

AMENDED IN ASSEMBLY MARCH 19, 2013

CALIFORNIA LEGISLATURE—2013–14 REGULAR SESSION

**ASSEMBLY BILL**

**No. 403**

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**Introduced by Assembly ~~Member~~ Members Stone and Eggman**

February 15, 2013

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An act to amend Section ~~47115~~ 118286 of the Health and Safety Code, and to repeal and add Article 3.3 (commencing with Section 47115) of Chapter 1 of Part 7 of Division 30 of the Public Resources Code, relating to solid waste.

LEGISLATIVE COUNSEL'S DIGEST

AB 403, as amended, Stone. Solid waste: home-generated sharps.

**Existing**

(1) Existing law requires a pharmaceutical manufacturer selling or distributing medication that is intended to be self-injected at home to submit, on an annual basis, to the Department of Resources Recycling and Recovery a plan supporting the safe collection and proper disposal of specified waste devices.

This bill would ~~make technical, nonsubstantive changes to that provision~~ require a producer of home-generated sharps or a stewardship organization designated by the producer to submit a home-generated sharps stewardship plan by April 1, 2015, to the Department of Resources Recycling and Recovery. The bill would require the plan to provide for the development and implementation of a recovery program to reduce the generation of, and manage the end-of-life of, home-generated sharps, and to include specified elements, including provisions to meet unspecified minimum collection rates for the home-generated sharps subject to the plan.

*The bill would provide for the review and approval of the plan by the department and would require the department, on January 1, 2016, or upon the date the first plan is approved, whichever is earlier, to post on its Internet Web site a list of producers for which the department has approved a plan. The bill would require a wholesaler, health care facility, retailer, or other distributor that distributes or sells home-generated sharps to monitor the department's Internet Web site to determine if the sale of a producer's home-generated sharps is in compliance with the bill. The bill would, as of 120 days after that posting, prohibit a producer or retailer from selling or offering for sale in this state home-generated sharps to a person in this state unless the producer of those home-generated sharps is in compliance with the bill's requirements.*

*The bill would require a producer or stewardship organization, by April 1, 2017, and every subsequent year thereafter, to prepare and submit to the department an annual report describing the activities carried out pursuant to the plan during the previous calendar year. The department would be required to review the report and would direct the department, if the annual report does not demonstrate the achievement of an unspecified collection rate increase, to require the program to take additional actions with regard to improving and increasing the number of home-generated sharps collection points, ensuring accessibility to those points, and providing additional education and outreach activities. The bill would authorize the department to exempt a producer or stewardship organization from the annual report requirements if the department determines that the collection rate for the home-generated sharps subject to a plan meets a 95% collection rate.*

*The bill would require a producer or stewardship organization submitting a plan to the department to pay the department an annual administrative fee in an amount that is sufficient to cover the department's full costs of administering and enforcing these provisions. The bill would require the department to deposit the fees in the Safe Sharps Disposal Account, which the bill would establish in the Integrated Waste Management Fund, and the department would be authorized to expend the moneys in that account, upon appropriation by the Legislature, to administer and enforce the bill's requirements.*

*The bill would require the department to enforce these provisions and would authorize the department to impose an administrative civil penalty on a person who violates the bill's requirements or on a*

*producer or stewardship organization that does not achieve the unspecified minimum collection rate. The department would be required to deposit all penalties collected into the Safe Sharps Disposal Penalty Account, which the bill would create in the Integrated Waste Management Fund, and the department would be authorized to expend the moneys in that account, upon appropriation by the Legislature, to enforce the bill's requirements.*

*The bill would also allow a producer who is subject to an approved plan and in compliance with the bill to bring a civil action to recover costs, damages, and fees from another producer for failure to comply with the bill's provisions.*

*(2) The existing Medical Waste Management Act, administered by the State Department of Public Health, prohibits a person from knowingly placing home-generated sharps waste in certain types of containers, requires that home-generated sharps waste be transported only in a sharps container, as defined in the act, or other container approved by the department or local enforcement agency, and requires that this waste be managed only at specified locations.*

*This bill would additionally allow home-generated sharps waste to be managed at a facility or collection point operated pursuant to an approved home-generated sharps stewardship plan.*

Vote: majority. Appropriation: no. Fiscal committee: ~~no~~-yes.  
State-mandated local program: no.

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

- 1     SECTION 1. Section 118286 of the Health and Safety Code is
- 2     amended to read:
- 3     118286. (a) ~~On or after September 1, 2008, no~~ A person shall
- 4     not knowingly place home-generated sharps waste in any of the
- 5     following containers:
- 6     (1) Any container used for the collection of solid waste,
- 7     recyclable materials, or greenwaste.
- 8     (2) Any container used for the commercial collection of solid
- 9     waste or recyclable materials from business establishments.
- 10    (3) Any roll-off container used for the collection of solid waste,
- 11    construction, and demolition debris, greenwaste, or other recyclable
- 12    materials.
- 13    (b) ~~On or after September 1, 2008, home-generated~~
- 14    Home-generated sharps waste shall be transported only in a sharps

1 container, or other containers approved by the enforcement agency,  
2 and shall only be managed at any of the following:

3 (1) A household hazardous waste facility pursuant to Section  
4 25218.13.

5 (2) A “home-generated sharps consolidation point” as defined  
6 in subdivision (b) of Section 117904.

7 (3) A medical waste generator’s facility pursuant to Section  
8 118147.

9 (4) A facility through the use of a medical waste mail-back  
10 container approved by the department pursuant to subdivision (b)  
11 of Section 118245.

12 (5) *A facility or other home-generated sharps collection point*  
13 *operated pursuant to a home-generated sharps stewardship plan*  
14 *approved pursuant to Article 3.3 (commencing with Section 47115)*  
15 *of Chapter 1 of Part 7 of Division 30 of the Public Resources Code.*

16 *SEC. 2. Article 3.3 (commencing with Section 47115) of*  
17 *Chapter 1 of Part 7 of Division 30 of the Public Resources Code*  
18 *is repealed.*

19 *SEC. 3. Article 3.3 (commencing with Section 47115) is added*  
20 *to Chapter 1 of Part 7 of Division 30 of the Public Resources Code,*  
21 *to read:*

22  
23 *Article 3.3. Safe Home-Generated Sharps Recovery Program*  
24

25 *47115. The Legislature finds and declares that the purpose of*  
26 *the safe home-generated sharps recovery program established by*  
27 *this article is to require the producers of injection devices to*  
28 *develop and implement a program to collect, transport, and process*  
29 *home-generated sharps, thereby reducing the costs, public health*  
30 *risks, and environmental impacts of the illegal and unsafe disposal*  
31 *of home-generated sharps in this state.*

32 *47116. For purposes of this article, the following terms have*  
33 *the following meanings:*

34 (a) *“Consumer” means a person that purchases or owns*  
35 *home-generated sharps.*

36 (b) *“Distributor” means a person that sells sharps or provides*  
37 *sharps for free to the general public for home use, which may*  
38 *include, but is not limited to, a retailer, a veterinarian, or a health*  
39 *clinic, health dispensary, or health facility licensed under Division*  
40 *2 (commencing with Section 1200) of the Health and Safety Code.*

1 (c) “Home-generated sharps” means hypodermic needles,  
2 syringes with needles attached, pen needles, intravenous needles,  
3 or any other similar device intended to self-inject medication at  
4 home.

5 (d) “Program” means the program implementing an approved  
6 home-generated sharps stewardship plan.

7 (e) “Retailer” means a person that sells home-generated sharps  
8 in the state to a consumer. A sale includes, but is not limited to, a  
9 transaction conducted through sales outlets, catalogs, or the  
10 Internet or any other similar electronic means.

11 (f) “Stewardship organization” means a nonprofit organization  
12 created by one or more producers that also includes at least four  
13 additional members, who shall be representatives from each of  
14 the following entities, but not more than one representative per  
15 entity, to the extent that the other entities do not have a  
16 representative:

17 (1) A local government.

18 (2) A distributor.

19 (3) A solid waste hauler.

20 (4) A consumer health organization that will implement the  
21 home-generated sharps stewardship plan.

22 (g) “Home-generated sharps stewardship plan” or “plan”  
23 means a plan submitted by an individual producer or by a  
24 stewardship organization on behalf of one or more producers.

25 (h) “Producer” means, with regard to home-generated sharps  
26 that are sold, offered for sale, or distributed in the state, one of  
27 the following:

28 (1) The person who manufactures home-generated sharps and  
29 who sells, offers for sale, or distributes those home-generated  
30 sharps in the state under that person’s own name or brand.

31 (2) If there is no person who sells, offers for sale, or distributes  
32 home-generated sharps in the state under the person’s own name  
33 or brand, the producer of the home-generated sharps is the owner  
34 or licensee of a trademark or brand under which the  
35 home-generated sharps are sold or distributed in the state, whether  
36 or not the trademark is registered.

37 (3) If there is no person who is a producer of the sharps for  
38 purposes of paragraphs (1) and (2), the producer of those sharps  
39 is the person who imports the home-generated sharps into the state  
40 for sale or distribution.

1 (i) “Stakeholder” means a person that is subject to, or will  
2 participate in, the program that will be implemented by a proposed  
3 home-generated sharps stewardship plan, including, but not limited  
4 to, consumers, retailers, distributors, and health care providers  
5 and facilities.

6 47117. (a) A producer or retailer shall not sell or offer for  
7 sale in this state home-generated sharps to a person in this state  
8 unless the producer of those home-generated sharps is in  
9 compliance with this article.

10 (b) The sales prohibition specified in subdivision (a) shall apply  
11 no earlier than 120 days after the date that the department posts  
12 on its Internet Web site a list of producers for which the department  
13 has approved a plan pursuant to paragraph (1) of subdivision (a)  
14 of Section 47121.

15 (c) The sales prohibition specified in subdivision (a) shall apply  
16 until the producer of the home-generated sharps is listed as  
17 compliant on the department’s Internet Web site or demonstrates  
18 compliance pursuant to subdivision (b) of Section 47122.

19 47118. (a) On or before April 1, 2015, a producer or a  
20 stewardship organization designated by the producer shall submit  
21 a home-generated sharps stewardship plan to the department. The  
22 home-generated sharps stewardship plan shall also be posted on  
23 the Internet Web site of the producer or stewardship organization.  
24 The plan shall provide for the implementation of the plan for each  
25 calendar year, commencing January 1, 2016.

26 (b) The producer, group of producers, or stewardship  
27 organization shall consult with stakeholders during the  
28 development of the home-generated sharps stewardship plan,  
29 including soliciting stakeholder comments and responding to  
30 stakeholder comments, and shall document those comments in the  
31 plan.

32 (c) The home-generated sharps stewardship plan shall provide  
33 for the development and implementation of a recovery program  
34 to reduce the generation of, and manage the end-of-life of,  
35 home-generated sharps, in an environmentally sound and medically  
36 safe manner, including collecting, transporting, processing, and  
37 disposing. The plan shall include, at a minimum, all of the  
38 following elements:

39 (1) Contact information for all participating producers.

- 1 (2) Procedures for calculating the collection rate for the  
2 home-generated sharps subject to the plan, which shall be  
3 determined using, as a baseline, the number of home-generated  
4 sharps collected by all producers subject to the plan, by weight,  
5 during the 2014 calendar year, as compared to the average number  
6 of home-generated sharps that are sold in the state during the  
7 2013 calendar year by producers that are subject to the plan.
- 8 (3) Provisions to meet the minimum collection rate for the  
9 home-generated sharps subject to the plan, which shall be  
10 determined in the following manner:
- 11 (A) On and after January 1, 2016, the minimum collection rate  
12 shall be \_\_\_\_\_ percent of the average number of home-generated  
13 sharps that are sold in the state during the previous three calendar  
14 years by the producers who are subject to the plan.
- 15 (B) On and after January 1, 2017, the minimum collection rate  
16 shall be \_\_\_\_\_ percent of the average number of home-generated  
17 sharps that are sold in the state during the previous three calendar  
18 years by the producers who are subject to the plan.
- 19 (C) On and after January 1, 2018, and annually thereafter, the  
20 collection rate shall be determined pursuant to Section 47120.
- 21 (4) (A) A demonstration of sufficient funding for the  
22 home-generated sharps stewardship program proposed by the  
23 plan, including a funding mechanism for securing and dispersing  
24 funds to cover administrative, operational, and capital costs.
- 25 (B) The plan shall require the producer, and not consumers, to  
26 be responsible for implementing the home-generated sharps  
27 stewardship program.
- 28 (C) The plan shall require that any surplus funds provided to  
29 implement the home-generated sharps stewardship program be  
30 used only to implement the program.
- 31 (5) Coordinate the home-generated sharps stewardship program  
32 with existing local medical waste collection programs, to the extent  
33 this requirement is reasonably feasible and mutually agreeable  
34 by those programs.
- 35 (6) Programs to reduce the number of postconsumer sharps  
36 that are illegally disposed of, and to maximize the proper  
37 end-of-life management of home-generated sharps, including the  
38 collection of home-generated sharps, as practical, based on current  
39 medical waste program information.

1 (7) Education and outreach efforts for consumers, the medical  
2 community, and retailers that would promote the collection of  
3 home-generated sharps. This information may include, but is not  
4 limited to, developing, and updating as necessary, educational  
5 and other outreach materials aimed at all retailers and distributors  
6 of home-generated sharps. These materials shall be made available  
7 to those parties and may include, but are not limited to, one or  
8 more of the following:

9 (A) Signage that is prominently displayed and easily visible to  
10 the consumer.

11 (B) Written materials and templates of materials for  
12 reproduction by retailers to be provided to the consumer at the  
13 time of purchase or delivery, or both. These written materials shall  
14 include information on the prohibition of the improper disposal  
15 of home-generated sharps.

16 (C) Advertising or other promotional materials, or both, that  
17 include references to home-generated sharps collection  
18 opportunities and the prohibition on the improper disposal of  
19 home-generated sharps.

20 (8) Methods for demonstrating to the department that the  
21 program implemented pursuant to the plan achieves the maximum  
22 improvement possible in achieving the minimum collection rate.

23 (9) The establishment of at least one home-generated sharps  
24 collection point in every county in the state, but no less than one  
25 home-generated sharps collection point for every 5,000 people in  
26 the state.

27 47119. A retailer may voluntarily participate as a  
28 home-generated sharps collection point pursuant to the  
29 home-generated sharps stewardship program.

30 47120. On or before January 1, 2018, the department shall  
31 consult with producers, stewardship organizations, local  
32 government, solid waste haulers, the health community, and all  
33 other stakeholders regarding the program performance. The  
34 department shall set a fair and reasonable minimum collection  
35 rate for the 2018 calendar year and for each subsequent calendar  
36 year to achieve the goal of safely managing all home-generated  
37 sharps in this state.

38 47121. (a) The department shall review a home-generated  
39 sharps stewardship plan submitted pursuant to Section 47118  
40 within 90 days of receipt. The department shall approve the plan

1 if the department determines the plan provides for the  
2 establishment of a home-generated sharps stewardship program  
3 that meets the requirements of Section 47118. If the department  
4 does not approve the plan, the department shall allow the producer  
5 or stewardship organization to resubmit the plan within 90 days  
6 after receiving notice of disapproval from the department.

7 (b) (1) The approved plan shall be a public record, except that  
8 financial, production, or sales data reported to the department by  
9 a producer or by the stewardship organization is not a public  
10 record under the California Public Records Act (Chapter 3.5  
11 (commencing with Section 6250) of Division 7 of Title 1 of the  
12 Government Code) and shall not be open to public inspection.

13 (2) Notwithstanding paragraph (1), the department may release  
14 a summary form of financial, production, or sales data if the  
15 department does not disclose financial, production, or sales data  
16 of a producer or stewardship organization.

17 (c) On or before \_\_\_\_\_, or three months after a plan is approved  
18 pursuant to subdivision (a), whichever is later, but no later than  
19 January 1, 2016, the producer or stewardship organization shall  
20 implement the home-generated sharps stewardship program  
21 described in the approved plan.

22 47122. (a) (1) On January 1, 2016, or upon the date the first  
23 plan is approved, whichever is earlier, the department shall post  
24 on its Internet Web site a list of producers for which the department  
25 has approved a plan pursuant to subdivision (a) of Section 42121.  
26 The department shall update this posting no less than once every  
27 six months thereafter.

28 (2) On and after July 1, 2016, the department shall post a notice  
29 on its Internet Web site listing producers that are in compliance  
30 with this article and shall update this posting no less than once  
31 every six months.

32 (b) A producer that is not listed on the department's Internet  
33 Web site pursuant to this section, but that demonstrates to the  
34 satisfaction of the department that it is in compliance with this  
35 chapter before the next notice is required to be posted pursuant  
36 to this section, may request a certification letter from the  
37 department stating that the producer is in compliance. The  
38 producer who receives that letter shall be deemed to be in  
39 compliance with this chapter.

1 (c) A wholesaler, health facility, as defined in Section 1250 of  
2 the Health and Safety Code, retailer, or other distributor that  
3 distributes or sells home-generated sharps shall monitor the  
4 department's Internet Web site to determine if the sale of a  
5 producer's home-generated sharps is in compliance with this  
6 chapter.

7 47123. On or before April 1, 2017, and every subsequent year  
8 thereafter, each producer or sharps stewardship organization  
9 implementing a plan shall prepare and submit to the department  
10 an annual report describing the activities carried out pursuant to  
11 the plan during the previous calendar year, commencing with the  
12 2016 calendar year. The annual report shall include, but is not  
13 limited to, all of the following elements:

14 (a) The number of home-generated sharps collected by the  
15 program in the previous calendar year and the collection rate  
16 achieved in the previous calendar year.

17 (b) A report of the total sales data for sharps sold to distributors  
18 in the state for the previous calendar year.

19 (c) A report on the feedback from a stakeholders' meeting, that  
20 shall be hosted by the producers subject to the plan and made  
21 available by Webcast, prior to submittal of the annual report.

22 (d) Independently audited financial statements that detail the  
23 financing method selected to sustainably fund the implementation  
24 of the plan to achieve the minimum collection rates described in  
25 the plan, pursuant to paragraph (3) of subdivision (c) of Section  
26 47118.

27 (e) Examples and descriptions of educational materials  
28 distributed to various stakeholders aimed at increasing collection.

29 (f) An evaluation of the effectiveness of the program specific to  
30 collection, public awareness, convenience, and reduced improper  
31 disposal associated with both legal and illegal drug use.

32 (g) Any programmatic changes the producer or the stewardship  
33 organization recommends based on new data provided in the  
34 report.

35 (h) The location, hours, and contact information for all  
36 home-generated sharps collection points established pursuant to  
37 the plan, including a certification that this information is accurate,  
38 that a home-generated sharps collection point has been established  
39 in every county in the state, and that the number of home-generated

1 sharps collection points is equal to at least one for every 5,000  
2 people in the state.

3 47124. (a) The department shall review the annual report  
4 submitted pursuant to Section 47123, including reviewing the  
5 accuracy of the list of home-generated sharps collection points  
6 that are certified to be established pursuant to the plan, and the  
7 data used to determine the collection rate, including sales and  
8 collection data. The department shall also determine whether all  
9 of the elements specified in subdivision (a) to (h), inclusive, of  
10 Section 47123 are included in the report.

11 (b) If the annual report does not demonstrate that the program  
12 has achieved a collection rate increase of \_\_\_ percent, the  
13 department may require the program to take additional actions  
14 with regard to improving and increasing the number of  
15 home-generated sharps collection points, ensuring accessibility  
16 to those points, and providing additional education and outreach  
17 activities.

18 (c) If the department does not disapprove a report within 45  
19 days of receipt, the report shall be deemed approved by the  
20 department.

21 (d) The department shall make all reports submitted to the  
22 department pursuant to this section available to the public on the  
23 department's Internet Web site.

24 47125. If the department determines that the collection rate  
25 for the home-generated sharps subject to a plan meets 95 percent,  
26 the department may exempt a producer or stewardship organization  
27 from any or all of the elements required to be included in the  
28 annual report specified in Section 47123.

29 47126. (a) A producer or stewardship organization submitting  
30 a plan to the department shall pay the department an annual  
31 administrative fee pursuant to subdivision (b).

32 (b) The department shall impose the annual fee in an amount  
33 that is sufficient to cover the department's full costs of  
34 administering and enforcing this article, including any program  
35 development costs or regulatory costs incurred by the department  
36 prior to the submittal of the plan. The department shall deposit  
37 the fees in the Safe Sharps Disposal Account, which is hereby  
38 established in the Integrated Waste Management Fund. The  
39 department may expend the moneys in the Safe Sharps Disposal

1 Account, upon appropriation by the Legislature, to administer and  
2 enforce this article.

3 47127. (a) The department shall enforce this article and may  
4 impose an administrative civil penalty on a person who violates  
5 this article in an amount of up to one thousand dollars (\$1,000)  
6 per violation per day.

7 (b) The department may impose an administrative civil penalty  
8 on a person who intentionally, knowingly, or negligently violates  
9 this article in an amount of up to ten thousand dollars (\$10,000)  
10 per violation per day.

11 (c) (1) The department may impose the civil penalty specified  
12 in subdivision (a) or (b) on a producer or stewardship organization  
13 for which the annual report submitted does not demonstrate that  
14 the \_\_\_\_ minimum collection rate has been achieved. In lieu of  
15 imposing a civil penalty, the department may require a producer  
16 or stewardship organization to take additional actions to comply  
17 with this article.

18 (2) In assessing a penalty pursuant to this subdivision on a  
19 producer or stewardship organization, the department shall  
20 consider any exigent circumstance that contributed to the producer  
21 or stewardship organization not meeting the required minimum  
22 collection rate.

23 (d) The department shall deposit all penalties collected pursuant  
24 to this section into the Safe Sharps Disposal Penalty Account,  
25 which is hereby created in the Integrated Waste Management  
26 Fund. Upon appropriation by the Legislature, moneys deposited  
27 into the Safe Sharps Disposal Penalty Account may be expended  
28 by the department to enforce this article.

29 47128. (a) A producer who is subject to an approved plan and  
30 in compliance with this article may bring a civil action to recover  
31 costs, damages, and fees, as specified in subdivision (c), from  
32 another producer for failure to comply with this article.

33 (b) An action under this section may be brought against one or  
34 more producers who is not in compliance with this article, except  
35 an action shall not be commenced under either of the following  
36 circumstances:

37 (1) No earlier than 60 days after a written notice of the  
38 producer's intention to file an action has been provided to the  
39 department and to the producer who is alleged to be noncompliant.

1 (2) If the department has commenced an enforcement action  
2 against the producer who is alleged to be noncompliant and is  
3 diligently pursuing that action.

4 (c) In an action under this section, the plaintiff may recover  
5 from a producer who has been found to be noncompliant all of the  
6 following:

7 (1) The costs the plaintiff incurred in collecting, handling,  
8 recycling, or properly disposing of home-generated sharps  
9 reasonably identified as having originated from the noncompliant  
10 producer.

11 (2) An amount of damages equal to no more than three times  
12 those costs specified in paragraph (1).

13 (3) The plaintiff's attorney's fees and costs of bringing the  
14 action.

15 (d) An action to recover the costs specified in this section may  
16 be brought in any court in the state, without regard to the amount  
17 in dispute.

18 47129. (a) Except as provided in subdivision (c), an action  
19 solely to increase the collection of home-generated sharps by a  
20 producer, stewardship organization, or retailer that affects the  
21 types or quantities being collected, or the cost and structure of  
22 any program implementing a stewardship plan, is not a violation  
23 of the statutes specified in subdivision (b).

24 (b) The following statutes are not violated by an action specified  
25 in subdivision (a):

26 (1) The Cartwright Act (Chapter 2 (commencing with Section  
27 16700) of Part 2 of Division 7 of the Business and Professions  
28 Code).

29 (2) The Unfair Practices Act (Chapter 4 (commencing with  
30 Section 17000) of Part 2 of Division 7 of the Business and  
31 Professions Code).

32 (c) Subdivision (a) shall not apply to any agreement establishing  
33 or affecting the price of home-generated sharps or the output or  
34 production of home-generated sharps, or any agreement restricting  
35 the geographic area or customers to which home-generated sharps  
36 will be sold.

37 ~~SECTION 1. Section 47115 of the Public Resources Code is~~  
38 ~~amended to read:~~

39 ~~47115. A pharmaceutical manufacturer that sells or distributes~~  
40 ~~a medication in California that is usually intended to be~~

1 self-injected at home through the use of a hypodermic needle, pen  
2 needle, intravenous needle, or any other similar device, shall, on  
3 or before July 1, 2010, and annually thereafter, submit to the  
4 department, a plan that describes how the manufacturer supports  
5 the safe collection and proper disposal of the waste devices.

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8 CORRECTIONS: \_\_\_\_\_

9 Text—Page 11.

10 \_\_\_\_\_

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