

STATE OF NEW YORK

9576--B

IN ASSEMBLY

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Introduced by M. of A. GUNTHER, THIELE, ORTIZ, ENGLEBRIGHT, STECK, STIRPE, HUNTER, COLTON, PELLEGRINO, PHEFFER AMATO, BRINDISI, CURRAN, ABINANTI, DE LA ROSA, GALEF, FAHY, MAGNARELLI, LIFTON, JAFFEE, HYNDMAN, CARROLL, MOSLEY, GOTTFRIED, O'DONNELL, STERN, LUPARDO, GLICK, BRONSON, SKOUFIS, L. ROSENTHAL, DINOWITZ, D. ROSENTHAL, JONES, SEAWRIGHT, WOERNER, PAULIN, BOHEN, BARNWELL, TAYLOR, WEPRIN, ARROYO, McDONOUGH, SANTABARBARA -- Multi-Sponsored by -- M. of A. BYRNE, EPSTEIN -- read once and referred to the Committee on Health -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee -- reported and referred to the Committee on Codes -- 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:

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

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

5 ARTICLE 2-B
6 DRUG TAKE BACK

7 Section 290. Definitions.

8 291. Drug take back.

9 292. Collection.

10 293. Violations.

11 294. Jurisdiction.

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

13 1. "Authorized collector" means: (a) a person, company, corporation or
14 other entity that is registered with the United States Drug Enforcement
15 Administration to collect controlled substances for the purposes of safe
16 disposal and destruction; (b) a law enforcement agency; or (c) a person,
17 company, corporation or other entity authorized by the department to
18

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

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1 provide alternative collection methods for covered drugs that are not
2 controlled substances.

3 2. "Covered drug" means any substance recognized as a drug under 21
4 USC § 321(g)(1), as amended, and any regulations promulgated thereunder
5 that is sold, offered for sale or dispensed in the state, whether
6 directly or through a wholesaler, in any form including prescription and
7 nonprescription drugs, drugs in medical devices and combination
8 products, brand and generic drugs and drugs for veterinary use; provided
9 however, covered drug shall not include: (a) vitamins or supplements;
10 (b) herbal-based remedies and homeopathic drugs, products or remedies;
11 (c) cosmetics, soap (with or without germicidal agents), laundry deter-
12 gent, bleach, household cleaning products, shampoos, sunscreens, tooth-
13 paste, lip balm, antiperspirants or other personal care products that
14 are regulated as both cosmetics and nonprescription drugs under the
15 Federal Food, Drug, and Cosmetic Act; (d) pet pesticide products
16 contained in pet collars, powders, shampoos, topical applications, or
17 other forms; (e) drugs that are biological products as defined in subdi-
18 vision twenty-seven of section sixty-eight hundred two of the education
19 law if the manufacturer already provides a take back program; (f) drugs
20 for which a manufacturer provides a take back program as part of a
21 Federal Food and Drug Administration managed risk evaluation and miti-
22 gation strategy; (g) emptied injector products or emptied medical
23 devices and their component parts or accessories; and (h) drugs that are
24 used solely in a clinical setting.

25 3. "Manufacturer" means a person, company, corporation or other entity
26 engaged in the manufacture of covered drugs sold in the state. Manufac-
27 turer does not include a repackager or wholesaler.

28 4. "Pharmacies" means all pharmacies registered under section sixty-
29 eight hundred eight of the education law that are part of a group of ten
30 or more establishments that conduct business under the same name, or
31 operate under a common ownership or management, or pursuant to a fran-
32 chise agreement with the same franchisor, and all nonresident pharmacies
33 registered pursuant to section sixty-eight hundred eight-b of the educa-
34 tion law that provide covered drugs to state residents by mail.

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

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

42 7. "Repackager" means an entity that owns or operates an establishment
43 that repacks and relabels a product or package containing a covered drug
44 for further sale or for distribution without further transaction.

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

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

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

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

52 2. Any manufacturer of a covered drug, individually or jointly, or a
53 drug take back organization contracted by a manufacturer of a covered
54 drug shall within one hundred eighty days from the effective date of
55 this section submit to the department, in a manner and form determined

1 by the department, a proposed drug take back program that meets, at a
2 minimum, the following requirements:

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

5 (b) Provides contact information for the person submitting the planned
6 drug take back program with whom the department shall direct all
7 inquiries;

8 (c) Details a collection system to provide convenient, ongoing
9 collection services to all persons seeking to dispose of covered drugs
10 pursuant to section two hundred ninety-two of this article that is
11 geographically distributed in a way to ensure access in rural and under-
12 served areas;

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

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

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

24 (g) Details how the costs of pharmacy collection and other authorized
25 collectors will be reimbursed which shall include costs retroactive to
26 the effective date of this article, and where more than one manufacturer
27 will be involved in the planned drug take back program, a plan for the
28 fair and reasonable manner of allocated costs among the participants in
29 such program such that the costs paid by each manufacturer is reasonably
30 related to the volume or value of covered drugs sold in the state; and

31 (h) Provides any further information deemed appropriate by the depart-
32 ment.

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

37 4. A manufacturer, individually or jointly, must pay all administra-
38 tive and operational fees associated with the drug take back program,
39 including the cost of collecting, transporting and disposing of covered
40 drugs from pharmacies and other authorized collectors and the recycling
41 or disposal, or both, of packing collected with the covered drug.
42 Manufacturers shall also pay costs incurred by the state in the adminis-
43 tration and enforcement of the drug take back program. Exclusive of
44 finances and penalties, the state shall only recover its actual cost of
45 administration and enforcement. In instances where manufacturers jointly
46 conduct a drug take back program, the costs of administration and
47 enforcement shall be fairly and reasonably allocated such that the
48 portion of costs is reasonably related to the volume or value of covered
49 drugs the manufacturers sell in the state. No manufacturer may charge a
50 point-of-sale or other fee to consumers, or a fee that could be passed
51 on to consumers, to recoup the cost of their drug take back program.

52 5. Within sixty days of receipt of a proposed drug take back program,
53 the department, in consultation with the department of environmental
54 conservation, shall determine whether such proposed drug take back
55 program complies with the requirements of this article and notify the
56 applicant. The department may conduct a noticed public hearing prior to

1 approval. If the drug take back program is approved, the department
2 shall notify the applicant in writing. If the drug take back program is
3 not approved, the department shall notify the applicant in writing and
4 the applicant shall submit a revised drug take back program proposal
5 within thirty days. If the department rejects the subsequent proposal,
6 the manufacturer or manufacturers at issue shall be out of compliance
7 with this article and subject to the enforcement provisions pursuant to
8 section two hundred ninety-four of this article. The department shall
9 provide, and update annually, on its website a list of all manufacturers
10 participating in a drug take back program approved by the department.

11 6. At least every three years, a manufacturer, jointly or individual-
12 ly, or a drug take back organization shall update its drug take back
13 program and submit an updated proposal to the department. A manufacturer
14 who begins to offer a covered drug in the state after the effective date
15 of this article, shall provide evidence of joining an existing approved
16 drug take back program or submit a proposal for a drug take back program
17 within ninety days following the initial offer for sale of a covered
18 drug. Any proposed change to a drug take back program shall be submitted
19 in writing and approved by the department prior to any change.

20 7. Each approved drug take back program shall report to the department
21 at a date and manner set by the department. The department shall submit
22 an annual report to the governor, speaker of the assembly and temporary
23 president of the senate by January first detailing all program activ-
24 ities, the weight collected by each program, a description of collection
25 activities, the name and location of all collection sites, public educa-
26 tion and outreach activities, an evaluation of the efficacy of the
27 program and each collection method, and any manufacturer out of compli-
28 ance or subject to penalties pursuant to section two hundred ninety-four
29 of this article.

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

32 (a) Offering drug collection by one or more of the following methods:
33 (i) On-site collection, dropbox, or receptacle meeting federal stand-
34 ards;
35 (ii) Mail-back collection by prepaid envelopes as authorized by feder-
36 al law and regulation; or
37 (iii) Other federal drug enforcement agency approved methods of
38 collection.
39 (b) Signage prominently displayed advertising such drug collection to
40 consumers.

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

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

48 4. For any city with a population of one hundred twenty-five thousand
49 or more as of the last decennial census, the commissioner shall estab-
50 lish by regulation a distribution plan that ensures that on-site
51 collection receptacle or dropbox placement shall be reasonably accessi-
52 ble to all residents and that provides for program cost efficiency.

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

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

4 § 294. Jurisdiction. Jurisdiction of all matters pertaining to drug
5 disposal by this article is vested exclusively in the state. Any
6 provision of any local law or ordinance, or any rule or regulation
7 promulgated prior to, or upon the effective date of this section, shall
8 be preempted.

9 § 3. Section 3343-b of the public health law, as amended by chapter
10 379 of the laws of 2015, is amended to read as follows:

11 § 3343-b. Safe disposal of unused controlled substances. 1. The
12 department shall oversee a program for the safe disposal of unused
13 controlled substances by consumers in accordance with federal law and
14 article two-B of this chapter. Individual members of the public shall
15 be authorized to voluntarily surrender controlled substances listed on
16 schedule II, III, IV or V of section thirty-three hundred six of this
17 article in a secure manner, without identifying themselves. Safe
18 disposal methods shall be publicized consistent with the prescription
19 pain medication awareness program established pursuant to section thir-
20 ty-three hundred nine-a of this article and article two-B of this chap-
21 ter.

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

26 3. ~~[Disposal]~~ Except as provided in article two-B of this chapter,
27 disposal sites shall be operated by law enforcement agencies, pharmacies
28 and other Federal Drug Enforcement Administration authorized collectors
29 on a voluntary basis, provided, however, that such disposal sites shall
30 not be precluded from operating as part of a drug take back program
31 established pursuant to article two-B of this chapter. Nothing in this
32 section shall require any political subdivision of the state to partic-
33 ipate in the program established in this section.

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

36 § 5. This act shall take effect on the one hundred eightieth day after
37 it shall have become a law. Effective immediately, the addition, amend-
38 ment and/or repeal of any rule or regulation necessary for the implemen-
39 tation of this act on its effective date are authorized to be made and
40 completed on or before such effective date.