERED DRUG" shall mean any substance recognized as a drug under United States Code ("USC") § 321(g)(1), as amended, and any regulations promulgated thereunder that is sold, offered for sale or dispensed in the state, whether directly or through a wholesaler, in any form including prescription and nonprescription drugs, drugs in medical devices and combination products, brand and generic drugs and drugs for veterinary use; provided however, covered drug shall not include: (a) vitamins or supplements; (b) herbal-based remedies and homeopathic drugs, products or remedies; (c) 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; (d) pet pesticide products contained in pet collars, powders, shampoos, topical applications, or other forms; (e) drugs that are biological products as defined in subdivision twenty-seven of section sixty-eight hundred two of the Education Law if the manufacturer already provides a take back program; (f) drugs for which a manufacturer provides a take back program as part of a Federal Food and Drug Administration managed risk evaluation and mitigation strategy; (g) emptied injector products or emptied medical devices and their component parts or accessories; and (h) drugs that are used solely in a clinical setting.

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3. "DEPARTMENT" shall mean the Ulster County Department of Health.
4. "MANUFACTURER" means a person, company, corporation, or other entity engaged in the manufacture of covered drugs sold in the state. Manufacturer does not include a repackager or wholesaler.
5. "PHARMACIES" means all pharmacies with locations in Ulster County which are registered under section sixty-eight hundred eight of the Education Law that are part of a group of ten or more establishments in New York state, that conduct business under the same name, or operate under a common ownership or management, or pursuant to a franchise agreement with the same franchisor.
6. "DRUG TAKE BACK ORGANIZATION" means an organization designated by a manufacturer or a group of manufacturers to act as an agent on behalf of the manufacturer or group of manufacturers to operate and implement a drug take back program as authorized by this article.
7. "WHOLESALER" means any person, company, corporation or other entity that sells or distributes drugs and covered drugs for resale to an entity in the state other than a consumer.

**SECTION 3. REGULATIONS OF DRUG TAKE BACK PROGRAM.**

~~4.~~ Pharmacies shall:

- (A) operate a drug take back program individually or jointly with other pharmacies acceptable under ~~NYSDOH~~ **New York State Department Of Health** regulations; or
- (B) enter into an agreement with a drug take back organization which shall operate a drug take back program.

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**SECTION 4. NOTIFICATION AND REQUIREMENTS.**

Any pharmacy of a covered drug, individually or jointly, or a drug take back organization contracted by a pharmacy of a covered drug shall within sixty (60) days from the effective date of this section submit to the department, in a manner and form determined by the department, a proposed drug take back program that meets, at a minimum, the following requirements:

- (A) Certifies the drug take back program will accept all covered drugs regardless of who produced them;
- (B) Provides contact information for the person submitting the planned drug take back program with whom the department shall direct all inquiries;
- (C) Details a collection system to provide convenient, ongoing collection services to all persons seeking to dispose of covered drugs in a manner that ensures access in rural and underserved areas;
- (D) Describes other collection methods by which covered drugs will be collected by authorized collectors;
- (E) Explains how covered drugs will be safely and securely tracked and handled from collection through final disposal and destruction, policies to ensure security and compliance with all applicable laws and regulations including disposal and destruction at a permitted waste disposal facility meeting federal requirements;
- (F) Describes the public education and outreach activities that will be undertaken which shall include advertising of collection locations on a website and through the use of signage and other written materials;
- (G) Details how the costs of pharmacy collection and other authorized collectors will be reimbursed and where more than one manufacturer will be involved in the planned drug take back program, a plan for the fair and reasonable manner of allocated costs among the participants in such program such that the costs paid by each manufacturer is reasonably related to the volume or value of covered drugs sold in the state; and

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(H) Provides any further information deemed appropriate by the department.

1. Within thirty days of the effective date of this section, each wholesaler that sells covered drugs in or into the state shall provide the department with a list of manufacturers that produce covered drugs. the department may request updated lists at its discretion.

2. A manufacturer, individually or jointly, must pay all administrative and operational fees associated with the drug take back program, including the cost of collecting, transporting and disposing of covered drugs from pharmacies and other authorized collectors and the recycling or disposal, or both, of packing collected with the covered drug. no manufacturer may charge a point-of-sale or other fee to consumers, or a fee that could be passed on to consumers, to recoup the cost of their drug take back program.

3. Within sixty days of receipt of a proposed drug take back program the department, in consultation with the Department of Environmental Conservation **to ensure the proposed program meets environmental protection requirements**, shall determine whether such proposed drug take back program complies with the requirements of this article and notify the applicant. The department may conduct a noticed public hearing prior to approval. If the drug take back program is approved, the department shall notify the applicant in writing. If the drug take back program is not approved, the department shall notify the applicant in writing and the applicant shall submit a revised drug take back program proposal within thirty days. If the department rejects the subsequent proposal, the manufacturer or manufacturers at issue shall be out of compliance with this article and subject to the enforcement provisions pursuant to section two hundred ninety-four of this article. The department shall provide, and update annually, on its website a list of all manufacturers participating in a drug take back program approved by the department.

4. At least every three years, a manufacturer, jointly or individually, or a drug take back organization shall update its drug take back program and submit an updated proposal to the department. Any proposed change to a drug take back program shall be submitted in writing and approved by the department prior to any change.

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5. Each approved drug take back program shall report to the department at a date and manner set by the department. The department shall submit and deliver an annual report to the Ulster County Legislature and Ulster County Executive by January 1<sup>st</sup> of each year, detailing all program activities, the weight collected by each program, a description of collection activities, the name and location of all collection sites, public education and outreach activities, an evaluation of the efficacy of the program and each collection method, and any manufacturer out of compliance or subject to penalties pursuant to section two hundred ninety-four of this article.

#### **SECTION 5. COLLECTION.**

1. All pharmacies shall provide for the safe collection of drugs, which shall include:

A) Offering drug collection by one or more of the following methods:

(I) On-site collection, dropbox, or receptacle meeting federal standards;

(II) Mail-back collection by prepaid envelopes as authorized by federal law and regulation; or

(III) Other federal drug enforcement agency approved methods of collection.

(B) signage prominently displayed advertising such drug collection to consumers.

**2. Participation of authorized collectors besides pharmacies shall be voluntary.**

~~All drug take back program operators shall notify other potential authorized collectors of the opportunity to serve as an authorized collector for the drug take back program. Participation of authorized collectors besides pharmacies shall be voluntary.~~

3. All costs of pharmacies and other authorized collectors shall be paid or reimbursed by the manufacturer, jointly or individually, as part of the drug take back programs required by this article.

4. Pharmacies providing for mail-back collection as part of the drug take back program shall provide a voucher for a prepaid envelope upon dispensing a covered drug. Such voucher shall include information on drug take back and safe drug disposal methods.

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**SECTION 6. VIOLATIONS.**

Violation of this article shall be subject to fines pursuant to section twelve of this chapter. Each day in which the violation continues shall constitute a separate violation. **Violators are not exempt from additional fines imposed by the State of New York.**

- Up to \$500 per violation
- Up to \$1,000 if a second violation occurs within a twelve month period, and

**A. An independent Administrative Hearing Officer is hereby created, established and authorized to issue orders assessing civil penalties for violations of this article.**

**B. The Officer shall be appointed by the County Legislature to serve at the pleasure of the County Legislature.**

**C. The UCDOH as complainant may institute a proceeding with the Officer, seeking an order assessing civil penalties for the violation of this article.**

**D. The Officer the authority to require the attendance of witnesses or the production of documentary evidence by subpoena.**

**E. Before issuing an order assessing a civil penalty, the Officer shall give to the person to be assessed such a penalty written notice of the proposed order and an opportunity to request a hearing on the proposed order.**

**F. The written notice shall include, at a minimum:**

- (1) A concise statement of the factual basis for the violation;**
- (2) The amount of the civil penalty that is proposed to be assessed;**
- (3) The provisions of this article alleged to have been violated;**
- (4) The right to request a hearing on the material facts and/or the amount of the civil penalty; and**
- (5) A copy of the rules of the hearing procedures.**

**G. The hearing shall provide a reasonable opportunity to be heard, cross-examine witnesses, and present evidence free from interference, coercion, restraint, discrimination, or reprisal, and the respondent shall have the right to be**

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represented by a person of his/her choice at any stage of the hearing and proceedings.

**H. If the respondent fails to appear at the hearing without good cause being shown and the Ulster County Health Department presents a prima facie case against the respondent, the respondent may be found in default. The motion for default and a proposed default order shall be served by the officer on all parties, and the defaulting party shall have 20 days from service to reply to the motion. The proposed default order may be set aside for good cause shown in accordance with the Civil Practice Law and Rules. Default by the complainant shall result in the dismissal of the complaint with prejudice.**

**SECTION 7. DISPOSAL.**

Except as provided herein, disposal sites shall be operated by law enforcement agencies, pharmacies, authorized one-day drop off programs and other State or Federal Drug Enforcement Administration authorized collectors, provided, however, that such disposal sites shall not be precluded from operating as part of a drug take back program established pursuant to this local law.

**SECTION 8. SEVERABILITY.**

If any clause, sentence, paragraph, section, subdivision, or other part of this Local Law or the application thereof shall be inconsistent with any Federal or State Statute, Law, Regulation, or Rule then the Federal or State Statute, Law, Regulation or Rule shall prevail. If any clause, sentence, paragraph, section, subdivision, or other part of this Local Law or its application shall be adjudged by a court of competent jurisdiction to be invalid or unconstitutional, such order or judgment shall not affect, impair or invalidate the remainder of the local law, which shall remain in full force and effect except as limited by such order or judgment.

**SECTION 10. EFFECTIVE DATE.**

This Local Law shall be effective six (6) months subsequent to filing with the Secretary of State.