§ 291. Drug take back. 1. Any manufacturer of a covered drug shall:

(a) operate a drug take back program approved by the department individually or jointly with other manufacturers;

(b) enter into an agreement with a drug take back organization which shall operate a drug take back program approved by the department; or

(c) enter into an agreement with the department to operate a drug take back program on its behalf.

2. Any manufacturer of a covered drug, individually or jointly, or a drug take back organization contracted by a manufacturer of a covered drug shall within one hundred eighty 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 pursuant to section two hundred ninety-two of this article that is geographically distributed in a way to ensure 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 use of signage and other written materials, and how effectiveness will be evaluated;

(g) Details how the costs of pharmacy collection and other authorized collectors will be reimbursed which shall include costs retroactive to

the effective date of this article, 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

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

3. 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.

4. 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. Manufacturers shall also pay costs incurred by the state in the administration and enforcement of the drug take back program. Exclusive of fines and penalties, the state shall only recover its actual cost of administration and enforcement. In instances where manufacturers jointly conduct a drug take back program, the costs of administration and enforcement shall be fairly and reasonably allocated such that the portion of costs is reasonably related to the volume or value of covered drugs the manufacturers sell in the state. 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.

5. Within sixty days of receipt of a proposed drug take back program, the department, in consultation with the department of environmental conservation, 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.

6. 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. A manufacturer who begins to offer a covered drug in the state after the effective date of this article, shall provide evidence of joining an existing approved drug take back program or submit a proposal for a drug take back program within ninety days following the initial offer for sale of a covered drug. Any proposed change to a drug take back program shall be submitted in writing and approved by the department prior to any change.

7. Each approved drug take back program shall report to the department at a date and manner set by the department. The department shall submit an annual report to the governor, speaker of the assembly and temporary president of the senate by January first 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.