

AMENDED IN ASSEMBLY AUGUST 17, 2015

AMENDED IN ASSEMBLY JULY 2, 2015

AMENDED IN ASSEMBLY JUNE 23, 2015

AMENDED IN ASSEMBLY JUNE 8, 2015

SENATE BILL

No. 225

Introduced by Senator Wieckowski

February 13, 2015

An act to amend Sections 117630, 117904, 117943, 117945, 117975, 118032, 118040, 118345, and 118275 of the Health and Safety Code, relating to medical waste, and declaring the urgency thereof, to take effect immediately.

LEGISLATIVE COUNSEL'S DIGEST

SB 225, as amended, Wieckowski. Medical waste.

(1) ~~Existing~~ *Under existing law, the Medical Waste Management Act, the California Department of Public Health regulates the disposal of medical waste, including requiring waste. The act requires* specified biohazard materials to be disposed of in biohazard bags and ~~requiring~~ *requires* specified treatment for medical waste. Transportation, storage, treatment, or disposal of medical waste in a manner not authorized by the act is a crime. Existing law defines specified terms for purposes of the Medical Waste Management Act, including "biohazard bag." Existing law defines a biohazard bag to mean a film bag that is impervious to moisture. Existing law requires the film bags that are used for transport to be marked and certified by the manufacturer as having passed specified tests prescribed for tear resistance and for impact resistance.

This bill would revise the definition of “biohazard bag” and would limit the application of the requirement that film bags used for transport be marked and certified by the manufacturer as having passed specified tests only to those film bags that are used for transport from the generator’s facility onto roadways and into commerce to a treatment and disposal facility. The bill would revise the requirements for biohazard bags that are used to collect medical waste within a facility, as specified.

(2) Existing law requires a hazardous waste transporter or generator transporting medical waste to maintain a completed shipping document in compliance with the United States Department of Transportation and a tracking document if the waste is transported to a facility other than the final medical waste treatment facility.

This bill would *instead* require ~~a shipping document only when a hazardous waste transporter that transports medical waste on a public roadway~~ *to maintain a tracking document in compliance with specified requirements for purposes of tracking medical waste from the point when the waste leaves the generator facility until the waste receives final treatment.* The bill would also require the ~~shipping document and tracking information~~ *document* to be maintained only by hazardous waste transporters, and not by generators transporting waste. *The bill would also make conforming changes.*

This bill would declare that it is to take effect immediately as an urgency statute.

Vote: $\frac{2}{3}$. Appropriation: no. Fiscal committee: yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Section 117630 of the Health and Safety Code
2 is amended to read:
3 117630. (a) “Biohazard bag” means a disposable film bag
4 used to contain medical waste. Notwithstanding subdivision (b)
5 of Section 117605, the film bags that are used to line the United
6 States Department of Transportation (USDOT)-approved shipping
7 containers for transport from the generator’s facility onto roadways
8 and into commerce to a treatment and disposal facility shall be
9 marked and certified by the manufacturer as having passed the
10 tests prescribed for tear resistance in the American Society for
11 Testing Materials (ASTM) D1922, “Standard Test Method for

1 Propagation Tear Resistance of Plastic Film and Thin Sheeting by
2 Pendulum Method” and for impact resistance in ASTM D1709,
3 “Standard Test Methods for Impact Resistance of Plastic Film by
4 the Free-Falling Dart Method,” as those documents were published
5 on January 1, 2014. The film bag shall meet an impact resistance
6 of 165 grams and a tearing resistance of 480 grams in both parallel
7 and perpendicular planes with respect to the length of the bag.

8 (b) The biohazard bag that is used to collect medical waste
9 within a facility shall be manufacturer certified to meet the ASTM
10 D1709 dart drop test, provided that when the bag is prepared for
11 transport offsite, it is placed into a USDOT-approved container
12 lined with a biohazard bag that is ASTM D1709 and ASTM D1922
13 certified.

14 (c) The color of the bag shall be red, except when yellow bags
15 are used to further segregate trace chemotherapy waste and white
16 bags are used to further segregate pathology waste. The biohazard
17 bag shall be marked with the international biohazard symbol and
18 may be labeled by reference as authorized by the USDOT.

19 *SEC. 2. Section 117904 of the Health and Safety Code is*
20 *amended to read:*

21 117904. (a) In addition to the consolidation points authorized
22 pursuant to Section 118147, the enforcement agency may approve
23 a location as a point of consolidation for the collection of
24 home-generated sharps waste, which, after collection, shall be
25 transported and treated as medical waste.

26 (b) A consolidation location approved pursuant to this section
27 shall be known as a “home-generated sharps consolidation point.”

28 (c) A home-generated sharps consolidation point is not subject
29 to the requirements of Chapter 9 (commencing with Section
30 118275), to the permit or registration requirements of this part, or
31 to any permit or registration fees, with regard to the activity of
32 consolidating home-generated sharps waste pursuant to this section.

33 (d) A home-generated sharps consolidation point shall comply
34 with all of the following requirements:

- 35 (1) All sharps waste shall be placed in sharps containers.
36 (2) Sharps containers ready for disposal shall not be held for
37 more than seven days without the written approval of the
38 enforcement agency.

39 (e) An operator of a home-generated sharps consolidation point
40 approved pursuant to this section shall not be considered the

1 generator of that waste, but shall be listed on the ~~shipping document~~
 2 ~~tracking documents~~ in compliance with ~~United States Department~~
 3 ~~of Transportation and the United States Postal Service~~
 4 ~~requirements~~. *requirements for waste shipped through mail back*
 5 *and on the tracking documents as required by the department.*

6 (f) The medical waste treatment facility which treats the sharps
 7 waste subject to this section shall maintain the ~~shipping and~~
 8 ~~tracking documents~~ *document* required by Sections 118040 and
 9 118165 with regard to that sharps waste.

10 *SEC. 3. Section 117943 of the Health and Safety Code is*
 11 *amended to read:*

12 117943. (a) A medical waste generator required to register
 13 pursuant to this chapter shall maintain for a minimum of three
 14 years individual treatment operating records, and if applicable,
 15 ~~shipping and the tracking documents~~ *document* for all untreated
 16 medical waste shipped offsite for treatment, and shall report or
 17 submit to the enforcement agency, upon request, all of the
 18 following:

19 (1) Treatment operating records. Operating records shall be
 20 maintained in written or electronic form.

21 (2) An emergency action plan complying with regulations
 22 adopted by the department.

23 (3) ~~Shipping and tracking~~ *Tracking* documents or electronically
 24 ~~archived shipping and tracking documents~~ maintained by the
 25 facility and medical waste hauler of all untreated medical waste
 26 shipped offsite for treatment.

27 (b) Documentation shall be made available to the enforcement
 28 agency onsite.

29 *SEC. 4. Section 117945 of the Health and Safety Code is*
 30 *amended to read:*

31 117945. (a) Small quantity generators who are not required
 32 to register pursuant to this chapter shall maintain on file in their
 33 office all of following:

34 (1) An information document stating how the generator contains,
 35 stores, treats, and disposes of any medical waste generated through
 36 any act or process of the generator.

37 (2) Records required by ~~the United States Department of~~
 38 ~~Transportation or the United States Postal Service~~ of any medical
 39 waste shipped offsite for treatment and disposal. The small quantity
 40 generator shall maintain, or have available electronically at the

1 facility or from the medical waste hauler or common carrier, these
2 records, for not less than three years.

3 (b) Documentation shall be made available to the enforcement
4 agency onsite.

5 *SEC. 5. Section 117975 of the Health and Safety Code is*
6 *amended to read:*

7 117975. (a) A large quantity medical waste generator required
8 to register pursuant to this chapter shall maintain for a minimum
9 of two years individual treatment records and ~~shipping and the~~
10 ~~tracking documents~~ *document* for all untreated medical waste
11 shipped offsite for treatment. The generator shall report or submit
12 to the enforcement agency, upon request, all of the following:

13 (1) Treatment operating records. Operating records shall be
14 maintained in written or electronic form.

15 (2) An emergency action plan in accordance with regulations
16 adopted by the department.

17 (3) ~~Shipping and tracking~~ *Tracking* documents or electronically
18 archived ~~shipping and tracking documents~~ *documents* maintained
19 by the facility or medical waste hauler of all untreated medical
20 wastes shipped offsite for treatment.

21 (b) Documentation shall be made available to the enforcement
22 agency onsite as soon as feasible, but no more than two business
23 days following the request.

24 *SEC. 6. Section 118032 of the Health and Safety Code is*
25 *amended to read:*

26 118032. A pharmaceutical waste generator or parent
27 organization that employs health care professionals who generate
28 pharmaceutical waste is exempt from the requirements of
29 subdivision (a) of Section 118000 if all of the following
30 requirements are met:

31 (a) The generator or parent organization has on file one of the
32 following:

33 (1) If the generator or parent organization is a small quantity
34 generator required to register pursuant to Chapter 4 (commencing
35 with Section 117925), a medical waste management plan prepared
36 pursuant to Section 117935.

37 (2) If the generator or parent organization is a small quantity
38 generator not required to register pursuant to Chapter 4
39 (commencing with Section 117925), the information document
40 maintained pursuant to subdivision (a) of Section 117945.

1 (3) If the generator or parent organization is a large quantity
2 generator, a medical waste management plan prepared pursuant
3 to Section 117960.

4 (b) The generator or health care professional who generated the
5 pharmaceutical waste transports the pharmaceutical waste himself
6 or herself, or directs a member of his or her staff to transport the
7 pharmaceutical waste to a parent organization or another health
8 care facility for the purpose of consolidation before treatment and
9 disposal, or contracts with a common carrier to transport the
10 pharmaceutical waste to a permitted medical waste treatment
11 facility or transfer station.

12 (c) Except as provided in subdivision (d), all of the following
13 requirements are met:

14 (1) Prior to shipment of the pharmaceutical waste, the generator
15 notifies the intended destination facility that it is shipping
16 pharmaceutical waste to it and provides a copy of the ~~shipping and~~
17 ~~tracking documents, document,~~ as specified in Section 118040.

18 (2) The generator and the facility receiving the pharmaceutical
19 waste maintain the ~~shipping and tracking documents, document,~~
20 as specified in Section 118040.

21 (3) The facility receiving the pharmaceutical waste notifies the
22 generator of the receipt of the pharmaceutical waste shipment and
23 any discrepancies between the items received and the ~~shipping~~
24 ~~and tracking documents, document,~~ as specified in Section 118040,
25 evidencing diversion of the pharmaceutical waste.

26 (4) The generator notifies the enforcement agency of any
27 discrepancies between the items received and the ~~shipping and~~
28 ~~tracking documents, document,~~ as specified in Section 118040,
29 evidencing diversion of the pharmaceutical waste.

30 (d) (1) Notwithstanding subdivision (c), if a health care
31 professional who generates pharmaceutical waste returns the
32 pharmaceutical waste to the parent organization for the purpose
33 of consolidation before treatment and disposal over a period of
34 time, a single-page form or multiple entry log may be substituted
35 for the tracking document, if the form or log contains all of the
36 following information:

37 (A) The name of the person transporting the pharmaceutical
38 waste.

39 (B) The number of containers of pharmaceutical waste. This
40 clause does not require any generator to maintain a separate

1 pharmaceutical waste container for every patient or to maintain
2 records as to the specified source of the pharmaceutical waste in
3 any container.

4 (C) The date that the pharmaceutical waste was returned.

5 (2) The form or log described in paragraph (1) shall be
6 maintained in the files of the health care professional who generates
7 the pharmaceutical waste and the parent organization or another
8 health care facility that receives the pharmaceutical waste.

9 (3) This subdivision does not prohibit the use of a single
10 document to verify the return of more than one container to a parent
11 organization or another health care facility, provided the form or
12 log meets the requirements specified in paragraphs (1) and (2).

13 ~~SEC. 2.~~

14 *SEC. 7.* Section 118040 of the Health and Safety Code is
15 amended to read:

16 118040. (a) Except with regard to sharps waste consolidated
17 by a home-generated sharps consolidation point approved pursuant
18 to Section 117904, a hazardous waste transporter transporting
19 medical waste shall maintain a completed ~~shipping~~ *tracking*
20 document in compliance with ~~United States Department of~~
21 ~~Transportation (USDOT) requirements when medical waste is~~
22 ~~transported on a public roadway. In addition to the shipping~~
23 ~~document required by USDOT, a hazardous waste transporter who~~
24 ~~transports medical waste to a facility, other than the final medical~~
25 ~~waste treatment facility, shall also maintain tracking information~~
26 ~~that shows the name, address, and telephone number of the medical~~
27 ~~waste generator, for purposes of tracking the generator of medical~~
28 ~~waste when the waste is transported to the final medical waste~~
29 ~~treatment facility. subdivision (b) for the purpose of tracking the~~
30 ~~medical waste from the point when the waste leaves the generator~~
31 ~~facility until it receives final treatment. At the time that the medical~~
32 ~~waste is received by a hazardous waste transporter, the transporter~~
33 ~~shall provide the medical waste generator with a copy of the~~
34 ~~shipping document and tracking document, if the waste is~~
35 ~~transported to a facility other than the final medical waste treatment~~
36 ~~facility for the generator's medical waste records. Information~~
37 ~~from the shipping document and the tracking document may be~~
38 ~~combined onto one form having the required information. tracking~~
39 ~~document.~~ The transporter transporting medical waste shall

1 maintain its copy of the ~~shipping, tracking, and combined~~
2 ~~documents~~ *tracking document* for three years.

3 (b) The tracking document shall include, but not be limited to,
4 all of the following information:

5 (1) The name, address, telephone number, and registration
6 number of the transporter, unless transported pursuant to Section
7 117946 or 117976.

8 (2) The type of medical waste transported and the quantity or
9 aggregate weight of medical waste transported.

10 (3) The name, address, and telephone number of the generator.

11 (4) The name, address, telephone number, permit number, and
12 the signature of an authorized representative of the permitted
13 facility receiving the medical waste.

14 (5) The date that the medical waste is collected or removed
15 from the generator's facility, the date that the medical waste is
16 received by the transfer station, the registered large quantity
17 generator, or point of consolidation, if applicable, and the date that
18 the medical waste is received by the treatment facility.

19 (c) A hazardous waste transporter ~~or generator~~ transporting
20 medical waste in a vehicle shall have the ~~shipping and tracking~~
21 ~~documents~~ *tracking document* in his or her possession while
22 transporting the medical waste. The tracking document shall be
23 shown upon demand to any enforcement agency personnel or
24 officer of the Department of the California Highway Patrol. If the
25 medical waste is transported by rail, vessel, or air, the railroad
26 corporation, vessel operator, or airline shall enter on the shipping
27 papers any information concerning the medical waste that the
28 enforcement agency may require.

29 (d) A hazardous waste transporter ~~or a generator~~ transporting
30 medical waste shall provide the facility receiving the medical waste
31 with the original ~~shipping and tracking documents~~. *tracking*
32 *document*.

33 (e) Each hazardous waste transporter and each medical waste
34 treatment facility shall provide tracking data periodically and in a
35 format as determined by the department.

36 ~~SEC. 3.~~

37 *SEC. 8.* Section 118275 of the Health and Safety Code is
38 amended to read:

1 118275. (a) To containerize or store medical waste, at the
2 point of generation and while collected in that room, a person shall
3 do all of the following:

4 (1) Medical waste, as defined in Section 117690, shall be
5 contained separately from other waste at the point of origin in the
6 producing facility. Sharps containers may be placed in biohazard
7 bags or in containers with biohazard bags.

8 (2) Biohazardous waste, as defined in paragraph (1) of
9 subdivision (b) of Section 117690, shall be placed in a biohazard
10 bag and labeled in compliance with Section 117630.

11 (3) Sharps waste, as defined in paragraph (4) of subdivision (b)
12 of Section 117690, including sharps and pharmaceutical waste
13 containerized pursuant to paragraph (7), shall be contained in a
14 United States Food and Drug Administration (USFDA) approved
15 sharps container that meets USFDA labeling requirements and is
16 handled pursuant to Section 118285.

17 (4) Trace chemotherapy waste, as defined in paragraph (5) of
18 subdivision (b) of Section 117690, shall be segregated for storage,
19 and, when placed in a secondary container, that container shall be
20 labeled with the words “Chemotherapy Waste,” “CHEMO,” or
21 other label approved by the department on the lid and sides, so as
22 to be visible from any lateral direction, to ensure treatment of the
23 biohazardous waste pursuant to Section 118222. Sharps waste that
24 is contaminated through contact with, or having previously
25 contained, chemotherapeutic agents, shall be placed in sharps
26 containers labeled in accordance with the industry standard with
27 the words “Chemotherapy Waste,” “CHEMO,” or other label
28 approved by the department, and shall be segregated to ensure
29 treatment of the sharps waste pursuant to Section 118222.

30 (5) Pathology waste, as defined in paragraph (2) of subdivision
31 (b) of Section 117690, shall be segregated for storage and, when
32 placed in a secondary container, that container shall be labeled
33 with the words “Pathology Waste,” “PATH,” or other label
34 approved by the department on the lid and sides, so as to be visible
35 from any lateral direction, to ensure treatment of the waste pursuant
36 to Section 118222.

37 (6) Pharmaceutical waste, as defined in paragraph (3) of
38 subdivision (b) of Section 117690, shall be segregated for storage
39 in accordance with the facility’s medical waste management plan.
40 When this waste is prepared for shipment offsite for treatment, it

1 shall be properly containerized for shipment in compliance with
2 United States Department of Transportation and the United States
3 Drug Enforcement Administration (DEA) requirements.

4 (A) Pharmaceutical wastes classified by the DEA as “controlled
5 substances” shall be disposed of in compliance with DEA
6 requirements.

7 (B) Nonradioactive pharmaceutical wastes that are not subject
8 to the federal Resource Conservation and Recovery Act of 1976
9 (Public Law 94-580), as amended, and that are regulated as medical
10 waste are placed in a container or secondary container labeled with
11 the words “HIGH HEAT” or “INCINERATION ONLY;” or with
12 another label approved by the department, on the lid and sides, so
13 as to be visible from any lateral direction, to ensure treatment of
14 the biohazardous waste pursuant to Section 118222.

15 (7) A person may consolidate into a common container, which
16 may be reusable, sharps waste, as defined in paragraph (4) of
17 subdivision (b) of Section 117690, and pharmaceutical wastes, as
18 defined in paragraph (3) of subdivision (b) of Section 117690,
19 provided that both of the following apply:

20 (A) The consolidated waste is treated by incineration or
21 alternative treatment technologies approved to treat that waste
22 pursuant to paragraph (1) or (3) of subdivision (a) of Section
23 118215 prior to disposal. That alternative treatment shall render
24 the waste unrecoverable and nonhazardous.

25 (B) The container meets the requirements of Section 118285.
26 The container shall be labeled with the biohazardous waste symbol
27 and the words “HIGH HEAT” or “INCINERATION ONLY;” or
28 with another label approved by the department, on the lid and
29 sides, so as to be visible from any lateral direction, to ensure
30 treatment of the waste pursuant to this subdivision.

31 (b) To containerize medical waste being held for shipment
32 offsite for treatment, the waste shall be labeled, as outlined in
33 subdivision (a), on the lid and sides of the container.

34 (c) When medical waste is containerized pursuant to
35 subdivisions (a) and (b) there is no requirement to label the
36 containers with the date that the waste started to accumulate.

37 *SEC. 9. Section 118345 of the Health and Safety Code is*
38 *amended to read:*

39 118345. (a) Any person who intentionally makes any false
40 statement or representation in any application, label, ~~shipping~~

1 document, tracking document, record, report, permit, registration,
2 or other document filed, maintained, or used for purposes of
3 compliance with this part that materially affects the health and
4 safety of the public is liable for a civil penalty of not more than
5 ten thousand dollars (\$10,000) for each separate violation or, for
6 continuing violations, for each day that the violation continues.

7 (b) Any person who fails to register or fails to obtain a medical
8 waste permit in violation of this part, or otherwise violates any
9 provision of this part, any order issued pursuant to Section 118330,
10 or any regulation adopted pursuant to this part, is liable for a civil
11 penalty of not more than ten thousand dollars (\$10,000) for each
12 violation of a separate provision of this part or, for continuing
13 violations, for each day that the violation continues.

14 ~~SEC. 4.~~

15 *SEC. 10.* This act is an urgency statute necessary for the
16 immediate preservation of the public peace, health, or safety within
17 the meaning of Article IV of the Constitution and shall go into
18 immediate effect. The facts constituting the necessity are:

19 In order to ensure that necessary and technical changes to the
20 laws governing the handling and disposal of medical waste are
21 implemented as soon as possible, it is necessary that this act take
22 effect immediately.