

STATE OF NEW YORK

9576

IN ASSEMBLY

January 23, 2018

Introduced by M. of A. GUNTHER -- read once and referred to the Committee on Health

AN ACT to amend the public health law, in relation to enacting the drug take back act

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

Section 1. This act shall be known and may be cited as the "drug take back act."

§ 2. The public health law is amended by adding a new article 2-B to read as follows:

ARTICLE 2-B DRUG TAKE BACK

Section 290. Definitions.

291. Drug take back.

292. Collection.

293. Violations.

294. Jurisdiction.

§ 290. Definitions. As used in this article, unless the context clearly requires otherwise:

1. "Authorized collector" means: (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; (c) a municipality; or (d) 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" means any substance recognized as a drug under 21 USC § 321(g)(1), as amended, 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 germi-

EXPLANATION--Matter in italics (underscored) is new; matter in brackets [-] is old law to be omitted.

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1 cidal agents), laundry detergent, bleach, household cleaning products,
2 shampoos, sunscreens, toothpaste, lip balm, antiperspirants or other
3 personal care products that are regulated as both cosmetics and nonpres-
4 cription drugs under the Federal Food, Drug, and Cosmetic Act; (d) pet
5 pesticide products contained in pet collars, powders, shampoos, topical
6 applications, or other forms; (e) drugs that are biological products as
7 defined in subdivision twenty-seven of section sixty-eight hundred two
8 of the education law if the manufacturer already provides a take back
9 program; (f) drugs for which a manufacturer provides a take back program
10 as part of a Federal Food and Drug Administration managed risk evalu-
11 ation and mitigation strategy; (g) medical devices or the component part
12 of such devices or accessories if such device or component part contains
13 no covered drug; and (h) drugs that are used solely in a clinical
14 setting.

15 3. "Manufacturer" means a person, company, corporation or other entity
16 engaged in the manufacture of drugs sold in the state.

17 4. "Pharmacies" means all pharmacies registered under section sixty-
18 eight hundred eight of the education law that are part of a group of ten
19 or more establishments that conduct business under the same name, or
20 operate under a common ownership or management, or pursuant to a fran-
21 chise agreement with the same franchisor, and all nonresident pharmacies
22 registered pursuant to section sixty-eight hundred eight-b of the educa-
23 tion law that provide covered drugs to state residents by mail.

24 5. "Drug take back organization" means an organization designated by a
25 manufacturer or a group of manufacturers to act as an agent on behalf of
26 the manufacturer or group of manufacturers to operate and implement a
27 drug take back program as authorized by this article.

28 6. "Wholesaler" means any person, company, corporation or other entity
29 that sells or distributes drugs and covered drugs for resale to an enti-
30 ty in the state other than a consumer.

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

32 (a) operate a drug take back program approved by the department indi-
33 vidually or jointly with other manufacturers;

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

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

38 2. Any manufacturer of a covered drug, individually or jointly, or a
39 drug take back organization contracted by a manufacturer of a covered
40 drug shall within one hundred eighty days from the effective date of
41 this section submit to the department, in a manner and form determined
42 by the department, a proposed drug take back program that meets, at a
43 minimum, the following requirements:

44 (a) Certifies the drug take back program will accept all covered drugs
45 regardless of who produced them;

46 (b) Provides contact information for the person submitting the planned
47 drug take back program with whom the department shall direct all
48 inquiries;

49 (c) Details a pharmacy collection system to provide convenient, ongo-
50 ing collection services to all persons seeking to dispose of covered
51 drugs pursuant to section two hundred ninety-two of this article;

52 (d) Describes other collection methods by which covered drugs will be
53 collected by authorized collectors;

54 (e) Explains how covered drugs will be safely and securely tracked and
55 handled from collection through final disposal and destruction, policies
56 to ensure security and compliance with all applicable laws and regu-

lations including disposal and destruction at a permitted hazardous 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 number 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 number 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

1 drug. Any proposed change to a drug take back program shall be submitted
2 in writing and approved by the department prior to any change.

3 7. Each approved drug take back program shall report to the department
4 at a date and manner set by the department. The department shall submit
5 an annual report to the governor, speaker of the assembly and temporary
6 president of the senate by January first detailing all program activ-
7 ities, the volume collected by each program, a description of collection
8 activities, the name and location of all collection sites, public educa-
9 tion and outreach activities, and any manufacturer out of compliance or
10 subject to penalties pursuant to section two hundred ninety-four of this
11 article.

12 § 292. Collection. 1. All pharmacies shall provide for the safe
13 collection of drugs, which shall include:

14 (a) Offering drug collection by:

15 (i) On-site collection receptacles meeting federal standards;

16 (ii) Mail-back collection by prepaid envelopes as authorized by feder-
17 al law and regulation; or

18 (iii) Other federal drug enforcement agency approved methods of
19 collection.

20 (b) Signage prominently displayed advertising such drug collection to
21 consumers.

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

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

29 § 293. Violations. Violation of this article shall be subject to fines
30 pursuant to section twelve of this chapter. Each day in which the
31 violation continues shall constitute a separate violation.

32 § 294. Jurisdiction. Jurisdiction of all matters pertaining to drug
33 disposal by this article is vested exclusively in the state. Any
34 provision of any local law or ordinance, or any rule or regulation
35 promulgated prior to, or upon the effective date of this section, shall
36 be preempted.

37 § 3. Section 3343-b of the public health law, as amended by chapter
38 379 of the laws of 2015, is amended to read as follows:

39 § 3343-b. Safe disposal of unused controlled substances. 1. The
40 department shall oversee a program for the safe disposal of unused
41 controlled substances by consumers in accordance with federal law and
42 article two-B of this chapter. Individual members of the public shall
43 be authorized to voluntarily surrender controlled substances listed on
44 schedule II, III, IV or V of section thirty-three hundred six of this
45 article in a secure manner, without identifying themselves. Safe
46 disposal methods shall be publicized consistent with the prescription
47 pain medication awareness program established pursuant to section thir-
48 ty-three hundred nine-a of this article and article two-B of this chap-
49 ter.

50 2. The surrender of a controlled substance pursuant to this section
51 and article two-B of this chapter shall not constitute the possession,
52 transfer or sale of such controlled substance for purposes of this arti-
53 cle or the penal law.

54 ~~[3. Disposal sites shall be operated by law enforcement agencies,~~
55 ~~pharmacies and other Federal Drug Enforcement Administration authorized~~
56 ~~collectors on a voluntary basis. Nothing in this section shall require~~

1 ~~any political subdivision of the state to participate in the program~~
2 ~~established in this section.]~~

3 § 4. The department of health may adopt regulations as necessary to
4 implement and enforce the provisions of this title.

5 § 5. This act shall take effect immediately; provided, however, that
6 the amendments to subdivision 1 of section 292 of the public health law,
7 as added by section two of this act, shall take effect on the one
8 hundred eightieth day after it shall have become a law.