

STATE OF NEW YORK

9576--A

IN ASSEMBLY

January 23, 2018

Introduced by M. of A. GUNTHER, THIELE, ORTIZ, ENGLEBRIGHT, STECK, SEPULVEDA, STIRPE, HUNTER, COLTON, PELLEGRINO, PHEFFER AMATO, BRINDISI, CURRAN, ABINANTI, DE LA ROSA, GALEF, FAHY, MAGNARELLI, LIFTON, JAFFEE, HYNDMAN -- read once and referred to the Committee on Health -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee

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; 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" 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

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

LBD14168-03-8

1 devices and combination products, brand and generic drugs and drugs for
2 veterinary use; provided however, covered drug shall not include: (a)
3 vitamins or supplements; (b) herbal-based remedies and homeopathic
4 drugs, products or remedies; (c) cosmetics, soap (with or without germi-
5 cidal agents), laundry detergent, bleach, household cleaning products,
6 shampoos, sunscreens, toothpaste, lip balm, antiperspirants or other
7 personal care products that are regulated as both cosmetics and nonpres-
8 cription drugs under the Federal Food, Drug, and Cosmetic Act; (d) pet
9 pesticide products contained in pet collars, powders, shampoos, topical
10 applications, or other forms; (e) drugs that are biological products as
11 defined in subdivision twenty-seven of section sixty-eight hundred two
12 of the education law if the manufacturer already provides a take back
13 program; (f) drugs for which a manufacturer provides a take back program
14 as part of a Federal Food and Drug Administration managed risk evalu-
15 ation and mitigation strategy; (g) medical devices or the component part
16 of such devices or accessories if such device or component part contains
17 no covered drug; and (h) drugs that are used solely in a clinical
18 setting.

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

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

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

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

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

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

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

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

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

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

50 (b) Provides contact information for the person submitting the planned
51 drug take back program with whom the department shall direct all
52 inquiries;

53 (c) Details a collection system to provide convenient, ongoing
54 collection services to all persons seeking to dispose of covered drugs
55 pursuant to section two hundred ninety-two of this article;

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

3 (e) Explains how covered drugs will be safely and securely tracked and
4 handled from collection through final disposal and destruction, policies
5 to ensure security and compliance with all applicable laws and regu-
6 lations including disposal and destruction at a permitted waste disposal
7 facility meeting federal requirements;

8 (f) Describes the public education and outreach activities that will
9 be undertaken which shall include advertising of collection locations on
10 a website and through use of signage and other written materials, and
11 how effectiveness will be evaluated;

12 (g) Details how the costs of pharmacy collection and other authorized
13 collectors will be reimbursed which shall include costs retroactive to
14 the effective date of this article, and where more than one manufacturer
15 will be involved in the planned drug take back program, a plan for the
16 fair and reasonable manner of allocated costs among the participants in
17 such program such that the costs paid by each manufacturer is reasonably
18 related to the number or value of covered drugs sold in the state; and

19 (h) Provides any further information deemed appropriate by the depart-
20 ment.

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

25 4. A manufacturer, individually or jointly, must pay all administra-
26 tive and operational fees associated with the drug take back program,
27 including the cost of collecting, transporting and disposing of covered
28 drugs from pharmacies and other authorized collectors and the recycling
29 or disposal, or both, of packing collected with the covered drug.
30 Manufacturers shall also pay costs incurred by the state in the adminis-
31 tration and enforcement of the drug take back program. Exclusive of
32 finances and penalties, the state shall only recover its actual cost of
33 administration and enforcement. In instances where manufacturers jointly
34 conduct a drug take back program, the costs of administration and
35 enforcement shall be fairly and reasonably allocated such that the
36 portion of costs is reasonably related to the number or value of covered
37 drugs the manufacturers sell in the state. No manufacturer may charge a
38 point-of-sale or other fee to consumers, or a fee that could be passed
39 on to consumers, to recoup the cost of their drug take back program.

40 5. Within sixty days of receipt of a proposed drug take back program,
41 the department, in consultation with the department of environmental
42 conservation, shall determine whether such proposed drug take back
43 program complies with the requirements of this article and notify the
44 applicant. The department may conduct a noticed public hearing prior to
45 approval. If the drug take back program is approved, the department
46 shall notify the applicant in writing. If the drug take back program is
47 not approved, the department shall notify the applicant in writing and
48 the applicant shall submit a revised drug take back program proposal
49 within thirty days. If the department rejects the subsequent proposal,
50 the manufacturer or manufacturers at issue shall be out of compliance
51 with this article and subject to the enforcement provisions pursuant to
52 section two hundred ninety-four of this article. The department shall
53 provide, and update annually, on its website a list of all manufacturers
54 participating in a drug take back program approved by the department.

55 6. At least every three years, a manufacturer, jointly or individual-
56 ly, or a drug take back organization shall update its drug take back

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

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

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

19 (a) Offering drug collection by:

20 (i) On-site collection, dropbox, or receptacle meeting federal stand-
21 ards;

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

24 (iii) Other federal drug enforcement agency approved methods of
25 collection.

26 (b) Signage prominently displayed advertising such drug collection to
27 consumers.

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

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

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

38 § 294. Jurisdiction. Jurisdiction of all matters pertaining to drug
39 disposal by this article is vested exclusively in the state. Any
40 provision of any local law or ordinance, or any rule or regulation
41 promulgated prior to, or upon the effective date of this section, shall
42 be preempted.

43 § 3. Section 3343-b of the public health law, as amended by chapter
44 379 of the laws of 2015, is amended to read as follows:

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

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

5 ~~[3. Disposal sites shall be operated by law enforcement agencies,~~
6 ~~pharmacies and other Federal Drug Enforcement Administration authorized~~
7 ~~collectors on a voluntary basis. Nothing in this section shall require~~
8 ~~any political subdivision of the state to participate in the program~~
9 ~~established in this section.]~~

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

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