

11. Initial 15-Day Public Comment Period for Proposed Revised Regulation (July 15, 2020 – August 3, 2020)

- a. Notice of Changes to Proposed Regulation
 - i. Initial Notice of 15-Day Comment Period
 - ii. Extension Requests & Responses
 - iii. Extension Notice of Initial 15-Day Comment Period
- b. Listserv Notices
 - i. Initial 15-Day Comment Period Listserv
 - ii. Extension to Initial 15-Day Comment Period Listserv
- c. Mailing Affidavit
- d. Comments Matrix
 - i. Sorted by Comment Letter
 - ii. *Sorted by Regulation Comment Section
- e. Comments Received
- f. Additional Comments and Responses Documents

*This document is not included in this rulemaking archive webpage, but is available upon request.



Date: July 14, 2020

To: Interested Parties

From: Jason Smyth, Supervising Senior Environmental Scientist

Subject: Notice of Changes to Proposed Regulations for the Pharmaceutical and Sharps Waste Stewardship Program

A 15-day written public comment period for the Proposed Regulations for the Pharmaceutical and Sharps Waste Stewardship Program will begin on July 15, 2020 and end on July 29, 2020 at 11:59 pm.

The revised proposed regulations are available on the Pharmaceutical and Sharps Waste Stewardship rulemaking website at: www.CalRecycle.ca.gov/laws/rulemaking/pharmasharps. Text shown in double underline (addition) and ~~double strikethrough~~ (deletion) depict changes made after the 45-day public comment period. CalRecycle staff is only required to respond to comments related to the newly proposed changes to the regulations.

Please submit written comments to pharmasharps@calrecycle.ca.gov.

During this 15-day written comment period, CalRecycle is providing the opportunity to review additional technical documents that were relied upon for the development of the proposed regulations but not previously included in the Initial Statement of Reasons. These documents are available for viewing online at the links below and at our offices between 9:00am and 3:30pm from July 15, 2020 to July 29, 2020.

- United States Postal Service. 2018. *What Are the Guidelines for Mailing Priority Mail*. <https://faq.usps.com/s/article/What-are-the-Guidelines-for-Mailing-Priority-Mail>
- Division 7, Chapter 17.5, Section 7295 of the Government Code. https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=GOV§ionNum=7295.

To make an appointment to view these documents or submit comments by mail, please contact:

Jason Smyth
Materials Management and Local Assistance Division
California Department of Resources, Recycling and Recovery (CalRecycle)
P.O. Box 4025
Sacramento, CA 95814

Fax: (916) 319-7147

Email: pharmasharps@calrecycle.ca.gov.

Initial 15-day Comment Period Extension Requests and Responses:

Jim Wilson Comment Period Extension Request:

Summary: Jim Wilson, from MED-Project, requested that CalRecycle extend its 15-day comment period until August 13 due to the large amount of regulatory text edits and challenges resulting from the COVID-19 pandemic. CalRecycle was not able to extend the comment period to August 13 because it needed to adhere to a strict timeline. But, CalRecycle agreed to extend the comment period by an additional 5 days in order to accommodate the request for an extension. CalRecycle sent a letter to Jim Wilson that rejected the idea of a 30-day extension and CalRecycle subsequently sent a notice about the 5-day extension.

Additionally, Jim Wilson stated that some of CalRecycle's regulatory text edits were not sufficiently related to the originally proposed text. CalRecycle disagrees with this comment. All of the proposed changes are sufficiently related because a reasonable member of the directly affected public could have determined from the notice that the proposed changes could have resulted.

Fielding Greaves Comment Period Extension Request

Summary: Fielding Greaves, from AdvaMed, requested that CalRecycle extend its 15-day comment period for an additional 30 days (from July 28) due to the large amount of regulatory text edits and challenges resulting from the COVID-19 pandemic. CalRecycle was not able to extend the comment period by 30 days because it needed to adhere to a strict timeline. But, CalRecycle agreed to extend the comment period by an additional 5 days in order to accommodate the request for an extension. CalRecycle sent a letter to Fielding Greaves and CalRecycle subsequently sent a notice about the 5-day extension.

From: [Jim Wilson](#)
To: [PharmaSharps; Smyth, Jason@CalRecycle](#)
Cc: [MED-Project \(California\)](#)
Subject: PLEASE CONFIRM RECEIPT: MED-Project USA Request for Comment Period Extension for SB212 Draft Regulations Issued July 14, 2020
Date: Monday, July 20, 2020 5:05:35 PM
Attachments: [image001.png](#)
[MED-Project Request for Comment Period Extension 07_20_2020.pdf](#)

[[EXTERNAL]]

Dear Mr. Smyth,

On July 14, 2020, California Department of Resources Recycling and Recovery (“CalRecycle”) announced a 15-day public comment period on proposed regulations implementing California Senate Bill No. 212 (“SB 212”) (the “Proposed Regulations”). MED-Project USA (“MED-Project”) appreciates the opportunity to comment on the Proposed Regulations. Given the nature and extent of CalRecycle’s revisions to the Proposed Regulations from the version released for public comment on January 3, 2020 (the “Jan. 2020 Proposed Regulations”), however, MED-Project requests that CalRecycle extend the public comment period to August 13, 2020. Please review the attached letter with MED-Project USA’s request for the comment period extension.

Please contact me with any questions concerning this letter.

Sincerely,

Jim Wilson, P.E.

Sr. Director, Compliance and Risk Management

MED-Project[™]
Medication Education & Disposal

(direct) 202/892-6502 (main) 833/633-7765 (e) jwilson@med-project.org | www.med-project.org

This e-mail transmission and any attachments that accompany it may contain information that is privileged, confidential or otherwise exempt from disclosure under applicable law and is intended solely for the use of the individual(s) to whom it was intended to be addressed. If you have received this e-mail by mistake, or you are not the intended recipient, any disclosure, dissemination, distribution, copying or other use or retention of this communication or its substance is prohibited. If you have received this communication in error, please immediately reply to the author via e-mail that you received this message by mistake and also permanently delete the original and all copies of this e-mail and any attachments from your computer.

July 20, 2020

SENT VIA ELECTRONIC MAIL

Mr. Jason Smyth
Supervising Senior Environmental Scientist
Materials Management & Local Assistance Division
California Department of Resources Recycling and Recovery
P.O. Box 4025
Sacramento, CA 95814
pharmasharps@calrecycle.ca.gov

Re: MED-Project USA Request for Extension of Public Comment Period

Dear Mr. Smyth:

On July 14, 2020, California Department of Resources Recycling and Recovery (“CalRecycle”) announced a 15-day public comment period on proposed regulations implementing California Senate Bill No. 212 (“SB 212”) (the “Proposed Regulations”). MED-Project USA (“MED-Project”) appreciates the opportunity to comment on the Proposed Regulations. Given the nature and extent of CalRecycle’s revisions to the Proposed Regulations from the version released for public comment on January 3, 2020 (the “Jan. 2020 Proposed Regulations”), however, MED-Project requests that CalRecycle extend the public comment period to August 13, 2020.

Under California’s Administrative Procedure Act, for proposed regulations previously made available to the public, “[i]f a sufficiently related change is made, the full text of the resulting adoption, amendment, or repeal, with the change clearly indicated, shall be made available to the public for at least 15 days before the agency adopts, amends, or repeals the resulting regulation.” Cal. Gov’t Code § 11346.8(c). However, “[i]f a change is substantial, but not sufficiently related to the original proposal (i.e. not reasonably foreseeable based on the notice of proposed action), the agency must then publish another 45-day notice in the California Regulatory Notice Register” Cal. Office of Administrative Law, About the Regular Rulemaking Process, *available at* https://oal.ca.gov/rulemaking_participation/ (last visited July 18, 2020); *see also* Cal. Gov’t Code § 11346.8(c).

CalRecycle should extend the public comment period to August 13, 2020 given the nature and extent of revisions to the Proposed Regulations. This additional time is the minimum necessary for MED-Project, covered entities, other stakeholders, and the public to review the Proposed Regulations given that a number of revisions appear not “sufficiently related to” the Jan. 2020 proposal. Such revisions include:

- Requirements for stewardship plans and annual reports to include “compliance certifications.” *See* 14 CCR §§ 18973.2(e)(2), 18973.3(d)(2), 18973.4(p), 18973.5(r). These requirements are novel to the Proposed Regulations; there were no related requirements in the Jan. 2020 proposal. CalRecycle’s need to revise the applicable Proposed Regulations’ stewardship plan subheadings to read “State Agency

Determinations *and Compliance Certifications*” further demonstrates that these compliance certification requirements departed from the Jan. 2020 Proposed Regulations. *See* 14 CCR §§ 18973.2(e)(2) (emphasis added), 18973.3(d)(2) (same).

- The requirement for covered drug annual reports to include certifications “by an authorized representative for each of the authorized collectors participating in the stewardship plan.” 14 CCR § 18973.4(q). Like other provisions requiring a certification, this requirement is novel to the Proposed Regulations. However, not only are certifications not contemplated in the Jan. 2020 Proposed Regulations, this provision potentially requires a whole new class of regulated entities – authorized collectors – to take part in preparing annual reports, something untraceable to the Jan. 2020 proposal.
- Administrative civil penalty and stewardship plan revocation, resubmittal, and compliance reporting sections. 14 CCR §§ 18975, 18975.1, 18975.2. The revisions would overhaul CalRecycle’s enforcement procedures and standards from what the Jan. 2020 Proposed Regulations provided. *Compare, e.g.*, Jan. 2020 Proposed Regulations § 18975.2(a) (“The Department may, after holding a public hearing, revoke a previously approved stewardship plan”) *with* Proposed Regulations § 18975.2(a) (“The department shall revoke a previously approved stewardship plan”). Such an abrupt change in approach was not contemplated or foreshadowed in the Jan. 2020 proposal. Tellingly, CalRecycle’s revisions to these provisions are so extensive that its redline strikes the original language in full rather than making individual edits.
- Numerous other provisions with no connection to the Jan. 2020 Proposed Regulations, including, but not limited to, 14 CCR §§ 18972.1(a)(6) (defining “Inert”), 18972.1(a)(12) (defining “Repeal”), and 18973.2(d)(5) (potential authorized collector appeals).

Even if CalRecycle, contrary to the reasons outlined above, somehow takes the position that these revisions are “sufficiently related to” the Jan. 2020 Proposed Regulations, and thus a 45-day comment period is not required, it should extend the comment period for an additional 15 days to August 13, 2020 given the extent of changes to the Proposed Regulations. The Proposed Regulations are 39 pages long and contain numerous substantial redlines. MED-Project, covered entities, other stakeholders, and the public require more than fifteen days to fully understand these revisions and formulate public comments.

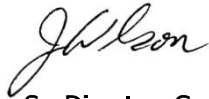
Additionally, in light of the ongoing COVID pandemic, which has created challenges for businesses across the country, and has created novel competing challenges for many stakeholders, including MED-Project and covered entities, we request that CalRecycle provide the public with more than 15 days to review the 39 pages of substantive revisions that are being proposed. Indeed, CalRecycle has already set this precedent by extending the comment period for the only other rulemaking issued during the COVID pandemic. *See* CalRecycle Sustainable Packaging for the State of California Act of 2018 Rulemaking Webpage, available at: <https://www.calrecycle.ca.gov/laws/rulemaking/foodservice> (“Due to the COVID-19 public health emergency, the 45-day formal public comment period was extended from April 28, 2020

to May 21, 2020.”) (last visited July 19, 2020). An additional 15 days of public comment is even more appropriate here, where the Proposed Regulations’ covered entities include pharmaceutical and sharps manufacturers working urgently to develop COVID treatments and vaccines.

Because the Proposed Regulations make substantial, unforeseeable, and extensive changes from the Jan. 2020 Proposed Regulations, and given the pandemic and its added pressures on MED-Project, covered entities (including pharmaceutical and sharps manufacturers), other stakeholders, and the public, CalRecycle should use its discretion to extend the comment period to August 13, 2020.

Thank you for considering this request,

Sincerely,



Sr. Director, Compliance and Risk Management
jwilson@med-project.org, or (202) 892-6502

From: Smyth_Jason@CalRecycle
To: "Jim Wilson"
Cc: [MED-Project \(California\); PharmaSharps](#)
Subject: RE: PLEASE CONFIRM RECEIPT: MED-Project USA Request for Comment Period Extension for SB212 Draft Regulations Issued July 14, 2020
Date: Friday, July 24, 2020 5:03:35 PM
Attachments: [Med-Project_Response_072420.pdf](#)
[image001.png](#)
[MED-Project Request for Comment Period Extension 07_20_2020.pdf](#)

Dear Mr. Wilson,

CalRecycle reviewed your letter and considered the request for the comment period extension. Please see the 1st attachment for CalRecycle's response that maintains the 15-day comment period.

Best regards,

Jason Smyth, Supervisor
Pharmaceutical & Sharps Unit
California Department of Resources Recycling and Recovery (CalRecycle)
jason.smyth@calrecycle.ca.gov (916) 341-6676



Department of
Resources Recycling and Recovery

Jared Blumenfeld
Secretary for Environmental Protection

Ken DaRosa
CalRecycle Acting Director

July 24, 2020

Sent Via Electronic Mail

Mr. Jim Wilson
Sr. Director, Compliance and Risk Management
Med-Project
jwilson@med-project.org

Dear Mr. Wilson,

CalRecycle understands the challenges businesses and stakeholders are experiencing because of the COVID pandemic and is sympathetic to your concerns. However, statute requires that the regulations be effective by January 1, 2021 per Public Resources Code 42031.2(a). Unfortunately, CalRecycle is unable to extend the 15-day comment period beyond July 29, 2020 as it would jeopardize the department's ability to fulfill its statutory responsibility to ensure the regulations are effective by January 1, 2021.

CalRecycle carefully considered your concern that the proposed changes are not sufficiently related to the regulations previously released for comment in January 2020. The department determined that the changes contained in regulations released for comment in July 2020 are sufficiently related to the notice of the proposed rulemaking. A proposed change is considered sufficiently related if a reasonable member of the directly affected public could have determined from the notice that such a proposed change could have resulted (California Code of Regulations, Title 1, Section 42). The changes in the latest draft are clarifications to the first regulatory draft and relate to broad aspects of SB 212 implementation about which the directly affected public were on reasonable notice. The clarifying changes do not relate to a new subject matter area. Therefore, a 45-day comment period is not required per the Administrative Procedures Act.

We appreciate Med-Project's participation in the rulemaking and greatly value the comments you have submitted to date. We look forward to your continued engagement with CalRecycle in the implementation of Senate Bill 212.

Best regards,

A handwritten signature in black ink, appearing to read "Jason Smyth".

Jason Smyth, Supervisor
Pharmaceutical & Sharps Unit
jason.smyth@calrecycle.ca.gov
(916) 341-6676

From: [Greaves, Fielding](#)
To: [PharmaSharps](#)
Cc: [Greaves, Fielding](#); "[Lisec, Asher](#)"; [Manny Heer](#); [Jackson, Jimmy](#); [Brett Michelin](#); [Jennifer Snyder](#); cgutierrez@chpa.org; [Maureen Higgins](#)
Subject: SB 212 Reg Comment Extension Letter - Life Sciences 7-28-20
Date: Tuesday, July 28, 2020 3:12:54 PM
Attachments: [image001.png](#)
[SB 212 Reg Comment Extension Letter - Life Sciences 7-28-20.pdf](#)
Importance: High

[[EXTERNAL]]

Hello,

Please see the attached letter from regulated industry under SB 212 – we are seeking an extension for the comment deadline.

We appreciate your consideration. Please let me know if you have any questions.

Thank you!

Fielding

FIELDING GREAVES

Senior Director | State Government & Regional Affairs (West)
Advanced Medical Technology Association (AdvaMed)
Mobile: [916-838-2264](tel:916-838-2264) | Office: [202-434-7265](tel:202-434-7265)
advamed.org | lifechanginginnovation.org





July 28, 2020

Mr. Jason Smyth
Senior Environmental Scientist
Pharmaceutical & Sharps Unit Supervisor
California Department of Resources Recycling and Recovery (CalRecycle)

VIA EMAIL: pharmasharps@calrecycle.ca.gov

Dear Mr. Smyth:

The organizations listed below appreciate the opportunity to comment on the new proposed draft regulations. We also appreciate that this is an extremely challenging time for staff to work for program implementation due to the ongoing COVID-19 pandemic.

Companies in the regulated community and life sciences are facing similar challenges as we are working to find treatments, therapies, cures and a vaccine for the disease while working to expand manufacturing capabilities to meet the demands for our health care work force and essential workers.

Given these challenges, we are asking for an additional 30 days be added to the comment period so we can provide thoughtful, meaningful and complete comments to the regulations.

Thank you for your consideration and please let us know if you have any questions.

Sincerely,

Advanced Medical Technology Association (AdvaMed)
Association of Accessible Medicines
Biocom
California Life Sciences Association
California Retailers Association
Consumer Healthcare Products Association
Pharmaceutical Research and Manufacturers of America

From: Smyth_Jason@CalRecycle
To: ["Greaves, Fielding"; PharmaSharps](#)
Cc: ["Lisec, Asher"; Manny Heer; Jackson, Jimmy; Brett Michelin; Jennifer Snyder; cgutierrez@chpa.org; Maureen Higgins](#)
Subject: RE: SB 212 Reg Comment Extension Letter - Life Sciences 7-28-20
Date: Thursday, July 30, 2020 6:55:14 PM
Attachments: [AdvaMed Response 7_30_20.pdf](#)
[SB 212 Reg Comment Extension Letter - Life Sciences 7-28-20.pdf](#)

Dear Mr. Greaves,

CalRecycle reviewed your letter and considered the request for the comment period extension. Please see the 1st attachment for CalRecycle's response that extends the comment period to 11:59pm August 3, 2020.

Best regards,

Jason Smyth, Supervisor
Pharmaceutical & Sharps Unit
California Department of Resources Recycling and Recovery (CalRecycle)
jason.smyth@calrecycle.ca.gov (916) 341-6676

July 30, 2020

Sent Via Electronic Mail

Mr. Fielding Greaves
Sr. Director, State Government & Regional Affairs (West)
Advanced Medical Technology Association (AdvaMed)
FGreaves@AdvaMed.org

Dear Mr. Greaves,

CalRecycle understands the challenges businesses and stakeholders are experiencing because of the COVID pandemic and is sympathetic to your concerns. However, CalRecycle is under a statutory mandate for the regulations be effective by January 1, 2021 per Public Resources Code 42031.2(a). The 15-day comment period has been extended to 11:59pm August 3, 2020. Unfortunately, CalRecycle is unable to further extend the comment period beyond August 3, 2020 as it would jeopardize CalRecycle's ability to fulfill its statutory responsibility to ensure the regulations are effective by January 1, 2021.

We appreciate AdvaMed's participation in the rulemaking and we look forward to your continued engagement with CalRecycle in the implementation of Senate Bill 212.

Best regards,



Jason Smyth, Supervisor
Pharmaceutical & Sharps Unit
jason.smyth@calrecycle.ca.gov
(916) 341-6676



Date: July 28, 2020

To: Interested Parties

From: Jason Smyth, Supervising Senior Environmental Scientist

Subject: Extension of Comment Period Through August 3, 2020 for the Second Draft of the Pharmaceutical and Sharps Waste Stewardship Program Proposed Regulations

A 15-day written public comment period for the Second Draft of the Proposed Regulations for the Pharmaceutical and Sharps Waste Stewardship Program began on July 15, 2020 and was previously scheduled to end on July 29, 2020 at 11:59 pm. CalRecycle has extended the comment period by five days. The written public comment period will now end on August 3, 2020 at 11:59 pm.

The revised proposed regulations are available on the Pharmaceutical and Sharps Waste Stewardship rulemaking website at: www.CalRecycle.ca.gov/laws/rulemaking/pharmasharps. Text shown in double underline (addition) and ~~double strikethrough~~ (deletion) depict changes made after the 45-day public comment period. CalRecycle staff is only required to respond to comments related to the newly proposed changes to the regulations.

Please submit written comments to pharmasharps@calrecycle.ca.gov.

During this written public comment period, CalRecycle is providing the opportunity to review additional technical documents that were relied upon for the development of the proposed regulations but not previously included in the Initial Statement of Reasons. These documents are available for viewing online at the links below and at our offices between 9:00am and 3:30pm from July 15, 2020 to August 3, 2020.

- United States Postal Service. 2018. *What Are the Guidelines for Mailing Priority Mail*. <https://faq.usps.com/s/article/What-are-the-Guidelines-for-Mailing-Priority-Mail>
- Division 7, Chapter 17.5, Section 7295 of the Government Code. https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=GOV§ionNum=7295.

To make an appointment to view these documents or submit comments by mail, please contact:

Jason Smyth
Materials Management and Local Assistance Division

California Department of Resources, Recycling and Recovery (CalRecycle)
P.O. Box 4025
Sacramento, CA 95814
Fax: (916) 319-7147
Email: pharmasharps@calrecycle.ca.gov.

List Archive Message Details

Pharmaceutical and Sharps Waste Stewardship

Message Details

Sent On

7/14/2020 4:47 PM

Priority

Normal

From

pharmasharps@calrecycle.ca.gov

Subject

Notice of Changes to Proposed Regulations for the Pharmaceutical and Sharps Waste Stewardship Program

Message

A 15-day written public comment period for the Proposed Regulations for the Pharmaceutical and Sharps Waste Stewardship Program will begin on July 15, 2020 and end on July 29, 2020 at 11:59 pm.

The revised proposed regulations are available on the Pharmaceutical and Sharps Waste Stewardship rulemaking website at:

www.CalRecycle.ca.gov/laws/rulemaking/pharmasharps. Text shown in double underline (addition) and double ~~strikethrough~~ (deletion) depict changes made after the 45-day public comment period. CalRecycle staff is only required to respond to comments related to the newly proposed changes to the regulations.

Please submit written comments to pharmasharps@calrecycle.ca.gov.

During this 15-day written comment period, CalRecycle is providing the opportunity to review additional technical documents that were relied upon for the development of the proposed regulations but not previously included in the Initial Statement of Reasons. These documents are available for viewing online at the links below and at our offices between 9:00am and 3:30pm from July 15, 2020 to July 29, 2020.

- United States Postal Service. 2018. *What Are the Guidelines for Mailing Priority Mail*. <https://faq.usps.com/s/article/What-are-the-Guidelines-for-Mailing-Priority-Mail>
- Division 7, Chapter 17.5, Section 7295 of the Government Code. https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=GOV&ionNum=7295.

To make an appointment to view these documents or submit comments by mail, please contact:

Jason Smyth

Materials Management and Local Assistance Division

California Department of Resources, Recycling and Recovery (CalRecycle)

P.O. Box 4025

Sacramento, CA 95814

Fax: (916) 319-7147

Email: pharmasharps@calrecycle.ca.gov

To unsubscribe from the Pharmaceutical and Sharps Waste Stewardship listserv, please go to <https://www2.calrecycle.ca.gov/listservs/Unsubscribe/73>.

CalRecycle Listservs: <https://www2.calrecycle.ca.gov/Listservs/>

Contact: Public Affairs Office (916) 341-6300

©1995, 2019 California Department of Resources Recycling and Recovery (CalRecycle)

List Archive Message Details

Pharmaceutical and Sharps Waste Stewardship

Message Details

Sent On

7/28/2020 5:12 PM

Priority

Normal

From

pharmasharps@calrecycle.ca.gov

Subject

Extension of Comment Period Through August 3, 2020 for the Second Draft of the Pharmaceutical and Sharps Waste Stewardship Program Proposed Regulations

Message

A 15-day written public comment period for the Second Draft of the Proposed Regulations for the Pharmaceutical and Sharps Waste Stewardship Program began on July 15, 2020 and was previously scheduled to end on July 29, 2020 at 11:59 pm. CalRecycle has extended the comment period by five days. The written public comment period will now end on August 3, 2020 at 11:59 pm.

The revised proposed regulations are available on the Pharmaceutical and Sharps Waste Stewardship rulemaking website at:

www.CalRecycle.ca.gov/laws/rulemaking/pharmasharps. Text shown in double underline (addition) and ~~double strikethrough~~ (deletion) depict changes made after the 45-day public comment period. CalRecycle staff is only required to respond to comments related to the newly proposed changes to the regulations.

Please submit written comments to pharmasharps@calrecycle.ca.gov.

During this written public comment period, CalRecycle is providing the opportunity to review additional technical documents that were relied upon for the development of the proposed regulations but not previously included in the Initial Statement of Reasons. These documents are available for viewing online at the links below and at our offices between 9:00am and 3:30pm from July 15, 2020 to August 3, 2020.

- United States Postal Service. 2018. *What Are the Guidelines for Mailing Priority Mail*. <https://faq.usps.com/s/article/What-are-the-Guidelines-for-Mailing-Priority-Mail>
- Division 7, Chapter 17.5, Section 7295 of the Government Code. https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=GOV&ionNum=7295.

To make an appointment to view these documents or submit comments by mail, please contact:

Jason Smyth

Materials Management and Local Assistance Division

California Department of Resources, Recycling and Recovery (CalRecycle)

P.O. Box 4025

Sacramento, CA 95814

Fax: (916) 319-7147

Email: pharmasharps@calrecycle.ca.gov.

To unsubscribe from the Pharmaceutical and Sharps Waste Stewardship listserv, please go to <https://www2.calrecycle.ca.gov/listservs/Unsubscribe/73>.

CalRecycle Listservs: <https://www2.calrecycle.ca.gov/Listservs/>

Contact: [Public Affairs Office](#) (916) 341-6300

©1995, 2019 California Department of Resources Recycling and Recovery (CalRecycle)

Statement of Mailing Notice

Re: Proposed Regulations for the Pharmaceutical and Sharps Waste Stewardship Act
First 15-Day comment period, 7/15/2020 – 8/03/2020

The Department of Resources Recycling and Recovery has complied with the provisions of Government Code Section 11346.8(c) and Section 44 of Title 1 of the California Code of Regulations, regarding the mailing of the notice of changes made to the regulatory text. In addition, CalRecycle has complied with the provisions of Government Code Section 11347.1 regarding the mailing of the notice to include additional documents relied upon. The notice, along with the Second Draft of the regulatory text, was mailed on July 14, 2020, 15 days prior to the close of the public comment period. As a result of stakeholder feedback expressing concerns regarding the short review timeframe during extenuating circumstances related to the COVID-19 global pandemic, a second notice was mailed on July 28, 2020, extending the comment period end date from July 29, 2020 to August 3, 2020. This extension provided stakeholders with a 20-day review period. The public comment period for the Second Draft of the regulatory text and additional documents relied upon began on July 15, 2020 and ended on August 3, 2020.

SB 212 15-Day Formal Public Comment Period (7/15/2020 – 8/3/2020)
Comments and Responses on the Second Draft Proposed Regulatory Text, Sorted by Comment Number

Comment Letter Number	Commenter	CalRecycle Response Pages
018	Stat-Medicament-Disposal Corporation	1-3
019	Sharps Compliance, Incorporated	3-7
020	Waste Management (WM) Curbside, LLC	7-11
021	Rural County Representatives of California	11-12
022	California Department of Public Health (CDPH)	12
023	Healthcare Distribution Alliance (HDA)	13-16
024	InMar Intelligence	17-18
025	California Product Stewardship Council (CSPC) and Coalition	18-20
026	Pharmaceutical Product Stewardship Work Group (PPSWG)	20-21
027	Los Angeles County (LAC) Solid Waste Management Committee/Integrated Waste Management Task Force (Task Force)	21-23
028	Med-Project USA	23-51
029	Stericycle	51-60
030	Los Angeles County (LAC) Department of Public Works	60-61
031	San Francisco Department of the Environment	61-62
032	Coalition for Prevention and Awareness in Los Angeles Metro (COPALM)	62-64

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
018-001	Stat-Medicament Disposal Corporation	Larry Kenemore	18972.1(a)(13)	N	(13)(A) How can addition of a mail-back program be a "Significant change" when this method is a foundational disposal method especially in the near future?	018-001. The comment does not specify a proposed change to the regulations. CalRecycle declines to clarify the definition of "significant change" and instead rely on statutory language. The definition of "significant change" has been removed in the proposed regulatory text. Please note that section 18973.1(i), which discusses the term "significant change", has been modified.
018-002	Stat-Medicament Disposal Corporation	Larry Kenemore	18973.2(d)	N	18973.2(d) There should be wording somewhere in this section as to Safe-Drug-Disposal sites. That is Safe Drug Disposal kiosks are not collection sites. It would appear from leaving out this language you are limiting Safe-Drug-Disposal to only in-home mail back program and relying on Take Back Collection only.	018-002. A change to the proposed regulatory text is not necessary. The proposed regulations and statutory language use the term "authorized collection site". The term "Safe Drug Disposal kiosk" is not used in the proposed regulations or authorizing statute. CalRecycle cannot specifically respond because the commenter has not defined Safe-Drug-Disposal or Safe Drug Disposal Kiosk, even though these are used as defined terms. A stewardship plan must establish a minimum number of authorized collection sites for covered drugs pursuant to the convenience standard in Public Resources Code section 42032.2(a)(1)(F). Pursuant to Public Resources Code, section 42032.2(c), if authorized by the department, after the stewardship plan has been approved, the operator of a stewardship program for covered drugs may establish a mail-back program or alternative collection program for covered products, or both, for a county in which it operates that does not have the minimum number of authorized collection sites, as specified.
018-003	Stat-Medicament Disposal Corporation	Larry Kenemore	18973.2(g)(4)	N	18973.2(g) Collection, transportation, and disposal system, description of the following (4) clearly leaves in place the misleading number promulgated by the Take back program of weight which includes (bottles, wrappers, blister-paks etc.) Should you not want to know the actual amount of drugs collected or disposed of?	018-003. A change to the proposed regulatory text is not necessary. CalRecycle disagrees with the commenter's recommendation. While CalRecycle acknowledges the potential ambiguity issues with weight as a collection statistic, maintaining flexibility for a program operator to propose metrics that balance accurate reporting with the logistical challenges of data collection is important. Public Resources Code section 42033.2(b)(3) requires reporting of the weight of covered drugs collected at each authorized collection site.
018-004	Stat-Medicament Disposal Corporation	Larry Kenemore	18973.2(g)(6)(C)	N	(g)(6)(C) the words metrics used to measure the "amount" should be changed as to the weight. Amount means nothing in disposal, weight is accurate and relates to drugs.	018-004. A change to the proposed regulatory text is not necessary. CalRecycle disagrees with the commenter's recommendation to specify the appropriate metrics. The proposed regulatory text provides flexibility for a program operator to select and propose its own metrics, applicable to unique collection systems in its stewardship program. Due to a reorganization of subsection 18973.2(g), subsection 18973.2(g)(6)(C) has been changed to 18973.2(g)(6)(E) in the proposed regulatory text. Note that section 42033.2(b)(3) of the Public Resources Code requires program operators to track the weight of covered products collected at authorized collection sites.

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
018-005	Stat-Medicament Disposal Corporation	Larry Kenemore	18973.2(g)(6)(C)	N	There is missing any wording for having a Safe-Drug-Disposal site all the wording only talks about "collection".	018-005. A change to the proposed regulatory text is not necessary. CalRecycle cannot provide a more specific response because the commenter has not defined a Safe-Drug-Disposal site, even though the commenter uses the phrase as a defined term. The proposed regulations and statutory language use the term "authorized collection site". It is the program operator's responsibility to ensure that covered drugs collected at authorized collection sites are properly disposed.
018-006	Stat-Medicament Disposal Corporation	Larry Kenemore	18973.2(h)	N	Throughout this section you continually talk about collection and then in (h) you talk about disposal. Should there not be language herein about safe-drug-disposal not just collection. That is there are currently two (2) programs "collection" "safe-drug-Disposal"	018-006. A change to the proposed regulatory text is not necessary. CalRecycle cannot provide a more specific response because the commenter has not defined safe-drug-Disposal, even though the commenter uses the phrase as a defined term. The proposed regulations and statutory language use the term "authorized collection site". It is the program operator's responsibility to ensure that covered drugs collected at authorized collection sites are properly disposed.
018-007	Stat-Medicament Disposal Corporation	Larry Kenemore	18973.2(j)	N	(j) should there not be a section here for school education as to Safe In-Home-Disposal.	018-007. A change to the proposed regulatory text is not necessary. A program operator could choose to provide educational materials to schools as part of a comprehensive education and outreach program (see Public Resources Code section 42031.6(a) and sections 18973.2(j) and 18973.3(i) of the proposed regulations). CalRecycle cannot provide a more specific response because the commenter has not defined or explained Safe In-Home-Disposal, even though the commenter uses the phrase as a defined term.
018-008	Stat-Medicament Disposal Corporation	Larry Kenemore	18973.4(c)(2)(E)	N	18973.4 (c)(2)(E) should not the wording be added as to a safe-drug-disposal not just collectors?	018-008. A change to the proposed regulatory text is not necessary. CalRecycle cannot provide a more specific response because the commenter has not defined safe-drug-disposal, even though the commenter uses the phrase as a defined term. Even though the commenter is specifically referencing a section that describes potential authorized collectors joining the program, CalRecycle will assume that the commenter is referring to safe disposal. It is the program operator's responsibility to ensure that covered drugs collected are safely and properly disposed. Program operators and authorized collectors must comply with all applicable laws and regulations related to handling, transport, and disposal of covered drugs.
018-009	Stat-Medicament Disposal Corporation	Larry Kenemore	18973.4(c)(3)	N	(3) language should be added to include safe-drug-disposal either in-home or kiosks.	018-009. A change to the proposed regulatory text is not necessary. If the commenter is referencing section 18973.4(c)(3), this text describes the convenience standard that establishes the minimum number of authorized collection sites that must operate in a county. It is the program operator's responsibility to ensure that covered drugs collected are safely and properly disposed, either through authorized collection sites or an approved mail-back or alternative collection program. The term "kiosk" is not used in the proposed regulations or authorizing statute. CalRecycle cannot provide a more specific

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
						response because the commenter has not defined safe-drug-disposal, even though the commenter uses the phrase as a defined term.
018-010	Stat-Medicament Disposal Corporation	Larry Kenemore	18973.4(c)(4)(B)	N	(4)(B) should it not have the language added weight of covered drugs again using the word amount is misleading.	018-010. A change to the proposed regulatory text is not necessary. CalRecycle disagrees with the commenter. Section 18973.4(c)(4)(B) of the proposed regulatory text requires the program operator to report on "Amount of covered drugs collected, as required in the stewardship plan pursuant to section 18973.2(g)(4)." Section 18973.2(g)(4) of the proposed regulatory text requires that the program operator include the weight of covered drugs collected as a specified metric, among other options. Therefore, weight is included as a reporting metric in the annual report. The proposed regulatory text provides flexibility for a program operator to select and propose its own metrics, in addition to weight, that are applicable to unique collection systems in its stewardship program.
018-011	Stat-Medicament Disposal Corporation	Larry Kenemore	18973.4(c)(6)	N	(6) Can there not be language added that includes safe drug disposal since collection is not the only method available.	018-011. A change to the proposed regulatory text is not necessary. If the commenter is referencing section 18973.4(c)(6), the text includes the word "disposal". It is the program operator's responsibility to ensure that covered drugs that are collected are safely and properly disposed. Program operators and authorized collectors must comply with all applicable laws and regulations related to handling, transport, and disposal of covered drugs.
019-001	Sharps Compliance, Incorporated	Kathryn Kane-Neilson	18972.1(a)(6)	Y	<p>(6) Proposed regulation: " 'Inert' means the covered drug or mixture of covered drugs is rendered chemically inactive prior to disposal and complies with all applicable local, state and federal laws and regulations, including those of the United State Drug Enforcement Administration and California statutes and regulations governing disposal in a municipal solid waste landfill."</p> <p>Issue: Per the California Department of Public Health's Medical Waste Management Program, charcoal-based pharmaceutical disposal products designed to render drug waste inert have not gained the department's approval for use in California as an alternative treatment technology since all pharmaceutical waste in California is required to be incinerated. Because such products are prohibited as a solid waste they can only be disposed of via a pharmaceutical waste container, thus rendering the purpose of such a product useless and instead necessitating the purchase of an additional disposal solution that would have to be routed for incineration via hazardous waste containment and servicing, since the Department of Transportation (DOT) classifies activated carbon products according to the lethality of their contents, which cannot be determined if conglomerate comprised of unidentifiable ultimate user medications (thereby rendering the product ineligible for USPS mailability).</p> <p>Proposed Resolution: Eliminate references allowing use of disposal systems that render drugs inert since cannot be placed in municipal solid waste landfills and would have to be coupled with an additional container</p>	019-001. CalRecycle agrees with the commenter that it is appropriate to remove the definition of "Inert" from the proposed regulatory text. CalRecycle prefers to rely on statutory language and other agencies with authority regarding the term "inert". CalRecycle declines to define the term "inert" as "non-retrievable" and may seek guidance from appropriate agencies about a particular proposal that involves a covered drug that has been rendered "inert". CalRecycle cannot eliminate references to this method in its regulations because the authorizing statute allows a program operator to incorporate such a method as long as it is compliant with all applicable statutes and regulations.

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					designed for pharmaceutical waste if routed for incineration; the DOT would dually consider this a hazardous waste (see below) and thus require containment compliant for hazardous waste transport.	
019-002	Sharps Compliance, Incorporated	Kathryn Kane-Neilson	18973.2(g)(6)(A)	N	<p>(g)(6)(A) Proposed regulation: “Locations where preaddressed, prepaid mail-back materials are distributed or an alternative form of collection and disposal system, pursuant to section 42032.2(c)(2) of the Public Resources Code, that would render the drug inert, is provided, if applicable.”</p> <p>Issue: In addition to the state’s prohibition of disposal of charcoal-based products in the solid trash, the DOT determines hazardous classification of activated carbon products according to the adsorbate contents, which cannot be determined upon unsupervised use by ultimate users; therefore used charcoal-based products would be prohibited by the USPS since the DOT would consider it a hazardous waste due to unproven lethality.</p> <p>Proposed Resolution: Eliminate references allowing use of disposal systems that render drugs inert since cannot be placed in trash nor mailed.</p>	<p>019-002. CalRecycle disagrees with the commenter. Pursuant to section 42032.2(c)(2) of the Public Resources Code, any alternative form of collection and disposal system proposed in the stewardship plan must comply with applicable state and federal law, including, but not limited to, United States Drug Enforcement Administration regulations. Additionally, the stewardship plan is subject to review and certification of compliance by other applicable relevant state agencies with authority to determine if a proposed alternative form of collection and disposal system, such as charcoal-based products, is prohibited. If such a collection and disposal system is determined to be non-compliant with applicable state and federal law, then the department would reject its use during the stewardship plan review. Furthermore, the use of the term “inert” in the proposed regulations in this context complies with the language in section 42032.2(a)(1)(G)(i) of the Public Resources Code. CalRecycle cannot limit the scope of the authorizing statute.</p> <p>CalRecycle made the following edits to subsection 18973.2(g)(6)(A) but not in response to this comment:</p> <p><u>(A) List of locations and/or description of mechanisms to provide ultimate users with Locations where preaddressed, prepaid mail-back materials are distributed or an alternative form of collection and disposal system, pursuant to section 42032.2(c)(2) of the Public Resources Code, that would render the covered drug inert, is provided, if applicable.</u></p>
019-003a	Sharps Compliance, Incorporated	Kathryn Kane-Neilson	18973.2(k)	Y	<p>(k) Proposed regulation: “Coordination Efforts. Description of how the program operator will make a good faith effort to work with the other stewardship program(s) in order to most effectively achieve the requirements of statute and regulations, coordinate with other program operators to avoid conflict, duplication, and confusion to the public and all program participants in the event that multiple stewardship programs for covered drugs are in operation concurrently or new stewardship programs begin operating.”</p> <p>Issue: How does CalRecycle plan on enforcing such coordination efforts? A descriptive means of how multiple stewardship programs can avoid conflict and/or duplication of operation efforts is needed.</p> <p>Proposed Resolution: Clarify CalRecycle’s oversight of coordination efforts and requirements of program operators to ensure distinct</p>	<p>019-003a. CalRecycle declines to outline the department’s oversight of coordination efforts in the proposed regulations. It is not the department’s intent to mediate between program operators or provide prescriptive parameters for coordination efforts that may inhibit collaborative endeavors between program operators. A change to the proposed regulations is not necessary, based on the commenter’s recommendation to describe how conflict and/or duplication can be avoided. The intent with this provision is to ascertain how program operators will work together to avoid confusion to the public when/if there are multiple stewardship programs concurrently operating. The success of a stewardship program is reliant upon clear messaging by program operators to ensure maximum participation by the public.</p> <p>However, the department has made the following revisions to subsection 18973.2(k) of the proposed regulatory text:</p>

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					parameters are established for the management of stewardship programs.	<u>(k) Coordination Efforts. Description of how the program operator will make a good faith effort to work with the other stewardship program(s) in order to most effectively achieve the requirements of statute and regulations, coordinate with other program operators to avoid conflict, duplication, and confusion to the public and all program participants in the event that multiple stewardship programs for covered drugs are in operation concurrently or new stewardship programs begin operating.</u>
019-003b	Sharps Compliance, Incorporated	Kathryn Kane-Neilson	18973.3(j)	N	<p>(j) Proposed regulation: “Coordination Efforts. Description of how the program operator will make a good faith effort to work with the other stewardship program(s) in order to most effectively achieve the requirements of statute and regulations, coordinate with other program operators to avoid conflict, duplication, and confusion to the public and all program participants in the event that multiple stewardship programs for covered drugs are in operation concurrently or new stewardship programs begin operating.”</p> <p>Issue: How does CalRecycle plan on enforcing such coordination efforts? A descriptive means of how multiple stewardship programs can avoid conflict and/or duplication of operation efforts is needed.</p> <p>Proposed Resolution: Clarify CalRecycle’s oversight of coordination efforts and requirements of program operators to ensure distinct parameters are established for the management of stewardship programs.</p>	<p>019-003b. CalRecycle declines to outline the department’s oversight of coordination efforts in the proposed regulations. It is not the department’s intent to mediate between program operators or provide prescriptive parameters for coordination efforts that may inhibit collaborative endeavors between program operators. A change to the proposed regulations is not necessary, based on the commenter’s recommendation to describe how conflict and/or duplication can be avoided. The intent with this provision is to ascertain how program operators will work together to avoid confusion to the public when/if there are multiple stewardship programs concurrently operating. The success of a stewardship program is reliant upon clear messaging by program operators to ensure maximum participation by the public.</p> <p>However, the department has made the following revisions to subsection 18973.3(j) of the proposed regulatory text:</p> <p><u>(j) Coordination Efforts. Description of how the program operator will make a good faith effort to work with the other stewardship program(s) in order to most effectively achieve the requirements of the statute and regulations, coordinate with other program operators to avoid conflict, duplication, and confusion to the public and all program participants in the event that multiple stewardship programs for home-generated sharps waste are in operation concurrently or new stewardship programs begin operating.</u></p>
019-003c	Sharps Compliance, Incorporated	Kathryn Kane-Neilson	18973.4(o)	N	<p>Pg 25 18973.4(n) Coordination Efforts</p> <p>Issue: How does CalRecycle plan on enforcing such coordination efforts? A descriptive means of how multiple stewardship programs can avoid conflict and/or duplication of operation efforts is needed.</p> <p>Proposed Resolution: Clarify CalRecycle’s oversight of coordination efforts and requirements of program operators to ensure distinct parameters are established for the management of stewardship programs.</p>	<p>019-003c. CalRecycle declines to outline the department’s oversight of coordination efforts in the proposed regulations. It is not the department’s intent to mediate between program operators or provide prescriptive parameters for coordination efforts that may inhibit collaborative endeavors between program operators. A change to the proposed regulations is not necessary, based on the commenter’s recommendation to describe how conflict and/or duplication can be avoided. The intent with this provision is to ascertain how program operators will work together to avoid confusion to the public when/if there are multiple stewardship programs concurrently operating. The success of a stewardship program is reliant upon clear messaging by program operators to ensure maximum participation by the public.</p>

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
						<p>However, the department has made the following revisions to subsection 18973.4(o), formerly (n), of the proposed regulatory text:</p> <p>(on) Coordination Efforts. Description of how the program operator coordinated with other program operators to avoid conflict, duplication, and confusion to the public and all program participants in the event that multiple stewardship programs for covered drugs are in operation concurrently or new stewardship programs begin operating. made a good faith effort to work with any other stewardship program(s) in order to most effectively achieve the requirements of the statute and regulations, if applicable.</p>
019-003d	Sharps Compliance, Incorporated	Kathryn Kane-Neilson	18973.5(o)	N	<p>Pg 25 18973.5(o) Coordination Efforts</p> <p>Issue: How does CalRecycle plan on enforcing such coordination efforts? A descriptive means of how multiple stewardship programs can avoid conflict and/or duplication of operation efforts is needed.</p> <p>Proposed Resolution: Clarify CalRecycle’s oversight of coordination efforts and requirements of program operators to ensure distinct parameters are established for the management of stewardship programs.</p>	<p>019-003d. CalRecycle declines to outline the department’s oversight of coordination efforts in the proposed regulations. It is not the department’s intent to mediate between program operators or provide prescriptive parameters for coordination efforts that may inhibit collaborative endeavors between program operators. A change to the proposed regulations is not necessary, based on the commenter’s recommendation to describe how conflict and/or duplication can be avoided. The intent with this provision is to ascertain how program operators will work together to avoid confusion to the public when/if there are multiple stewardship programs concurrently operating. The success of a stewardship program is reliant upon clear messaging by program operators to ensure maximum participation by the public.</p> <p>However, the department has made the following revisions to subsection 18973.5(o) of the proposed regulatory text:</p> <p>(o) Coordination Efforts. Description of how the program operator coordinated with other program operators to avoid conflict, duplication, and confusion to the public and all program participants in the event that multiple stewardship programs for home-generated sharps waste are in operation concurrently or new stewardship programs begin operating. made a good faith effort to work with any other stewardship program(s) in order to most effectively achieve the requirements of the statute and regulations.</p>
019-004	Sharps Compliance, Incorporated	Kathryn Kane-Neilson	18973.3(f)(2)(A)	N	<p>(f)(2)(A) Proposed regulation: “Containers and mail-back materials shall be distributed in amounts sufficient to accommodate the volume of sharps purchased by the ultimate user over a selected time period.”</p> <p>Issue: Who is responsible for determining what amounts to a sufficient provision of mail-back materials to accommodate sharps waste volume over a selected time period and how would these calculations be assessed?</p>	<p>019-004. A change to the proposed regulatory text is not necessary. The program operator is responsible for meeting this component of the stewardship plan. However, this provision allows a program operator discretion to determine how they will provide the appropriate amount and volume of sharps waste containers to meet the varying needs of the ultimate user. Meeting the requirement to provide containers and mail-back materials of a sufficient volume “over a selected time period” could involve internal calculations, estimations, and collaboration between a program operator and pharmacies to determine the most</p>

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					Proposed Resolution: Clarify who is responsible for determining and tracking fulfillment volume of sharps waste containers according to specified time ranges customized according to drug type and/or ultimate user prescription.	effective amount and volume of containers to distribute. The department prefers to maintain this flexibility by not clarifying who is responsible for determining the distribution and tracking of sharps waste containers and mail-back materials provided to ultimate users in the regulations. These details can be managed on a case-by-case basis.
020-001	WM Curbside, LLC	Reggie B Pestano	18972.1(a)(11) (A)	N	Pg 2 Line 31: This maybe an infringement on the users' privacy if their names/address are on a list that need sharps containers. Medical sharps users already provide themselves with sharps containers.	020-001. A change to the proposed regulatory text is not necessary. The comment does not specify a proposed change to the regulations. Program operators are provided sufficient flexibility to design an implementation that protects user privacy, as appropriate.
020-002	WM Curbside, LLC	Reggie B Pestano	General	N	Also, supplying each user with sharps containers will be a logistical challenge.	020-002. The comment does not specify a proposed change to the regulations. Section 42032.2(d)(1)(F)(i) requires that a stewardship program "provides or initiates distribution of a sharps waste container and mail-back materials at the point of sale, to the extent allowable by law." Each program operator has responsibility to figure out the logistics to comply with this requirement.
020-003	WM Curbside, LLC	Reggie B Pestano	18972.1(a)(11) (B)	Y	Mailing bulky items within 4 days is not feasible unless done with express mail which will be very costly for the program. I suggest to drop them off/switch out on the same day as the scheduled sharps pickup.	020-003. CalRecycle rejects the commenter's suggestion for sharps waste containers to be dropped off and switched out on the same day as the scheduled sharps pickup. Per the definition of "provides or initiates distribution of a sharps waste container and mail-back materials" in section 18972.1(a)(11) of the proposed regulatory text, mailing a sharps waste container and mail-back materials to the ultimate user is optional. Alternatively, a program operator can provide a sharps waste container and mail-back materials at the point of sale or prior. CalRecycle acknowledges the difficulties of guaranteeing that a sharps container be sent to an ultimate user and arrive within four business days, and proposes extending this deadline in the proposed regulations to five business days. Delays in delivery times may occur, and five business days is a reasonable timeframe that still upholds convenience for the ultimate user without being overly burdensome on a program operator.
020-004	WM Curbside, LLC	Reggie B Pestano	18973.1	N	How will the initial budget and annual budget work since we do not have the number of users that we will need to service for sharps? Sharps users will have different levels of use.	020-004. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. The proposed regulations intend to provide flexibility for the program operator to determine the costs and appropriate budgets for their stewardship program. It is the program operator's responsibility to determine program budget needs.
020-005	WM Curbside, LLC	Reggie B Pestano	18973.1	N	Pg 5 Line 27 - If there is already an existing contract between a government agency and a service provider to pickup and dispose of sharps from residents and local government facilities such as City Hall, libraries, etc, will the existing contracts be superseded by the stewardship program?	020-005. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. Existing contracts are outside the scope of these regulations. However, in accordance with section 42036.2 of the Public Resources Code, jurisdictions with existing local stewardship programs (enacted through an ordinance and effective before April 18, 2018) do not have to comply with this Article. If a jurisdiction repeals a local stewardship

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
						program ordinance, drugs and sharps sold in that jurisdiction become subject to SB 212.
020-006	WM Curbside, LLC	Reggie B Pestano	18973.1	N	Does this mean the contract will be terminated and may offer the service to another service provider?	020-006. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. Existing contracts are outside the scope of these regulations. However, in accordance with section 42036.2 of the Public Resources Code, jurisdictions with existing local stewardship programs (enacted through an ordinance and effective before April 18, 2018) do not have to comply with this Article. If a jurisdiction repeals a local stewardship program ordinance, drugs and sharps sold in that jurisdiction become subject to SB 212.
020-007	WM Curbside, LLC	Reggie B Pestano	18973.1	N	What will be included in the annual report at the initial submission of the stewardship plan? I think this is required after the first year of the implementation of the stewardship program.	020-007. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. Program operators shall prepare and submit an annual report to the department on or before March 31, 2022, and each year thereafter. Section 18973.4 details the requirements of what must be included in the annual report for covered drugs. Section 18973.5 details the requirements of what must be included in the annual report for home-generated sharps waste.
020-008	WM Curbside, LLC	Reggie B Pestano	18973.2(b)	N	Pg 8 Line 17 - Is the covered entity (responsible for paying for the program) a pharmaceutical/ drug store or the city government where the store is located?	020-008. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. Section 18972.2 of the proposed regulations points to the tiered definition of "covered entity" in Public Resources Code section 42030(f)(1)(A) through (E), and provides sufficient clarity to determine a covered entity. Entities that could be considered covered entities based on the statutory definition should endeavor to coordinate amongst appropriate entities within their respective supply chains to determine how the statutory requirements will be met. It is the responsibility of covered entities to self-identify through the submission of covered products lists to the Board of Pharmacy for verification pursuant to Public Resources Code section 42031(a) through (d).
020-009	WM Curbside, LLC	Reggie B Pestano	18973.2(b)	N	Will there be a feasibility study if the covered entity can afford to pay for this program?	020-009. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. The authorizing statute does not require that feasibility studies be conducted. This comment is irrelevant because it does not pertain to an edit made in the second draft of the regulatory text.
020-010	WM Curbside, LLC	Reggie B Pestano	18973.2(c)	N	Pg 8 Line 29 - Is the list of covered drug sold/offered for sale will be inclusive?	020-010. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. Pursuant to Section 42031(a)(1) of the Public Resources Code, a covered entity shall provide a list of covered products, and a list and description of any drugs or sharps that are not covered products, that it sells or offers for sale in the state to the state board.
020-011	WM Curbside, LLC	Reggie B Pestano	18973.2(d)	N	Pg 9 Line 2 - If there is already an existing contract between a government agency and a service provider to pickup and dispose of pharmaceuticals deposited by residents in receptacles located in local	020-011. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. Existing contracts are outside the scope of these regulations.

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					government facilities such as City Hall, libraries, etc, will the existing contracts be superseded by the stewardship program?	However, in accordance with section 42036.2 of the Public Resources Code, jurisdictions with existing local stewardship programs (enacted through an ordinance and effective before April 18, 2018) do not have to comply with this Article. If a jurisdiction repeals a local stewardship program ordinance, drugs and sharps sold in that jurisdiction become subject to SB 212.
020-012	WM Curbside, LLC	Reggie B Pestano	18973.2(d)	N	Pg 9 Line 2 - Does this mean the contract will be terminated and may offer the service to another service provider under the stewardship program?	020-012. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. Existing contracts are outside the scope of these regulations. However, in accordance with section 42036.2 of the Public Resources Code, jurisdictions with existing local stewardship programs (enacted through an ordinance and effective before April 18, 2018) do not have to comply with this Article. If a jurisdiction repeals a local stewardship program ordinance, drugs and sharps sold in that jurisdiction become subject to SB 212.
020-013	WM Curbside, LLC	Reggie B Pestano	18973.2(g)(4)	N	Pg 10 Line 30 - Will the authorized collection site going to be tabulating each resident's pharmaceutical deposit into the receptacle? This is going to be a tedious process.	020-013. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. The program operator must include in their annual report for covered drugs the amount of covered drugs collected from ultimate users at each authorized collection site, as required in the stewardship plan pursuant to Section 18973.2(g)(4). There is no requirement that each ultimate user's deposit be measured.
020-014	WM Curbside, LLC	Reggie B Pestano	18973.2(g)(6)	N	Pg 11 Line 3 - Can any entity apply for the stewardship program for pharmaceuticals and only manage the receptacle but without including the mail-back option into the program?	020-014. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. Please refer to the requirements in the authorizing statute and section 18973.2 and 18973.4 of the proposed regulations for specific requirements regarding mail-back options.
020-015	WM Curbside, LLC	Reggie B Pestano	18973.2(g)(6)(B)	N	Pg 11 Line 10 - If a user is homeless, how do we mail the pre-addressed/pre-paid mail-back materials?	020-015. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. There is no requirement to mail the pre-addressed/pre-paid mail-back materials to an individual who is homeless. Materials <i>may</i> be mailed to the ultimate user, <i>upon request</i> . Please refer to section 18973.2(g)(6) of the proposed regulations for more information about mail-back services or an alternative form of collection and disposal.
020-016	WM Curbside, LLC	Reggie B Pestano	18973.2(g)(9)	N	Pg 11 Line 29 - Since nobody can predict when each pharmaceutical receptacle will be full, there will be an option for an emergency pickup with an additional fee. However, if an emergency pickup is not possible, the service provider should not be penalized.	020-016. A change to the proposed regulatory text is not necessary. The program operator is required to work with authorized collectors and to implement a process by which collection receptacles will be monitored and determine a service schedule that will ensure collection receptacles do not reach capacity and identify the procedures followed if capacity is reached. Because a variety collection models may satisfy this requirement, the proposed regulations provide program operators flexibility in determining collection methods that provide the most effective services to meet the needs of the authorized collectors and

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
						ultimate users and will promote innovation and vendor competition. The onus is on the program operator to ensure that collections, including any emergency pickups, occur in a manner that meets this requirement.
020-017	WM Curbside, LLC	Reggie B Pestano	18973.2(h)	N	Pg 12 Line 18 - Will regular UHWM be used for collection of covered pharmaceuticals and sharps? Right now, we only use a Non-Hazardous Tracking Form.	020-017. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. If the question is referring to specific covered product transportation rules, it is outside of the department's authority.
020-018	WM Curbside, LLC	Reggie B Pestano	18973.2(j)	N	Pg 13 Line 27 - Separating covered from uncovered products will be difficult to implement or enforce.	020-018. A change to the proposed regulatory text is not necessary. Pursuant to section 42031.6(a)(5), the education and outreach program must encourage ultimate users to separate products that are not covered products from covered products, when appropriate. It is the program operator's responsibility to conduct their education and outreach program comprehensively in order to ensure product separation is done correctly by ultimate users before submitting the covered products to an authorized collection site or mail-back program.
020-019	WM Curbside, LLC	Reggie B Pestano	18973.3(f)(5)(A)	N	Pg 17 Line 4 - Can a service provider for the sharps stewardship program opt not to a mail-back option for sharps?	020-019. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. The commenter uses the term 'service provider', but the reference to the proposed regulatory text is for program operators. CalRecycle is making the assumption that the commenter is using the terms "service provider" to mean "program operator". Program operators can opt to implement a receptacle-based program using authorized and approved home-generated sharps consolidation points. However, Pursuant to Section 42032.2. (d)(1)(F), a stewardship program for home-generated sharps waste must include a mail-back program. Supplemental collection method(s) for home-generated sharps waste may be provided in addition to the mail-back program.
020-020	WM Curbside, LLC	Reggie B Pestano	18973.3(i)(4)	N	Pg 19 Line 31 - Will email also be an option for residents to request sharps containers from providers?	020-020. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. Section 18973.3(i) requires a stewardship program to establish an internet website that includes a mechanism to accept requests for sharps waste containers and mail-back materials, and establish a toll-free telephone number to serve as an option for ultimate users to request sharps waste containers and mail-back materials. The comprehensive education and outreach program may include email as an additional option for ultimate users to request sharps waste containers and mail-back materials.
020-021	WM Curbside, LLC	Reggie B Pestano	18973.5	N	Will this annual sharps report be separate from the quarterly report to submit to CA Dept of Health for sharps and pharmaceutical collections?	020-021. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. Program operators shall prepare and submit annual reports to the department on or before March 31, 2022, and each year thereafter. This annual report is separate from the reporting requirements of any other Department.

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
020-022	WM Curbside, LLC	Reggie B Pestano	General	N	Under the rules of the CA Dept of Pharmacists, they require two witnesses when packaging non-controlled pharmaceuticals at a pharmacist's location during each pickup for disposal. Many pharmacists do not like this idea because of the added overhead cost of an extra witness (it used to be just one witness) so they decided not take residential pharmaceuticals anymore. Will the rule remain the same requiring two witnesses for each pickup?	020-022. The comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. The CA Dept of Pharmacists does not exist and the department believes the commenter is referring to the CA State Board of Pharmacy. The requirement noted by the commenter falls under the purview of the State Board of Pharmacy and is outside the scope of these regulations.
021-001	Rural County Representatives of California	Staci Heaton	General	N	In general, RCRC and ESJPA continue to support the regulatory model as proposed and we appreciate many of the changes to the original proposed draft, which were largely clarifying in nature. Overall, it is our objective to ensure these stewardship programs do not result in a reduction of currently available services in counties. With regard to the specific changes made, we appreciate the inclusion of notification procedures to local agencies, and others, for safety and security incidents related to collection, transportation and disposal of covered drugs, as well as secure receptacle collection of sharps.	021-001. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. CalRecycle acknowledges the commenter's support of the regulatory model as proposed. In accordance with section 42036.2 of the Public Resources Code, jurisdictions with existing local stewardship programs (enacted through an ordinance and effective before April 18, 2018) do not have to comply with this Article. If a jurisdiction repeals a local stewardship program ordinance, drugs and sharps sold in that jurisdiction become subject to SB 212. Program operators will be required to submit stewardship plans that meet the minimum convenience standards pursuant to subsection (1)(F) of subdivision (a) of section 42032.2 of the Public Resources Code.
021-002	Rural County Representatives of California	Staci Heaton	18973.2	N	There should be a mechanism to ensure local agencies can recover costs by covered entities to mitigate pharmaceuticals that wind up in solid waste, wastewater or sanitation facilities, not to mention parks or other public places.	021-002. A change to the proposed regulatory text is not necessary. Public Resources Code section 42032.2(d)(1)(F)(ii) requires a program operator to either reimburse local agencies for disposal costs related to home-generated sharps waste or provide for the removal of the home-generated sharps waste from the local household hazardous waste facility. Statute does not extend a similar provision for covered drugs, and thus requiring a program operator to accommodate local agency requests relating to covered drugs is outside the scope and authority of these regulations.
021-003	Rural County Representatives of California	Staci Heaton	18973.2	N	Further, local agencies that conduct testing of inert drugs, such as an aquatic toxicity test, should be reimbursed for these activities in the course of ensuring that pharmaceuticals are properly disposed and managed.	021-002. A change to the proposed regulatory text is not necessary. Public Resources Code section 42032.2(d)(1)(F)(ii) requires a program operator to either reimburse local agencies for disposal costs related to home-generated sharps waste or provide for the removal of the home-generated sharps waste from the local household hazardous waste facility. Statute does not extend a similar provision for covered drugs, and thus requiring a program operator to accommodate local agency reimbursement requests for aquatic toxicity testing is outside the scope and authority of these regulations.
021-004	Rural County Representatives of California	Staci Heaton	18973.3(g)	N	Stewardship Organization(s) should be encouraged to financially contribute to a local agency's advertisements rather than create separate campaigns for education and outreach. Local entities, for example, provide public education through its HHW programs. Residents and consumers should receive consistent and comprehensive messaging.	021-004. A change to the proposed regulatory text is not necessary. Statute requires a program operator to conduct a comprehensive education and outreach campaign and does not require it to contribute financially to a local agency's advertisements. Thus, adding such a requirement in regulation would be outside the scope and authority of these regulations.
021-005	Rural County Representative	Staci Heaton	18973.3(g)	N	HHW programs should have an opportunity to receive sharps containers and dispose collected sharps under the stewardship program. This avenue could be one of the options under section 18972.1 (a)(11)(C).	021-005. A change to the proposed regulatory text is not necessary. It is not the department's role to mediate contract discussions between a program operator and household hazardous waste programs.

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
	es of California				Many of these HHW programs have large (e.g. 30-gallon) containers to hold collected sharps, which should be eligible for free disposal rather than having to stockpile mail-away containers.	However, the statute does not require home-generated sharps waste consolidated at a household hazardous waste facility to have been brought to the facility directly by an ultimate user, and also does not require that home-generated sharps waste be transferred to mail-back containers in order to be eligible for reimbursement or removal.
022-001	CDPH	Sheetal Singh	18972.1(a)(6)	Y	<p><u>(6) "Inert" means the covered drug or mixture of covered drugs is rendered chemically inactive prior to disposal and complies with all applicable local, state and federal laws and regulations, including those of the United State Drug Enforcement Administration and California statutes and regulations governing disposal in a municipal solid waste landfill.</u></p> <p>COMMENT: Is there an agency that determines whether or not a disposal system makes the covered drug(s) chemically inactive prior to disposal?</p>	<p>022-001. A change to the proposed regulatory text is necessary for clarity. CalRecycle has removed the definition of "inert" from the regulatory text. CalRecycle prefers to rely on statutory language and other agencies with authority regarding the term "inert".</p> <p>It is the responsibility of the program operator, that proposes an alternative form of a collection and disposal system that must render a covered drug inert, to comply with all applicable federal and state laws and regulations regarding handling, collection, and transportation of such inert substances. CalRecycle may consult with other agencies, regarding a proposed alternative form of collection and disposal that must render a drug inert, and will determine which agencies are appropriate based on the proposal.</p>
022-002	CDPH	Sheetal Singh	18973.3(f)(5)(A)	Y	<p>Pg 17, lines 1-10.</p> <p>COMMENT: The proposed regulations state that the program operator shall use an authorized and approved home-generated sharps consolidation point. It would help clarify the approval process if the proposed regulations did not delete (strikethrough) the information that stated the program operator shall have home-generated sharps consolidation points approved by the applicable city, county, or state enforcement agency that implements the Medical Waste Management Act.</p>	<p>022-002. CalRecycle agrees with the commenter that program operators shall have home-generated sharps consolidation points approved by the applicable city, county, or state enforcement agency that implements the Medical Waste Management Act program and has chosen to modify proposed regulatory text section 18973.3(f)(5)(A) as follows:</p> <p><u>(A) Secure receptacle collection. If a program operator proposes to implement a receptacle-based program to supplement its mail-back program and using authorized and approved home-generated sharps consolidation points under the Medical Waste Management Act are authorized and approved by the city, county, or state enforcement authority that provides oversight of the Medical Waste Management Act, then the following information, as applicable, shall be included, but not be limited to:</u></p>
022-003	CDPH	Sheetal Singh	18973.3(f)(5)(B)	Y	<p>Pg 18, lines 1-2.</p> <p>COMMENT: The proposed regulations should state that the take-back collection event shall be authorized and approved as a home-generated sharps consolidation points by the appropriate city, county, or state enforcement agency.</p>	<p>022-003. CalRecycle agrees with the commenter that take-back collection events shall be authorized and approved as a home-generated sharps consolidation points by the appropriate city, county, or state enforcement agency that implements the Medical Waste Management Act program and has chosen to modify proposed regulatory text section 18973.3(f)(5)(B) as follows:</p> <p><u>(B) Take-back collection events, shall be authorized and approved as a home-generated sharps consolidation point under the Medical Waste Management Act. Describe when take-back events are necessary and how they will be conducted Date and location of events, ifas applicable.</u></p>

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
023-001	HDA	Leah Lindahl	18972.2	N	The proposed regulatory text fails to provide any clarity around the term “Covered Entity,” instead reverting back to the legislative text which was specifically noted during the legislative process and within the Governor’s signing message as needing additional clarity through regulations. As provided within comments throughout the rulemaking process, the current language creates uncertainty as to which entity is ultimately responsible and could result in a multi-layer fee where the manufacturer, wholesaler, repackager, licensee, importer, etc. fund the disposal of a single product.	023-001. CalRecycle declines to further clarify the term “covered entity” because the statutory definition is sufficient to determine the priority in which a covered entity is identified. The tiered definition allows CalRecycle to determine the appropriate covered entity within a complex and dynamic supply chain on a case-by-case basis. To ensure multi-layer fees are not assessed by a stewardship organization, potential covered entities should coordinate within their respective supply chains to determine how the statutory requirements will be met.
023-Supp.001	HDA	Leah Lindahl	18972.2	N	Commented [HDA1]: As noted by the legislative committee of jurisdiction, the Governor’s signing message and stakeholder comments, the term “covered entity” needs to be further clarified within the regulations. Additional clarity is also necessary in regard to the process the department will undergo when utilizing the tiered definition. HDA offers these recommended changes which will provide a clear process to determine which entity should be considered the “covered entity” as well as allow the department to work with the Board of Pharmacy on a procedure on how to utilize the tiered definition. (a)The department shall consider any manufacturer with products offered for sale in the state of California as being responsible for participating as the covered entity. The department will consider all manufacturers of covered products that are sold, offered for sale, or dispensed in California, whether they are program operators or are represented by a stewardship organization, as the covered entities. (b)The department will use the priority set forth in subsections(1)(B)-(E) of subdivision (f)of section 42030 of the Public Resources Code to identify the covered entity for any covered products consistent with subdivision (f) of section 42030, which do not meet the definition of subsection (1)(A) of subdivision (f) of section 42030 of the Public Resources Code.	023-Supp.001. A change to the proposed regulatory text is not necessary. See response to comment 023-001.
023-002	HDA	Leah Lindahl	18972.2	N	Additionally, the language also fails to offer a definition as to what constitutes a “manufacturer.”	023-002. A change to the proposed regulatory text is not necessary. CalRecycle declines to define “manufacturer” because it is a common term.
023-003	HDA	Leah Lindahl	18972.2	N	HDA request the proposed regulations stipulate that any manufacturer who avails itself of the California market should be the responsible entity required to participate in the stewardship program. In other words, if a manufacturer’s product is for sale within the state of California, they are therefore “in” the state and responsible for participating in the Pharmaceutical and Sharps Waste Stewardship Program. Based on current case law, the state of California clearly has jurisdiction over pharmaceutical manufacturers whose products are dispensed in California to comply with the proposed statewide take back program. It is clear the legislative intent was to compel all manufacturers to participate	023-003. A change to the proposed regulatory text is not necessary. The statutory definition makes clear that the operative facts for whether an entity is a “covered entity” is whether or not it sells covered products “in or into the state,” not whether or not the entity is located within the state. Regardless of complex market dynamics, an entity in the supply chain for a covered product must either propose a stewardship plan or join a stewardship organization to manage that covered product in compliance with SB 212. It is the responsibility of covered entities to self-identify through the submission of covered

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					<p>in the stewardship program, therefore the regulations should effectively execute this legislative intent.</p> <p>HDA recommends inserting the following language into the regulations to alleviate these concerns: <i>(a) The department shall consider any manufacturer with products offered for sale in the state of California as being responsible for participating as a covered entity.</i></p>	products lists to the Board of Pharmacy for verification pursuant to Public Resources Code section 42031(a) through (d).
023-004 023-Supp. 004	HDA	Leah Lindahl	18972.2	N	<p>Further, HDA request the regulations stipulate a clear process by which CalRecycle will identify the manufacturer and how the department would utilize the tiered definition should the manufacturer not be identifiable. This request has been echoed by other stakeholders during the formal rulemaking process and has been left unanswered. HDA recommends the inclusion of the below section, which will allow CalRecycle and the Board of Pharmacy to further develop procedures to address these concerns:</p> <p><i>(b) The department, in collaboration with the California Board of Pharmacy, will develop and implement procedures to communicate with manufacturers of covered products, or the selected stewardship organization, and ensure understanding of compliance responsibilities. Only when there is sufficient evidence that such efforts have failed, the department will utilize the priority set forth in subsections(1)(B)-(E) of subdivision (f) of section 42030 of the Public Resource Code.</i></p>	023-004. A change to the proposed regulatory text is not necessary. CalRecycle declines to further clarify the terms “manufacturer” and “covered entity” because the statutory definition of “covered entity” is sufficient to determine the priority in which a covered entity is identified. Compliance determinations are made on a case-by-case basis. Entities that could be considered covered entities based on the statutory definition should endeavor to coordinate amongst appropriate entities within their respective supply chains to determine how the statutory requirements will be met. It is the responsibility of covered entities to self-identify through the submission of covered products lists to the Board of Pharmacy for verification pursuant to Public Resources Code section 42031(a) through (d).
023-005 023-Supp. 005	HDA	Leah Lindahl	18972.2	N	<p>HDA also requests that a clear definition is developed as to what constitutes a “Manufacturer” and offers the below definition for consideration: <i>(c) “Manufacturer” means a person, company, corporation or other entity engaged in the manufacture of (a) a covered drug as defined in subsection (e)(1) of section 42030 of the Public Resources Code sold, offered for sale, or dispensed in the state or (b) sharps sold, offered for sale, or dispensed in the state. Manufacturer does not include the activities of a repackager, relabeler, private label distributor or wholesale distributor.</i></p>	023-005. A change to the proposed regulatory text is not necessary. The term “manufacturer” has a common meaning and does not need further definition. Furthermore, the statutory definition makes clear that the operative facts for whether an entity is a “covered entity” is whether or not it sells covered products “in or into the state,” not whether or not the entity is located within the state.
023-006	HDA	Leah Lindahl	18974.3	N	<p>We appreciate CalRecycle’s efforts to provide more clarity on how wholesalers and others will verify products being sold in or into California. HDA recommends the regulations stipulate that reporting entities review the website at least annually and provide a listing of apparent non-compliant manufacturers or covered entities to the department in a format that has been agreed upon by the industry and the department.</p>	023-006. A change to the proposed regulatory text is not necessary. CalRecycle rejects the commenter’s recommendation to require reporting entities to review the website at least annually. Reporting entities are required to monitor the website regularly to determine which covered entities and program operators are in compliance with the law. Considering the frequency of the introduction of covered products into the market place, limiting reviews to a minimum of “at least annually” provides an opportunity for a covered product to be sold, offered for sale, or distributed by a covered entity that is not operating under an approved stewardship plan. Sections 18974.3(a) and (b) of the proposed regulatory text specify that a distributor, wholesaler, pharmacy, and retailer is required to monitor CalRecycle’s website to identify noncompliant covered entities, not non-compliant

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
						<p>covered products. If a covered entity is listed on the website as being compliant, then all covered products that a distributor, wholesaler, pharmacy, and retailer sells, offers for sale, or dispenses under that covered entity are determined to be in compliance.</p> <p>Regarding the commenter's recommendation that a listing of non-compliant covered entities be provided to the department in an agreed upon format, a change to the proposed regulatory text is not necessary. Public Resources Code section 42035.6(d)(2) indicates that CalRecycle may, but is not required to, post a notice on the department's Internet web site of non-compliant covered entities. CalRecycle reserves the right to post lists in a format it deems necessary.</p>
023-Supp. 006	HDA	Leah Lindahl	18974.3(a)	N	<p>Commented [HDA2]: To ensure conformity and clarity, HDA recommends the department require reporting to be conducted at least annually and work with industry to establish a standardized format for the reports. HDA further requests the Department notify licensed or reporting entities when they identify a non-compliant stewardship organization or covered entity.</p> <p><u>(a) Each distributor, wholesaler, pharmacy, and retailer that sells, offers for sale, or dispenses a covered product shall:</u> successfully log onto the department's internet website at least annually to verify determine if a covered entity of that covered products to be sold, offered for sale, or dispensed are in compliance with the law, <u>by verifying that the covered entities providing the covered product(s) are in compliance with the law.</u></p> <p><u>(b)</u> Should a distributor, wholesaler, pharmacy, other retailer, or a designated responsible party for any of the foregoing identify a noncompliant covered entity or stewardship organization, the distributor, wholesaler, pharmacy, other retailer, or designated responsible party shall report, in an agreed upon format, the discovery to the department within 30 days.</p>	023-Supp. 006. A change to the proposed regulatory text is not necessary. See response to comment 023-006.
023-007	HDA	Leah Lindahl	18974.3(a)	N	HDA also requests the department, in coordination with the board, notify licensees and reporting entities when a non-compliant entity has been identified.	023-007. A change to the proposed regulatory text is not necessary. Pursuant to Public Resources Code section 42035, distributors, wholesalers, pharmacies, and pharmacy chains are required to monitor the department website for covered entities that are compliant. If a covered entity or stewardship organization is not listed, then it may be out of compliance. Further, the department may post a notice in association with the list the department maintains pursuant to Public Resources Code section 42035 of those entities no longer in compliance.
023-Supp. 007	HDA	Leah Lindahl	18974.3(a)	N	<u>(c)</u> Should the Department determine a covered entity or stewardship organization is not in compliance, the Department	023-Supp. 007. A change to the proposed regulatory text is not necessary. See comment response to 023-007.

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					in collaboration with the Board shall notify all licensees of the non-compliance.	The department's position is that the website notices it is required to provide pursuant to section 42035 of the Public Resources Code is sufficient notice about non-compliance. Industry is responsible for monitoring the department's website per sections 42035(c) and (d) of the Public Resources Code.
023-008	HDA	Leah Lindahl	18974.3(b)	N	HDA further recommends the regulations provide clarity that reporting entities shall be held harmless for any assessment of penalties placed on the actual manufacturer for lack of participation in the stewardship program.	023-008. A change to the proposed regulatory text is not necessary. Pursuant to Public Resources Code 42035.2, the department may impose an administrative penalty on a covered entity, program operator, stewardship organization, or authorized collector, as appropriate that violates the authorizing statute and its implementing regulations. The department retains discretion for assessment of penalties.
023-009	HDA	Leah Lindahl	18975	N	HDA requests the proposed regulations establish a process by which the department will inform covered entities when it will utilize the priority set forth in subsections(1)(B)- (E) of subdivision (f) of section 42030 of the Public Resources Code to identify the covered entity for any covered products, which do not meet the definition of subsection (1)(A) of subdivision (f) of section 42030 of the Public Resources Code.	023-009. A change to the proposed regulatory text is not necessary. Entities that could potentially be considered covered entities based on the statutory definition should endeavor to coordinate amongst appropriate entities within their respective supply chains to determine how the statutory requirements will be met. For instance, this may require the establishment of contractual or other terms that clarify the party responsible for participating in a stewardship program or reporting annually to the Board of Pharmacy.
023-Supp. 009	HDA	Leah Lindahl	18975	N	Commented [HDA3]: HDA recommends the following changes in order to ensure that should the Department utilize the tiered definition of covered entity, the newly responsible entity is alerted and held harmless of any penalties assessed on the previously reported non-compliant entity. (b) The department will establish a process to alert potential covered entities when it will utilize the priority set forth in subsections(1)(B)-(E) of subdivision (f) of section 42030 of the Public Resources Code to identify the covered entity for any covered products, which do not meet the definition of subsection (1)(A) of subdivision (f) of section 42030 of the Public Resources Code and ensure the potential covered entities are aware of the regulations and responsibility before assessing any administrative penalty.	023-Supp. 009. A change to the proposed regulatory text is not necessary. See comment response to 023-009.
023-010	HDA	Leah Lindahl	18975	N	Further, we request the proposed regulations stipulate that any identified covered entity shall not be penalized or assessed any fines due to non-compliance of a previously reported non-compliant covered entity. HDA recommends the inclusion of the following language to address these concerns:	023-010. A change to the proposed regulatory text is not necessary. Limiting in regulations the Department's ability to take an enforcement action could result in unintended consequences
023-Supp. 010	HDA	Leah Lindahl	18975	N	(c) Should the department utilize the priority set forth in subsections(1)(B)-(E) of subdivision (f) of section 42030 of the Public Resources Code to identify the covered entity for any covered products, which do not meet the definition of subsection (1)(A) of subdivision (f) of section 42030 of the Public Resources Code, the subsequent participation entity shall be held harmless for the assessment of penalties on the non-compliant covered entity.	023-Supp. 010. A change to the proposed regulatory text is not necessary. See comment response to 023-010.

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
024-001	Inmar Intelligence	Domingo Isasi	18973.3(g)(2)	N	<p>Within six months of the adoption date of the regulations in this Article by the department, a program operator shall submit a stewardship plan to the department.</p> <p>(g)Local Agency Requests: “Program operators shall respond to requests by local agencies within 14 days of receipt of the request...”</p> <p><u>COMMENT:</u> As an experienced provider of pharmaceutical return services, Inmar recommends a 30 day deadline, which would be more operationally practical while still fulfilling the goals of the program.</p>	024-001. A change to the proposed regulatory text is not necessary. The regulation merely requires a response within 14 days of receipt to the request by local agencies. The 14 day deadline is not requiring that the program operator act and carry out its obligation to reimburse the local agency or pick-up the waste in that timeframe. 18973.3(g)(2)(A) requires reimbursement within 45 days of receipt if that is the method chosen to resolve the request.
024-002	Inmar Intelligence	Domingo Isasi	18973.2(j)	N	<p>(j)Education and Outreach</p> <p>(3)Establishment of an internet website designed with functionality for mobile platforms, provided with language options suited to local demographics, and maintained to ensure all information is up to date and accurate.</p> <p>4)Establishment of a toll-free telephone number to: 1) accept requests for mail-back materials from ultimate users who are homeless, homebound, or disabled, and 2) to provide disposal options, and other program information to ultimate users without access to the internet.</p> <p>Comment: CalRecycle is responsible for the administration of pharmaceutical and sharps stewardship and in that capacity should prioritize convenience and ease of use for state residents. Accordingly, CalRecycle should allocate sufficient state funding, and if necessary, a portion of any fees collected pursuant to the statute, to coordinate the consumer-facing aspects of the program, specifically the website and the toll-free number.</p>	024-002. A change to the proposed regulatory text is not necessary. CalRecycle is charged with providing oversight to the pharmaceutical and sharps stewardship program and does not serve the role of program operator for the consumer-facing website and toll-free phone number. The authorizing statute does not authorize CalRecycle to allocate state funding as the commenter proposes.
024-003	Inmar Intelligence	Domingo Isasi	18973.2(j)	N	The multiple program operators can provide the information for the maintenance of the website. However, asking or requiring competing program operators to coordinate in the establishment and launch of a website outside of the confines of a trade association or similar body invites a potential violation of the Sherman Act (15 U.S.C. §§ 1 and 2), for which the state would have to take multiple additional steps to provide potential federal immunity.	024-003. Section 42031.6(a)(3) clearly states that responsibility for establishment of an Internet Web site is beholden upon a program operator. A program operator can be a single covered entity or a stewardship organization on behalf of a group of covered entities. If multiple competing covered entities decide to join a stewardship organization, the stewardship organization will be required to comply with section 42031.6. Moreover, Section 42036(b)(1) of the Public Resources Code states that the “creation, implementation, or management of a stewardship plan approved by the department” is not a violation of multiple antitrust laws. The department cannot provide federal immunity, nor is it necessary to do so.
024-004	Inmar Intelligence	Domingo Isasi	18973.2(j)	N	At a minimum, the state should ensure that it owns the website and toll-free number to ensure continuity between potential changes in program operators. If a program operator owns the website or number and then exits the program, establishment of a new number would create unnecessary confusion for consumers.	024-004. CalRecycle disagrees with the commenter that the Department shall own the website developed to provide information to consumers as part of a comprehensive education and outreach program. CalRecycle cannot serve the role of program operator in any part of stewardship program implementation as the authorizing statute does not authorize CalRecycle to allocate state funding as the commenter proposes and section 42031.6(a)(3) clearly states that

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
						responsibility belongs to the program operator. Program operators also have responsibility to ensure continuity of program services, including education and outreach, and as such are responsible for designing programs with contingencies to adapt to changes with minimal negative impacts to consumers.
025-001	CPSC and Coalition	Doug Kobold, Heidi Sanborn	18972.1(a)(11)	Y	<p>Section 18972.1(a)(11) creates a definition for “Provides or initiates the distribution of a sharps waste container” and provides three possible meanings for this phrase. Two of them – 18972.1(a)(11)(A) and (B) are consistent with the authorizing statute, but (C) is not. As we note above, (C) states that a program operator can utilize “other methods” if the options in (A) or (B) are not allowed by law or “is not reasonably feasible”. The department simply does not have authority under the authorizing statute to make the allowance for “other methods” if feasibility is the only perceived barrier to providing a sharps container and mail-back materials at the point of sale under (A) or initiating the distribution of those items at the point of sale under (B). This should be struck from the definition.</p> <p>We strongly encourage the department to strike the words “or is not reasonably feasible” from lines 5 and 6 of page 3 of the second draft of proposed regulations because they are inconsistent with the authorizing statute and could significantly weaken the program.</p>	025-001. CalRecycle agrees to remove the “or is not reasonably feasible” clause. CalRecycle believes that the options (with the phrase removed) under the proposed regulations text definition in section 18972.1(a)(10) offer the program operator sufficient flexibility while maintaining convenience for the ultimate user.
025-002	CPSC and Coalition	Doug Kobold, Heidi Sanborn	18975.1	N	<p>Our major concern in this area is that the department, to the degree possible, avoids a situation where the process of submitting, reviewing, and approving stewardship plans doesn’t drag on in ways that jeopardize program efficacy, such as multiple resubmittals of the draft plan or future amendments to the plan. We commented on our past letter about the process for determining plan completeness, as well as the process for approving/disapproving plans. While the second draft of proposed regulations don’t necessarily adopt our prior suggestions, we do believe that the statute and regulations provide the department enough authority to enforce the law.</p> <p>PRC 42032(a)(1) requires a program operator to submit a complete stewardship plan that meets the requirements of the law within six months of the regulations being approved. PRC 42032(g) requires a program operator to fully implement their stewardship plan within 270 days of the department’s approval. PRC 42035.2 gives the department authority to impose a civil penalty to a covered entity, program operator, or stewardship organization that provides, sells, or offers for sale a covered product that isn’t covered by a stewardship plan. We believe the regulations, in Sections 18975, 18975.1, and 18975.2, also provide the department with the tools necessary to ensure that this program is implemented in a timely and effective manner.</p> <p>We strongly encourage the department to utilize this enforcement and penalty authority if program operators do not meet implementation timelines and standards. The covered entities required to perform under the law have years of experience implementing local ordinances and will</p>	025-002. This comment is general in nature and does not specify a change to the proposed regulatory text. CalRecycle acknowledges the commenter’s concern regarding the length of the stewardship plan review process, but notes that program operators have an incentive to act quickly because any covered products sold in California must be subject to an approved stewardship plan within one year of the adoption of the regulations, pursuant to Public Resources Code section 42031.4(a). Separately, CalRecycle acknowledges the commenter’s support for the multiple enforcement options available to the department under SB 212.

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					<p>have had nearly three years of ramp-up time between the passage of SB 212 and the deadline to implement the program. There is simply no excuse for a program operator to be unprepared to meet their responsibility under the law.</p> <p>Similarly, we hope the department will utilize its authority in Section 18975.2 to enforce key aspects of the program. Subsection (a) requires the department to revoke a previously approved stewardship plan if the department finds that a material requirement of the article is not being met by a program operator.</p>	
025-003a	CPSC and Coalition	Doug Kobold, Heidi Sanborn	18973.2(j)	N	<p>We strongly support the changes to the education and outreach portions of the regulations (Section 18973.2(j) for medicines and 18973.3(i) for sharps) because they significantly strengthen the regulations and provide clear direction to program operators.</p> <p>The second draft proposed regulations require program operators to coordinate closely with other program operators or stewardship organizations on their efforts to promote awareness and participation in their stewardship programs, develop educational signage and materials in multiple languages depending on local need, develop internet websites and mobile platforms to provide vital information, establish a toll-free telephone number that provides service for the hearing- and speech-impaired and is also answered by a human representative, and metrics to evaluate and recalibrate efforts as needed. All of these components are necessary for an effective education and outreach program and we support their inclusion in the regulations.</p> <p>While we understand that the plan development, submission, and approval process will ultimately determine what is in the actual education and outreach programs, we believe the regulations provide a strong foundation for success. We urge the department to be vigilant in terms of this portion of the product stewardship plan – if program operators don't get the education and outreach program correct then the entire effort will suffer.</p>	025-003a. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. CalRecycle acknowledges the commenter's support of the proposed outreach and education sections of the regulations.
025-003b	CPSC and Coalition	Doug Kobold, Heidi Sanborn	18973.3(i)	N	<p>We strongly support the changes to the education and outreach portions of the regulations (Section 18973.2(j) for medicines and 18973.3(i) for sharps) because they significantly strengthen the regulations and provide clear direction to program operators.</p> <p>The second draft proposed regulations require program operators to coordinate closely with other program operators or stewardship organizations on their efforts to promote awareness and participation in their stewardship programs, develop educational signage and materials in multiple languages depending on local need, develop internet websites and mobile platforms to provide vital information, establish a toll-free telephone number that provides service for the hearing- and speech-impaired and is also answered by a human representative, and metrics to evaluate and recalibrate efforts as needed. All of these components are</p>	025-003b. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. CalRecycle acknowledges the commenter's support of the proposed outreach and education sections of the regulations.

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					<p>necessary for an effective education and outreach program and we support their inclusion in the regulations.</p> <p>While we understand that the plan development, submission, and approval process will ultimately determine what is in the actual education and outreach programs, we believe the regulations provide a strong foundation for success. We urge the department to be vigilant in terms of this portion of the product stewardship plan – if program operators don't get the education and outreach program correct then the entire effort will suffer.</p>	
025-004a	CPSC and Coalition	Doug Kobold, Heidi Sanborn	18973.2(j)(6)	Y	In our comments on the first draft of proposed regulations we stated that we thought the prohibition against promoting disposal options inconsistent with the purposes of the program, contained in PRC 42031.6(b), should be re-stated in the regulations. We still believe this would be wise because of experiences on the local level where stewardship organization websites linked to information on disposal that was unquestionably in conflict with the purposes of the program.	<p>025-004a. CalRecycle agrees with the commenter's recommendation and proposes the following addition to section 18973.2(j):</p> <p>(7) How the program operator will comply with the requirement in section 42031.6(b) of the Public Resources Code.</p>
025-004b	CPSC and Coalition	Doug Kobold, Heidi Sanborn	18973.3(i)	Y	In our comments on the first draft of proposed regulations we stated that we thought the prohibition against promoting disposal options inconsistent with the purposes of the program, contained in PRC 42031.6(b), should be re-stated in the regulations. We still believe this would be wise because of experiences on the local level where stewardship organization websites linked to information on disposal that was unquestionably in conflict with the purposes of the program.	<p>025-004b. CalRecycle agrees with the commenter's recommendation and proposes the following addition to section 18973.3(i):</p> <p>(7) How the program operator will comply with the requirement in section 42031.6(b) of the Public Resources Code.</p>
026-001	PPSWG	Anne Vogel-Marr	18975.1	N	<p>PPSWG has concerns with the new administrative procedures that the Department is proposing in Section 18975.1, which would apply to proposed actions by the Department that could result in the assessment of tens of thousands, or even hundreds of thousands of dollars, in administrative penalties.</p> <p>Under the original version of the proposed regulations issued on January 3, 2020, Section 18975.1 stated that proceedings held on a proposed administrative penalty action by the Department were subject to the procedures in Chapter 4.5 of the California Administrative Procedures Act ("APA"), Gov't Code section 11455.10 <i>et seq.</i> As you likely know, the procedures in Chapter 4.5 apply to informal hearings conducted by state agencies, like CalRecycle, and incorporate minimum due process protections afforded to respondents under California law, including, namely those set forth in the Administrative Adjudicative Bill of Rights, Gov't Code §§ 11425.10 – 11425.60.</p> <p>For reasons unclear from the rulemaking file, the Department has removed all references to the APA in the Revised Proposed Regulations and Section 18975.1 now includes what appears to be a novel set of procedures that the Department has created for use in future proposed administrative penalty actions. The procedures now proposed in Section</p>	<p>026-001. For purposes of this response, "Authorizing Statute" refers to Chapter 2 of Part 3 of Division 30 of the Public Resources Code. A change to the proposed regulatory text is not necessary. CalRecycle is not abrogating a respondent's due process rights by not explicitly mentioning them in its regulations. Hearings under these circumstances are allowed by law to be informal hearings since the authorizing statute did not require them to be formal. The Administrative Procedure Act "Bill of Rights" (Gov. Code 11425.10 through 11425.60) applies to hearings conducted under these regulations and mandate minimum due process regardless of whether the procedure is reflected in these regulations. Therefore the regulatory text is not arbitrary or capricious and comports with minimum due process protections.</p>

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					<p>18975.1 are extremely scant and fail to address all aspects of an adjudicatory proceeding. Moreover, the procedures that the Department is now proposing do not comport with the minimum due process protections that are conferred upon respondents under California's Administrative Adjudicative Bill of Rights, Cal. Gov't Code §§ 11425.10 – 11425.60.</p> <p>As such, the Section 18975.1(b)-(f) of the Revised Proposed Regulation should be revised as follows:</p> <p>(b)The department shall commence an action to impose administrative civil penalties by serving an accusation upon the respondent that includes a notice informing the respondent of their right to a hearing. The accusation shall state the legal and factual basis for the imposition of penalties, including a description of how the department applied the criteria in Section 18975(b).</p> <p>...</p> <p>(d)A <u>written</u> request for a hearing to contest the proposed actions shall be submitted to the department within thirty (30) days of receipt of the accusation. The hearing request shall be in writing and shall state the basis for objecting to the department's action. Upon a failure to submit a timely hearing request under this subdivision, the respondent shall be deemed to have waived its right to hearing and the department shall issue a penalty order to the respondent requiring payment of penalties at the levels described in the accusation.</p> <p>(e)The hearing shall be held before the Director of the Department of Resources Recycling and Recovery. A party shall be afforded the opportunity to present evidence and testimony on all relevant issues. Any relevant evidence shall be admitted if it is the sort of evidence on which responsible persons are accustomed to rely in the conduct of serious affairs, regardless of the existence of any common law or statutory rule which might make improper the admission of the evidence over objection in civil actions. <u>If a hearing is requested pursuant to subdivision (d), the hearing shall be held in accordance with the provisions governing adjudicative proceedings in Government Code Title 2, Division 3, Part 1, Chapter 4.5 (Section 11400 et seq.).</u></p> <p>(f)The Director of the Department of Resources Recycling and Recovery shall issue a written decision within sixty (60) days from the date the hearing is concluded.</p>	
026-002	PPSWG	Anne Vogel-Marr	General	N	Our understanding is that MED-Project USA is submitting comments on the Revised Proposed Regulations addressing the Revised Proposed Regulations' definitions, stewardship plan requirements, annual reporting and budgets, and administrative procedures. PPSWG supports the comments submitted by MED-Project USA.	026-002. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. CalRecycle acknowledges PPSWG's support for comments submitted by Med-Project USA. Please see 028-001 through 028-039 for CalRecycle's responses to Med-Project USA's comments.
027-001	LAC Task Force	Margaret Clark	18972.1(a)(11)	Y	In statute 42032.2(d)(1)(F)(i) it clearly states:	027-001. CalRecycle agrees to remove the "or is not reasonably feasible" clause. CalRecycle believes that the options (with the phrase

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					<p>(i)The program provides or initiates distribution of a sharps waste container and mail-back materials at the point of sale, to the extent allowable by law. We respectfully request the removal of the language “or is not reasonably feasible”.</p> <p>Second Draft Regulations: (C)Other methods of providing a sharps waste container and mail-back materials, if the method identified in subpart (A) above is not allowed by law or is not reasonably feasible, and if the method identified in subpart (B) above is not allowed by law or is not reasonably feasible. These methods must be approved by the department in a stewardship plan and result in substantially the same level of convenience to the ultimate user as the methods identified in subparts (A) and (B) above.</p> <p>There is no allowance in the statute for this primary convenience standard requirement to be compromised except for being limited by “to the extent allowable by law”. This convenience standard is of primary importance because the success of Extended Producer Responsibility (EPR) programs are greatly determined by convenience for end users. The inclusion of the language “or is not feasible” allows the stewardship organization an off-ramp that is not allowed by law and was specifically not included in the law. SB 212 was largely a negotiated compromise between industry and stakeholders and while industry insisted on a mail-back program only, stakeholders insisted on certain convenience standard provisions to ensure the success of the program.</p>	removed) under the proposed regulations text definition in section 18972.1(a)(10) offer the program operator sufficient flexibility while maintaining convenience for the ultimate user.
027-002a	LAC Task Force	Margaret Clark	18973.2(j)	N	The changes to the Education and Outreach sections for pharmaceuticals and sharps enhances educational and outreach in provisions of materials, signage, labeling, extensive internet and toll-free telephone number functionality, key metrics for evaluation, and coordination. These additions add comprehension and clarification of these provisions and will help to optimize awareness, increase user participation, and contribute to their success.	027-002a. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. CalRecycle acknowledges the commenter’s support of the proposed outreach and education sections of the regulations.
027-002b	LAC Task Force	Margaret Clark	18973.3(i)	N	The changes to the Education and Outreach sections for pharmaceuticals and sharps enhances educational and outreach in provisions of materials, signage, labeling, extensive internet and toll-free telephone number functionality, key metrics for evaluation, and coordination. These additions add comprehension and clarification of these provisions and will help to optimize awareness, increase user participation, and contribute to their success.	027-002b. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. CalRecycle acknowledges the commenter’s support of the proposed outreach and education sections of the regulations.
027-003	LAC Task Force	Margaret Clark	18975, 18975.1, 18975.2	N	Section 18975, 18975.1, and 18975.2 Enforcement. These sections pertain to the Criteria to Impose an Administrative Civil Penalty, Procedure for Imposing Administrative Civil Penalties, and the Procedure for Stewardship Plan Revocation, Resubmittal, or Additional Compliance Reporting. These provisions authorize CalRecycle to exercise sufficient corrective actions to achieve the success of the SB 212’s EPR programs. The importance of the pharmaceutical and sharps management at end of	027-003. A change to the proposed regulatory text is not necessary. The department will assess penalties based on the requirements and criteria in the authorizing statute and its implementing regulations (see proposed regulatory text, sections 18975, 18975.1, and 18975.2).

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					life and the extensive stakeholder support for the development and implementation of these programs warrant that any failure to comply ought to be handled with sufficient penalties to ensure reasonable actions for success.	
028-001	MED-Project USA	Michael R. Van Winkle	18972.1(a)(10)	N	<p>Section 18972.1(a)(10): MED-Project suggests further clarifying the term “Online Marketplace” and the Department’s use of the term “Covered Product” in the definition of “Point of Sale.”</p> <p><u>1. The Department should clarify the term “Online Marketplace.”</u></p> <p>MED-Project's February 17, 2020 public comments identified several issues regarding online sales under the version of the regulations released for public comment on January 3, 2020 (the “Jan. 2020 Proposal”). Although some of those issues still remain, MED-Project supports the Department’s “Point of Sale” definition in the Revised Proposed Regulations, which addresses online sales as sales occurring through an “online marketplace,” as compared to the broader Point of Sale definition referring to “online sales” in the Jan. 2020 Proposal.</p>	028-001. CalRecycle acknowledges the commenter’s support for the definition of “point of sale” in the Second Draft Proposed Regulations; however, CalRecycle declines to further clarify “online marketplace” and instead is replacing that term with “online retailer.” CalRecycle does not seek to restrict the scope of online sharps sales covered by SB 212 to solely those that occur in a “marketplace;” it is the responsibility of covered entities to understand their distribution networks and work with retailers (online or otherwise) so that sharps waste containers and mail-back materials can be distributed no matter where the sharps are sold.
028-002	MED-Project USA	Michael R. Van Winkle	18972.1(a)(10)	N	<p>Section 18972.1(a)(10): MED-Project suggests further clarifying the term “Online Marketplace” and the Department’s use of the term “Covered Product” in the definition of “Point of Sale.”</p> <p>See Revised Proposed Regulations § 18972.1(a)(10) (“Point of sale’ means the point in time at which an ultimate user purchases a covered product at a pharmacy, other retailer, or online marketplace.”); Jan. 2020 Proposal § 18972.1(i). By establishing parameters for the scope of online activity subject to SB 212, this definition will better allow Program Operators to identify when they must “provide[] or initiate[] distribution of a sharps waste container and mail-back materials” See Cal. Pub. Res. Code (“PRC”) § 42032.2(d)(1)(F)(i). That was not possible under the Jan. 2020 Proposal, which defined Point of Sale so broadly that it included online sharps sales to an “Ultimate User” (as defined in PRC § 42030(z)) through any website worldwide. See Jan. 2020 Proposal § 18972.1(i).</p>	028-002. CalRecycle does not seek to restrict the scope of online sharps sales covered by SB 212 to solely those that occur in a “marketplace.” CalRecycle declines to “establish parameters for the scope of online activity subject to SB 212.” It is the responsibility of covered entities to understand their distribution networks and work with retailers (online or otherwise) so that sharps waste containers and mail-back materials can be distributed no matter where the sharps are sold.
028-003	MED-Project USA	Michael R. Van Winkle	18972.1(a)(10)	Y	In supporting the Department’s Point of Sale definition, MED-Project suggests that the Department further clarify the term “online marketplace” to better identify when sharps waste containers or mail-back materials must be provided. Without this clarification, the Department, Program Operators, “Covered Entities” (as defined in PRC § 42030(f)), and the public may have different expectations regarding what the Revised Proposed Regulations cover.	028-003. CalRecycle declines to clarify “online marketplace,” and is replacing the term with “online retailer” in the definition of “point of sale” as to not limit the scope of online sales. Section 42032.2(d)(1)(F)(i) of the Public Resources Code requires the program operator to “provide or initiate distribution of a sharps waste container and mail-back materials at the point of sale, to the extent allowable by law.” Statute does not exempt any particular online sales from this requirement. Thus, it is the responsibility of covered entities to understand their distribution networks and work with retailers (online or otherwise) so that sharps waste containers and mail-back materials can be distributed no matter where the sharps are sold.
028-004	MED-Project USA	Michael R. Van Winkle	18972.1(a)(10)	Y	The Department should make this clarification by: Cross-referencing the California Department of Tax and Fee Administration’s definition of “marketplace.” See 18 CCR § 1684.5(a)(9) (“Marketplace’ means a physical or electronic place, including, but not limited to, a store, booth,	028-004. CalRecycle declines to clarify “online marketplace,” and is replacing the term with “online retailer” in the definition of “point of sale” as to not limit the scope of online sales. Section 42032.2(d)(1)(F)(i) of the Public Resources Code requires the program

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					internet website, catalog, television or radio broadcast, or a dedicated sales software application, where a marketplace seller sells or offers for sale tangible personal property for delivery in this state regardless of whether the tangible personal property, marketplace seller, or marketplace has a physical presence in this state.”). Adding this cross reference to the definition of Point of Sale will remove ambiguity regarding the meaning of an online marketplace in a manner consistent with existing California regulations.	operator to “provide or initiate distribution of a sharps waste container and mail-back materials at the point of sale, to the extent allowable by law.” Statute does not exempt any particular online sales from this requirement. Thus, it is the responsibility of covered entities to understand their distribution networks and work with retailers (online or otherwise) so that sharps waste containers and mail-back materials can be distributed no matter where the sharps are sold.
028-005	MED-Project USA	Michael R. Van Winkle	18973.3	N	<i>(continuation from comments 028-001 through 004)</i> The Department should make this clarification by: Requiring “Stewardship Plans” (as defined in PRC § 42030(x)) to identify each online marketplace that they will work with to provide sharps waste containers or mail-back materials at the Point of Sale. This requirement will allow the Department to confirm each “Stewardship Program” (as defined in PRC § 42030(y)) has identified and is working with the online marketplaces necessary to provide Ultimate Users sharps containers and mailback materials.	028-005. CalRecycle declines to require that a stewardship plan submitted to the department for approval contain the list of each online marketplace that the program will work with to distribute sharps containers and mail-back materials. It is the responsibility of covered entities to understand their distribution networks and work with retailers (online or otherwise) so that sharps waste containers and mail-back materials can be distributed no matter where the sharps are sold. Requiring a list of online marketplaces upfront in the stewardship plan could undermine convenience for the ultimate user in situations where the department later discovers online sales not covered by the stewardship plan, or if new sources of online sales come into existence after stewardship plan approval.
028-006	MED-Project USA	Michael R. Van Winkle	18972.1(a)(10)	N	These minor additions to the Revised Proposed Regulations would provide greater clarity for the Department, Program Operators, Covered Entities, and the public, while allowing the Department to ensure Ultimate Users have access to the services SB 212 and the Revised Proposed Regulations require. As revised with respect to this issue (see below for an additional comment), the Point of Sale definition would read: “Point of sale’ means the point in time at which an ultimate user purchases a covered product at a pharmacy, <u>or</u> other retailer, or online “marketplace” <u>as defined in 18 CCR § 1684.5(a)(9) and identified in a program operator’s stewardship plan.</u>	028-006. CalRecycle disagrees that the proposed change would ensure ultimate users have access to sharps waste containers and mail-back materials. Section 42032.2(d)(1)(F)(i) of the Public Resources Code requires the program operator to “provide or initiate distribution of a sharps waste container and mail-back materials at the point of sale, to the extent allowable by law.” Statute does not exempt any particular online sales from this requirement. Regardless of whether the proposed change would provide more certainty to program operators and covered entities, it is the responsibility of covered entities to understand their distribution networks and work with retailers (online or otherwise) so that sharps waste containers and mail-back materials can be distributed no matter where the sharps are sold.
028-007	MED-Project USA	Michael R. Van Winkle	18972.1(a)(10)	Y	<u>2. The Department should clarify the use of the term “Covered Product” in the Point of Sale definition.</u> Under SB 212, Stewardship Programs must meet the following requirement: The program provides or initiates distribution of a sharps waste container and mail-back materials at the point of sale, to the extent allowable by law. Containers and mail-back materials shall be provided at no cost to the ultimate user. The program operator shall select and distribute a container and mail-back materials sufficient to accommodate the volume of sharps purchased by an ultimate user over a selected time period.	028-007. CalRecycle agrees with the commenter that the phrase “purchases a covered product” is unclear, and proposes replacing “covered product” with “covered drug or sharp” in the proposed definition for “point of sale.”

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					<p>PRC § 42032.2(d)(1)(F)(i). The Revised Proposed Regulations similarly state that a Stewardship Plan for home-generated sharps waste must, among other things, describe how “stewardship plan implementation ... provides or initiates distribution of sharps waste containers and mail-back materials ... at no cost to ultimate users at the point of sale.” Revised Proposed Regulations § 18973.3(f)(2).</p> <p>The Revised Proposed Regulations would define the term Point of Sale to mean “the point in time at which an ultimate user purchases a covered product at a pharmacy, other retailer, or online marketplace.” Revised Proposed Regulations § 18972.1(a)(10). “Covered Product” is defined in PRC § 42030(g) as a covered drug or home-generated sharps waste and, therefore, it is unclear why the Department used the phrase “purchases a covered product” in defining Point of Sale. MED-Project seeks clarification on CalRecycle’s intent in adding the phrase “purchases a covered product” in the definition of Point of Sale.</p>	
028-008	MED-Project USA	Michael R. Van Winkle	18972.1(a)(11)	Y	<p>Section 18972.1(a)(11): The definition of “Provides or Initiates Distribution of a Sharps Waste Container” should provide for sharps waste container and mail-back materials to arrive within five business days.</p> <p>MED-Project appreciates the Department recognizing that arranging at the Point of Sale for a sharps waste container or mail-back materials to arrive within three business days is impracticable. See Revised Proposed Regulations § 18972.1(a)(11) (requiring such materials to arrive within four business days). However, MED-Project continues to propose that the Department define “Provides or Initiates Distribution of a Sharps Waste Container” as providing for these materials to arrive within five business days. See id. As explained in MED-Project’s February 17, 2020 comments, Program Operators cannot guarantee common carrier delivery dates. In light of this reality, the Department should revise the Revised Proposed Regulations to require that Program Operators ship sharps waste containers and mail-back materials to arrive within five business days. This revision requires Program Operators to provide sharps waste containers and mail-back materials promptly, but decouples common carrier reliability from Program Operator compliance. Accordingly, Revised Proposed Regulations § 18972.1(a)(11) should require Program Operators: “[t]o arrange, at the point of sale or prior, for a sharps waste container and mail-back materials to be sent to the ultimate user and <u>shipped to arrive within three five business days at no cost or inconvenience to the ultimate user</u>”</p>	028-008. CalRecycle acknowledges the commenter’s concern regarding common carrier delivery dates, and agrees to extend the deadline for an ultimate user to receive a sharps waste container and mail-back materials to five business days. However, the department declines to incorporate the phrase “shipped to arrive,” because this phrase would add ambiguity as to whether the ultimate user must receive the sharps waste container and mail-back materials within five business days (which is the intended meaning), or whether the program operator only has to “ship” the sharps waste container and mail-back materials within five business days (which is substantially less convenient for the ultimate user).
028-009	MED-Project USA	Michael R. Van Winkle	18972.1(a)(13)	Y	<p>Section 18972.1(a)(13): The definition of “Significant Change” should not include “service providers,” ambiguous language, or subjective standards.</p>	028-009. The definition of “significant change” has been removed in the proposed regulatory text. Please note that section 18973.1(i), which discusses the term “significant change”, has been modified to align with the language in the authorizing statute. CalRecycle disagrees with the commenter that changes of service providers are

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					<p>Program Operators need the flexibility to adapt their Stewardship Programs as markets for “Covered Drug” (as defined in PRC § 42030(e)) and “Home-Generated Sharps Waste” (as defined in PRC § 42030(l)) take-back services mature, legal requirements evolve, and Program Operators and the Department become more experienced in best serving Ultimate Users. At the same time, the Department’s change management processes must ensure that it has notice of proposed changes that affect Stewardship Program compliance with SB 212. While the Jan. 2020 Proposal carefully balanced the needs for flexibility and oversight, the Revised Proposed Regulations upset this balance and introduce ambiguity by defining “Significant Change” to include:</p> <p>[A] change that is not consistent with an approved stewardship plan that the department determines has a material impact on the operation of a stewardship program, including, but not limited to: . . . Any changes of the service providers or facility(ies) used to transport, handle, or dispose of covered drugs or home-generated sharps waste collected through the stewardship program.</p> <p>Revised Proposed Regulations § 18972.1(a)(13). To promote effective Stewardship Program operations and Department oversight, the Department should return to the Jan. 2020 Proposal’s definition of Significant Change. See Jan. 2020 Proposal § 18972.1(k). Requiring prior Department approval for changes to service providers will be burdensome and, in some cases, infeasible for the Program Operator and Department. Stewardship Program transporters change with some frequency given the many transportation networks these programs involve (e.g., transport from a reverse distributor’s location to Disposal Facility X, Disposal Facility Y, etc.). Program Operators seeking, and the Department reviewing and approving, each of these changes will frustrate efforts to provide the most effective services. In addition to constraining Program Operator flexibility to provide the best collection services possible, this paperwork exercise will distract from more critical Program Operator and Department functions, especially given that the Department does not have jurisdiction over how Stewardship Programs transport or dispose of waste out of state. See <i>Daniels Sharpsmart, Inc. v. Smith</i>, 889 F.3d 608 (9th Cir. 2018) (upholding an injunction prohibiting California from applying the California Medical Waste Management Act to disposal activities occurring wholly outside California because California’s action likely violated the “dormant commerce clause” of the United States Constitution).</p>	<p>not, by definition, “significant changes.” This should be decided on a case-by-case basis.</p> <p>It is the program operator’s responsibility to notify CalRecycle regarding significant changes, as outlined in the authorizing statute and proposed regulations (see section 18973.1(i)).</p> <p>CalRecycle will work with program operators on a case-by-case basis to address significant changes to an approved stewardship plan. CalRecycle will determine, on a case-by-case basis, if the program operator has violated section 18973.1(i) of the proposed regulations and may take appropriate enforcement actions.</p> <p>With regard to the commenter’s assertion that “the department does not have jurisdiction over how Stewardship Programs transport or dispose of waste out of state”, it is the program operator’s responsibility to comply with all applicable federal and state laws and regulations when handling, transporting, and disposing of covered drugs and sharps. The issue is whether there is a significant change to a stewardship plan. The authorizing statute requires that CalRecycle review and approve significant changes before a program operator can implement them. If a significant change to a stewardship plan is made, the program operator must re-certify that the plan, containing the significant change, is compliant with all laws and regulations. If a determination of non-compliance is made by another federal or state agency, CalRecycle can take appropriate enforcement actions based on such a determination under the authorizing statute and its implementing regulations.</p>
028-010	MED-Project USA	Michael R. Van Winkle	18972.1(a)(13)	Y	<p>The Revised Proposed Regulations also introduce ambiguity into the definition of Significant Change by referring to “a change that is not consistent with an approved stewardship plan that the department determines has a material impact on the operation of a stewardship program” Revised Proposed Regulations § 18972.1(a)(13). What is “a change that is not consistent with an approved stewardship plan?” It appears to mean that some changes to a Stewardship Plan do not require</p>	<p>028-010. CalRecycle agrees with the commenter that the phrase “a change that is not consistent with an approved stewardship plan that the department determines has a material impact on the operation of a stewardship program” is overly ambiguous. However, rather than returning to the version of “significant change” present in the First Draft Proposed Regulations, CalRecycle prefers to delete the definition entirely and add language to section 18973.1(i) of the proposed</p>

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					Department approval because, even if they have a material impact on Stewardship Program operations or are enumerated in Revised Proposed Regulations § 18972.1(a)(13)(A)-(F), they are consistent with that Stewardship Plan. How Program Operators will determine which changes are consistent with their Stewardship Plans and which are not is unclear. The Jan. 2020 Proposal avoided these ambiguities.	regulatory text. The first sentence of this section comes directly from statute (Public Resources Code, Section 42032(e)). It is difficult to foresee exactly which changes would have a material impact on the stewardship program. Thus, it is more effective for the department to work with program operators on a case-by-case basis to address significant changes to an approved stewardship plan. CalRecycle will determine, on a case-by-case basis, if the program operator has violated section 18973.1(i) of the proposed regulations and may take appropriate enforcement actions.
028-011	MED-Project USA	Michael R. Van Winkle	18972.1(a)(13)	Y	Additionally, defining Significant Change as those the “department determines” have a material impact on Stewardship Program operations makes the definition subjective and unworkable. Under some interpretations of this requirement, the Department would have almost unfettered discretion to determine what changes are significant. That puts Program Operators in the difficult position of predicting how the Department will react to a specific change. The definition also creates a timing issue. A Program Operator must seek approval for a change “not consistent with an approved stewardship plan that the department determines has a material impact” on Stewardship Plan operations, but does not know whether a change is material until the Department determines it is – creating a “chicken or the egg” problem regarding whether Department approval is required. See Revised Proposed Regulations § 18972.1(a)(13). To address these issues and provide Program Operators meaningful notice of what constitutes a Significant Change, the Department should provide an objective definition for Significant Change by returning to the Jan. 2020 Proposal’s definition of that term.	028-011. CalRecycle agrees that the current definition of “significant change” ambiguous. However, rather than returning to the version of “significant change” present in the First Draft Proposed Regulations, CalRecycle prefers to delete the definition entirely and add language to section 18973.1(i) of the proposed regulatory text. The first sentence of this section comes directly from statute (Public Resources Code, Section 42032(e)). It is difficult to foresee exactly which changes would have a material impact on the stewardship program. Thus, it is more effective for the department to work with program operators on a case-by-case basis to address significant changes to an approved stewardship plan.
028-012	MED-Project USA	Michael R. Van Winkle	18973.2(d)(5)	Y	<p>Section 18973.2(d)(5): The Revised Proposed Regulations should require Program Operators to inform potential Authorized Collectors rejected from Stewardship Program participation why they were rejected and how they can again offer to participate, rather than provide for appeals.</p> <p>Because the Revised Proposed Regulations would require Stewardship Plans to describe the reasons they exclude any potential “Authorized Collectors” (as defined in PRC § 42030(b)) from the Stewardship Program, and annual reports must identify rejected potential Authorized Collectors and the reasons for each rejection, Program Operators will only reject potential Authorized Collectors for reasons approved by the Department. See Revised Proposed Regulations §§ 18973.2(d)(4), 18973.4(c)(2)(E). Such reasons could include suspension of a pharmacy license, unwillingness to place a collection receptacle in compliance with United States Drug Enforcement Administration requirements, etc. Program Operators are not governmental entities with independent oversight bodies to which potential Authorized Collectors can appeal a rejection of their offer to participate in a Stewardship Program. Once a</p>	<p>028-012. CalRecycle agrees that an appeals process for potential authorized collectors who were rejected from joining the stewardship program may not be an appropriate procedure. However, instead of the specific phrasing in the commenter’s proposed change, the department proposes the following edits to section 18973.2(d)(5) of the Second Draft Proposed Regulatory Text:</p> <p>(57) Description of the process how the program operator will notify any potential authorized collectors can utilize to appeal a rejection, by the program operator, for of the reasons they were rejected from inclusion in the stewardship program and what changes the potential authorized collector can make in order to join the stewardship program.</p> <p>CalRecycle prefers including “what changes the potential authorized collector can make in order to join the stewardship program” instead of “how they can offer to participate in the future” in order to ensure that the program operator will comply with sections 42032.2(b)(1) and (b)(3) of the Public Resources Code. Section 42032.2(b)(1) requires the program operator to commence good faith negotiations with the</p>

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					<p>Program Operator has rejected a potential Authorized Collector for a Department-approved reason, an appeal by that potential Authorized Collector will not change the Program Operator’s decision, and SB 212 never contemplates such appeals.</p> <p>Instead of requiring Stewardship Plans to describe how potential Authorized Collectors can appeal to a Program Operator that has already decided to reject them, the Proposed Regulations should require Program Operators to inform potential Authorized Collectors why they were rejected from Stewardship Program participation and how they can again offer to participate. This revised requirement would allow the potential Authorized Collectors to address the reasons they were rejected and give them a path towards Stewardship Program participation, rather than a fruitless appeal. For these reasons the Revised Proposed Regulations should be amended to read: “Description of <u>how the program operator will notify any the process potential authorized collectors of the reasons they were rejected from can utilize to appeal a rejection, by the program operator, for inclusion in the stewardship program and how they can offer to participate in the future.</u>”</p>	<p>potential authorized collector within 30 days if that potential authorized collector expressed interest in participating in the stewardship program. Moreover, section 42032.2(b)(3) requires the program operator to include any potential authorized collector that offers to participate in the stewardship program, in writing and without compensation, regardless of whether the convenience standards outlined in section 42032.2(a)(1)(F)(i) of the Public Resources Code have been met. While there may be legitimate reasons for rejecting an offer (such as compliance issues with other laws and regulations), CalRecycle emphasizes that a potential authorized collector that meets all the requirements must be able to “join the stewardship program,” not just “offer to participate in the future.”</p>
028-013a	MED-Project USA	Michael R. Van Winkle	18973.2(e)(2), 18973.3(d)(2)	Y	<p>Sections 18973.2(e)(2), 18973.3(d)(2): The Department should clarify the requirement for Covered Drug and Home-Generated Sharps Waste Stewardship Plan certifications.</p> <p>The Revised Proposed Regulations introduce a brand new requirement for Stewardship Plans to provide: Written certification, by an authorized representative of the program operator, that: the <i>stewardship plan</i>, including the collection, transportation, and disposal of covered drugs, <i>is in compliance with</i> all applicable local, state, and federal laws and regulations, including, but not limited to United States Drug Enforcement Administration regulations.</p> <p>Revised Proposed Regulations §§ 18973.2(e)(2) (emphasis added), 18973.3(d)(2) (analogous requirement for home-generated sharps waste). Certification requirements like these must be crystal clear so that Program Operators know what they are certifying and for what they may be held responsible. The Department should revise these certification requirements to remove ambiguity regarding their applicability and scope. Currently, these certification requirements do not specify whether they apply as of the date the certification is made or, alternatively, act as a continuing certification for some undefined period. The Department should clarify that these certifications apply only as of the date the Program Operator submits the Stewardship Plan for Department approval. While MED-Project puts in place many mechanisms to operate and maintain compliant Stewardship Programs, it cannot certify as to those programs’ future compliance status. The Department should amend</p>	<p>028-013a. CalRecycle agrees that the timeframe applicable to the certification statement is ambiguous, and proposes the following edits to sections 18973.2(e)(2) and 18973.3(d)(2) of the Second Draft Proposed Regulatory Text:</p> <p><u>(2) Written certification, by an authorized representative of the program operator, that, at the time of submission to the department, the stewardship plan, including all aspects of the plan related to the collection, transportation, and disposal of covered drugs, is in compliance with all applicable local, state, and federal laws and regulations, including, but not limited to United States Drug Enforcement Administration regulations.</u></p> <p><u>(2) Written certification, by an authorized representative of the program operator, that, at the time of submission to the department, the stewardship plan, including all aspects of the plan related to the handling, transportation, and disposal of home-generated sharps waste is in compliance with all applicable local, state, and federal laws and regulations.</u></p> <p>These edits clarify that the certification statements are meant to apply as of the date of stewardship plan submittal.</p> <p>The program operator has an ongoing responsibility to ensure compliance because all handling, transport, and disposal undertaken as part of the stewardship program “shall comply with applicable state and federal laws, including, but not limited to, regulations adopted by</p>

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					the Revised Proposed Regulations to avoid any suggestion that the certifications are made on a continuing basis.	the United States Drug Enforcement Administration” (see Section 42035.8 of the Public Resources Code).
028-013b	MED-Project USA	Michael R. Van Winkle	18973.2(e)(2), 18973.3(d)(2)	Y	<p>Sections 18973.2(e)(2), 18973.3(d)(2): The Department should clarify the requirement for Covered Drug and Home-Generated Sharps Waste Stewardship Plan certifications.</p> <p>The Revised Proposed Regulations introduce a brand new requirement for Stewardship Plans to provide: Written certification, by an authorized representative of the program operator, that: the <i>stewardship plan</i>, including the collection, transportation, and disposal of covered drugs, <i>is in compliance with</i> all applicable local, state, and federal laws and regulations, including, but not limited to United States Drug Enforcement Administration regulations.</p> <p>Revised Proposed Regulations §§ 18973.2(e)(2) (emphasis added), 18973.3(d)(2) (analogous requirement for home-generated sharps waste). Certification requirements like these must be crystal clear so that Program Operators know what they are certifying and for what they may be held responsible. The Department should revise these certification requirements to remove ambiguity regarding their applicability and scope. Currently, these certification requirements do not specify whether they apply as of the date the certification is made or, alternatively, act as a continuing certification for some undefined period. The Department should clarify that these certifications apply only as of the date the Program Operator submits the Stewardship Plan for Department approval. While MED-Project puts in place many mechanisms to operate and maintain compliant Stewardship Programs, it cannot certify as to those programs’ future compliance status. The Department should amend the Revised Proposed Regulations to avoid any suggestion that the certifications are made on a continuing basis.</p>	<p>028-013b. CalRecycle agrees that the timeframe applicable to the certification statement is ambiguous, and proposes the following edits to sections 18973.2(e)(2) and 18973.3(d)(2) of the Second Draft Proposed Regulatory Text:</p> <p><u>(2) Written certification, by an authorized representative of the program operator, that, at the time of submission to the department, the stewardship plan, including all aspects of the plan related to the collection, transportation, and disposal of covered drugs, is in compliance with all applicable local, state, and federal laws and regulations, including, but not limited to United States Drug Enforcement Administration regulations.</u></p> <p><u>(2) Written certification, by an authorized representative of the program operator, that, at the time of submission to the department, the stewardship plan, including all aspects of the plan related to the handling, transportation, and disposal of home-generated sharps waste is in compliance with all applicable local, state, and federal laws and regulations.</u></p> <p>These edits clarify that the certification statements are meant to apply as of the date of stewardship plan submittal.</p> <p>The program operator has an ongoing responsibility to ensure compliance because all handling, transport, and disposal undertaken as part of the stewardship program “shall comply with applicable state and federal laws, including, but not limited to, regulations adopted by the United States Drug Enforcement Administration” (see Section 42035.8 of the Public Resources Code).</p>
028-014a	MED-Project USA	Michael R. Van Winkle	18973.2(e)(2), 18973.3(d)(2)	Y	<p>Furthermore, the Department should clarify the scope of these certifications. As drafted, the Revised Proposed Regulations are unclear regarding whether these certifications cover the Stewardship Plan itself or also the many participating Authorized Collectors, service providers, disposal facilities, etc. Because the certifications refer to the “stewardship plan” being “in compliance with all applicable local, state, and federal laws and regulations,” it appears that these certifications apply only to the Stewardship Plan itself; i.e., implementing the Stewardship Plan’s text would provide for a Stewardship Program compliant with all applicable laws, regulations, and other legal requirements.</p> <p>An interpretation of the Revised Proposed Regulations that the Program Operator is making a certification with regard to the compliance status of each participating Authorized Collector, service provider, disposal facility, etc. would require Program Operators to make certifications for parties</p>	<p>028-014a. CalRecycle agrees that the scope of the certification statements is ambiguous, and proposes the following edits to sections 18973.2(e)(2) and 18973.3(d)(2) of the Second Draft Proposed Regulatory Text:</p> <p><u>(2) Written certification, by an authorized representative of the program operator, that, at the time of submission to the department, the stewardship plan, including all aspects of the plan related to the collection, transportation, and disposal of covered drugs, is in compliance with all applicable local, state, and federal laws and regulations, including, but not limited to United States Drug Enforcement Administration regulations.</u></p> <p><u>(2) Written certification, by an authorized representative of the program operator, that, at the time of submission to the department, the stewardship plan, including all aspects of the plan related to the</u></p>

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					<p>and actions beyond Program Operators' knowledge and control. Program Operators can require by contract that all participating Authorized Collectors, service providers, disposal facilities, etc. comply with all applicable laws, regulations, and other legal requirements, but they cannot control these independent entities' compliance statuses, do not have real time knowledge thereof, and cannot make certifications on their behalves. Additionally, as a Stewardship Program includes hundreds of participating entities, requiring Program Operators to certify as to each participating Authorized Collectors', service providers', and disposal facilities' compliance status would be a tremendous undertaking requiring months of work, something never contemplated in SB 212. See PRC §§ 42032, 42032.2.</p>	<p><u>handling, transportation, and disposal of home-generated sharps waste is in compliance with all applicable local, state, and federal laws and regulations.</u></p> <p>The phrase "All aspects of the plan related to" was added to the regulatory text to emphasize that the program operator is required, pursuant to Section 42032.2(a)(1)(E) of the Public Resources Code, to "provide for a handling, transport, and disposal system that complies with applicable state and federal laws, including but not limited to, regulations by the United States Drug Enforcement Administration." If compliance means ensuring that all of the entities that a program operator contracts with are also compliant, it is the program operator's responsibility to do so.</p> <p>Moreover the program operator has an ongoing responsibility to ensure compliance because all handling, transport, and disposal undertaken as part of the stewardship program "shall comply with applicable state and federal laws, including, but not limited to, regulations adopted by the United States Drug Enforcement Administration" (see Section 42035.8 of the Public Resources Code).</p> <p>Statute requires CalRecycle to approve stewardship plans and ensure compliance with all applicable laws and regulations (Public Resources Code sections 42032.2(a)(1)(E), 42032.2(d)(1)(D), and 42035.8). But, CalRecycle cannot make determinations of compliance regarding regulations that are outside of CalRecycle's authority. Therefore, in order to implement the Statute and approve stewardship plans, CalRecycle must rely on either a supporting response from an applicable state agency or certification of compliance by the program operator. It is the program operator's responsibility, pursuant to Public Resources Code sections 42032.2(a)(1)(E), 42032.2(d)(1)(D) and 42035.8, to maintain compliance with all applicable local, state, and federal laws and regulations.</p>
028-014b	MED-Project USA	Michael R. Van Winkle	18973.2(e)(2), 18973.3(d)(2)	Y	<p>Furthermore, the Department should clarify the scope of these certifications. As drafted, the Revised Proposed Regulations are unclear regarding whether these certifications cover the Stewardship Plan itself or also the many participating Authorized Collectors, service providers, disposal facilities, etc. Because the certifications refer to the "stewardship plan" being "in compliance with all applicable local, state, and federal laws and regulations," it appears that these certifications apply only to the Stewardship Plan itself; i.e., implementing the Stewardship Plan's text would provide for a Stewardship Program compliant with all applicable laws, regulations, and other legal requirements.</p> <p>An interpretation of the Revised Proposed Regulations that the Program Operator is making a certification with regard to the compliance status of each participating Authorized Collector, service provider, disposal facility,</p>	<p>028-014b. CalRecycle agrees that the scope of the certification statements is ambiguous, and proposes the following edits to sections 18973.2(e)(2) and 18973.3(d)(2) of the Second Draft Proposed Regulatory Text:</p> <p><u>(2) Written certification, by an authorized representative of the program operator, that, at the time of submission to the department, the stewardship plan, including all aspects of the plan related to the collection, transportation, and disposal of covered drugs, is in compliance with all applicable local, state, and federal laws and regulations, including, but not limited to United States Drug Enforcement Administration regulations.</u></p>

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					<p>etc. would require Program Operators to make certifications for parties and actions beyond Program Operators' knowledge and control. Program Operators can require by contract that all participating Authorized Collectors, service providers, disposal facilities, etc. comply with all applicable laws, regulations, and other legal requirements, but they cannot control these independent entities' compliance statuses, do not have real time knowledge thereof, and cannot make certifications on their behalves. Additionally, as a Stewardship Program includes hundreds of participating entities, requiring Program Operators to certify as to each participating Authorized Collectors', service providers', and disposal facilities' compliance status would be a tremendous undertaking requiring months of work, something never contemplated in SB 212. See PRC §§ 42032, 42032.2.</p>	<p><u>(2) Written certification, by an authorized representative of the program operator, that, at the time of submission to the department, the stewardship plan, including all aspects of the plan related to the handling, transportation, and disposal of home-generated sharps waste is in compliance with all applicable local, state, and federal laws and regulations.</u></p> <p>The phrase "All aspects of the plan related to" was added to the regulatory text to emphasize that the program operator is required, pursuant to Section 42032.2(d)(1)(D) of the Public Resources Code, to "Provide for a handling, transport, and disposal system, at no cost to the ultimate user, that complies with applicable state and federal laws." If compliance means ensuring that all of the entities that a program operator contracts with are also compliant, it is the program operator's responsibility to do so.</p> <p>Moreover the program operator has an ongoing responsibility to ensure compliance because all handling, transport, and disposal undertaken as part of the stewardship program "shall comply with applicable state and federal laws, including, but not limited to, regulations adopted by the United States Drug Enforcement Administration" (see Section 42035.8 of the Public Resources Code).</p> <p>Statute requires CalRecycle to approve stewardship plans and ensure compliance with all applicable laws and regulations (Public Resources Code sections 42032.2(a)(1)(E), 42032.2(d)(1)(D), and 42035.8). But, CalRecycle cannot make determinations of compliance regarding regulations that are outside of CalRecycle's authority. Therefore, in order to implement the Statute and approve stewardship plans, CalRecycle must rely on either a supporting response from an applicable state agency or certification of compliance by the program operator. It is the program operator's responsibility, pursuant to Public Resources Code sections 42032.2(a)(1)(E), 42032.2(d)(1)(D) and 42035.8, to maintain compliance with all applicable local, state, and federal laws and regulations.</p>
028-015a	MED-Project USA	Michael R. Van Winkle	18973.2(e)(2)	Y	<p>For the reasons described above, the Department should clarify the applicability and scope of Revised Proposed Regulations §§ 18973.2(e)(2) through the following revisions:</p> <p>Section 18973.2(e)(2): Written certification, by an authorized representative of the program operator <u>and made as of the date of Stewardship Plan submission pursuant to PRC § 42032(a)(1), that:</u> the stewardship plan, including the collection, transportation, and disposal of covered drugs, is in compliance with all applicable local, state, and federal laws and regulations, including, but not limited to United States Drug Enforcement Administration regulations.</p>	<p>028-015a. CalRecycle prefers the following edit to section 18973.2(e)(2) of the Second Draft Proposed Regulatory Text, as discussed in the responses to comments 028-013 and 028-014:</p> <p><u>(2) Written certification, by an authorized representative of the program operator, that, at the time of submission to the department, the stewardship plan, including all aspects of the plan related to the collection, transportation, and disposal of covered drugs, is in compliance with all applicable local, state, and federal laws and regulations, including, but not limited to United States Drug Enforcement Administration regulations.</u></p>

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
						<p>The department's proposed edits differ from the commenter's proposed edits in two ways:</p> <ol style="list-style-type: none"> 1) Incorporating the reference to section 42032(a)(1) of the Public Resources Code would limit certification statements to only stewardship plan submittals that occur within six months of the date the regulations are adopted. CalRecycle does not seek to exclude other potential scenarios from this requirement, such as a stewardship plan resubmittal pursuant to section 42035.4(a) of the Public Resources Code. 2) CalRecycle declines to delete the phrase "including the collection, transportation, and disposal of covered drugs," because this is a statutory requirement (see Public Resources Code, Sections 42032.2(a)(1)(E) and 42035.8.
028-015b	MED-Project USA	Michael R. Van Winkle	18973.2(e)(2), 18973.3(d)(2)	Y	<p>For the reasons described above (<i>see comments 028-013 through -014</i>), the Department should clarify the applicability and scope of Revised Proposed Regulations §§ 18973.2(e)(2) and 18973.3(d)(2), respectively, through the following revisions:</p> <p>Section 18973.3(d)(2): Written certification, by an authorized representative of the program operator <u>and made as of the date of Stewardship Plan submission pursuant to PRC § 42032(a)(1), that:</u> the stewardship plan, including the handling, transportation, and disposal of home-generated sharps waste, is in compliance with all applicable local, state, and federal laws and regulations.</p>	<p>028-015b. CalRecycle prefers the following edit to section 18973.3(d)(2) of the Second Draft Proposed Regulatory Text, as discussed in the responses to comments 028-013 and 028-014:</p> <p><u>(2) Written certification, by an authorized representative of the program operator, that, at the time of submission to the department, the stewardship plan, including all aspects of the plan related to the handling, transportation, and disposal of home-generated sharps waste is in compliance with all applicable local, state, and federal laws and regulations.</u></p> <p>The department's proposed edits differ from the commenter's proposed edits in two ways:</p> <ol style="list-style-type: none"> 1) Incorporating the reference to section 42032(a)(1) of the Public Resources Code would limit certification statements to only stewardship plan submittals that occur within six months of the date the regulations are adopted. CalRecycle does not seek to exclude other potential scenarios from this requirement, such as a stewardship plan resubmittal pursuant to section 42035.4(a) of the Public Resources Code. 2) CalRecycle declines to delete the phrase "including the handling, transportation, and disposal of home-generated sharps waste," because this is a statutory requirement (see Public Resources Code, Sections 42032.2(d)(1)(D) and 42035.8
028-016a	MED-Project USA	Michael R. Van Winkle	18973.2(j)(2), 18973.3(i)(2)	N	<p>Sections 18973.2(j)(2), 18973.3(i)(2): The Revised Proposed Regulations should promote education and outreach to Ultimate Users without creating confusion regarding hospital waste streams.</p> <p>Hospitals have independent obligations to manage medical waste under the California Medical Waste Management Act. See Cal. Health & Safety Code § 117600 et seq. Consistent with these independent obligations, SB 212's definition of "Ultimate User" clearly excludes hospitals. See PRC §</p>	<p>028-016a. CalRecycle declines to delete the references to "hospitals" in sections 18973.2(j)(2) and 18973.3(i)(2) of the Second Draft Proposed Regulations. These sections are consistent with section 42036.1(a)(1) of the Public Resources Code, which requires a program operator to "promote its stewardship program to ultimate users by providing signage for hospitals, pharmacies, and other locations, as necessary." A hospital may be an effective setting for an ultimate user to learn about a stewardship program, as many ultimate users obtain</p>

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					<p>42030(z) (“Ultimate User’ does not include . . . a medical waste generator, as defined in Section 117705 of the Health and Safety Code.”); Cal. Health & Safety Code 117705 (defining “medical waste generator” to include “hospitals”). Despite this exclusion, however, SB 212 requires Program Operators to “[p]romote [their] stewardship program[s] to ultimate users by providing signage for hospitals . . . as necessary.” See PRC § 42031.6(a)(1). The Revised Proposed Regulations also require Stewardship Programs to describe how they will include “signage for hospitals . . . as necessary.” Revised Proposed Regulations §§ 18973.2(j)(2), 18973.3(i)(2).</p> <p>The Department should strike the reference to “hospitals” in Revised Proposed Regulations §§ 18973.2(j)(2) and 18973.3(i)(2). Providing Stewardship Program education and outreach in hospitals could confuse Ultimate Users being treated at the hospital, potentially causing them to mistakenly deposit medical waste in a Stewardship Program collection receptacle. Such departures from hospital procedures for managing medical waste could raise compliance and safety concerns. By excluding hospitals from the definition of Ultimate User, SB 212 helped keep Stewardship Program and hospital waste streams separate, consistent with existing California law. While the Department cannot change SB 212 requirements, it should not add requirements in the Revised Proposed Regulations that cause confusion regarding proper medical waste management in hospitals. Stewardship Program outreach should target Ultimate Users, but not in a hospital setting where there are existing procedures for managing medical waste.</p>	<p>prescriptions in hospitals and purchase covered drugs or sharps in hospital pharmacies. Effective messaging on education and outreach materials can help minimize any potential mixing of medical waste from hospitals with SB 212-related collection services.</p>
028-016b	MED-Project USA	Michael R. Van Winkle	18973.2(j)(2), 18973.3(i)(2)	N	<p>Sections 18973.2(j)(2), 18973.3(i)(2): The Revised Proposed Regulations should promote education and outreach to Ultimate Users without creating confusion regarding hospital waste streams.</p> <p>Hospitals have independent obligations to manage medical waste under the California Medical Waste Management Act. See Cal. Health & Safety Code § 117600 et seq. Consistent with these independent obligations, SB 212’s definition of “Ultimate User” clearly excludes hospitals. See PRC § 42030(z) (“Ultimate User’ does not include . . . a medical waste generator, as defined in Section 117705 of the Health and Safety Code.”); Cal. Health & Safety Code 117705 (defining “medical waste generator” to include “hospitals”). Despite this exclusion, however, SB 212 requires Program Operators to “[p]romote [their] stewardship program[s] to ultimate users by providing signage for hospitals . . . as necessary.” See PRC § 42031.6(a)(1). The Revised Proposed Regulations also require Stewardship Programs to describe how they will include “signage for hospitals . . . as necessary.” Revised Proposed Regulations §§ 18973.2(j)(2), 18973.3(i)(2).</p>	<p>028-016b. CalRecycle declines to delete the references to “hospitals” in sections 18973.2(j)(2) and 18973.3(i)(2) of the Second Draft Proposed Regulations. These sections are consistent with section 42036.1(a)(1) of the Public Resources Code, which requires a program operator to “promote its stewardship program to ultimate users by providing signage for hospitals, pharmacies, and other locations, as necessary.” A hospital may be an effective setting for an ultimate user to learn about a stewardship program, as many ultimate users obtain prescriptions in hospitals and purchase covered drugs or sharps in hospital pharmacies. Effective messaging on education and outreach materials can help minimize any potential mixing of medical waste from hospitals with SB 212-related collection services.</p>

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					The Department should strike the reference to “hospitals” in Revised Proposed Regulations §§ 18973.2(j)(2) and 18973.3(i)(2). Providing Stewardship Program education and outreach in hospitals could confuse Ultimate Users being treated at the hospital, potentially causing them to mistakenly deposit medical waste in a Stewardship Program collection receptacle. Such departures from hospital procedures for managing medical waste could raise compliance and safety concerns. By excluding hospitals from the definition of Ultimate User, SB 212 helped keep Stewardship Program and hospital waste streams separate, consistent with existing California law. While the Department cannot change SB 212 requirements, it should not add requirements in the Revised Proposed Regulations that cause confusion regarding proper medical waste management in hospitals. Stewardship Program outreach should target Ultimate Users, but not in a hospital setting where there are existing procedures for managing medical waste.	
028-017a	MED-Project USA	Michael R. Van Winkle	18973.2(j)(3), 18973.3(i)(3)	N	<p>Sections 18973.2(j)(3), 18973.3(i)(3): Clarification is needed regarding website accessibility language added by the Department.</p> <p>In the education and outreach provisions of the Revised Proposed Regulations at Sections 18973.2(j)(3) and 18973.3(i)(3), the Department has added language stating that the internet website established as part of a Stewardship Plan must have “digital content and navigability” that is “accessible to disabled individuals.” The terms “accessible” and “disabled individuals” do not have universally accepted meanings. Therefore, clarification is needed regarding the Department’s intent in this regard; e.g., adding a cross-reference to the accessibility standards that all Stewardship Plan websites should adhere to.</p>	028-017a. CalRecycle declines to incorporate specific accessibility standards into the proposed regulatory text. Instead, the current language provides program operators with the flexibility to design and incorporate accessibility provisions on program websites in a way that does not undermine the content available to all ultimate users.
028-017b	MED-Project USA	Michael R. Van Winkle	18973.2(j)(3), 18973.3(i)(3)	N	<p>Sections 18973.2(j)(3), 18973.3(i)(3): Clarification is needed regarding website accessibility language added by the Department.</p> <p>In the education and outreach provisions of the Revised Proposed Regulations at Sections 18973.2(j)(3) and 18973.3(i)(3), the Department has added language stating that the internet website established as part of a Stewardship Plan must have “digital content and navigability” that is “accessible to disabled individuals.” The terms “accessible” and “disabled individuals” do not have universally accepted meanings. Therefore, clarification is needed regarding the Department’s intent in this regard; e.g., adding a cross-reference to the accessibility standards that all Stewardship Plan websites should adhere to.</p>	028-017b. CalRecycle declines to incorporate specific accessibility standards into this section of the proposed regulatory text. Instead, the current language provides program operators with the flexibility to design and incorporate accessibility provisions on program websites in a way that does not undermine the content available to all ultimate users.
028-018a	MED-Project USA	Michael R. Van Winkle	18973.2(k), 18973.3(j)	Y	<p>Sections 18973.2(k), 18973.3(j): Program Operators must comply with applicable federal and state antitrust requirements.</p> <p>MED-Project supports the Revised Proposed Regulations removing language regarding Program Operators working with other Stewardship Programs to “most effectively” achieve statutory and regulatory goals, as that language could raise federal and state antitrust and related concerns</p>	028-018a. CalRecycle acknowledges the commenter’s concern regarding state and federal antitrust requirements in this particular context, and accepts the commenter’s proposed change as written.

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					<p>among Program Operators, which are industry competitors as it relates to Covered Entity participation. See Jan. 2020 Proposal §§ 18973.2(k), 18973.3(j). However, the Department should revise these sections to remove language requiring Stewardship Plans to describe how the Program Operator will coordinate with other Program Operators “to avoid conflict, duplication” Revised Proposed Regulations §§ 18973.2(k), 18973.3(j). Such coordination to avoid “conflict” or “duplication” could raise federal and state antitrust and related concerns among Program Operators, which are industry competitors. Program Operators can coordinate to avoid confusion to the public and all program participants, but, as competitors, Program Operators will necessarily have conflict as they compete to provide the most effective collection and disposal services. For example, Program Operators will compete for certain participating Covered Entities and potential Authorized Collectors, and with regard to “Local Agency” (as defined in Revised Proposed Regulations § 18972.1(a)(7)) requests. See Revised Proposed Regulations § 18973.3(g). They will almost certainly provide duplicative services as each Program Operator works to independently satisfy statutory and regulatory Stewardship Program requirements. Because of the antitrust and related concerns associated with asking Program Operators to avoid “conflict” or “duplication,” the Department should remove references to these terms from the Revised Proposed Regulations. The new language in Revised Proposed Regulations §§ 18973.2(k) and 18973.3(j) should read:</p> <p style="padding-left: 40px;">Coordination Efforts. Description of how the program operator will coordinate with other program operators to avoid conflict, duplication, and confusion to the public and all program participants in the event that multiple stewardship programs for [covered drugs or home-generated sharps waste] are in operation concurrently or new stewardship programs begin operating.</p>	
028-018b	MED-Project USA	Michael R. Van Winkle	18973.2(k), 18973.3(j)	Y	<p>Sections 18973.2(k), 18973.3(j): Program Operators must comply with applicable federal and state antitrust requirements.</p> <p>MED-Project supports the Revised Proposed Regulations removing language regarding Program Operators working with other Stewardship Programs to “most effectively” achieve statutory and regulatory goals, as that language could raise federal and state antitrust and related concerns among Program Operators, which are industry competitors as it relates to Covered Entity participation. See Jan. 2020 Proposal §§ 18973.2(k), 18973.3(j). However, the Department should revise these sections to remove language requiring Stewardship Plans to describe how the Program Operator will coordinate with other Program Operators “to avoid conflict, duplication” Revised Proposed Regulations §§ 18973.2(k), 18973.3(j). Such coordination to avoid “conflict” or “duplication” could raise federal and state antitrust and related concerns among Program Operators, which are industry competitors. Program Operators can coordinate to avoid confusion to the public and all program participants,</p>	028-018b. CalRecycle acknowledges the commenter’s concern regarding state and federal antitrust requirements in this particular context, and accepts the commenter’s proposed change as written.

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					<p>but, as competitors, Program Operators will necessarily have conflict as they compete to provide the most effective collection and disposal services. For example, Program Operators will compete for certain participating Covered Entities and potential Authorized Collectors, and with regard to “Local Agency” (as defined in Revised Proposed Regulations § 18972.1(a)(7)) requests. See Revised Proposed Regulations § 18973.3(g). They will almost certainly provide duplicative services as each Program Operator works to independently satisfy statutory and regulatory Stewardship Program requirements. Because of the antitrust and related concerns associated with asking Program Operators to avoid “conflict” or “duplication,” the Department should remove references to these terms from the Revised Proposed Regulations. The new language in Revised Proposed Regulations §§ 18973.2(k) and 18973.3(j) should read:</p> <p style="padding-left: 40px;">Coordination Efforts. Description of how the program operator will coordinate with other program operators to avoid conflict, duplication, and confusion to the public and all program participants in the event that multiple stewardship programs for [covered drugs or home-generated sharps waste] are in operation concurrently or new stewardship programs begin operating.</p>	
028-019	MED-Project USA	Michael R. Van Winkle	18973.3(g)(2)	N	<p>Section 18973.3(g)(2): CalRecycle should require local agencies to distribute requests equally among Program Operators and such requests should comply with SB 212 requirements.</p> <p>Revised Proposed Regulations § 18973.3(g) establishes a process for Local Agency requests for removal of certain Home-Generated Sharps Waste that seems to contemplate only a single Program Operator. Because each Program Operator has an independent obligation to resolve these Local Agency requests, the Revised Proposed Regulations should establish a system requiring Local Agencies to distribute these requests equally among Program Operators. See PRC § 42032.2(d)(1)((F)(ii); Revised Proposed Regulations § 18973.3(g). If not equally distributed, these Local Agency requests could create competitive imbalances among Program Operators as they compete for Covered Entities. Additionally, without equally distributed requests, Program Operators could be incentivized to drive Local Agency requests to other Program Operators through barriers to submitting requests. To avoid these competitive imbalances, inefficiencies, and the associated decline in service for Local Agencies (and, thus, Ultimate Users), the Department should require Local Agencies to request from each approved Program Operator the reimbursement or removal of an equal amount of Home-Generated Sharps Waste, measured as reported in Revised Proposed Regulations § 18973.5(p)(2)(C), to the extent practicable. [Note that an internal cross reference in Section 18973.5(p)(2)(C) should be revised to refer to Section 18973.3(f)(8), rather than (f)(9)].</p>	<p>028-019. CalRecycle disagrees that the proposed regulatory text should require that local agencies equally distribute requests related to home-generated sharps waste amongst multiple program operators. There may be legitimate reasons why a local agency makes a request to one program operator over another, and program operators and local agencies are free to coordinate how requests are distributed. Requiring an equal distribution of requests in regulation would limit the flexibility for all parties to coordinate these requests in a logical and cost-effective manner. Moreover, CalRecycle cannot be placed in the position of potentially arbitrating disputes between these parties. Section 18973.3(g)(1) of the proposed regulatory text requires a program operator to provide a description in the stewardship plan of the process for coordinating with local agencies, and thus the department will be able to evaluate the stewardship plan for any potential “barriers” to receiving local agency requests.</p> <p>Separately, CalRecycle agrees that the internal cross reference in section 18973.5(p)(2)(C) should be revised to refer to Section 18973.3(f)(8), rather than (f)(9).</p>

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
028-020	MED-Project USA	Michael R. Van Winkle	18973.3(g)(2)	N	The Local Agencies are best situated to equally allocate these requests, rather than requiring the Department to referee among Program Operators or, alternatively, raising federal and state antitrust or related risks through Program Operator coordination in distributing these requests amongst themselves. To assist these Local Agencies, the “to the extent practicable” qualification recognizes that there may be subtle variations in the amount of qualifying home-generated sharps waste Program Operators remove from Local Agencies over the course of a year, as each load removed is unlikely to have an identical weight.	028-020. As described in the response to comment 028-019, CalRecycle declines to require that local agencies equally distribute requests related to home-generated sharps waste, regardless of whether doing so is “practicable.” Local agencies are free to work with program operators to distribute requests in a logical and cost-effective manner. Consistent with the requirements listed under section 42032.2(d)(1)(F)(ii) of the Public Resources Code, local agencies ultimately have the right to distribute requests as they see fit, and a program operator that does not accept requests consistent with statutory requirements may be subject to enforcement actions.
028-021	MED-Project USA	Michael R. Van Winkle	18973.3(g)(2)	Y	Additionally, the Revised Proposed Regulations should account for SB 212’s express limits on the scope of Local Agency requests. See PRC § 42032.2(d)(1)(F)(ii) (generally prohibiting Local Agencies from requesting reimbursement for disposal expenses relating to a municipal needle exchange program or medical waste generator, and limiting reimbursable costs to actual transportation and disposal costs). Consistent with SB 212, the Revised Proposed Regulations should also require that Local Agencies submit requests for reimbursement “with a declaration under penalty of perjury that the local agency has not knowingly requested reimbursement for expenses prohibited by this section.” See <i>id.</i> Although the Revised Proposed Regulations restate many other SB 212 requirements, they omit these Local Agency request requirements. As CalRecycle envisioned the Proposed Regulations as a “one-stop-shop” for SB 212 requirements, the Revised Proposed Regulations should reflect these SB 212 requirements.	028-021. CalRecycle agrees that the requirements of section 42032.2(d)(1)(F)(ii) of the Public Resources Code should be incorporated into the proposed regulatory text. Thus, CalRecycle proposes the following edit to section 18973.3(g)(2): <u>(2) Requests by local agencies, or an agent on behalf of a local agency, shall include an invoice and shall be submitted to the program operator, as necessary. Such requests shall comply with the requirements in subsection (1)(F)(ii) of subdivision (d) of section 42032.2 of the Public Resources Code. Program operators shall will respond to requests by local agencies within 14 days of receipt of the request in a timely manner and identify the method to resolve the request by selecting either reimbursement or removal from household hazardous waste facility(ies).</u>
028-022	MED-Project USA	Michael R. Van Winkle	18973.3(g)(2)	Y	As revised to address multiple Program Operators and SB 212 requirements for Local Agency requests, Revised Proposed Regulations § 18973.3(g)(2) should read: Requests by local agencies, or an agent on behalf of a local agency, shall include an invoice and shall be submitted to the program operator, as necessary. <u>Such requests shall comply with the requirements in PRC § 42032.2(d)(1)(F)(ii). Local agencies shall request from each approved program operator the reimbursement or removal of an equal amount of home-generated sharps waste, as reported in section 18973.5(p)(2)(C), to the extent practicable.</u> Program Operators shall respond to requests by local agencies within 14 days of receipt of the request and identify the method to resolve the request by selecting either reimbursement or removal from household hazardous waste facility(ies).	028-022. As discussed in response to comment 028-021, CalRecycle agrees to incorporate the requirements of section 42032.2(d)(1)(F)(ii) of the Public Resources Code into section 18973.3(g)(2) of the proposed regulatory text. However, as discussed in response to comments 028-019 and 028-020, CalRecycle declines to require that local agencies equally distribute requests related to home-generated sharps waste, regardless of whether doing so would be “practicable.”
028-023	MED-Project USA	Michael R. Van Winkle	18973.3(g)(2)(B)	Y	Section 18973.3(g)(2)(B): The “and” added in the Revised Proposed Regulations is inconsistent with state law and should be deleted. Section 18973.3(g)(2)(B) of the Revised Proposed Regulations was revised by the Department so that it now reads that a Program Operator that provides for the removal of home-generated sharps waste from a	028-023. CalRecycle agrees with the commenter and accepts the proposed change to section 18973.3(g)(2)(B) of the Second Draft Proposed Regulations.

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					local household hazardous waste facility shall do so “as often as required according to section 117904 of the Health and Safety Code <u>and</u> /or by the local enforcement authority. Section 117904(d)(2) of the Health and Safety Code provides that sharps containers “shall not be held for more than seven days without the written approval of the enforcement agency.” Thus, Section 18973.3(g)(2)(B) was consistent with state law as originally draft; i.e., either the seven-day timeline set in Section 117904 controls <i>or</i> another timeline controls if authorized by the local enforcement agency. Thus, the “and” added by the Department in the Revised Proposed Regulations should be deleted.	
028-024	MED-Project USA	Michael R. Van Winkle	18973.3	N	<p>New Section in 18973.3: Stewardship Plans should identify the online marketplaces at which the Program Operator will Provide or Initiate Distribution of a Sharps Waste Container at the Point of Sale.</p> <p>As described in Section I.A (<i>see comments 028-003 through -005</i>) of these comments, and consistent with MED-Project’s proposed definition of Point of Sale, the Department should require Stewardship Plans to identify the online marketplaces through which they are making a good faith effort to Provide or Initiate Distribution of a Sharps Waste Container at the Point of Sale. Requiring Stewardship Plans to identify these online marketplaces for the Department’s review and approval will allow the Department to confirm a Stewardship Plan is serving Ultimate Users purchasing sharps through an online marketplace to the extent the Proposed Regulations require and, given that Program Operators cannot compel online marketplace participation in efforts under SB 212, to the extent practicable. Identifying these online marketplaces in a Stewardship Plan will also give Program Operators the certainty that, upon the Department’s approval of the Stewardship Plan, they are working with the online marketplaces necessary to satisfy the Revised Proposed Regulations’ requirements. This new section should require Home-Generated Sharps Waste Stewardship Plans to: Provide a list of the online marketplaces for which the program operator will make a good faith effort to provide or initiate the distribution of a sharps waste container at the point of sale.</p>	028-024. CalRecycle declines to require that a stewardship plan submitted to the department for approval contain the list of each online marketplace that the program will work with to distribute sharps containers and mail-back materials. Section 42032.2(d)(1)(F)(i) of the Public Resources Code requires the program operator to “provide or initiate distribution of a sharps waste container and mail-back materials at the point of sale, to the extent allowable by law.” Statute does not exempt any particular online sales from this requirement. The authorizing statute does not allow for a program operator to merely make a “good faith effort”. It is the responsibility of covered entities to understand their distribution networks and work with retailers (online or otherwise) so that sharps waste containers and mail-back materials can be distributed no matter where the sharps are sold. Requiring a list of online marketplaces upfront in the stewardship plan could undermine convenience for the ultimate user in situations where the department later discovers online sales not covered by the stewardship plan, or if new sources of online sales come into existence after stewardship plan approval.
028-025	MED-Project USA	Michael R. Van Winkle	18973.2(c)(4)	N	<p>Section 18973.4(c)(4): The granular level of detail that is still sought in the annual reports for each collection site is unreasonable and impracticable.</p> <p>MED-Project appreciates the minor changes that the Department made to the collection site-specific information that is required to be included in the annual reports for Covered Drugs at Revised Proposed Regulations § 18973.4(c)(4). However, MED-Project is still concerned with the granular level of detail that is being sought in the Revised Proposed Regulations. Section 18973.4(c)(4)(E) of the Revised Proposed Regulations currently</p>	028-025. CalRecycle declines deleting or modifying the secure collection receptacle reporting requirement stated in section 18973.4(c)(4)(E) of the proposed regulatory text. Program operators are already required to collect data from each participating authorized collection site in order to comply with other SB 212 requirements (for example, section 42033.2(b)(3) of the Public Resources Code). Simply requesting that authorized collection sites record and communicate the reasons and durations of any instances where the secure collection receptacle was unavailable to the public during business hours is neither unreasonable nor impracticable. This information is crucial for

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					<p>states that the annual reports must include the following information by collection site:</p> <p>Number of instances and corresponding amount of time the secure collection receptacle was not available to the public during business hours. For each instance, provide a description of why the secure collection receptacle was not available.</p> <p>As explained in our February 17, 2020 Comment Letter, SB 212 limits the Department's authority with respect to annual reports by stating that it may only require additional information, above and beyond what is required by the statute, if the information is "reasonably require[d]." PRC § 42033.2(b)(9). SB 212 does not require that annual reports contain this type of granular information regarding availability statistics kiosk-by-kiosk and, therefore, this provision of the Revised Proposed Regulations is subject to the reasonableness requirement in PRC § 42033.2(b)(9).</p>	the department to be able to evaluate compliance with the convenience standards listed in section 42032.2(a)(1)(F)(i) of the Public Resources Code; if, for example, a program operator has five authorized collection sites operating in a rural county but the collection receptacle at one site becomes unavailable, then the program operator could be considered out of compliance with the convenience standards during that time period.
028-026	MED-Project USA	Michael R. Van Winkle	18973.4(c)(4)	N	The additional information that is being sought by the Department here - the total number of instances and amount of time over the course of a 365-day reporting period that each and every kiosk across the state of California is "not available to the public during business hours" for any reason - is not only unreasonable, but also impracticable. There are approximately 2,100 business hours in a year, and there will likely be over 1,000 kiosks throughout the state of California under a MED-Project Stewardship Plan. Obtaining complete and accurate information on the total number of instances and total amount of time that a kiosk at each collection site in the state of California was closed or otherwise inaccessible to the public during business hours for any given reason (renovations, employee errors, etc.) is impossible as a practical matter.	028-026. CalRecycle declines deleting or modifying the secure collection receptacle reporting requirement stated in section 18973.4(c)(4)(E) of the proposed regulatory text. Program operators are already required to collect data from each participating authorized collection site in order to comply with other SB 212 requirements (for example, section 42033.2(b)(3) of the Public Resources Code). Simply requesting that authorized collection sites record and communicate the reasons and durations of any instances where the secure collection receptacle was unavailable to the public during business hours is neither unreasonable nor impracticable. This information is crucial for the department to be able to evaluate compliance with the convenience standards listed in section 42032.2(a)(1)(F)(i) of the Public Resources Code; if, for example, a program operator has five authorized collection sites operating in a rural county but the collection receptacle at one site becomes unavailable, then the program operator could be considered out of compliance with the convenience standards during that time period.
028-027	MED-Project USA	Michael R. Van Winkle	18973.4(c)(4)	N	Further, despite the justifiable concerns previously raised by MED-Project regarding the reasonableness and practicability of the granular level of detail required in Section 18973.4(c)(4)(E), the Department's Revised Proposed Regulations add on more requirements to an already unreasonable and unworkable provision. Section 18973.4(c)(4)(E) now also requires that a Program Operator describes " why " each instance occurred at each kiosk throughout the state of California during the 365-day reporting year. The Department's expectation on reporting here is patently unreasonable.	028-027. As discussed in response to comments 028-025 and 028-026, CalRecycle declines deleting or modifying the requirement in section 18973.4(c)(4)(E) of the proposed regulatory text, since this requirement is neither unreasonable nor impracticable and it is essential to evaluating compliance with the statutory convenience standards. In the event that the convenience standards are not met due to a secure collection receptacle being unavailable to the public, understanding why the receptacle was unavailable is essential for the department to be able to determine an appropriate enforcement action.
028-028	MED-Project USA	Michael R. Van Winkle	18973.4(c)(4)	N	In order to make this reporting requirement workable from an operational perspective, MED-Project recommends that the reporting obligation in Section 18973.4(c)(4)(E) be limited to only include instances that the Program Operator is aware of, either because they were reported to the	028-028. As discussed in response to comments 028-025 and 028-026, CalRecycle declines deleting or modifying the requirement in section 18973.4(c)(4)(E) of the proposed regulatory text, since this requirement is neither unreasonable nor impracticable and it is

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					<p>Program Operator by the collection site or because they were observed during a site inspection.</p> <p>For the above described reasons, Section 18973.4(c)(4)(E) of the Revised Proposed Regulation should be revised to read: (E) Number of instances and corresponding amount of time the secure collection receptacle was not available to the public during business hours. For each instance, provide, including a description if provided, as reported to the Program Operator by a collection site and/or identified during a site inspection. of why the secure collection receptacle was not available.</p>	essential to evaluating compliance with the statutory convenience standards. The commenter acknowledges that this requirement is “workable from an operational perspective” if it involves reporting from the collection site; the program operator thus can comply with this requirement in a “workable” manner if it simply incorporates such reporting into the policies and procedures agreed upon with each authorized collection site. Limiting this requirement to instances discovered during site inspections or adding the qualifier “if provided” would mean that this requirement is no longer sufficient for the department to adequately determine compliance with statutory convenience standards.
028-029a	MED-Project USA	Michael R. Van Winkle	18973.4(p), 18973.5(r)	Y	<p>Sections 18973.4(p), 18973.5(r): The new written certifications required by Program Operators in annual reports are either redundant or unreasonable and should be stricken.</p> <p>The Department’s Revised Proposed Regulations include a brand new “written certification” requirement applicable to Program Operators in annual reports for both Covered Drugs and Home-Generated Sharps Waste. The new provisions in the Revised Proposed Regulations state that annual reports must include: Written certification, by an authorized representative of the program operator, that: <i>the stewardship plan</i>, including the collection, transportation, and disposal of covered drugs [or home-generated sharps waste, respectively], <i>is in compliance with</i> all applicable local, state, and federal laws and regulations, including, but not limited to United States Drug Enforcement Administration regulations.</p> <p>Revised Proposed Regulations §§ 18973.4(p) & 18973.5(r) (emphasis added).</p> <p>The intent of the above-quoted text is unintelligible on its face in the context of an annual report. Is the Department’s intent to require that a Program Operator certifies that the Stewardship Plan, <i>as written</i>, complies with all applicable laws, regulations, and other legal requirements? If so, the Program Operator would have already made that certification in the Stewardship Plan approval process and re-requiring that certification is redundant. See Revised Proposed Regulations §§ 18973.2(e)(2), 18973.3(d)(2). Alternatively, is the Department’s intent that the annual report include a certification that all <i>activities</i> occurring in the Stewardship Program during the reporting period comply with all applicable laws, regulations, and other legal requirements? If the Department’s intent is the latter, then MED-Project has serious concerns with the new provision, as MED-Project does not and will not have knowledge of all third-party activities (including those taken by Authorized Collectors, vendors and disposal facilities) that are taken throughout the reporting year and, therefore, such a certification is impossible. Even if it was possible, for the reasons described in Section II.B of these</p>	<p>028-029a. CalRecycle acknowledges the commenter’s concerns about the annual report certification requirements in sections 18973.4(p) and 18973.5(r) of the Second Draft Proposed Regulations. The department agrees to delete these requirements from the proposed regulatory text.</p> <p>The program operator has an ongoing responsibility to ensure compliance because all handling, transport, and disposal undertaken as part of the stewardship program “shall comply with applicable state and federal laws, including, but not limited to, regulations adopted by the United States Drug Enforcement Administration” (see Section 42035.8 of the Public Resources Code).</p>

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					<p>comments, preparing such certifications would take months given the hundreds of participating entities, an effort SB 212 never contemplates.</p> <p>It is MED-Project's position that the new written certification requirements imposed on Program Operators at Revised Proposed Regulations §§ 18973.4(p) and 18973.5(r) are either redundant of the certifications provided under Sections 18973.2(e)(2) and 18973.3(d)(2) and unnecessary given all the other disclosures that are required in plan and annual reporting submissions, or they are unreasonable, and thus, contrary to the legislative limitations imposed on the Department at PRC § 42033.2(b)(9). Thus, Sections 18973.4(p) and 18973.5(r) should be stricken in full. If the Department does not strike Sections 18973.4(p) and 18973.5(r), it should clarify them consistent with the comments in Section II.B.</p>	
028-029b	MED-Project USA	Michael R. Van Winkle	18973.4(p), 18973.5(r)	Y	<p>Sections 18973.4(p), 18973.5(r): The new written certifications required by Program Operators in annual reports are either redundant or unreasonable and should be stricken.</p> <p>The Department's Revised Proposed Regulations include a brand new "written certification" requirement applicable to Program Operators in annual reports for both Covered Drugs and Home-Generated Sharps Waste. The new provisions in the Revised Proposed Regulations state that annual reports must include:</p> <p style="padding-left: 40px;">Written certification, by an authorized representative of the program operator, that: <i>the stewardship plan</i>, including the collection, transportation, and disposal of covered drugs [or home-generated sharps waste, respectively], <i>is in compliance with</i> all applicable local, state, and federal laws and regulations, including, but not limited to United States Drug Enforcement Administration regulations.</p> <p>Revised Proposed Regulations §§ 18973.4(p) & 18973.5(r) (emphasis added).</p> <p>The intent of the above-quoted text is unintelligible on its face in the context of an annual report. Is the Department's intent to require that a Program Operator certifies that the Stewardship Plan, <i>as written</i>, complies with all applicable laws, regulations, and other legal requirements? If so, the Program Operator would have already made that certification in the Stewardship Plan approval process and re-requiring that certification is redundant. See Revised Proposed Regulations §§ 18973.2(e)(2), 18973.3(d)(2). Alternatively, is the Department's intent that the annual report include a certification that all <i>activities</i> occurring in the Stewardship Program during the reporting period comply with all applicable laws, regulations, and other legal requirements? If the Department's intent is the latter, then MED-Project has serious concerns with the new provision, as MED-Project does not and will not have knowledge of all third-party activities (including those taken by Authorized</p>	<p>028-029b. CalRecycle acknowledges the commenter's concerns about the annual report certification requirements in sections 18973.4(p) and 18973.5(r) of the Second Draft Proposed Regulations. The department agrees to delete these requirements from the proposed regulatory text.</p> <p>The program operator has an ongoing responsibility to ensure compliance because all handling, transport, and disposal undertaken as part of the stewardship program "shall comply with applicable state and federal laws, including, but not limited to, regulations adopted by the United States Drug Enforcement Administration" (see Section 42035.8 of the Public Resources Code).</p>

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					<p>Collectors, vendors and disposal facilities) that are taken throughout the reporting year and, therefore, such a certification is impossible. Even if it was possible, for the reasons described in Section II.B of these comments, preparing such certifications would take months given the hundreds of participating entities, an effort SB 212 never contemplates.</p> <p>It is MED-Project's position that the new written certification requirements imposed on Program Operators at Revised Proposed Regulations §§ 18973.4(p) and 18973.5(r)) are either redundant of the certifications provided under Sections 18973.2(e)(2) and 18973.3(d)(2) and unnecessary given all the other disclosures that are required in plan and annual reporting submissions, or they are unreasonable, and thus, contrary to the legislative limitations imposed on the Department at PRC § 42033.2(b)(9). Thus, Sections 18973.4(p) and 18973.5(r) should be stricken in full. If the Department does not strike Sections 18973.4(p) and 18973.5(r), it should clarify them consistent with the comments in Section II.B.</p>	
028-030a	MED-Project USA	Michael R. Van Winkle	18973.4(q)	Y	<p>Section 18973.4(q): The novel proposal of requiring Program Operators to collect and include third party certifications in annual reports is unreasonable and unworkable in practice.</p> <p>As with the new written certification requirements applicable to Program Operators in Sections 18973.4(p) and 18973.5(r) of the Revised Proposed Regulations, the new third party certification requirement for annual reports added by the Department at Section 18973.4(q) is unreasonable and impossible to implement or enforce in practice.</p> <p>MED-Project is not aware of any federal, state or local requirement that is similar in scope or nature. The reason is evident: it is impossible to expect or require that a regulated entity obtain and submit written certifications from dozens of third-party vendors attesting to their compliance with all laws and regulations over the course of a year, and on an annual basis, for submission to a regulatory authority.</p> <p>MED-Project does not anticipate that it would be able to obtain such certifications from all vendors on an annual basis. For instance, what if a third-party vendor was technically out of compliance with a paperwork requirement and, therefore, could not in good faith prepare such a certification? Alternatively, what if a third-party vendor's legal counsel advises the company should not furnish such a certification for liability purposes? What is the consequence of this? Would the Department seek to penalize MED-Project for the failure of a third party to prepare and provide a submission that the company itself has no legal obligation to furnish? This novel concept is wholly unworkable and unreasonable in concept and application. Accordingly, Section 18973.4(q) should be struck in its entirety.</p>	<p>028-030a. CalRecycle acknowledges the commenter's concern about the authorized collector certification requirement in section 18973.4(q) of the Second Draft Proposed Regulations. The department agrees to delete this requirement from the proposed regulatory text.</p> <p>The program operator has an ongoing responsibility to ensure compliance because all handling, transport, and disposal undertaken as part of the stewardship program "shall comply with applicable state and federal laws, including, but not limited to, regulations adopted by the United States Drug Enforcement Administration" (see Section 42035.8 of the Public Resources Code).</p>

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
028-030b	MED-Project USA	Michael R. Van Winkle	18973.4(p), 18973.5(r)	Y	<p>As with the new written certification requirements applicable to Program Operators in Sections 18973.4(p) and 18973.5(r) of the Revised Proposed Regulations, the new third party certification requirement for annual reports added by the Department at Section 18973.4(q) is unreasonable and impossible to implement or enforce in practice.</p> <p>MED-Project is not aware of any federal, state or local requirement that is similar in scope or nature. The reason is evident: it is impossible to expect or require that a regulated entity obtain and submit written certifications from dozens of third-party vendors attesting to their compliance with all laws and regulations over the course of a year, and on an annual basis, for submission to a regulatory authority.</p> <p>MED-Project does not anticipate that it would be able to obtain such certifications from all vendors on an annual basis. For instance, what if a third-party vendor was technically out of compliance with a paperwork requirement and, therefore, could not in good faith prepare such a certification? Alternatively, what if a third-party vendor's legal counsel advises the company should not furnish such a certification for liability purposes? What is the consequence of this? Would the Department seek to penalize MED-Project for the failure of a third party to prepare and provide a submission that the company itself has no legal obligation to furnish? This novel concept is wholly unworkable and unreasonable in concept and application. Accordingly, Section 18973.4(q) should be struck in its entirety.</p>	<p>028-030b. CalRecycle acknowledges the commenter's concern about the authorized collector certification requirement in section 18973.4(q) of the Second Draft Proposed Regulations. The department agrees to delete this requirement from the proposed regulatory text.</p> <p>The program operator has an ongoing responsibility to ensure compliance because all handling, transport, and disposal undertaken as part of the stewardship program "shall comply with applicable state and federal laws, including, but not limited to, regulations adopted by the United States Drug Enforcement Administration" (see Section 42035.8 of the Public Resources Code).</p>
028-031	MED-Project USA	Michael R. Van Winkle	18973.6	Y	<p>Section 18973.6: SB 212 does not confer the Department with the authority to require the inclusion of actual expenses in annual Stewardship Program budget submissions.</p> <p>MED-Project appreciates the revisions that have been made by the Department to date on the Stewardship Program budget provisions of the Revised Proposed Regulations including, namely, consolidating the nine (9) separate subcategories of anticipated costs at section 18973.6(b) into five. However, MED-Project still feels that the scope of information sought by the Department in the annual budget submissions is inconsistent with the plain language of SB212, and thus, is in excess of the Department's authority.</p> <p>As stated in MED-Project's February 17, 2020 comment letter, although the legislature expressly authorized the Department to request additional information above and beyond that which is required in the statute, subject to the limitation that the additional information is "reasonably require[d]", no such authorization was granted to the Department in SB212 for annual budget submissions. <i>Compare</i> PRC § 42033.2(b)(9), <i>with</i> § 42033.2(c). As a matter of law, this distinction has meaning, and that meaning can only be read to mean that the legislature <i>did not</i> intend to allow the Department to promulgate regulations which would require additional information in program budgets above and beyond that which is</p>	<p>028-031. CalRecycle disagrees with the commenter that the scope of information required is inconsistent with the plain language of the authorizing statute, CalRecycle has moved the program budget requirement in 18973.6(f) to the annual report sections of the proposed regulatory text (as new subdivisions 18973.4(n) and 18973.5(q)). A list of actual expenses incurred during the previous reporting period is more appropriately summarized as part of the annual report. Section 42033.2(b)(9) of the Public Resources Code states that the annual report must contain "any other information the department reasonably requires." Including actual program expenses in the annual report is reasonable as program operators must compile this information anyway as a part of standard accounting processes and in order to bill participating covered entities (if applicable). Furthermore, this information is essential for the department to be able to evaluate whether or not the stewardship program adhered to its approved program budget during the reporting period.</p> <p>Even if CalRecycle did not move this requirement into the annual report sections, the scope of information required is consistent with the plain language of the authorizing statute,</p>

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					<p>enumerated by statute. See <i>Azusa Land Partners v. Dep't of Indus. Relations</i>, 191 Cal. App. 4th 1, 20 (2010) (“[W]hen the Legislature has carefully employed a term in one place and has excluded it in another, it should not be implied where excluded”); <i>California Soc’y of Anesthesiologists v. Brown</i>, 204 Cal. App. 4th 390, 404 (2012) (“While every word of a statute must be presumed to have been used for a purpose, it is also the case that every word excluded from a statute must be presumed to have been excluded for a purpose”). And, as noted in MED-Project’s February 17th comments, this construction is consistent with SB212’s legislative history and the distinction in this regard from other stewardship programs administered by the Department is warranted because the Pharmaceutical and Sharps Waste Stewardship Program is not publicly funded. Based on the foregoing, MED-Project continues to believe that Section 18973.6 of the Revised Proposed Regulations should be revised to require no more than is required by SB212, and as described in PRC § 42033.2(c). However, at a minimum, the requirement to include not only anticipated costs, but also actual expenses at Section 18973.6(f), should be stricken in its entirety.</p> <p>(f) Beginning with the first annual program budget, include all actual expenses incurred during the previous program year. Expenses shall be summarized in accordance with the budget categories specified in section 18973.6(b).</p>	<p>In regards to the general comment that the program budgets section “should be revised to require no more than is required by SB212,” the plain words of Public Resources Code section 42033.2(c), which are operative, are: that an annual program budget shall include, “at a minimum...” the information required in subdivisions (1) and (2). Moreover, under subdivision (2), the costs that are listed are not the only ones the department can require the program operator to provide: they are part of what the department can require. Section 42033.2(c)(2) of the Public Resources Code requires the program operator to submit “[a]nticipated costs and the recommended funding level necessary to implement the stewardship program, <i>including but not limited to...</i>”. The commenter asserts that only the specifically listed costs in subdivision (2) are required, which is not the case. The statutory language does not rule out some level of itemization of budget categories.</p>
028-032	MED-Project USA	Michael R. Van Winkle	18975.1, 18975.2	N	<p>THE DEPARTMENT’S WHOLESALE REVISIONS TO THE ADMINISTRATIVE PROCEDURES CONTAINED IN SECTIONS 18975.1 AND 18975.2 ARE INTERNALLY INCONSISTENT, BEYOND THE STATUTORY AUTHORITY CONFERRED BY SB 212 AND OTHERWISE LEGALLY DEFECTIVE.</p> <p>The Revised Proposed Regulations propose completely new language in Sections 18975 (Criteria to Impose an Administrative Civil Penalty), Section 18975.1 (Procedure for Imposing An Administrative Penalties) and Section 18975.2 (Procedure for Stewardship Plan Revocation, Resubmittal, or Additional Compliance Reporting). The rationale for why these wholesale revisions are being proposed now, at this juncture of the rulemaking process is not discernable from the materials currently available in the rulemaking file, and no explanation has been offered by the Department (in its July 14, 2020 Notice of Changes to Proposed Regulations or elsewhere). MED-Project has serious concerns with the new language being proposed by the Department and, for the reasons explained below, believes that the revised provisions are arbitrary, capricious, inconsistent with SB212, beyond the Department’s authority and otherwise unlawful, as they fail to satisfy minimum due process protections that attach to the proposed actions that may be taken under the subject provisions.</p>	<p>028-032. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. The department can make changes to the regulatory text, and the explanations for the changes will be part of the Final Statement of Reasons in the rulemaking file. This is an introductory statement that summarizes the commenter’s proposals. These proposals and responses from the department appear below. Please refer to comments 028-033 through 028-039 for a more thorough discussion.</p>

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
028-033	MED-Project USA	Michael R. Van Winkle	18975.1(a), 18975.2(b)	N	<p>A. Sections 18975.1(a), 18975.2(b): The new proposed language in Sections 18975.1(a) and 18975.2(b) is internally inconsistent and contrary to SB212.</p> <p>Section 18975.1 of the Revised Proposed Regulations is titled “Procedures for Imposing Administrative Civil Penalties”; however, the first sentence of Section 18975.1(a) now states that the “department shall issue a notice of violation (NOV) to the respondent if the department determines that the respondent has violated a material requirement of this Article or Chapter 2 of Part 3 of Division 30 of the Public Resources Code.” (emphasis added). It is unclear what the intended scope and meaning of this new proposed language is, given that it is internally inconsistent with Department’s own Revised Proposed Regulations, and is also in direct conflict with the authorizing legislation at PRC §§ 42035.2 and 42035.4.</p>	<p>028-033. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. For purposes of this response “PRC” refers to the Public Resources Code, and “NOV” refers to notice of violation(s).</p> <p>Section 18975.1(a) of the proposed regulatory text discusses a NOV, by which the department intends to notify a respondent about a violation of the material requirement of the authorizing statute or its implementing regulations. The purpose of this procedure is to provide notice to the respondent that the department has determined that a violation has occurred and afford the respondent an opportunity to possibly address the violation before CalRecycle takes disciplinary action. This is why this provision appears under the heading titled “Procedures for Imposing Administrative Civil Penalties”.</p> <p>This provision is not internally inconsistent with the department’s regulations. The commenter has not provided any reasoning for this statement. If the commenter believes that issuing a notice of violation before taking a disciplinary action is inconsistent with the department’s own regulations, the department disagrees. The issuance of a NOV occurs before CalRecycle takes disciplinary action and is not internally inconsistent.</p> <p>Moreover, the provision is not in direct conflict with the authorizing legislation at PRC Sections 42035.2 and 42035.4. Section 42035.2 of the PRC allows the department to impose penalties. It does not prohibit the department from providing advanced notice (in the form of a NOV) to a respondent to allow the respondent to possibly correct the violation before the department takes disciplinary action. Section 42035.4 of the PRC discusses the process for a revocation/resubmittal of a stewardship plan and/or requirement to provide more information (in addition to the authority to impose penalties under PRC Section 42035.2). Section 42035.4 and is not internally inconsistent with the NOV provision. The department has added a NOV section under the penalties section (18975.1) to ensure a respondent knows that a written warning and an opportunity to possibly correct the violation is available.</p> <p>If the commenter is taking the position that the department is only allowed to take the actions outlined in section 42035.4 of the PRC if the respondent violates a material requirement of the authorizing statute (and by extension, its implementing regulations), the department disagrees. The authorizing statute gives the department authority to impose penalties under PRC, Section 42035.2. In addition to or alternatively, the authorizing statute allows the department to revoke/require resubmittal of stewardship plans and/or require provision of additional information under PRC, Section 42035.4.</p>

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
028-034	MED-Project USA	Michael R. Van Winkle	18975.1(a), 18975.2(b)	N	<p>First, SB212 is clear in that the Department is only authorized to “impose an administrative civil penalty on a[] covered entity, program operator, stewardship organization, or authorized collector that sells, offers for sale, or provides a covered product in violation of this chapter.” PRC § 2035.2(a)(1). In other words, the operative act that triggers the Department’s authority to assess a monetary penalty is the sale, offering or distribution of a <i>covered product</i>. If the alleged conduct <i>does not</i> involve the sale, offering or distribution of a covered product, but pertains to the alleged violation of a “<i>material requirement</i>” of the statute, then SB 212 unequivocally limits the Department’s authority to taking the following types of punitive action:</p> <ul style="list-style-type: none"> (a) Revoke the program operator’s stewardship plan approval or require the program operator to resubmit the plan. (b) Require additional reporting relating to compliance with the material requirement of this chapter that was not met. <p>PRC § 42035.4(a)-(b).</p> <p>Indeed, the limited scope of the Department’s authority in this regard was acknowledged in the written comments submitted on this rulemaking by the California Product Stewardship Council, the National Stewardship Action Council, Zero Waste Sonoma and the County of Santa Clara. See, Comments in Response to CalRecycle’s SB 212 45-Day Formal Rulemaking Comment Period, Letter 5: 2-14-2020 Nat’l Stewardship Action Council, CalPSC, County of Santa Clara, & Zero Waste Sonoma at page 12 (“The application of civil penalties is relatively limited by the statute and applies only to the sale of a covered product in violation of the chapter. This seems to limit the department’s recourse in addressing material programmatic deficiencies to revocation of the plan.”). Notwithstanding the limitations which are clearly imposed and commonly understood to apply to the Department, for unknown reasons the Revised Proposed Regulations now discuss issuing notices for alleged violations of a material requirement of the statute in the Section titled “Procedures for Imposing Administrative Civil Penalties”.</p>	<p>028-034. For purposes of this response, “PRC” refers to the Public Resources Code. The department disagrees with the commenter’s position that the department can only impose penalties for a direct act of a sale, offer for sale, or provision of a covered product. In Section 42035.2 of the PRC, which lists entities upon which CalRecycle can impose penalties, the legislature specifically included program operators and stewardship organizations. A stewardship organization or a program operator (which runs a stewardship organization) does not directly sell or offer covered drugs or sharps for sale. This means that the commenter is suggesting that the authorizing statute does not authorize the department to issue penalties against a program operator (that runs a stewardship organization) or stewardship organization because they don’t sell, offer for sale, or provide covered drugs or sharps.</p> <p>The commenter further argues that the department can only take steps outlined in Section 42035.4 of the PRC as “punitive action[s]” for programmatic deficiencies that do not involve the sale, offer for sale, or provision of covered products.</p> <p>A statutory provision must be read in the context of the entire statute. PRC, Section 42035.2(a)(1) cannot be read in isolation. To interpret the meaning of PRC, Section 42035.2(a)(1) as to exclude the authority to impose penalties on program operators (who run stewardship programs) and on stewardship organizations would thwart the legislative intent. The legislature intended to authorize the department to impose penalties on all of the entities listed in PRC, Section 42035.2(a)(1), regardless if such entities sell, offer for sale, or provide a drug or sharp. Section 42035.2(b) of the PRC provides an exception pursuant to which the department should not impose a penalty on a program operator or stewardship organization. This exception would not have been specifically included and would not make sense if Section 42035.2(a)(1) did not allow for imposition of penalties against a program operator or stewardship organization. If there is an exception to imposition of penalties – penalties must be authorized in the first place. If the exception under subdivision (b) does not apply, the department has the authority to impose penalties against a program operator or stewardship organization for violations of the authorizing statute and its implementing regulations.</p> <p>Moreover, the authorizing statute also references the department’s authority to impose penalties on a program operator and stewardship organization in Section 42035.6(d) of the PRC, stating <i>that issuance of penalties under Section 42035.2 of the PRC is one of the disciplinary actions “the department may take ... against a ... stewardship organization, program operator,”</i> and other entities for failure to provide access to certain required information. For all of the foregoing reasons,</p>

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
						<p>the writers intended to provide the department with authority to impose penalties on a program operator and stewardship organization for failure to comply with the authorizing statute or its implementing regulations. The intent <i>was not</i> to solely allow penalties for the act of sale, offer for sale, or provision of covered drugs or sharps in violation of the authorizing statute. If an entity listed in PRC, Section 42035.2(a)(1) is in violation of the authorizing statute or its implementing regulations, the department has the authority to impose penalties on that entity.</p> <p>The commenter is taking the position that the department is only allowed to take actions outlined in PRC, Section 42035.4(a) and (b) if the respondent violates a material requirement of the authorizing statute. The department disagrees with this position. The authorizing statute gives the department authority to impose penalties under PRC, Section 42035.2. In addition to or alternatively, the authorizing statute allows the department to revoke/require resubmittal of stewardship plans and/or require provision of additional information under PRC, Section 42035.4.</p>
028-035	MED-Project USA	Michael R. Van Winkle	18975.1(a), 18975.2(b)	Y	<p>Second, Section 18975.1(a) is also internally inconsistent with the Revised Proposed Regulations, and these inconsistencies and ambiguities lead to an overall lack of clarity regarding the process and procedures that are intended to apply to the various types of proposed actions that may be taken by the Department. Under Section 18975.1(a), a “NOV” can be issued for an alleged violation of a “material requirement” of SB212. However, Section 18975.2(a) and (b) states that a “written notice” shall be issued if the Department determines that a Program Operator “had failed to meet a material requirement” of SB212. It is unclear which process is intended to actually apply to an allegation by the Department that a Program Operator has violated a “material requirement” of SB212: does Section 18975.1 or Section 18975.2 apply?</p>	<p>028-035. For purposes of this response, “PRC” refers to the Public Resources Code.</p> <p>Section 18975.1(a) of the proposed regulatory text discusses a NOV, by which the department intends to notify a respondent about a violation of the material requirement of the authorizing statute or its implementing regulations. The purpose of this procedure is to provide notice to the respondent that the department has determined that a violation has occurred and afford the respondent an opportunity to possibly address the violation before the department takes disciplinary action. The department does not require a statutory authorization to issue NOVs. The written notice in subsection 18975.2(b) commences the action to take the disciplinary actions described in subsection 18975.2(a) and notifies the respondent about the same. The NOV will be issued prior to the written notice described in subsection (b) to allow the respondent to correct the violation(s). The department has added a NOV section under the penalties section (18975.1) to ensure a respondent knows that a written warning and an opportunity to possibly correct the violation is available.</p> <p>A program operator will receive a NOV, which is a written finding to notify the program operator about a violation of a material requirement of the authorizing statute and its implementing regulations. Following the issuance of an NOV, if necessary, the department is authorized to impose penalties outlined in PRC, Section 42035.2 and/or take the actions outlined in PRC, Section 42035.4(a) and (b).</p>

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
028-036	MED-Project USA	Michael R. Van Winkle	18975.1(a), 18975.2(b)	N	<p>It is unclear why the language in the first sentence of section 18975.1(a) of the Revised Proposed Regulations was intentionally added. Nevertheless, the enforcement provisions and procedures that are now laid out in Sections 18975.1 and 18975.2 are internally inconsistent and indiscernible. Further, as currently written, Section 18975.1 can now be read as authorizing the Department to impose an administrative civil penalty on a Program Operator that violates a material requirement of SB212. This is categorically beyond the authority conferred by the legislature and therefore invalid on its face. As such, Section 18975.1(a) should be deleted in its entirety, as follows:</p> <p>(a) The department shall issue a notice of violation (NOV) to the respondent if the department determines that the respondent has violated a material requirement of this Article or Chapter 2 of Part 3 of Division 30 of the Public Resources Code. The NOV shall list and describe the nature of the violation(s). The department shall issue a NOV before commencing an action to impose administrative civil penalties.</p> <p>1 It is also noteworthy, but less relevant, to point out that the legislature did not authorize the Department to issue a "Notice of Violation" for any of the types of activities that are actionable under the statute, nor is it logical to include such a process – which is viewed as a type of informal enforcement action – in the same provision of the regulation that applies to a formal enforcement action taken by the Department to assess an administrative penalty.</p>	<p>028-036. A change to the proposed regulatory text is not necessary based on the comment. For purposes of this response, "PRC" refers to the Public Resources Code, and "NOV" refers to a notice of violation. As discussed in the response to comment 028-034, the department has authority to impose administrative civil penalties on program operators that violate material requirements of the authorizing statute and its implementing regulations.</p> <p>The department made minor edits to section 18975(a) of the proposed regulatory text for clarity. The department also added language in section 18975(b) to illustrate that penalties can be imposed for violations of the authorizing statute and its implementing regulations under PRC, Section 42035.2, including for failure to provide required access to information, as outlined in PRC, Section 42035.6.</p> <p>The department disagrees that "the enforcement provisions and procedures that are now laid out in Sections 18975.1 and 18975.2 are internally inconsistent and indiscernible." The commenter offers no specific rationale for the "internally inconsistent and indiscernible" argument.</p> <p>Section 18975.1(a) of the proposed regulatory text discusses a NOV, by which the department intends to notify a respondent about a violation of the material requirement of the authorizing statute or its implementing regulations. The purpose of this procedure is to provide notice to the respondent that the department has determined that a violation has occurred and afford the respondent an opportunity to possibly address the violation before the department takes disciplinary action. This is why this provision appears under the heading titled "Procedures for Imposing Administrative Civil Penalties".</p> <p>The department does not require statutory authorization to issue NOVs. It is not necessary for the authorizing statute to grant the department specific authority to provide a written warning to a respondent before imposing penalties. A NOV is a common written warning that the department uses to notify a respondent about statutory and regulatory violations.</p> <p>The legislature, in PRC, Section 42031.2(a), authorized the department to "adopt regulations for the implementation of the [authorizing statute]". Moreover, the department "shall adopt rules and regulations, as necessary, to carry out this division." (see PRC, Section 40502(a)). The proposed regulations are consistent with the authorizing statute, do not alter or amend it, and do not enlarge or impair its scope. Therefore, the department may impose penalties for</p>

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
028-037	MED-Project USA	Michael R. Van Winkle	18975.1(a), 18975.2(b)	N	<p>B. Section 18975.1(a): SB212 does not confer CalRecycle with enforcement authority for alleged violations of a “material requirement” of CalRecycle’s regulations.</p> <p>The Revised Proposed Regulations at Section 18975.1(a) have also been modified such that now, a “notice of violation (NOV)” may now be issued “if the department determines that the respondent has violated a material requirement of <i>this Article</i> or Chapter 2 of Part 3 of Division 30 of the Public Resource Code.” (emphasis added). Similarly, the new language in Section 18975.2(a) provides that CalRecycle “shall” take certain enumerated punitive action “if the Department finds that a program operator has failed to meet a material requirement of <i>this Article</i> or Chapter 2 of Part 3 of Division 30 of the Public Resources Code.” (emphasis added).</p> <p>The breadth of enforcement authority the Department has conferred upon itself in the above-quoted language is in direct conflict with the plain language of SB 212 and unambiguously beyond the scope of the powers conferred by the legislature. SB212 states:</p> <p style="padding-left: 40px;">Upon a written finding that a covered entity, program operator, stewardship organization, or authorized collector has not met a material requirement of <i>this chapter</i>, ..., the department may take one or both of the following actions to ensure compliance with the requirements of <i>this chapter</i>, after affording the covered entity, stewardship organization, or authorized collector a reasonable opportunity to respond to, or rebut, the finding:</p> <p style="padding-left: 40px;">(a) Revoke the program operator’s stewardship plan approval or require the program operator to resubmit the plan.</p> <p style="padding-left: 40px;">(b) Require additional reporting relating to compliance with the material requirement of this chapter that was not met.</p> <p>As such, the legislature only authorized CalRecycle to take certain forms of punitive action if it finds that there was noncompliance with a material requirement of <i>the statute</i>. Had the legislature also intended to authorize CalRecycle to act on an alleged violation of the implementing regulations that the Department is required to promulgate, it would have said so. See <i>California Soc’y of Anesthesiologists v. Brown</i>, 204 Cal. App. 4th 390, 404 (2012) (“While every word of a statute must be presumed to have been used for a purpose, it is also the case that every word excluded from a statute must be presumed to have been excluded for a purpose”); <i>PaintCare v. Mortensen</i>, 233 Cal.App.4th 1292, 1306-07 (2015) (an administrative agency cannot be “inconsistent with a statute ... or enlarge ... its scope”). Accordingly, Section 18975.2(a) of the Revised Proposed Regulations must be amended to read:</p>	<p>violations of authorizing statute as well as violations of its implementing regulations.</p> <p>028-037. For purposes of this response, “PRC” refers to the Public Resources Code. A change to the proposed regulations is not necessary.</p> <p>A statutory provision must be read in the context of the entire statute and other relevant statutes. The legislature, in PRC, Section 42031.2(a), authorized the department to “adopt regulations for the implementation of the [authorizing statute]”. Moreover, the department “shall adopt rules and regulations, as necessary, to carry out this division.” (see PRC, Section 40502(a)). The proposed regulations are consistent with the authorizing statute, do not alter or amend it, and do not enlarge or impair its scope. Therefore, the department may impose penalties for violations of authorizing statute as well as violations of its implementing regulations because these regulations help implement the authorizing statute. The commenter’s interpretation that the department may only take enforcement actions for violations of the authorizing statute is contrary to the legislative intent.</p>

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					<p>(a) if the department finds that a program operator has failed to meet a material requirement of this Article or Chapter 2 of Part 3 of Division 30 of the Public Resources Code.</p> <p>Additionally, if, notwithstanding MED-Project's above comment in section IV.A, CalRecycle retains the current language in Section 18975.1(a) discussing noncompliance with a "material requirement" in the context of administrative penalties (despite the clear inconsistency with the corresponding language in SB 212), Section 18975.1(a) must also be revised to read:</p> <p>(a) if the department determines that the respondent has violated a material requirement of this Article or Chapter 2 of Part 3 of Division 30 of the Public Resources Code.</p>	
028-038	MED-Project USA	Michael R. Van Winkle	18975.2	N	<p>C. Section 18975.2: The newly proposed procedures must be revised to satisfy minimum due process requirements.</p> <p>The Department's Revised Proposed Regulations also propose an entirely new section on the procedures that would apply to a proposed action by CalRecycle to revoke a Program Operator's approved Stewardship Plan, require a Program Operator to resubmit a Stewardship Plan, or require additional reporting associated with compliance with the material requirements of SB 212. The previous version of Section 18975.2 proposed by the Department incorporated the established procedures governing adjudicative hearings under the California Administrative Procedures Act ("APA"), and this was consistent with analogous provisions adopted by CalRecycle for the other stewardship programs that it administers, see 14 C.C.R. §§ 18945.3, 18955.3 & 18971; however, for unknown reasons the Revised Proposed Regulations no longer adopt, cross-reference or otherwise conform with the APA. MED-Project believes that the new language proposed in Section 18975.2 is arbitrary, capricious and fails to comport with the minimum due process protections that attach to a proposed action that could result in the revocation of a formal government approval granting a business the right to operate in the state.</p>	028-038. A change to the proposed regulatory text is not necessary. CalRecycle is not abrogating a respondent's due process rights by not explicitly mentioning them in its regulations. Hearings under these circumstances are allowed by law to be informal hearings since the authorizing statute did not require them to be formal. The Administrative Procedure Act "Bill of Rights" (Gov. Code 11425.10 through 11425.60) applies to hearings conducted under these regulations and mandates minimum due process regardless of whether the procedure is reflected in these regulations. Therefore the regulatory text is not arbitrary or capricious and comports with minimum due process protections.
028-039	MED-Project USA	Michael R. Van Winkle	18975.2	N	<p>The procedures now proposed in Section 18975.2(b)-(e) are extremely scant and fail to address all aspects of an adjudicatory proceeding. Moreover, the procedures that the Department is now proposing do not comport with the minimum due process protections that are conferred upon respondents that are subject to such types of proposed agency action pursuant to California's Administrative Adjudicative Bill of Rights, Cal. Gov't Code §§ 11425.10 – 11425.60, or the basic process laid out in SB 212 at PRC § 42035.4. As such, the Section 18975.2(b)-(e) of the Revised Proposed Regulation should be revised as follows:</p> <p>(b) Upon making the finding in subdivision (a), the department shall issue a written notice to the program operator of the department's intent to revoke an approved stewardship plan, require resubmittal</p>	028-039. A change to the proposed regulatory text is not necessary. CalRecycle is not abrogating a respondent's due process rights by not explicitly mentioning them in its regulations. Hearings under these circumstances are allowed by law to be informal hearings since the authorizing statute did not require them to be formal. The Administrative Procedure Act "Bill of Rights" (Gov. Code 11425.10 through 11425.60) applies to hearings conducted under these regulations and mandate minimum due process regardless of whether the procedure is reflected in these regulations. The legal and factual basis for the proposed action will, by definition, include the findings made by the department to support the proposed action, so the commenter's proposed addition to subsection (b) regarding the same

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					<p>of an approved stewardship plan, require additional compliance reporting, or all three. The notice shall state the legal and factual basis for the proposed action, <u>including a summary of all findings made by the Department to support the proposed action, and inform the respondent of their right to a hearing.</u></p> <p>...</p> <p>(d) A program operator may submit to the department a <u>written request for a hearing to contest the proposed action within thirty (30) days of receipt of the notice issued pursuant to subdivision (b).</u> The hearing request shall be in writing and shall state the basis for objecting to the department's action. Upon a failure to submit a timely hearing request under this subdivision, the program operator shall be deemed to have waived its right to hearing and the department may revoke an approved stewardship plan, require resubmittal of an approved stewardship plan, require additional compliance reporting, or all three.</p> <p>(e) The hearing shall be held before the Director of the Department of Resources Recycling and Recovery. A party shall be afforded the opportunity to present evidence and testimony on all relevant issues. Any relevant evidence shall be admitted if it is the sort of evidence on which responsible persons are accustomed to rely in the conduct of serious affairs, regardless of the existence of any common law or statutory rule which might make improper the admission of the evidence over objection in civil actions. If a hearing is requested pursuant to subdivision (d), the hearing shall be held in accordance with the provisions governing adjudicative proceedings in Government Code Title 2, Division 3, Part 1, Chapter 4.5 (Section 11400 et seq.).</p> <p>(f) The Director of the Department of Resources Recycling and Recovery shall issue a written decision within sixty (60) days from the date the hearing is concluded.</p>	is unnecessary. Subsection (d) of the proposed text outlines the procedure for requesting a hearing, so it is unnecessary to include the commenter's following proposed language in subsection (b): "... and inform the respondent of their right to a hearing."
029-001	Stericycle	Cara Simaga	18972.1	N	<p><i>Definitions of "Covered Drug" and "Home-Generated Sharps Waste"</i></p> <p>We recommend including the definitions from the statute for ease of reference and clarity.</p>	029-001. A change to the proposed regulatory text is not necessary. CalRecycle disagrees and does not believe selectively repeating statutory definitions increases ease of reference or clarity.
029-002	Stericycle	Cara Simaga	18972.1(a)(6)	Y	<p><i>"Inert" means the covered drug or mixture of covered drugs is rendered chemically inactive prior to disposal and complies with all applicable local, state and federal laws and regulations, including those of the United State Drug Enforcement Administration and California statutes and regulations governing disposal in a municipal solid waste landfill.</i></p> <p>"Inert" is not a term used to define or describe treatment of waste to meet applicable local, state, and federal laws and regulations, including those of the United States Drug Enforcement Administration (DEA). DEA uses the term "non-retrievable" which means: "for the purpose of destruction, the condition or state to which a controlled substance shall be rendered</p>	029-002. CalRecycle agrees with the commenter that it is appropriate to remove the definition of "Inert" from the proposed regulatory text. CalRecycle prefers to rely on statutory language and other agencies with authority regarding the term "inert". CalRecycle declines to define the term "inert" as "non-retrievable" and may seek guidance from appropriate agencies about a particular proposal that involves a covered drug that has been rendered "inert". CalRecycle cannot eliminate references to this method in its regulations because the authorizing statute allows a program operator to incorporate such a method as long as it is compliant with all applicable statutes and regulations.

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					following a process that permanently alters that controlled substance's physical or chemical condition or state through irreversible means and thereby renders the controlled substance unavailable and unusable for all practical purposes. The process to achieve a non-retrievable condition or state may be unique to a substance's chemical or physical properties. A controlled substance is considered "non-retrievable" when it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue. The purpose of destruction is to render the controlled substance(s) to a non-retrievable state and thus prevent diversion of any such substance to illicit purposes." (Source: 21 CFR 1300.05(b)) The reference to DEA in this definition should be removed, or, the definition should be eliminated as it is only used in one other place in the regulations and we recommend later in these comments to remove that section as well.	
029-003	Stericycle	Cara Simaga	18972.1(a)(13)	Y	<p>"Significant change" means a change that is not consistent with an approved stewardship plan that the department determines has a material impact on the operation of a stewardship program, including, but not limited to:</p> <p>...</p> <p>(E) Any changes of the service providers or facility(ies) used to transport, handle, or dispose of covered drugs or home-generated sharps waste collected through the stewardship program</p> <p>...</p> <p>Stericycle had agreed with the prior definition of "significant change", however the new verbiage in this draft, in conjunction with new language in 18973.1(i) on page 7 has changed our opinion, especially due to the new wording in (E) regarding changes of service providers or facilities that transport, handle, or dispose of covered drugs or home-generated sharps waste. We will comment further below in our comment to 18973.1(i).</p>	029-003. CalRecycle agrees with the commenter that the language regarding what constitutes a significant change requires reconsideration. CalRecycle has deleted the definition of "significant change" and instead relies on statutory language. Please note that section 18973.1(i), which discusses the term "significant change", has been modified.
029-004	Stericycle	Cara Simaga	18973.1(i)	Y	<p>18973.1(i): Any significant changes to an approved stewardship plan shall be submitted in accordance with the requirements of section 18973, and shall follow the review process outlined in subdivisions (a) through (h) above.</p> <p>This new language, in conjunction with new wording to the definition of "significant change" found in 18972.1 needs to be reconsidered. According to that definition, and this new language, changes of service providers or facilities that transport, handle, or dispose of covered drugs or home-generated sharps waste would need to follow the extensive review process for a stewardship plan, initial program budget, annual report, or annual budget. Though we agree that some changes would certainly warrant following this process, changes to service providers or facilities that transport, handle, or dispose of covered drugs or home-generated sharps should not require such an extensive review process, especially if the change is simply to a facility that has already been identified in the plan or that meets the requirements described in the plan.</p>	<p>029-004. CalRecycle agrees with the commenter that the language regarding what constitutes a significant change requires reconsideration and has deleted the definition of significant change and modified the language in section 18973.1(i) as follows:</p> <p><u>(i) A program operator shall submit any significant changes to a stewardship plan in writing for approval by the department, and shall not implement the changes prior to that approval. Any significant changes to an approved stewardship plan shall be submitted to the department in accordance with the requirements of section 18973, and shall follow the review process outlined in subdivisions (a) through (h) above.</u> The program operator shall also include a re-certification that the stewardship plan containing the significant changes is compliant with all applicable laws and regulations, in accordance with section 18973.2(e)(2) or 18973.3(d)(2), as applicable.</p>

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					<p>The plan should require a list of the facilities that the operator has partnered with for transportation and disposal and the operator should be able to choose and switch between those facilities at any time without having to resubmit their plan. The regulations should be flexible enough to allow plan operators to adapt to unforeseeable changes that are consistent with the intent of the plan and have no material impact on transportation and disposal, such as a facility that changes hands but remains in compliance with all requirements. As currently written, operations could be significantly delayed while waiting for a months-long approval process, which could jeopardize consumers' access to convenient disposal. Perhaps the option of having several that are pre-approved and having that spelled out that this would not be a significant change would be helpful for this section and ease the burden we are concerned about.</p>	<p>It is the program operator's responsibility to notify CalRecycle regarding significant changes, as outlined in the authorizing statute and proposed regulations (see section 18973.1(i)).</p> <p>CalRecycle will work with program operators on a case-by-case basis to address significant changes to an approved stewardship plan. CalRecycle will determine, on a case-by-case basis, if the program operator has violated section 18973.1(i) of the proposed regulations and may take appropriate enforcement actions.</p> <p>The statutory language provides the program operator with flexibility to adapt to unforeseeable changes. It is a case-by-case determination whether a change in the service provider constitutes a significant change. The proposed regulations allow for program operators to list multiple service providers in the stewardship plan. This provides flexibility during program implementation for the program operator to switch between pre-approved service providers to meet the needs of the program.</p>
029-005	Stericycle	Cara Simaga	18973.2(g)(1)	N	<p>18973.2(g)(1): Collection, Transportation, and Disposal System. Descriptions of the following: (1) Processes and policies that will be used to safely and securely collect, track, and properly manage covered drugs from collection through final disposal.</p> <p>It is imperative that hosts be able to safely continue to operate kiosks without security risks potentially caused by sharing specific security practices beyond those in direct need of the information. Likewise, it is imperative that service technicians, transporters, and all other persons involved in the program can safely perform their work without security risks potentially caused by sharing specific security practices beyond those in direct need of the information. Therefore, we strongly recommend that the plan include only broad descriptions of this information. In addition, this information should be marked confidential to prevent release to the general public with potentially nefarious intent. Full details of this type should not be publicly available.</p>	<p>029-005. A change to the proposed regulatory text is not necessary. CalRecycle agrees that sharing specific security practices with the general public may pose a security risk; however, the document submitter has the option to identify such information as confidential or proprietary for proper management of the information. The information is necessary for CalRecycle to determine compliance with statute and regulatory requirements.</p> <p>To the extent that a document may contain proprietary or confidential information, those portions of the document may be redacted from what is publicly made available, but they are potentially subject to a Public Records Act request. Consistent with Public Resources Code section 40062 and Title 14, Division 7, Chapter 1 of the California Code of Regulations under Article 4, Public Records (Section 17041 et seq.), when a public records act request is made, there is a process for determining if the claimed confidential records are in fact confidential. This process involves notifying the entity claiming confidentiality for them to provide an explanation of the basis for that claim. The requirement in these regulations is designed to streamline that process and potentially allow a faster determination. If the initial explanation is sufficient, no further action would be needed from the covered entity to maintain confidentiality. If the initial explanation is not sufficient to verify the claim of confidentiality, CalRecycle would provide a program operator notice of a public records act request pursuant to Title 14, Division 7, Chapter 1 of the California Code of Regulations, Section 17046 in order to provide additional explanation.</p>

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
029-006	Stericycle	Cara Simaga	18973.2(g)(6)(A)	Y	<p>18973.2(g)(6)(A) 11 Mail-back services or an alternative form of collection and disposal system, pursuant to section 42032.2(c) of the Public Resources Code, to be provided to ultimate users, including, but not limited to, the following:</p> <p>(A) Locations where preaddressed, prepaid mail-back materials are distributed or an alternative form of collection and disposal system, pursuant to section 42032.2(c)(2) of the Public Resources Code, that would render the drug inert, is provided, if applicable.</p> <p>Disposal systems that render drugs inert, but do not require the material to be mailed back, would create an issue with the reporting structure. Use of these types of systems does not provide a way to identify what was used, how they were used, the amounts disposed, or the final disposition. There is also question as to the effectiveness of these products as discussed in our cover letter to these comments.</p>	<p>029-006. CalRecycle acknowledges the commenter's concern regarding the effectiveness of alternative forms of collection and disposal systems that would render a covered drug inert and the challenges that approving use of these systems would pose for program operators related to reporting requirements. The commenter notes that use of these disposal systems would result in a "lack of ability to report on usage, amounts disposed, or final disposition". While CalRecycle understands these concerns, compliant disposal systems that render drugs inert were contemplated by the authorizing statute. If utilization of such disposal systems are approved by authorizing agencies and a program operator proposes this type of disposal system in a stewardship plan, CalRecycle will review the stewardship plan for compliance with this Article prior to approval and implementation. CalRecycle has modified subsection 18973.2(g)(6)(A) as follows:</p> <p><u>(A) List of locations and/or description of mechanisms to provide ultimate users with Locations where preaddressed, prepaid mail-back materials are distributed or an alternative form of collection and disposal system, pursuant to section 42032.2(c)(2) of the Public Resources Code, that would render the covered drug inert, is provided, if applicable.</u></p> <p>CalRecycle defers to other agencies with authority to determine whether these products are effective enough to be compliant with existing laws and regulations.</p>
029-Supp. 006	Stericycle	Cara Simaga	18973.2(g)(6)(A)	Y	<p>Section 18973.2(g)(6)(A) currently allows for the use of alternative forms of collection or disposal that would render the collected drugs inert. We would like to point out some concerns with these types of products, in addition to our comment in the attached regarding the lack of ability to report on usage, amounts disposed, or final disposition. The Federal Government Accountability Office wrote a paper outlining the effectiveness of these types of systems (https://www.gao.gov/assets/710/701126.pdf). The following statement was made in the document which supports our questioning of the effectiveness and environmental safety: "Disposal of opioids in the trash—either with an unpalatable substance or in-home disposal product—removes them from the home, but this option may not be permanent and the drugs still may be available for misuse. Drugs that are disposed in the trash ultimately are introduced to landfills, where they can escape landfill containment and enter wastewater streams or ground water sources." A study produced for the San Francisco Department of the Environment provides further detail and discussion on specific products but also raises concern on products used to render drugs inert: "By physically immobilizing most of the drugs, even reversibly, or making the drug mixture noxious, the products may make the medicines less appealing and make illicit access more difficult. However, most of the</p>	<p>029-Supp. 006. CalRecycle acknowledges the commenter's concern regarding the effectiveness of alternative forms of collection and disposal systems that would render a covered drug inert. CalRecycle defers to other agencies with authority to determine whether these products are effective enough to be compliant with existing laws and regulations. Compliant disposal systems that render drugs inert were contemplated by the authorizing statute. See response to comment 029-006 regarding "lack of ability to report on usage, amounts disposed, or final disposition".</p>

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					<p>products are in liquid form after use, creating counterbalancing concerns about potential human exposure to dissolved pharmaceuticals as well as environmental releases if a bottle or pouch is spilled during use or when the container is crushed in a garbage compactor truck.” (https://sfenvironment.org/sites/default/files/fliers/files/medicinedisposalproducts_march2019.pdf)</p> <p>Variables such as the drug type and amounts disposed could impact effectiveness at rendering a drug or drugs inert. The safety of these products for both the user and the environment when disposed needs to be considered as the byproducts and their long-term impacts for final disposal are not yet understood. The additional packaging being introduced to landfill should also be considered. Our recommendation is that the agency reconsider this new section on alternative forms of collection and disposal and remove it from the conditions.</p>	
029-007	Stericycle	Cara Simaga	18973.2(g)(7)	Y	<p>18973.2(g)(7): If applicable, any alternative form of collection and disposal system that complies with applicable local, state, and federal laws and regulations including, but not limited to, United States Drug Enforcement Administration regulations, that is used as a supplemental service for any county that does not meet the minimum authorized collection site threshold due to circumstances out of the program operator’s control</p> <p>We recommend clarifying this section to refer to pharmaceutical take back events. Section 18973.2(g) should specifically reference take back events for drugs, as 18973.3(f) does for sharps. If 18973.2(g)(7) is referring to events, it should be clarified.</p>	<p>029-007. CalRecycle agrees with the commenter and has modified the section as follows:</p> <p>(C76) Pursuant to section 42032.2(c)(2) of the Public Resources Code, description of if applicable, a Any mail-back program or alternative form of collection and disposal system that complies with applicable local, state, and federal laws and regulations including, but not limited to, United States Drug Enforcement Administration regulations, that will be is used as a supplemental service for any county that does not have not meet the minimum number of authorized collection sitesite threshold due to circumstances beyond out of the program operator’s control, is applicable.</p> <p>Due to reorganization of this section, 18973.2(g)(7), has been changed to 18973.2(g)(6)(C).</p> <p>The section does not solely refer to pharmaceutical take back events as the only alternative form of collection and is intended to provide the program operator with flexibility to design program collection and disposal systems that meet all applicable requirements.</p>
029-008	Stericycle	Cara Simaga	18973.2(g)(9)	N	<p>18973.2(g)(9): Description of a service schedule that meets the needs of each authorized collection site. Process by which collection receptacles will be monitored, explanation of how service schedules are determined to ensure that collection receptacles do not reach capacity, and procedures to be followed if capacity is reached. The service schedule must meet the needs of each authorized collection site to ensure that collected covered drugs are transported to final disposal in a timely manner.</p> <p>The phrase "timely manner" needs to be removed or better defined as the phrase could be interpreted in many ways. The timeframe of the request should be defined, we would suggest the timeframe begins when the first call is made to notify of a full collection container. We would also like to</p>	<p>029-008. A change to the proposed regulatory text is not necessary. The proposed regulatory text provides flexibility for a program operator to design stewardship program schedules (that comply with applicable laws and regulations) that meet programmatic needs and those of their service providers. Further defining “timely manner”, may limit program design and mandate program operators to design service schedules that do not consider such factors as user frequency and geographic/location variances.</p> <p>Due to reorganization of this section, 18973.2(g)(9), has been changed to 18973.2(g)(7).</p>

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					remind that transportation to disposal of collected covered drugs ultimately falls on the common carrier (UPS/FedEx) and shipping times can vary should that be what this this section is referring to.	
029-009	Stericycle	Cara Simaga	18973.2(g)(10)	Y	18973.2(g)(10): What corrective actions will be taken if a program operator discovers critical deviations from stewardship plan policies and procedures. "Critical deviations" needs to be defined or explained as this term is too subjective. We would suggest defining "critical deviation" as follows: any occurrence where diversion of consumer-generated medication is confirmed and/or where consumer-generated medication is not destroyed in compliance with DEA regulations.	029-009. CalRecycle declines to define the term, and upon further analysis, has removed the term "critical deviations" from the proposed regulatory text. Replacement language utilizes the term "critical instances of noncompliance" as it better aligns with section 42033.2(b)(6) of the Public Resources Code. A program operator must assess whether an instance of noncompliance is "critical".
029-010	Stericycle	Cara Simaga	18973.2(g)(12)	N	18973.2(g)(12): Standard operating procedures that will address incidents related to safety and security including processes to ensure that the department and applicable local, state, and federal agencies are notified of the incident. This description shall also explain the actions that will be taken to change policies, procedures, and tracking mechanisms to alleviate the problems with safety and security and improve safety and security. This section of the proposed regulations existed prior, however, the new language on notifications to the department, and applicable local, state, and federal agencies leads to the need to clarify what is meant by "incidents related to safety and security". Because notification to the aforementioned agencies is now required, we would suggested a focus on reporting of incidents specifically related to diversion of covered drugs as they could potentially include controlled substances. Incidents that require the involvement of law enforcement, result in serious injury, or involve likely diversion could also be included in this new notification requirement.	029-010. A change to the proposed regulatory text is not necessary. Clarification of what is meant by "incidents related to safety and security" is not necessary. The language was modified for clarity and consistency with subsection (1)(H) of subdivision (a) of section 42032.2 of the Public Resources Code. CalRecycle needs the standard operating procedure information in order to evaluate whether a program operator is meeting the requirements of statute and regulations. Limiting reporting requirements to specific incidents related to diversion of covered drugs, incidents involving law enforcement, incidents resulting in serious injury, or incidents that likely involve diversion would not provide the appropriate authorities sufficient notice of the challenges that program operators address related to safety and security during program implementation.
029-011	Stericycle	Cara Simaga	18973.3	Y	General Comment for this section: Mail back programs defined in this section have been left open (meaning doesn't stipulate the use of United States Postal Service - USPS). Stericycle agrees with leaving the options open. However, if a system choses to use the USPS it is recommended that there is language in the regulation that is clear that it must meet all criteria for USPS. As stated in previous comments, we recommend that the department add language that if the mail back system is developed to be used and shipped under the United States Postal Service (USPS) that all requirements under USPS for mail back of sharps and medical waste must be met. The sharps system being used through the USPS must meet minimum criteria as outlined in the domestic mail manual and must have approved authorization for the package for shipment through USPS. If an alternative shipping vendor/method is selected, the stewardship	029-011. CalRecycle agrees with the commenter that program operators must meet all criteria of the mailing method proposed in the submitted stewardship plan. Program operators have various mailing and delivery options to meet this requirement. CalRecycle declines to add language stating that if a program operator chooses to use the USPS system, it must meet all criteria for USPS mailing as stated in the domestic mail manual. To clarify the requirement that the chosen mailing and delivery option must meet all applicable requirements, CalRecycle has modified section 18973.3(d)(2) as follows: <u>(2) Written certification, by an authorized representative of the program operator, that, at the time of submission to the department, the stewardship plan, including all aspects of the plan related to the handling, transportation, and disposal of home-generated sharps</u>

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					program operator should be required to provide documentation that their shipping vendor approves the program and packaging.	<u>waste is in compliance with all applicable local, state, and federal laws and regulations.</u>
029-012	Stericycle	Cara Simaga	18973.3(f)(5)(A)	N	<p>18973.3(f)(5)(A): Supplemental collection method(s) for home-generated sharps waste that may be provided, in addition to, but not in lieu of, the mail-back program. These methods may include, but are not limited to: (A)Secure receptacle collection. If a program operator proposes to implement a receptacle-based program using authorized and approved home-generated sharps consolidation points then the following information, as applicable, shall be included, but not be limited to:(i-iv not copied here for brevity)</p> <p>We recommend describing/defining what is meant by "secure receptacle". Unlike collection receptacles used for collecting controlled substances, we are not aware of any design standards for sharps collection receptacles. The department should consider adding language to describe secure design features.</p>	029-012. A change to the proposed regulatory text is not necessary. CalRecycle does not want to limit the ability of program operators to utilize collection receptacles that they determine meet the definition of "secure receptacle" and are compliant with all applicable laws and regulations. CalRecycle understands that although design standards may not exist at this time, they may exist in the future and further defining such standards may limit a program operator's use of such products.
029-013	Stericycle	Cara Simaga	18973.3(f)(5)(A)(iv)	N	<p>18973.3(f)(5)(A)(iv): Standard operating procedures that will address incidents related to safety and security, including processes to ensure that the department and applicable local, state, and federal agencies are notified of the incident. This description shall also explain the actions that will be taken to change policies, procedures, and tracking mechanisms to alleviate the problems with safety and security and improve safety and security.</p> <p>This section of the proposed regulations existed prior, however, the new language on notifications to "the department, and applicable local, state, and federal agencies" would require clarification on "incidents related to safety and security". We are not aware of safety or security incidents that have occurred involving sharps collection receptacles that would warrant such notification. Furthermore, if local, state, and federal agencies have such reporting requirements already (though we are not aware of any other than spill reporting requirements by the Department of Transportation (DOT)), referencing those requirements here is duplicative of their regulations. We suggest requiring notification to the department only as they are the entity providing oversight to the program.</p>	029-013. A change to the proposed regulatory text is not necessary. The proposed regulatory language is meant to capture any incidents related to safety and security and further definition on "incidents related to safety and security" is not necessary The language in this section was modified for clarity and consistency with subsection (1)(H) of subdivision (a) of section 42032.2 of the Public Resources Code. Although safety or security incidents involving sharps collection receptacles may not have occurred, incidents may occur in the future. CalRecycle agrees that referencing Department of Transportation or other agency notification requirements is duplicative and has declined to do so in this section of the proposed regulatory text.
029-014	Stericycle	Cara Simaga	18973.3(f)(9)	Y	<p>18973.3(f)(9): Corrective actions that will be taken if a program operator discovers critical deviations from stewardship plan policies and procedures.</p> <p>"Critical deviations" needs to be defined or explained as this term is too subjective. We have suggested in other comments in this document that this term reflect diversion related issues for covered drugs. When the term is used to describe sharps stewardship plans or policies, we would suggest referring to issues related to DOT or USPS regulations for packagings and/or containers.</p>	029-014. CalRecycle declines to define the term, and upon further analysis, has removed the term "critical deviations" from the proposed regulatory text. Replacement language utilizes the term "critical instances of noncompliance" as it better aligns with section 42033.2(b)(6) of the Public Resources Code. A program operator must assess whether an instance of noncompliance is "critical".

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
029-015	Stericycle	Cara Simaga	18973.4(e)	Y	<p>18973.4(e): Corrective actions taken if the program operator discovered critical deviations from stewardship plan policies and procedures and a description of each critical deviation.</p> <p>"Critical deviations" needs to be defined or explained as this term is too subjective. We would suggest defining "critical deviation" as follows: any occurrence where diversion of consumer-generated medication is confirmed and/or where consumer-generated medication is not destroyed in compliance with DEA regulations.</p>	029-015. CalRecycle declines to define the term, and upon further analysis, has removed the term "critical deviations" from the proposed regulatory text. Replacement language utilizes the term "critical instances of noncompliance" as it better aligns with section 42033.2(b)(6) of the Public Resources Code. A program operator must assess whether an instance of noncompliance is "critical".
029-016	Stericycle	Cara Simaga	18973.4(h)	N	<p>18973.4(h): Safety and Security. Describe the general nature of any incidents with safety or security related to collection, transportation, or disposal of collected covered drugs. Explain what corrective actions were taken to address the issue and improve safety and security. Information about any incident(s) shall be made available to the department upon request, and shall include, but not be limited to:</p> <p>Describing the process and incidents that occurred related to safety or security failures could be a potential risk. This would require this information (corrective actions and updates to safety and security plans) to have to go through the confidential documentation process to prevent information on security practices from being available to the public to minimize risk of diversion, which is a more lengthy process. Our recommendation would be to minimize the information that is required to be submitted with the annual report. This information should only be made available to the department upon request and in this way the program is in place, but does not have to be submitted to the agency directly and have to be maintained under confidentiality constraints. As stated in comments above, It is imperative that hosts be able to safely continue to operate kiosks without security risks potentially caused by sharing specific security practices beyond those in direct need of the information. Likewise, it is imperative that service technicians, transporters, and all other persons involved in the program can safely perform their work without security risks potentially caused by sharing specific security practices beyond those in direct need of the information. Therefore, we strongly recommend that the plan include only broad descriptions of this information. In addition, this information should be marked confidential to prevent release to the general public with potentially nefarious intent. Full details of this type should not be publicly available and/or be included in the annual report.</p>	<p>029-016. A change to the proposed regulatory text is not necessary. CalRecycle agrees that sharing specific security practices with the general public may pose a security risk; however, the document submitter has the option to identify such information as confidential or proprietary to inform the department of such instances. CalRecycle needs the detailed information in order to determine compliance with statute and regulatory requirements.</p> <p>The proposed regulatory language states that information about incidents "shall be made available to the department upon request" and does not require detailed information in the annual report. The requirement of the annual report is to provide "the general nature of any incidents with safety or security related to collection, transportation, or disposal of collected covered drugs".</p> <p>To the extent that a document may contain proprietary or confidential information, those portions of the document may be redacted from what is publicly made available, but they are potentially subject to a Public Records Act request. Consistent with Public Resources Code section 40062 and Title 14, Division 7, Chapter 1 of the California Code of Regulations under Article 4, Public Records (Section 17041 et seq.), when a public records act request is made, there is a process for determining if the claimed confidential records are in fact confidential. The information required to be submitted under this law is in no way automatically confidential without justification, just because it is labelled as such.</p>
029-Supp. 016	Stericycle	Cara Simaga	18973.4(h)	N	<p>Information on safety and security breaches as well as corrective actions is relevant and important, but should only be shared with a limited audience, particularly those directly involved in management of these programs, not the general public. The proposed regulation allows for information to be submitted under confidentially (18973(c)), however, taking extra steps to follow the requirements is not ideal. We recommend</p>	029-Supp. 016. A change to the proposed regulatory text is not necessary. See response to comment 029-016.

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					that the plans and reports do not require specific detail on matters related to processes and incidents relevant to safety or security. We would also recommend that the Department include language to allow for the ability to request more specific information on safety and security related incidents and that such information be provided by the appropriate party upon request. Limiting the sharing of information on safety and security risks will protect those that operate programs as well as those that service, transport, and dispose of the materials that are collected.	
029-017	Stericycle	Cara Simaga	18973.4(h)(5)	N	<p>18973.4(h)(5): Regulatory or law enforcement agencies involved and any litigation, arbitration, or other legal proceedings that result from each incident.</p> <p>As noted in prior comments, the language of this section should be clarified to require the stewardship program operator to identify and track the number of incidents and legal issues under their scope. The authorized collectors may be involved in incidents of which the stewardship program operator are unaware of, or are outside the scope of responsibility of the program operator. There may also be circumstances where the authorized collector will not provide information to the program operator due to legal issues, liability, or other corporate reasons. The program operator may not have any control or visibility to a host collector issue. Our recommendation would be to have the authorized collection sites track and maintain information on only the issues they are having with regulatory or other law enforcement as we believe this requirement is outside of the scope of this legislation and regulation.</p>	029-017. A change to the proposed regulatory text is not necessary. The proposed regulatory language was modified for clarity and consistency with subsection (1)(H) of subdivision (a) of section 42032.2 of the Public Resources Code. CalRecycle understands that a program operator may not be aware of all incidents and legal issues related to the operations of the authorized collector; however CalRecycle needs the information required per this section in order to evaluate whether a program operator is meeting the requirements of statute and regulations. Program operators are afforded the flexibility to design incident reporting systems that capture this information from their authorized collectors.
029-018	Stericycle	Cara Simaga	18973.5(e)	Y	<p>18973.5(e): Corrective actions taken if the program operator discovered critical deviations from stewardship plan policies and procedures, and a description of each critical deviation.</p> <p>"Critical deviations" need to be defined or explained as this term is too subjective. We would suggest defining "critical deviation" as follows: any occurrence where diversion of consumer-generated medication is confirmed and/or where consumer-generated medication is not destroyed in compliance with DEA regulations.</p>	029-018. CalRecycle declines to define the term, and upon further analysis, has removed the term "critical deviations" from the proposed regulatory text. Replacement language utilizes the term "critical instances of noncompliance" as it better aligns with section 42033.2(b)(6) of the Public Resources Code. A program operator must assess whether an instance of noncompliance is "critical".
029-019	Stericycle	Cara Simaga	18973.5(h)	N	<p>18973.5(h): Safety and Security. Describe the general nature of any incidents with safety or security related to collection, transportation, or disposal of home-generated sharps waste. Explain the corrective actions taken to address the issue and improve safety and security. Information about any incident(s) shall be made available to the department, upon request, and shall include, but not be limited to:</p> <p>Describing the process and incidents that occurred related to safety or security failures could be a potential risk. This would require this information (corrective actions and updates to safety and security plans) to have to go through the confidential documentation process to prevent information on security practices from being available to the public to</p>	<p>029-019. A change to the proposed regulatory text is not necessary. CalRecycle agrees that sharing specific security practices with the general public may pose a security risk; however, the document submitter has the option to identify such information as confidential or proprietary while informing the department of such instances and CalRecycle needs the detailed information in order to determine compliance with statute and regulatory requirements.</p> <p>The proposed regulatory language states that information about incidents "shall be made available to the department upon request" and does not require detailed information in the annual report. The requirement of the annual report is to provide "the general nature of</p>

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					minimize risk of diversion, which is a more lengthy process. Our recommendation would be to minimize the information that is required to be submitted with the annual report. This information should only be made available to the department upon request and in this way the program is in place, but does not have to be submitted to the agency directly and have to be maintained under confidentiality constraints. As stated in comments above, It is imperative that hosts be able to safely continue to operate programs without security risks potentially caused by sharing specific security practices beyond those in direct need of the information. Likewise, it is imperative that service technicians, transporters, and all other persons involved in the program can safely perform their work without security risks potentially caused by sharing specific security practices beyond those in direct need of the information. Therefore, we strongly recommend that the plan include only broad descriptions of this information. In addition, this information should be marked confidential to prevent release to the general public with potentially nefarious intent. Full details of this type should not be publicly available and/or be included in the annual report.	any incidents with safety or security related to collection, transportation, or disposal of collected covered drugs". To the extent that a document may contain proprietary or confidential information, those portions of the document may be redacted from what is publicly made available, but they are potentially subject to a Public Records Act request. Consistent with Public Resources Code section 40062 and Title 14, Division 7, Chapter 1 of the California Code of Regulations under Article 4, Public Records (Section 17041 et seq.), when a public records act request is made, there is a process for determining if the claimed confidential records are in fact confidential. The information required to be submitted under this law is in no way automatically confidential without justification, just because it is labelled as such.
029-Supp. 019	Stericycle	Cara Simaga	18973.5(h)	N	Information on safety and security breaches as well as corrective actions is relevant and important, but should only be shared with a limited audience, particularly those directly involved in management of these programs, not the general public. The proposed regulation allows for information to be submitted under confidentially (18973(c)), however, taking extra steps to follow the requirements is not ideal. We recommend that the plans and reports do not require specific detail on matters related to processes and incidents relevant to safety or security. We would also recommend that the Department include language to allow for the ability to request more specific information on safety and security related incidents and that such information be provided by the appropriate party upon request. Limiting the sharing of information on safety and security risks will protect those that operate programs as well as those that service, transport, and dispose of the materials that are collected.	029-Supp. 019. A change to the proposed regulatory text is not necessary. See response to comment 029-019.
030-001	LAC Public Works	Coby J. Skye	18972.1(a)(11)	Y	We request the removal of the language "or is not reasonably feasible" from the regulation text. Public Resources Code 42032.2(d)(1)(F)(i), establishes a convenience standard for the program: (i) The program provides or initiates distribution of a sharps waste container and mail-back materials at the point of sale, to the extent allowable by law as this additional allowance is not within the scope defined by statute. The draft regulations Section 18972.1 is currently inconsistent with this statute as the language includes the language "or is not reasonably feasible". By including a convenience standard, the success of the stewardship program may be undermined by allowing other considerations other than legal limitations. <ul style="list-style-type: none"> Proposed Regulatory Text and Recommended Changes/Revisions: 	030-001. CalRecycle agrees to remove the "or is not reasonably feasible" clause. CalRecycle believes that the options (with the phrase removed) under the proposed regulations text definition in section 18972.1(a)(10) offer the program operator sufficient flexibility while maintaining convenience for the ultimate user.

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					(C) Other methods of providing a sharps waste container and mail-back materials, if the method identified in subpart (A) above is not allowed by law or is not reasonably feasible , and if the method identified in subpart (B) above is not allowed by law or is not reasonably feasible . These methods must be approved by the department in a stewardship plan and result in substantially the same level of convenience to the ultimate user as the methods identified in subparts (A) and (B) above.	
030-002a	LAC Public Works	Coby J. Skye	18973.2(j)	N	The Education and Outreach provisions of these sections are enhanced by the changes made for the current draft. The provisions for materials, signage, labeling, internet and toll-free telephone number functionality, key metrics for evaluation, and coordination will most likely help maximize awareness, user participation, and the success of the programs.	030-002a. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. CalRecycle acknowledges the commenter's support of the proposed outreach and education sections of the regulations.
030-002b	LAC Public Works	Coby J. Skye	18973.3(i)	N	The Education and Outreach provisions of these sections are enhanced by the changes made for the current draft. The provisions for materials, signage, labeling, internet and toll-free telephone number functionality, key metrics for evaluation, and coordination will most likely help maximize awareness, user participation, and the success of the programs.	030-002b. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. CalRecycle acknowledges the commenter's support of the proposed outreach and education sections of the regulations.
031-001a	San Francisco Department of the Environment	Jen Jackson	18973.2(j)	N	The Department is encouraged by the changes CalRecycle made in the current Proposed Regulations, as we believe the revisions address many of the comments we voiced in our February 14, 2020 letter. Notably, the revised Outreach and Education and Stewardship Plan Coordination requirements provide CalRecycle with an improved framework and toolkit to help ensure the statewide medicine and sharps stewardship programs are implemented in a robust, accessible, and cohesive manner.	031-001a. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. CalRecycle acknowledges the commenter's support of the proposed outreach and education sections of the regulations.
031-001b	San Francisco Department of the Environment	Jen Jackson	18973.3(i)	N	The Department is encouraged by the changes CalRecycle made in the current Proposed Regulations, as we believe the revisions address many of the comments we voiced in our February 14, 2020 letter. Notably, the revised Outreach and Education and Stewardship Plan Coordination requirements provide CalRecycle with an improved framework and toolkit to help ensure the statewide medicine and sharps stewardship programs are implemented in a robust, accessible, and cohesive manner.	031-001b. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. CalRecycle acknowledges the commenter's support of the proposed outreach and education sections of the regulations.
031-002	San Francisco Department of the Environment	Jen Jackson	General	N	We also want to recognize and commend CalRecycle's hard work and diligence advancing these important regulations amid such unprecedented times. We urge CalRecycle to maintain this commitment to meeting the statute's rulemaking and implementation deadlines so these critical programs become available to Californians across the state as soon as possible.	031-002. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. CalRecycle acknowledges the commenter's emphasis on the department meeting the implementation timeline.
031-003	San Francisco Department of the Environment	Jen Jackson	18973.4(c)(2)(D)	N	We welcome the addition of Section 18973.4(c)(2)(D) that requires the Annual Report for Covered Drugs to include a description of "Efforts between the program operator and retail pharmacy chains to meet the requirement stated in" Section 42032.2(b)(2) of the statute ("Retail Pharmacy Chain Participation Requirement")	031-003. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. CalRecycle acknowledges the commenter's support of Section 18973.4(c)(2)(D) of the proposed regulations.

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
						Due to a reorganization of subsection 18973.4(c), the requirement of the text in subsection 18973.4(c)(2)(D) has been moved to 18973.4(c)(2)(C) in the proposed regulatory text.
031-004	San Francisco Department of the Environment	Jen Jackson	18973.2(d)(4)	Y	<p>(See comment 031-003) However, we are concerned that the Proposed Regulations do not require a similar description in the Stewardship Plan, prior to program implementation. Given the ongoing communication and coordination that will be needed for a program operator and a retail pharmacy chain(s) to comply with this requirement, establishing clear roles and a detailed process from the outset is especially critical. This will help ensure compliance during initial program implementation and on an ongoing basis in response to changes in the number of participating authorized collectors in each county.</p> <p>Although meeting this requirement is a shared responsibility between the program operator and retail pharmacy chains, the program operator is the logical entity to assign responsibility for monitoring convenience standard levels in each county and, as applicable, notifying a pharmacy chain(s) that they are obligated to serve as an authorized collector(s). To that end, we urge CalRecycle to add a new subparagraph to Section 18973.2(d) as follows:</p> <p><i>(6) Pursuant to Section 42032.2(b)(2) of the Public Resources Code, description of the process for monitoring the minimum convenience standard threshold in each county, notifying retail chain pharmacies of their obligation to serve as an authorized collector(s), as applicable, and including them in the stewardship program.</i></p>	<p>031-004. CalRecycle agrees with the commenter's recommendation, but prefers the following addition to section 18973.2(d) of the proposed regulatory text:</p> <p>(4) Description of efforts to work with retail pharmacies and retail pharmacy chains to fulfill the requirement in section 42032.2(b)(2) of the Public Resources Code, if applicable.</p>
031-005a	San Francisco Department of the Environment	Jen Jackson	18973.2(j)	N	We strongly support proposed revisions to the Education and Outreach requirements for both the Covered Drugs and Home-Generated Sharps Stewardship Plan sections of the Proposed Regulations (Section 18973.2(j) and Section 18973.3(i), respectively). Providing a robust, accessible, and consistent outreach and education program is critical to a stewardship program's overall success. The revised language better aligns with this priority and that statutes' requirement for a "comprehensive education and outreach program" while providing program operators concrete guidance. We also appreciate additions such as multi-language support for the website and toll-free telephone number, readily understandable kiosk signage design, and other accessibility provisions. Collectively, these requirements will help ensure the diverse audience of ultimate users across California can easily access important program information and services.	031-005a. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. CalRecycle acknowledges the commenter's support of the proposed outreach and education sections of the regulations.
031-005b	San Francisco Department of the Environment	Jen Jackson	18973.3(i)	N	We strongly support proposed revisions to the Education and Outreach requirements for both the Covered Drugs and Home-Generated Sharps Stewardship Plan sections of the Proposed Regulations (Section 18973.2(j) and Section 18973.3(i), respectively). Providing a robust, accessible, and consistent outreach and education program is critical to a stewardship program's overall success. The revised language better	031-005b. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. CalRecycle acknowledges the commenter's support of the proposed outreach and education sections of the regulations.

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					aligns with this priority and that statutes' requirement for a "comprehensive education and outreach program" while providing program operators concrete guidance. We also appreciate additions such as multi-language support for the website and toll-free telephone number, readily understandable kiosk signage design, and other accessibility provisions. Collectively, these requirements will help ensure the diverse audience of ultimate users across California can easily access important program information and services.	
031-006	San Francisco Department of the Environment	Jen Jackson	18973.2(k)	N	As stated in our February 14, 2020 comment letter, establishing minimum coordination requirements and prescriptive criteria for the coordination of multiple stewardship plans is extremely important to minimize the possibility of conflicting messages or instructions from different program operators. We believe that revised language in the Proposed Regulations is a step in the right direction, as it moves away from a "good faith effort" standard in favor of a more explicit, outcome-based guidance.	031-006. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. CalRecycle acknowledges the commenter's support of revised language in section 18973.2(k) of the proposed regulations.
031-007	San Francisco Department of the Environment	Jen Jackson	18973.2(k)	N	We suggest that CalRecycle further expand the plan coordination language to require a single system of program design and promotion and to specify elements of program promotion on which multiple program operators are required to collaborate.	031-007. A change to the proposed regulatory text is not necessary. CalRecycle declines to require a single system of program design or to specify elements on which program operators are required to collaborate. Per section 18973.2 (k) of the proposed regulations, program operators will coordinate to avoid confusion to the public and all program participants. CalRecycle prefers to allow program operators the flexibility to innovate program design and promotion, rather than creating one system that multiple program operators are required to utilize.
031-008	San Francisco Department of the Environment	Jen Jackson	18973.2(k)	N	In addition, we urge CalRecycle to promote program operator collaboration and coordination to the extent feasible through the stewardship plan review and approval process.	031-008. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. CalRecycle acknowledges the commenter's emphasis on program operator coordination.
032-001a	COPALM	Bryan Zaragoza Hurtado	18973.2(j)	N	While we strongly support Senate Bill 212 in its current form, our coalition proposes that the following recommendations be incorporated: Providing necessary resources and funding for nonprofit organizations and community-based programs to assist with information/resource dissemination, outreach, and to educate the community on implementing methods of proper safe disposal and identifying disposal locations.	032-001a. A change to the proposed regulatory text is not necessary. Cooperation between a program operator and nonprofit organizations to assist with education and outreach to the community on safe disposal and disposal locations is neither prohibited nor required. Statute requires a program operator to conduct a comprehensive education and outreach program pursuant to Public Resources Code section 42031.6. There are many options a program operator may utilize to achieve the comprehensive requirement, thus, the proposed regulations allow program operators flexibility in the design of their education and outreach programs. If a covered entity decides not to run its own stewardship program, it will be doing so through a non-profit stewardship organization.
032-001b	COPALM	Bryan Zaragoza Hurtado	18973.3(i)	N	While we strongly support Senate Bill 212 in its current form, our coalition proposes that the following recommendations be incorporated: Providing necessary resources and funding for nonprofit organizations and community-based programs to assist with information/resource	032-001b. A change to the proposed regulatory text is not necessary. Cooperation between a program operator and nonprofit organizations to assist with education and outreach to the community on safe disposal and disposal locations is neither prohibited nor required. Statute requires a program operator to conduct a comprehensive

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					dissemination, outreach, and to educate the community on implementing methods of proper safe disposal and identifying disposal locations.	education and outreach program pursuant to Public Resources Code section 42031.6. There are many options a program operator may utilize to achieve the comprehensive requirement, thus, the proposed regulations allow program operators flexibility in the design of their education and outreach programs.
032-002	COPALM	Bryan Zaragoza Hurtado	18973.2(f)	N	Pharmaceutical companies and manufacturers should be responsible for any costs associated with the above recommendations without increasing the retail price of prescription drugs for consumers.	032-002. In the comment, the phrase “with the above recommendations” refers to the recommendations made in comment 031-001a. The recommendations are to provide resources and funding to local programs and non-profit organizations for education regarding safe and proper disposal of covered products. A change to the proposed regulatory text is not necessary. Financial provisions requiring covered entities to pay all costs associated with establishing and implementing the stewardship plan and program are contained in both Public Resources Code sections 42034 and 42034.2 and proposed regulatory text sections 18973.2(f), 18973.3(e), and 18974.1. Mandating that the retail price of prescription drugs shall not increase due to Senate Bill 212 is outside the scope and authority of these regulations.
032-003	COPALM	Bryan Zaragoza Hurtado	18973.2(j)	N	Pharmacies including retailers such as Walgreens and Rite-Aid be required to include safe disposal instructions and information on their instructions page for all medications prescribed.	032-003. A change to the proposed regulatory text is not necessary. There are many options available to a program operator for providing safe disposal instructions and information. CalRecycle declines to limit a program operator’s flexibility in utilizing as many options as necessary to disseminate this information.
032-004	COPALM	Bryan Zaragoza Hurtado	General	N	Prescription medicine misuse has a tremendous public health impact on the communities that we serve. As a result, many nonprofit organizations have taken the responsibility of informing community members on prescription use/misuse and safe disposal. For this reason, we feel that SB 212 should provide support to the organizations currently engaging in this work.	032-004. A change to the proposed regulatory text is not necessary. Statute requires a program operator to conduct a comprehensive education and outreach program pursuant to Public Resources Code section 42031.6. Cooperation between a program operator and nonprofit organizations to assist with education and outreach to the community on safe disposal and disposal locations is neither prohibited nor required. There are many options a program operator may utilize to achieve the comprehensive requirement, thus, the proposed regulations allow program operators flexibility in the design of their education and outreach programs. If a covered entity decides not to run its own stewardship program, it will be doing so through a non-profit stewardship organization.
032-005	COPALM	Bryan Zaragoza Hurtado	General	N	In addition, considering that many of our low income community members already struggle to afford healthcare and prescription medications costs, we do not believe they should be burdened with the costs of implementing the recommendations in SB 212.	032-005. A change to the proposed regulatory text is not necessary. Financial provisions requiring covered entities to pay all costs associated with establishing and implementing the stewardship plan and program are contained in both Public Resources Code sections 42034 and 42034.2 and proposed regulatory text sections 18973.2(f), 18973.3(e), and 18974.1. Mandating that the retail price of prescription drugs shall not increase due to Senate Bill 212 is outside the scope and authority of these regulations.

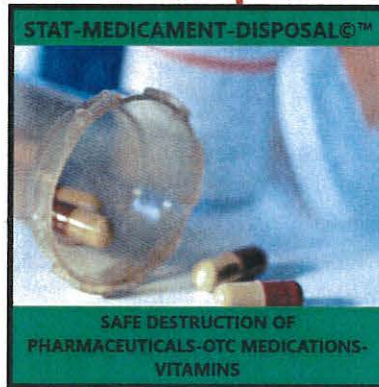
**Comments Received in Response to CalRecycle's
SB 212 Initial 15-Day Formal Rulemaking Comment Period**

Comment Letter Number:	Comments Submitted By:	Representative Organization: (If Applicable)
018	Larry Kenemore	Stat-Medicament-Disposal Corporation
019	Kathryn Kane-Neilson	Sharps Compliance, Incorporated
020	Reggie B Pestano	Waste Management Curbside, LLC
021	Staci Heaton	Rural County Representatives of California
022	Sheetal Singh	California Department of Public Health
023	Leah Lindahl	Healthcare Distribution Alliance
024	Domingo Isasi	InMar Intelligence
025	Doug Kobold, Heidi Sanborn	California Product Stewardship Council and Coalition
026	Anne Vogel-Marr	Pharmaceutical Product Stewardship Work Group
027	Margaret Clark	Los Angeles County Solid Waste Management Committee/Integrated Waste Management Task Force
028	Michael R. Van Winkle	Med-Project USA
029	Cara Simaga	Stericycle
030	Coby J. Skye	Los Angeles County Department of Public Works
031	Jen Jackson	San Francisco Department of the Environment
032	Bryan Zaragoza Hurtado	Coalition for Prevention and Awareness in Los Angeles Metro (COPALM)

From: Larry Kenemore Jr. <larry5@statmeddisposal.net>
Sent: Thursday, July 23, 2020 9:21 AM
To: PharmaSharps
Subject: Response to July 2020 Proposed Regulations
Attachments: July 23, 2020 Response on Regs.docx
Categories: Mary

[[EXTERNAL]]

Stat-Medicament-Disposal Corporation



**THE ONLY AWARD WINNING SAFE-DRUG-DISPOSAL PROGRAM
SOLVING THE OPIOID CRISIS ONE HOME AT A TIME
PROTECTING YOUR DRINKING WATER FROM PHARMACEUTICAL POLLUTION**

Gentlemen;
Find attached our response to the July 2020 Regulations.
Larry Kenemore CEO



Larry Kenemore CEO

Home Office:
10092 Bianchi Way #207 Cupertino CA 95014
(855) 873-4965
Cell (913) 705-0983
larry5@statmeddisposal.net
207 Western Hills Dr. Siloam Springs AR.72761



[CLICK HERE TO WATCH BOTTLE BEING USED](#)



[CLICK HERE TO WATCH THE ONLY](#)

[AWARD WINNING KIOSK](#)

CONFIDENTIALITY NOTICE

Copyright 2020 Stat-Medicament-Disposal Corporation and Larry Kenemore. The contents of this email message and any attachments are intended solely for the addressee(s) and may contain confidential and/or privileged information and may legally be protected from disclosure. If you are not the intended recipient of this message or their agent, or if this message has been addressed to you in error, please immediately alert the sender by reply mail and delete this message and any attachments. If you are not the intended recipient, you are hereby notified, that any use dissemination, copying or storing of this message or it's attachments is strictly prohibited.



Stat-Medicament-Disposal Corporation™

Stat-Medicament-Disposal Corporation

**Home Office: 10092 Bianchi Way #207
Cupertino, California 95014 (855) 873-4965
<https://statmeddisposal.net>**



**INVENTORS OF THE ONLY AWARD-WINNING
SAFE-DRUG-DISPOSAL PROGRAM**

CEO

Larry Kenemore .
(855) 873-4965 Ext. 6
larry5@statmeddisposal.net

Corporate Counsel

Kim Dobson Walker
(855) 873-4965 Ext.4
kadobson@statmeddisposal.net

President

Richard Dickerson
(855) 873-4965 Ext. 708
rdickerson@statmeddisposal.net

Secretary

Anne Marie Dickerson
(855) 873-4965 Ext 709
Annemarie1@statmeddisposal.net

Vice-President

Lillian Small
(855) 873-4965 Ext. 721
lsmall@statmeddisposal.net

Vice President-IT

Bill Shepherd
(855) 873-4965 Ext. 705
billshepherd@statmeddisposal.net

Treasurer

Corey Schneider
(855) 873-4965
coreyschneider@fillabox.net

Special Needs

Employees
Helen Bearden
(855) 873-4965 Ext. 701
helenbearden@fillaboxrecycling.com

Members at Large

Brittany Kenemore
(714) 274-5539
(855) 873-4965 Ext.704
bkenemore@yahoo.com

Violette Brown
(855) 873-4965 Ext. 716
violettebrown@statmeddisposal.net

July 23, 2020

Cal-Recycle via pharmasharps@calrecycle.ca.gov

Response to July 2020 Second Draft Proposed Regulations

Gentlemen;

After review of these proposed regulations here is our response and thoughts.

We first will again point you to the recent May 22, 2020 Congressional Bipartisan Opioid Task Force letter to the DEA outlining the need for in-home Safe-Drug-Disposal. Also, our meeting with ODNCP on July 22, 2020 wherein the Administration is pushing to the forefront the need to Safe-In-Home Drug-Disposal and theirs and Congress concerns as to the effect on the drinking water of Drugs and disposal.

We do see the way the Law was written, and your having to implement that law as written. However, we have found there is a place for Safe-Drug-Disposal in-home in your regulations that are developing.

1. Definitions 18972.1 (13)(A) How can addition of a mail-back program be a “Significant change” when this method is a foundational disposal method especially in the near future? 018-001
2. 18972.2(d) There should be wording somewhere in this section as to Safe-Drug-Disposal sites. That is Safe Drug Disposal kiosks are not collection sites. It would appear from leaving out this language you are limiting Safe-Drug-Disposal to only in-home mail back program and relying on Take Back Collection only. 018-002
3. (g) Collection, transportation, and disposal system, description of the following (4) clearly leaves in place the misleading number promulgated by the Take back program of weight which includes (bottles, wrappers, blister-paks etc.) Should you not want to know the actual amount of drugs collected or disposed of? 018-003
4. (g)(6)(C) the words metrics used to measure the”amount” should be changed as to the weight. Amount means nothing in disposal, weight is accurate and relates to drugs. 018-004
5. There is missing any wording for having a Safe-Drug-Disposal site all the wording only talks about “collection”. 018-005
6. Throughout this section you continually talk about collection and then in (h) you talk about disposal. Should there not be language herein about safe-drug-disposal not just collection. That is there are currently two (2) programs “collection” “safe-drug-Disposal” 018-006

- 018-007 **7. (j) should there not be a section here for school education as to Safe In-Home-Disposal.**
- 018-008 **8. 18973.4 (c)(E) should not the wording be added as to a safe-drug-disposal not just collectors?**
- 018-009 **9. (3) language should be added to include safe-drug-disposal either in-home or kiosks.**
- 018-010 **10. (4)(B) should it not have the language added weight of covered drugs again using the word amount is misleading.**
- 018-011 **11. (6) Can there not be language added that includes safe drug disposal since collection is not the only method available.**

We thank you for the opportunity to add our input into these new regulations and look forward to having an impact on the opioid crisis and polluted drinking water.

Larry Kenemore CEO

From: [Kathryn Kane-Neilson, BS, CT\(ASCP\)](#)
To: [PharmaSharps](#)
Cc: [Regulatory Compliance](#)
Subject: Formal comments to Second Draft Proposed Regulations - SB 212
Date: Thursday, July 23, 2020 12:32:18 PM
Attachments: [CA SB212 Second Draft Proposed Regulations July 2020 Letter.pdf](#)
[CA SB212 Formal Comments to Second Draft Proposed Regulations July 2020.pdf](#)

[[EXTERNAL]]

To Whom It Concerns:

Please accept the attached comments and recommended modifications to the Second Draft Proposed Regulations for 15-day Comment Period, July 2020 – Senate Bill (SB) 212.

Sharps Compliance, Inc. (Sharps) has been a leader in the Regulated Medical Waste Industry since 1994. We offer nationwide disposal solutions including both mail-back and direct servicing options. All Sharps Compliance disposal systems and services are compliant with EPA, DEA, USPS, OSHA, and DOT collection, transport, treatment, and disposal of regulated medical waste, hazardous waste, and pharmaceutical waste.

We appreciate the opportunity to provide feedback on the SB 212 regulations and look forward to the outcome.

Thank you,

Kathryn Kane-Neilson, BS, CT(ASCP) | Clinical Specialist, Regulatory Compliance
Sharps Compliance, Inc. | www.sharpsinc.com
d- 713-353-1155 | o- 800-772-5657 | f- 713-353-1281 | m- 281-740-1458

As a leader in healthcare waste management, Sharps Compliance strives to reduce, recycle and repurpose treated materials for a better and sustainable environment.

PRIVACY NOTICE: This information is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential or exempt from disclosure under applicable federal or state law. If the reader of this message is not the intended recipient or the employee or agent responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution or copying of communication is strictly prohibited. If you have received this communication in error, contact the sender and delete the material from any computer.



July 23, 2020

California's Department of Resources Recycling and Recovery (CalRecycle)
pharmasharps@calrecycle.ca.gov

RE: Sharps Compliance, Inc. Public Comments on the Second Draft Proposed Regulations for 15-day Comment Period, July 2020 – Senate Bill (SB) 212

To Whom It Concerns:

Please accept the attached comments and recommended modifications to the Second Draft Proposed Regulations for Senate Bill (SB) 212; and, recommending the consideration of state (Department of Public Health) and federal restrictions on use of products designed to render drugs inert.

Sharps Compliance, Inc. (Sharps) has been a leader in the Regulated Medical Waste Industry since 1994. We offer nationwide disposal solutions including both mail-back and direct servicing options. All Sharps Compliance disposal systems and services are compliant with EPA, DEA, USPS, OSHA, and DOT collection, transport, treatment, and disposal of regulated medical waste, hazardous waste, and pharmaceutical waste.

We appreciate the opportunity to provide feedback on the SB 212 regulations and look forward to the outcome.

Thank you,

Kathryn Kane-Neilson, CS, CT (ASCP)
Clinical Specialist, Regulatory Compliance
Sharps Compliance, Inc.
kneilson@sharpsinc.com
www.sharpsinc.com
281-740-1458



**Formal Comments to Proposed Regulations, Second Draft
SB212 Pharmaceutical and Sharps Stewardship Program
Comment Period: July 15, 2020 – July 29, 2020**

Pg. 3 Ln 11 Proposed regulation: “ ‘Inert’ means the covered drug or mixture of covered drugs is rendered chemically inactive prior to disposal and complies with all applicable local, state and federal laws and regulations, including those of the United State Drug Enforcement Administration and California statutes and regulations governing disposal in a municipal solid waste landfill.”

019-001

Issue: Per the California Department of Public Health’s [Medical Waste Management Program](#), charcoal-based pharmaceutical disposal products designed to render drug waste inert have not gained the department’s approval for use in California as an alternative treatment technology since all pharmaceutical waste in California is required to be incinerated. Because such products are prohibited as a solid waste they can only be disposed of via a pharmaceutical waste container, thus rendering the purpose of such a product useless and instead necessitating the purchase of an additional disposal solution that would have to be routed for incineration via hazardous waste containment and servicing, since the Department of Transportation (DOT) classifies activated carbon products according to the lethality of their contents, which cannot be determined if conglomerate comprised of unidentifiable ultimate user medications (thereby rendering the product ineligible for USPS mailability).

Proposed Resolution: Eliminate references allowing use of disposal systems that render drugs inert since cannot be placed in municipal solid waste landfills and would have to be coupled with an additional container designed for pharmaceutical waste if routed for incineration; the DOT would dually consider this a hazardous waste (see below) and thus require containment compliant for hazardous waste transport.

Pg. 12 Ln 6 Proposed regulation: “Locations where preaddressed, prepaid mail-back materials are distributed or an alternative form of collection and disposal system, pursuant to section 42032.2(c)(2) of the Public Resources Code, that would render the drug inert, is provided, if applicable.”

019-002

Issue: In addition to the state’s prohibition of disposal of charcoal-based products in the solid trash, the DOT determines hazardous classification of activated carbon products according to the adsorbate contents, which cannot be determined upon unsupervised use by ultimate users; therefore used charcoal-based products would be prohibited by the USPS since the DOT would consider it a hazardous waste due to unproven lethality.

Proposed Resolution: Eliminate references allowing use of disposal systems that render drugs inert since cannot be placed in trash nor mailed.

Pg. 14 Ln 30 Proposed regulation: “~~Coordination Efforts. Description of how the program operator will make a good faith effort to work with the other stewardship program(s) in order to most effectively achieve the requirements of statute and regulations, coordinate with other program operators to avoid conflict, duplication, and confusion to the public and all program participants in the event that multiple stewardship programs for covered drugs are in operation concurrently or new stewardship programs begin operating.~~”

Issue: How does CalRecycle plan on enforcing such coordination efforts? A descriptive means of how multiple stewardship programs can avoid conflict and/or duplication of operation efforts is needed.

019-003a
019-003b
019-003c
019-003d

**Formal Comments to Proposed Regulations, Second Draft
SB212 Pharmaceutical and Sharps Stewardship Program
Comment Period: July 15, 2020 – July 29, 2020**

Proposed Resolution: Clarify CalRecycle’s oversight of coordination efforts and requirements of program operators to ensure distinct parameters are established for the management of stewardship programs.

Pg. 17 Ln 5 Proposed regulation: “Containers and mail-back materials shall be distributed in amounts sufficient to accommodate the volume of sharps purchased by the ultimate user over a selected time period.”

019-004

Issue: Who is responsible for determining what amounts to a sufficient provision of mail-back materials to accommodate sharps waste volume over a selected time period and how would these calculations be assessed?

Proposed Resolution: Clarify who is responsible for determining and tracking fulfillment volume of sharps waste containers according to specified time ranges customized according to drug type and/or ultimate user prescription.

From: [Pestano, Regalado](#)
To: [PharmaSharps](#)
Subject: Questions/Comments
Date: Sunday, July 26, 2020 1:22:25 PM
Attachments: [Stewardship Program Questions & Comments 7-26-20.pdf](#)

[[EXTERNAL]]

Good afternoon,

Attached is a lost of questions/comments regarding the 2nd draft proposal for the Stewardship Program.

Thank you.

Reggie B Pestano
District Operations Manager
WM Curbside, LLC
Email: rpestano@wm.com
10633 Ruchti Road,
South Gate, CA 90280
Office #: (562) 674-1090
Mobile #: (209) 597-0210

Recycling is a good thing. Please recycle any printed emails.

Letter 20 - WM Curbside, LLC

**COMMENTS/QUESTIONS FOR THE SECOND DRAFT OF PROPOSED REGULATIONS
PHARMACEUTICAL AND SHARPS WASTE STEWARDSHIP PROGRAM**

PAGE	LINE NUMBER	COMMENT/QUESTIONS
2	020-001 31 020-002	This maybe an infringement on the users' privacy if their names/address are on a list that need sharps containers. Medical sharps users already provide themselves with sharps containers. Also, supplying each user with sharps containers will be a logistical challenge.
3	020-003 1	Mailing bulky items within 4 days is not feasible unless done with express mail which will be very costly for the program. I suggest to drop them off/switch out on the same day as the scheduled sharps pickup.
5	020-004 25	How will the initial budget and annual budget work since we do not have the number of users that we will need to service for sharps? Sharps users will have different levels of use.
5	020-005 27 020-006	If there is already an existing contract between a government agency and a service provider to pickup and dispose of sharps from residents and local government facilities such as City Hall, libraries, etc, will the existing contracts be superseded by the stewardship program? Does this mean the contract will be terminated and may offer the service to another service provider?
5	020-007 27	What will be included in the annual report at the initial submission of the stewardship plan? I think this is required after the first year of the implementation of the stewardship program.
8	020-008 17 020-009	Is the covered entity (responsible for paying for the program) a pharmaceutical/ drug store or the city government where the store is located? Will there be a feasibility study if the covered entity can afford to pay for this program?
8	29 020-010	Is the list of covered drug sold/offered for sale will be inclusive?
9	020-011 020-012 2	If there is already an existing contract between a government agency and a service provider to pickup and dispose of pharmaceuticals deposited by residents in receptacles located in local government facilities such as City Hall, libraries, etc, will the existing contracts be superseded by the stewardship program? Does this mean the contract will be terminated and may offer the service to another service provider under the stewardship program?
10	020-013 30	Will the authorized collection site going to be tabulating each resident's pharmaceutical deposit into the receptacle? This is going to be a tedious process.
11	020-014 3	Can any entity apply for the stewardship program for pharmaceuticals and only manage the receptacle but without including the mail-back option into the program?
11	10 020-015	If a user is homeless, how do we mail the pre-addressed/pre-paid mail-back materials?
11	020-016 29	Since nobody can predict when each pharmaceutical receptacle will be full, there will be an option for an emergency pickup with an additional fee. However, if an emergency pickup is not possible, the service provider should not be penalized.
12	020-017 18	Will regular UHWM be used for collection of covered pharmaceuticals and sharps?. Right now, we only use a Non-Hazardous Tracking Form.
13	27 020-018	Separating covered from uncovered products will be difficult to implement or enforce.
17	020-019 4	Can a service provider for the sharps stewardship program opt not to a mail-back option for sharps?
19	31 020-020	Will email also be an option for residents to request sharps containers from providers?
26	020-021 2	Will this annual sharps report be separate from the quarterly report to submit to CA Dept of Health for sharps and pharmaceutical collections?

From: [Leigh Kammerich](#)
To: [PharmaSharps](#)
Cc: senator.jackson@senate.ca.gov; [Staci Heaton](#)
Subject: 15-Day Comments, Pharmaceutical and Sharps Waste Stewardship Program
Date: Wednesday, July 29, 2020 2:21:55 PM
Attachments: [Pharmaceutical and Sharps Waste Stewardship Program Ltr to CalRecycle_07292020.pdf](#)

[[EXTERNAL]]

Mr. Smyth,

On behalf of the Rural County Representatives of California (RCRC), attached please find our 15-Day comments to the Pharmaceutical and Sharps Waste Stewardship Program Rulemaking to implement Senate Bill 212 (Jackson, 2018).

Thank you,

Leigh Kammerich

Regulatory Affairs Specialist

Rural County Representatives of California (RCRC)

1215 K Street, Suite 1650

Sacramento, CA 95814

(916) 447-4806 office

lkammerich@rcrcnet.org



July 29, 2020

Mr. Jason Smyth
Materials Management and Local Assistance Division
California Department of Resources
Recycling and Recovery
P.O. Box 4025
Sacramento, CA 95814

Transmittal Via E-mail: pharmasharps@calrecycle.ca.gov

RE: Pharmaceutical and Sharps Waste Stewardship Program, 15-Day Public Comments

Dear Mr. Smyth:

On behalf of the Rural County Representatives of California (RCRC), I write in response to the Notice of Changes to Proposed Rulemaking for the Pharmaceutical and Sharps Waste Stewardship Program to implement Senate Bill 212 (Chapter 1004, 2018). RCRC is an association of thirty-seven rural California counties, and the RCRC Board of Directors is comprised of elected county supervisor from those member counties. In addition, twenty-four of RCRC member counties have formed the Rural Counties Environmental Services Joint Powers Authority (ESJPA) to assist solid waste managers in rural counties. These solid waste managers are charged with ensuring their respective counties meet state-imposed requirements in order to reduce waste being disposed and increase recycling/re-use efforts for certain products.

In general, RCRC and ESJPA continue to support the regulatory model as proposed and we appreciate many of the changes to the original proposed draft, which were largely clarifying in nature. Overall, it is our objective to ensure these stewardship programs do not result in a reduction of currently available services in counties. With regard to the specific changes made, we appreciate the inclusion of notification procedures to local agencies, and others, for safety and security incidents related to collection, transportation and disposal of covered drugs, as well as secure receptable collection of sharps.

021-001

Mr. Jason Smyth
Pharmaceutical and Sharps Waste
Stewardship Program
July 29, 2020
Page 2

We urge CalRecycle to reconsider many of our overlooked requests that would greatly improve Household Hazardous Waste (HHW) programs, especially in rural areas facing tight budgets and limited economies of scale. Specifically:

- 021-002 ➤ There should be a mechanism to ensure local agencies can recover costs by covered entities to mitigate pharmaceuticals that wind up in solid waste, wastewater or sanitation facilities, not to mention parks or other public places. Further, local agencies that conduct testing of inert drugs, such as an aquatic toxicity test, should be reimbursed for these activities in the course of ensuring that pharmaceuticals are properly disposed and managed.
- 021-003
- 021-004 ➤ Stewardship Organization(s) should be encouraged to financially contribute to a local agency's advertisements rather than create separate campaigns for education and outreach. Local entities, for example, provide public education through its HHW programs. Residents and consumers should receive consistent and comprehensive messaging.
- 021-005 ➤ HHW programs should have an opportunity to receive sharps containers and dispose collected sharps under the stewardship program. This avenue could be one of the options under section 18972.1 (a)(11)(C). Many of these HHW programs have large (e.g. 30-gallon) containers to hold collected sharps, which should be eligible for free disposal rather than having to stockpile mail-away containers.

Thank you for your consideration of our comments. Please contact me at sheaton@rcrcnet.org if you have any questions or would like to further discuss our comments.

Sincerely,



STACI HEATON
Senior Regulatory Affairs Advocate

cc: Members of the Rural Counties' Environmental Services Joint Powers Authority
Board of Directors
The Honorable Hannah-Beth Jackson, Member of the State Senate

From: Asoo.Thomas@CDPH
To: [PharmaSharps](#)
Cc: Singh.Sheetal@CDPH; Horner.Thomas@CDPH
Subject: Comments to CalRecycle"s 15 Day Public Comment Period for the Pharmaceutical and Sharps Waste Stewardship Program Proposed Regulations (second draft)
Date: Saturday, August 1, 2020 9:10:24 AM
Attachments: [SB 212 15 day Comment Period 20200715 ver 2 - SS - signed.pdf](#)

[[EXTERNAL]]

Dear Mr. Smyth,

The Medical Waste Management Program of the California Department of Public Health is submitting the attached comments regarding the Proposed Regulations for the Pharmaceutical and Sharps Waste Stewardship Program.

If you have further questions regarding our comments, please feel free to contact me at (916) 210-8525 or email at thomas.asoo@cdph.ca.gov.

Thank you.

Tommy Asoo
Medical Waste Management Program
California Department of Public Health
MS-7405, IMS K-2
P.O. Box 997377
Sacramento, CA 95899-7377
916-210-8525
www.cdph.ca.gov/medicalwaste



SONIA Y. ANGELL, MD, MPH
State Public Health Officer & Director

State of California—Health and Human Services Agency
California Department of Public Health



GAVIN NEWSOM
Governor

DATE: July 31, 2020

TO: Jason Smyth
Materials Management and Local Assistance Division
California Department of Resources, Recycling and Recovery (CalRecycle)
P.O. Box 4025
Sacramento, CA 95814

FROM: Sheetal Singh
Environmental Program Manager
Emergency, Restoration & Waste Management Section
Environmental Management Branch
California Department of Public Health
1725 23rd Street, Suite 110
Sacramento, California 95816

SUB: 15-day written public comment period for the Proposed Regulations for the Pharmaceutical and Sharps Waste Stewardship Program

The Medical Waste Management Program (MWMP) of the California Department of Public Health (CDPH) is submitting comments to the Proposed Regulations for the Pharmaceutical and Sharps Waste Stewardship Program.

If you need further assistance regarding our comments, please feel free to contact Tom Asoo of my staff at (916) 210-8525, email at thomas.asoo@cdph.ca.gov.



Comments to CalRecycle’s 15 Day Public Comment Period for the Pharmaceutical and Sharps Waste Stewardship Program Proposed Regulations (Second Draft)

Page 2, lines 11 – 15. (6) “Inert” means the covered drug or mixture of covered drugs is rendered chemically inactive prior to disposal and complies with all applicable local, state and federal laws and regulations, including those of the United State Drug Enforcement Administration and California statutes and regulations governing disposal in a municipal solid waste landfill.

COMMENT: Is there an agency that determines whether or not a disposal system makes the covered drug(s) chemically inactive prior to disposal?

022-001

Page 17, lines 1 – 10. (5~~6~~) Supplemental collection method(s) for home-generated sharps waste that may be provided, in addition to, but not in lieu of, the mail-back program. These methods may include, but are not limited to:

(A) Secure receptacle collection. If a program operator proposes to implement a receptacle-based program to supplement its mail back program and using authorized and approved home-generated sharps consolidation points are authorized and approved by the city, county, or state enforcement authority that provides oversight of the Medical Waste Management Act, then the following information, as applicable, shall be included, but not be limited to:

COMMENT: The proposed regulations state that the program operator shall use an authorized and approved home-generated sharps consolidation point. It would help clarify the approval process if the proposed regulations did not delete (strikethrough) the information that stated the program operator shall have home-generated sharps consolidation points approved by the applicable city, county, or state enforcement agency that implements the Medical Waste Management Act.

022-002

Page 18, lines 1 – 2. Take-back collection events. Date and location of events, ~~if~~ applicable.

022-003

COMMENT: The proposed regulations should state that the take-back collection event shall be authorized and approved as a home-generated sharps consolidation point by the appropriate city, county, or state enforcement agency.

From: [Lindahl, Leah](#)
To: [Smyth, Jason@CalRecycle](mailto:Smyth_Jason@CalRecycle); [PharmaSharps](#)
Subject: HDA Comments - 15-Day Comment Period on SB 212 Implementation
Date: Monday, August 3, 2020 11:03:02 AM
Attachments: [image693895.png](#)
[HDA Redline_CalRecycle_SecondDraftProposedRegulations.pdf](#)
[HDA Comments_Pharmaceutical and Sharps Waste Stewardship Program_Second Draft Proposed Regulations.pdf](#)

[[EXTERNAL]]

Good Morning Jason,

Please find the Healthcare Distribution Alliance comment letter and red-lined version of the proposed regulations attached to this email in response to the 15-day written public comment period for the Second Draft Proposed Regulations on SB 212 implementation.

Please let me know if you have any questions or need further information.

Thank you,

Leah Lindahl

Leah Lindahl

Senior Director, State Government Affairs, Western Region

Direct: (703) 885-0243

Mobile: (303) 829-4121



[Healthcare Distribution Alliance](#)

PATIENTS MOVE US.



PATIENTS MOVE US.

July 29, 2020

Jason Smyth
Materials Management and Local Assistance Division
California Department of Resources Recycling and Recovery
P.O. Box 4025
Sacramento, CA 95812-4025

Re: HDA comments regarding the 15-Day written public comment period on the proposed regulation to implement the Pharmaceutical and Sharps Waste Stewardship Act [Chapter 1004, Statutes of 2018 (Jackson, Senate Bill 212)]

Mr. Smyth:

On behalf of the Healthcare Distribution Alliance (HDA) please find the below comments and attached revisions in response to the 15-Day Written Public Comment Period on the proposed regulations to implement the Pharmaceutical and Sharps Waste Stewardship Act [Chapter 1004, Statutes of 2018 (Jackson, Senate Bill 212)].

HDA and our member companies appreciate the opportunity to again provide comments to CalRecycle on the proposed regulations. After reviewing the second draft and the stakeholder input shared with CalRecycle to date, we believe the suggested language provided in our comments will address outstanding issues and provide additional regulatory clarity which was requested by both the state legislature and Governor upon enactment. Incorporating these suggested changes will help to establish a more effective and viable pharmaceutical stewardship program for the state of California.

Background:

HDA represents primary pharmaceutical wholesale distributors, the vital link between the nation's pharmaceutical manufacturers and more than 200,000 pharmacies, hospitals, long-term care facilities, clinics and others nationwide, with over 17,000 located in California. Since 1876, HDA has helped members navigate regulations and innovations to get the right medicines to the right patients at the right time, safely and efficiently. HDA distributor members do not research, develop, manufacture pharmaceuticals or market them to physicians or patients. Wholesalers do not prescribe or dispense medications to patients or have any impact on a patient's pharmacy benefit design. Wholesale distributors' role is to purchase pharmaceutical products from state and federally licensed manufacturers, securely store, and finally safely deliver them to state and federally licensed healthcare providers. HDA members operate 24

hours a day, 365 days a year, shipping approximately 15 million products across the nation every day. Simply put, wholesale distributors are logistics experts that ensure pharmacies and hospitals keep their shelves stocked with medications their patients need.

HDA and our primary pharmaceutical wholesale distributor members recognize the importance of efforts to ensure the safe, secure, and convenient disposal of unused, unwanted, or expired medications. However, unlike other enacted state-wide pharmaceutical disposal programs, the language included in SB 212 presents a series of concerns primarily due to the lack of clarity surrounding definitions and enforcement. HDA and our members believe the obligation for such take-back or disposal efforts related to pharmaceuticals should lie with the actual manufacturer of the product in its finished dosage form. In other words, the manufacturer that first introduces the product into commerce. These actual manufacturers are in the best position to manage product stewardship activities and to reduce waste generation, rather than those entities in the middle of the pharmaceutical supply chain that “handle” products such as wholesalers, private label distributors, repackagers, retailers etc.

On behalf of HDA’s member companies we would like to provide the following comments in addition to the attached revisions to the proposed regulations:

Comments and Recommendations:

1. 18972.2 Criteria for Determining a Covered Entity:

- 023-001 The proposed regulatory text fails to provide any clarity around the term “Covered Entity,” instead reverting back to the legislative text which was specifically noted during the legislative process and within the Governor’s signing message as needing additional clarity through regulations. As provided within comments throughout the rulemaking process, the current language creates uncertainty as to which entity is ultimately responsible and could result in a multi-layer fee where the manufacturer, wholesaler, repackager, licensee, importer, etc. fund the disposal of a single product. Additionally,
- 023-002 the language also fails to offer a definition as to what constitutes a “manufacturer.”
- 023-003 HDA request the proposed regulations stipulate that any manufacturer who avails itself of the California market should be the responsible entity required to participate in the stewardship program. In other words, if a manufacturer’s product is for sale within the state of California, they are therefore “in” the state and responsible for participating in the Pharmaceutical and Sharps Waste Stewardship Program. Based on current case law, the state of California clearly has jurisdiction over pharmaceutical manufacturers whose products are dispensed in California to comply with the proposed statewide take back program. It is clear the legislative intent was to compel all manufacturers to participate in the stewardship program, therefore the regulations should effectively execute this

legislative intent. HDA recommends inserting the following language into the regulations to alleviate these concerns:

(a) The department shall consider any manufacturer with products offered for sale in the state of California as being responsible for participating as a covered entity.

023-004

Further, HDA request the regulations stipulate a clear process by which CalRecycle will identify the manufacturer and how the department would utilize the tiered definition should the manufacturer not be identifiable. This request has been echoed by other stakeholders during the formal rulemaking process and has been left unanswered. HDA recommends the inclusion of the below section, which will allow CalRecycle and the Board of Pharmacy to further develop procedures to address these concerns:

(b) The department, in collaboration with the California Board of Pharmacy, will develop and implement procedures to communicate with manufacturers of covered products, or the selected stewardship organization, and ensure understanding of compliance responsibilities. Only when there is sufficient evidence that such efforts have failed, the department will utilize the priority set forth in subsections(1)(B)-(E) of subdivision (f) of section 42030 of the Public Resource Code.

023-005

HDA also requests that a clear definition is developed as to what constitutes a “Manufacturer” and offers the below definition for consideration:

(c) “Manufacturer” means a person, company, corporation or other entity engaged in the manufacture of (a) a covered drug as defined in subsection (e)(1) of section 42030 of the Public Resources Code sold, offered for sale, or dispensed in the state or (b) sharps sold, offered for sale, or dispensed in the state. Manufacturer does not include the activities of a repackager, relabeler, private label distributor or wholesale distributor.

2. 18974.3. Retailer, Wholesaler, Distributor Product Verification:

023-006

We appreciate CalRecycle’s efforts to provide more clarity on how wholesalers and others will verify products being sold in or into California. HDA recommends the regulations stipulate that reporting entities review the website at least annually and provide a listing of apparent non-compliant manufacturers or covered entities to the department in a format that has been agreed upon by the industry and the department.

- 023-007 HDA also requests the department, in coordination with the board, notify licensees and reporting entities when a non-compliant entity has been identified. HDA further
- 023-008 recommends the regulations provide clarity that reporting entities shall be held harmless for any assessment of penalties placed on the actual manufacturer for lack of participation in the stewardship program.

HDA recommends the following additions and changes to the proposed regulations:

- (a) *Each distributor, wholesaler, pharmacy, and retailer that sells, offers for sale, or dispenses a covered product shall: successfully log onto the department's internet website at least annually to determine if a covered entity of covered products ~~to be~~ sold, offered for sale, or dispensed are in compliance with the law, by verifying that the covered entities providing the covered product(s) are in compliance with the law.*
- (b) *Should a distributor, wholesaler, pharmacy, other retailer, or a designated responsible party for any of the foregoing identify a noncompliant covered entity or stewardship organization, the distributor, wholesaler, pharmacy, other retailer, or designated responsible party shall report, in an agreed upon format, the discovery to the department within 30 days.*
- (c) *Should the Department determine a covered entity or stewardship organization is not in compliance, the Department in collaboration with the Board shall notify all licensees of the non-compliance.*

3. 18975. Criteria to Impose An Administrative Civil Penalty

- 023-009 HDA requests the proposed regulations establish a process by which the department will inform covered entities when it will utilize the priority set forth in subsections(1)(B)-(E) of subdivision (f) of section 42030 of the Public Resources Code to identify the covered entity for any covered products, which do not meet the definition of subsection (1)(A) of subdivision (f) of section 42030 of the Public Resources Code.
- 023-010 Further, we request the proposed regulations stipulate that any identified covered entity shall not be penalized or assessed any fines due to non-compliance of a previously reported non-compliant covered entity. HDA recommends the inclusion of the following language to address these concerns:

(b) The department will establish a process to alert potential covered entities when it will utilize the priority set forth in subsections(1)(B)-(E) of subdivision (f) of section 42030 of the Public Resources Code to identify the covered entity for any covered products, which do not meet the definition of subsection (1)(A) of

subdivision (f) of section 42030 of the Public Resources Code and ensure the potential covered entities are aware of the regulations and responsibility before assessing any administrative penalty.

(c) Should the department utilize the priority set forth in subsections(1)(B)-(E) of subdivision (f) of section 42030 of the Public Resources Code to identify the covered entity for any covered products, which do not meet the definition of subsection (1)(A) of subdivision (f) of section 42030 of the Public Resources Code, the subsequent participation entity shall be held harmless for the assessment of penalties on the non-compliant covered entity.

Conclusion:

HDA and our member companies appreciate the ongoing work of CalRecycle and the proposed regulations to implement Senate Bill 212. We believe the above comments and suggestions provided within this document and the attached revisions would help to address the wholesale industry's concerns and support the Department in establishing an effective stewardship program for the state of California.

Thank you for your consideration of our comments, we look forward to being engaged as the process moves forward. Please do not hesitate to contact Leah Lindahl, Senior Director, State Government Affairs at Llindahl@hda.org or (303) 829-4121 for additional assistance.

Sincerely,



Leah Lindahl
Senior Director, State Government Affairs
Healthcare Distribution Alliance (HDA)

Letter 23: Supplemental - Healthcare Distribution Alliance

Please find the Healthcare Distribution Alliance comment letter and red-lined version of the proposed regulations attached to this email in response to the 15-day written public comment period for the Second Draft Proposed Regulations on SB 212 implementation.

Please let me know if you have any questions or need further information.

Thank you,
Leah Lindahl

Leah Lindahl

Senior Director, State Government Affairs, Western Region

Direct: (703) 885-0243

Mobile: (303) 829-4121

Healthcare Distribution Alliance

PATIENTS MOVE US.

1 Note: Authority cited: Sections 40401, 42031.2, and 40502, Public Resources Code.
2 Reference: Sections 42030, 42031, 42031.2, 42031.4, 42031.6, 42032, 42032.2,
3 42033, 42033.2, 42033.4, 42033.5, 42033.6, 42034, 42034.2, 42034.4, 42035, 42035.2,
4 42035.4, 42035.6, 42035.8, 42036, 42036.2 and 42036.4, Public Resources Code;
5 Medicare Benefit Policy Manual, Chapter 15, 60.4.1; 42 U.S.C. Section 254b, U.S.
6 Code on Public Health and Welfare; Section 117904, Health and Safety Code; and
7 Section 4040, Business and Professions Code.

8 **18972.2. CRITERIA FOR DETERMINING A COVERED ENTITY.**

9 ~~(a)-The department shall consider any manufacturer with products offered for sale in the~~
10 ~~state of California as being responsible for participating as the covered entity. The~~
11 ~~department will consider all manufacturers of covered products that are sold,~~
12 ~~offered for sale, or dispensed in California, whether they are program operators or are~~
13 ~~represented by a stewardship organization, as the covered entities.~~

14 ~~(b) The department will use the priority set forth in subsections(1)(B)-(E) of subdivision~~
15 ~~(f) of section 42030 of the Public Resources Code to identify the covered entity for any~~
16 ~~covered products consistent with subdivision (f) of section 42030, which do not meet the~~
17 ~~definition of subsection (1)(A) of subdivision (f) of section 42030 of the Public~~
18 ~~Resources Code.~~

19 ~~(b) The department, in collaboration with the California Board of Pharmacy, will develop and~~
20 ~~implement procedures to communicate with manufacturers of covered products, or the selected~~
21 ~~stewardship organization, and ensure understanding of compliance responsibilities. Only when~~
22 ~~there is sufficient evidence that such efforts have failed, the department will utilize the priority~~
23 ~~set forth in subsections(1)(B)-(E) of subdivision (f) of section 42030 of the Public Resource Code.~~

24 ~~(c) "Manufacturer" means a person, company, corporation or other entity engaged in the~~
25 ~~manufacture of (a) a covered drug as defined in subsection (e)(1) of section 42030 of~~
26 ~~the Public Resources Code sold, offered for sale, or dispensed in the state or (b) sharps~~
27 ~~sold, offered for sale, or dispensed in the state. Manufacturer does not include the~~
28 ~~activities of a repackager, relabeler, private label distributor or wholesale distributor.~~

29 Note: Authority cited: Sections 40401, 42031.2 and 40502, Public Resources Code.

30 Reference: Section 42030, Public Resources Code.

31 **18973. DOCUMENT SUBMITTALS: STEWARDSHIP PLAN, INITIAL PROGRAM**
32 **BUDGET, ANNUAL REPORT, AND ANNUAL BUDGET.**

33 ~~(a) A corporate officer, acting on behalf of the program operator, shall submit to the~~
34 ~~department contact information of the corporate officer responsible for submitting and~~
35 ~~overseeing the document, including, but not limited to:~~

36 ~~(1) Contact name and title~~

37 ~~(2) Name of program operator~~

38 ~~(3) Mailing and physical address(es)~~

39 ~~(4) Phone number~~

40 ~~(5) Email address~~

023-Supp. 001

Commented [HDA1]: As noted by the legislative committee of jurisdiction, the Governor's signing message and stakeholder comments, the term "covered entity" needs to be further clarified within the regulations. Additional clarity is also necessary in regard to the process the department will undergo when utilizing the tiered definition.

HDA offers these recommended changes which will provide a clear process to determine which entity should be considered the "covered entity" as well as allow the department to work with the Board of Pharmacy on a procedure on how to utilize the tiered definition.

023- Supp. 004

023-Supp. 005

1 **18974.1. ADMINISTRATIVE AND OPERATIONAL COSTS AND DEPARTMENTAL**
2 **ADMINISTRATIVE FEE TO DEPARTMENT OF RESOURCES RECYCLING AND**
3 **RECOVERY.**

4 (a) Each covered entity, either individually or through a stewardship organization, shall
5 pay all administrative and operational costs associated with establishing and
6 implementing the stewardship program in which it participates, including the cost of
7 collecting, transporting, and disposing of covered products.

8 (b) On or before the end of the 2022-23 fiscal year, and once every three (3) months
9 thereafter, a program operator shall pay to the department a departmental
10 administrative fee. The department will set the departmental administrative fee pursuant
11 to subsection (1) of subdivision (a) of sections 42034.4 and 42034.2 of the Public
12 Resources Code.

13 (c) For a stewardship organization, the departmental administrative fee paid pursuant to
14 subsection (b) shall be funded by the covered entities that make up the stewardship
15 organization. This departmental administrative fee shall be in addition to the
16 administrative and operational costs paid pursuant to subsection (a). A stewardship
17 organization may require its participating covered entities to pay the departmental
18 administrative fee and the administrative and operational costs paid pursuant to
19 subsection (a) at the same time.

20 Note: Authority cited: Sections 40401, 42031.2, and 40502, Public Resources Code.
21 Reference: Sections 42030, 42034 and, 42034.2, Public Resources Code.

22 **18974.2. STEWARDSHIP ORGANIZATION AUDITS OF COVERED ENTITIES OR**
23 **AUTHORIZED COLLECTORS.**

24 If a stewardship organization conducts an audit of covered entities or authorized
25 collectors pursuant to section 42034.4 of the Public Resources Code, the stewardship
26 organization shall provide a copy of the audit to the department within 30 days of its
27 completion.

28 Note: Authority cited: Sections 40401, 42031.2 and 40502, Public Resources Code.
29 Reference: Sections 42030 and 42034.4, Public Resources Code.

30 **18974.3. DISTRIBUTOR, RETAILER, WHOLESALER, DISTRIBUTOR, PHARMACY,**
31 **AND RETAILER PRODUCT VERIFICATION.**

32 ~~Each distributor, wholesaler, pharmacy, and retailer that sells, offers for sale, or~~
33 ~~dispenses a covered product shall:~~

34 (a) Each distributor, wholesaler, pharmacy, and retailer that sells, offers for sale, or
35 dispenses a covered product shall: ~~s~~Successfully log onto the department's internet
36 ~~W~~website at least annually to verify determine if a covered entity of that covered
products ~~to be~~ sold, offered for sale, or

Commented [HDA2]: To ensure conformity and clarity, HDA recommends the department require reporting to be conducted at least annually and work with industry to establish a standardized format for the reports. HDA further requests the Department notify licensed or reporting entities when they identify a non-compliant stewardship organization or covered entity.

023-Supp. 006

1 dispensed are in compliance with the law, by verifying that the covered entities
2 providing the covered product(s) are in compliance with the law.

3 (b) Should a distributor, wholesaler, pharmacy, other retailer, or a designated
4 responsible party for any of the foregoing identify a noncompliant covered entity product
5 or stewardship organization, the distributor, wholesaler, pharmacy, other retailer, or
6 designated responsible party for any of the foregoing shall report, in an agree upon
7 format, the discovery to the
8 department's Enforcement Unit within 30 days.

8 (c) Should the Department determine a covered entity or stewardship organization is not
in compliance, the Department in collaboration with the Board shall notify all licensees
of the non-compliance.

79 _____

§10 Note: Authority cited: Sections 40401, 42031.2 and 40502, Public Resources Code.

§11 Reference: Sections 42030, 42035, 42035.2, 42035.4, 42035.6 and 42035.8, Public
Resources Code.

1413 ~~18975. CRITERIA TO IMPOSE AN ADMINISTRATIVE CIVIL PENALTY.~~

1214 (a) A covered entity is not in compliance with this chapter and is subject to
1315 administrative penalties if it sells or offers for sale a covered product which is not
1416 subject to an approved stewardship plan that has been submitted by the covered entity
1517 or by a stewardship organization that includes the covered entity.

1618 (b) In assessing or reviewing the amount of an administrative penalty imposed for a
1719 violation of this Article, the department shall consider the totality of the circumstances,
1820 which may include, but is not limited to, the following:

1921 (1) The nature, circumstances, extent, and gravity of the violation(s)

2022 (2) The number and severity of the violation(s)

2123 (3) Evidence that the violation was intentional, knowing, or negligent

2224 (4) The size of the violator

2325 (5) History of violation(s) of the same or similar nature

2426 (6) The willfulness of the violator's misconduct

2527 (7) Whether the violator took good faith measures to comply with this chapter and
2628 the period of time over which these measures were taken

2729 (8) Evidence of any financial gain resulting from the violation(s)

2830 (9) The economic effect of the penalty on the violator

2931 (10) The deterrent effect that the imposition of the penalty would have on both
3032 the violator and the regulated community

3133 (11) Any other factor that justice may require

023-Supp. 007

~~1 Note: Authority cited: Sections 40401, 42031.2 and 40502, Public Resources Code.~~
~~2 Reference: Sections 42030, 42035, 42035.2, 42035.4, 42035.6 and 42035.8, Public~~
~~3 Resources Code.~~

4 **18975. CRITERIA TO IMPOSE AN ADMINISTRATIVE CIVIL PENALTY.**

5 (a) The department shall impose an administrative civil penalty if it determines that any
6 covered entity, program operator, stewardship organization, or authorized collector
7 sells, offers for sale, or provides a covered product in violation of this Article or Chapter
8 2 of Part 3 of Division 30 of the Public Resources Code.

9 (b) The department will establish a process to alert potential covered entities when it will
utilize the priority set forth in subsections(1)(B)-(E) of subdivision (f) of section 42030 of
the Public Resources Code to identify the covered entity for any covered products,
which do not meet the definition of subsection (1)(A) of subdivision (f) of section 42030
of the Public Resources Code and ensure the potential covered entities are aware of
the regulations and responsibility before assessing any administrative penalty.

10 (c) Should the department utilize the priority set forth in subsections(1)(B)-(E) of
subdivision (f) of section 42030 of the Public Resources Code to identify the covered
entity for any covered products, which do not meet the definition of subsection (1)(A) of
subdivision (f) of section 42030 of the Public Resources Code, the subsequent
participation entity shall be held harmless for the assessment of penalties on the non-
compliant covered entity.

911 (bd) In assessing or reviewing the amount of an administrative penalty imposed for a
4012 violation of this Article or Chapter 2 of Part 3 of Division 30 of the Public Resources
4413 Code, the department shall consider the totality of the circumstances, which may
4214 include, but is not limited to, the following:

4315 (1) The nature, circumstances, extent, and gravity of the violation(s)

4416 (2) The number and severity of the violation(s)

4517 (3) Evidence that the violation was intentional, knowing, or reckless

4618 (4) The size of the violator's business and/or the financial position of the violator

4719 (5) History of violation(s) of the same or similar nature

4820 (6) The willfulness of the violator's misconduct

4921 (7) Whether the violator took good faith measures to comply with this Article and
2022 Chapter 2 of Part 3 of Division 30 of the Public Resources Code and the period
2423 of time over which these measures were taken

2224 (8) Evidence of any financial gain resulting from the violation(s)

2325 (9) The economic effect of the penalty on the violator

Commented [HDA3]: HDA recommends the following changes in order to ensure that should the Department utilize the tiered definition of covered entity, the newly responsible entity is alerted and held harmless of any penalties assessed on the previously reported non-compliant entity.

023-Supp. 009

023-Supp. 008

023-Supp. 010

From: [Kristen Kavakava](#)
To: [PharmaSharps](#)
Cc: [Ashley Schmidt](#)
Subject: Inmar Comments Regarding Pharmaceutical and Sharps Stewardship Act (SB 212)
Date: Monday, August 3, 2020 11:38:35 AM
Attachments: [Inmar Comments Regarding Pharmaceutical and Sharps Stewardship Act \(SB 212\).docx](#)

[[EXTERNAL]]

Good Afternoon,

Please find attached Inmar's comments regarding Pharmaceutical and Sharps Stewardship Act (SB 212). Please confirm receipt and do not hesitate to reach out if there are any questions or concerns.

Thank you,

Kristen Kavakava

Manager, Regulatory and Compliance Expansion



kristen.kavakava@inmar.com
635 Vine Street, Winston Salem, NC 27101
p: 336-631-2628 | c: 757-831-0708
www.inmar.com | [LinkedIn](#) | [Facebook](#) | [Twitter](#)

Inmar Confidentiality Note: This e-mail and any attachments are confidential and intended to be viewed and used solely by the intended recipient. If you are not the intended recipient, be aware that any disclosure, dissemination, distribution, copying or use of this e-mail or any attachment is prohibited. If you received this e-mail in error, please notify us immediately by returning it to the sender and delete this copy and all attachments from your system and destroy any printed copies. Thank you for your cooperation.

Notice of Protected Rights: The removal of any copyright, trademark, or proprietary legend contained in this e-mail or any attachment is prohibited without the express, written permission of Inmar, Inc. Furthermore, the intended recipient must maintain all copyright notices, trademarks, and proprietary legends within this e-mail and any attachments in their original form and location if the e-mail or any attachments are reproduced, printed or distributed.



July 29, 2020

VIA E-MAIL (PharmaSharps@CalRecycle.ca.gov)

Jason Smyth
Senior Environmental Scientist, Pharmaceutical & Sharps Unit Supervisor
Materials Management & Local Assistance Division
California Department of Resources Recycling and Recovery
1001 I Street
Sacramento, CA 95812-4025

Re: Inmar Comments Regarding Pharmaceutical and Sharps
Stewardship Act (SB 212)

Cal. Pub. Resources Code Div. 30, Pt. 3, Ch. 2
Proposed Regulations: 2019 Cal. Reg. Notice Register 03505

Second Draft Proposed Regulations for 15-day Comment Period, July 2020

Proposed Regulations, Pharmaceutical and Sharps Waste Stewardship
Program, available at <https://www2.calrecycle.ca.gov/Docs/Web/117711>

Dear Mr. Smyth:

Inmar Rx Solutions, Inc. (“Inmar”) appreciates the opportunity to provide these additional comments to the California Department of Resources, Recycling, and Recovery (“CalRecycle” or the “Department”) regarding the implementation of California Senate Bill No. 212 (“SB 212”) the “Pharmaceutical and Sharps Stewardship Act.”

Inmar is a national leader in pharmaceutical returns, servicing over 27,000 pharmacies and 80 percent of hospitals and health systems. Inmar processes over 95 percent of the industry’s wholesale returns. Additionally, Inmar has three years of experience managing drug take-back programs with over 1,100 receptacles in 42 states, primarily driven through retail and hospital collectors.

Inmar handles physical processing, financial transaction, and disposition of returns, including full, partial, recalls, and expired medications. Our technological systems drive increased efficiency and value retention, manage risk, and minimize the environmental impact of returns.

Inmar reiterates its comments previously submitted on February 17, 2020 and incorporates those comments into this submittal.

I. COMMENTS

18973.3. STEWARDSHIP PLAN FOR HOME-GENERATED SHARPS WASTE.

Within six months of the adoption date of the regulations in this Article by the department, a program operator shall submit a stewardship plan to the department.

(g) Local Agency Requests: “Program operators shall respond to requests by local agencies within 14 days of receipt of the request...”

024-001 Comment: As an experienced provider of pharmaceutical return services, Inmar recommends a 30 day deadline, which would be more operationally practical while still fulfilling the goals of the program.

18973.2. STEWARDSHIP PLAN FOR COVERED DRUGS.

(j) Education and Outreach

(3) Establishment of an internet website designed with functionality for mobile platforms, provided with language options suited to local demographics, and maintained to ensure all information is up to date and accurate.

4) Establishment of a toll-free telephone number to: 1) accept requests for mail-back materials from ultimate users who are homeless, homebound, or disabled, and 2) to provide disposal options, and other program information to ultimate users without access to the internet.

024-002 Comment: CalRecycle is responsible for the administration of pharmaceutical and sharps stewardship and in that capacity should prioritize convenience and ease of use for state residents. Accordingly, CalRecycle should allocate sufficient state funding, and if necessary, a portion of any fees collected pursuant to the statute, to coordinate the consumer-facing aspects of the program, specifically the website and the toll-free number.

024-003 The multiple program operators can provide the information for the maintenance of the website. However, asking or requiring competing program operators to coordinate in the establishment and launch of a website outside of the confines of a trade association or similar body invites a potential violation of the Sherman Act (15 U.S.C. §§ 1 and 2), for which the state would have to take multiple additional steps to provide potential federal immunity.

024-004 At a minimum, the state should ensure that it owns the website and toll-free number to ensure continuity between potential changes in program operators. If a program operator owns the website or number and then exits the program, establishment of a new number would create unnecessary confusion for consumers.

Thank you for your consideration of our comments. We welcome the opportunity to further discuss this program. I can be reached at (336) 770-3588 or domingo.isasi@inmar.com, or contact Jennifer

Snyder, Capitol Advocacy at (916) 444-0400. Please do not hesitate to contact us. We look forward to participating in the implementation of SB 212 with CalRecycle.

Sincerely,

A handwritten signature in black ink, appearing to read "D Isasi".

Domingo Isasi
Vice President

From: [Nate Pelczar](#)
To: [PharmaSharps](#)
Cc: [Doug Kobold](#); [Heidi Sanborn](#); [Emily Barnett](#); [Sherman, Alison](#); [Mina Layba](#); [Wolfberg, Shelly](#); [Bruckner, Austin](#); [BOS Dist 4](#); [Roa, Amanda](#); [Jennifer Lombardi](#); [Tim Flanagan](#); [Veronica Pardo](#); [Sabrina Marson](#); [Griffis, Amanda](#); [Leslie Lukacs](#); [Courtney Scott](#)
Subject: Coalition letter regarding SB 212 regulations
Date: Monday, August 3, 2020 12:21:32 PM
Attachments: [image005.png](#)
[SB212 Reg Comments - Second Draft - 2020.08.03.pdf](#)

[[EXTERNAL]]

Dear Mr. Smyth,

Please see the attached coalition letter regarding SB 212 regulations.

Best regards,
Nate

Nate Pelczar | Special Projects Manager

T: 916.706.3420

C: 279.444.7481

E: Nate@CalPSC.org

A: 1822 21st St., Sacramento, CA 95811





August 3, 2020

Jason Smyth
Materials Management and Local Assistance Division
California Department of Resources Recycling and Recovery
P.O. Box 4025
Sacramento, CA 95812-4025

EMAIL: pharmasharps@calrecycle.ca.gov

**Subject: Second Draft Proposed Regulations (July 2020)
Pharmaceutical and Sharps Waste Stewardship Program**

Dear Mr. Smyth,

We, the undersigned organizations, would like to thank you for the opportunity to submit comments on the second draft of proposed regulations to implement the Pharmaceutical and Sharps Waste Stewardship Program established by SB 212 (2018 - Jackson, Ting, and Gray). The work you are doing to implement this program for the people of California is vitally important, and we hope our comments provide additional perspective as you complete this task. We have provided several comments below on specific portions of the regulations that have been amended in the most recent draft.

Proposed Regulations are Inconsistent with Authorizing Statute

The core of the sharps program is the requirement that a sharps waste container and mail-back materials are either provided to the ultimate user at the point of sale, or the provision of those materials is initiated at the point of sale. This requirement functions as the convenience standard for this program and is therefore quite important to proper operation. The language in PRC 42032.2(d)(1)(F)(i) is very clear:

“The program provides of initiates distribution of a sharps waste container and mail-back materials at the point-of-sale, to the extent allowable by law. Containers and mail-back materials shall be provided at no cost to the ultimate user. The program operator shall select and distribute a container and mail-back materials sufficient to accommodate the volume of sharps purchased by an ultimate user over a selected period of time.”

For purposes of establishing a foundational fact for the comment we are about to make, we’d stress that the authorizing statute simply does not allow a program operator any flexibility in the requirement to provide or initiate distribution of a sharps container and mail-back materials at the point of sale unless providing or initiating distribution at the point of sale is specifically prohibited by law.

The problem with both the first and second draft of proposed regulations is that they allow a program operator an offramp from the statutory requirement to provide the sharps container and mail-back materials at the point of sale for a reason that is simply not allowed by the law – feasibility.

Section 18972.1(a)(11) creates a definition for “Provides or initiates the distribution of a sharps waste container” and provides three possible meanings for this phrase. Two of them – 18972.1(a)(11)(A) and (B) are consistent with the authorizing statute, but (C) is not. As we note above, (C) states that a program operator can utilize “other methods” if the options in (A) or (B) are not allowed by law or “is not reasonably feasible”. The department simply does not have authority under the authorizing statute to make the allowance for “other methods” if feasibility is the only perceived barrier to providing a sharps container and mail-back materials at the point of sale under (A) or initiating the distribution of those items at the point of sale under (B). This should be struck from the definition.

Although we believe the legal reality described above is unquestionably accurate, we’d also like to make a more general argument in favor of striking the allowance of “other methods” based on feasibility. SB 212 was largely a negotiated compromise – especially the sharps portion of the bill. The sharps industry insisted on a mail-back only program. Stakeholders, to ensure the success of this industry-devised mail-back method, insisted on some very important provisions. Those are:

- That the mail-back container and materials be provided at the point of sale. This is vitally important to ensuring convenience for consumers. We know through experience all over the world that convenience is the most important factor in determining the success of producer responsibility programs and so this was an extremely important requirement.
- That program operators be responsible for either reimbursing local governments for sharps disposal of sharps in the waste stream or come pick them up and dispose of them.

Combined, these two provisions ensure convenience for the ultimate user and create a significant incentive for the producer to design and implement an effective program. They are foundational to the effective operation of the mail-back only program. We do not believe that the regulations should even consider the possibility of a stewardship plan for sharps that does either provide or initiate the delivery of the sharps container and mail-back materials at the point of sale unless there is a demonstrable legal concern. To do so would be inconsistent with legislative intent.

025-001

We strongly encourage the department to strike the words “or is not reasonably feasible” from lines 5 and 6 of page 3 of the second draft of proposed regulations because they are inconsistent with the authorizing statute and could significantly weaken the program.

Enforcement of Implementation Timeline and Programmatic Requirements

Our major concern in this area is that the department, to the degree possible, avoids a situation where the process of submitting, reviewing, and approving stewardship plans doesn’t drag on in ways that jeopardize program efficacy, such as multiple resubmittals of the draft plan or future amendments to the plan. We commented on our past letter about the process for determining plan completeness, as well as the process for approving/disapproving plans. While the second draft of proposed regulations don’t necessarily adopt our prior suggestions, we do believe that the statute and regulations provide the department enough authority to enforce the law.

PRC 42032(a)(1) requires a program operator to submit a complete stewardship plan that meets the requirements of the law within six months of the regulations being approved. PRC 42032(g) requires a program operator to fully implement their stewardship plan within 270 days of the department’s

approval. PRC 42035.2 gives the department authority to impose a civil penalty to a covered entity, program operator, or stewardship organization that provides, sells, or offers for sale a covered product that isn't covered by a stewardship plan. We believe the regulations, in Sections 18975, 18975.1, and 18975.2, also provide the department with the tools necessary to ensure that this program is implemented in a timely and effective manner.

025-002

We strongly encourage the department to utilize this enforcement and penalty authority if program operators do not meet implementation timelines and standards. The covered entities required to perform under the law have years of experience implementing local ordinances and will have had nearly three years of ramp-up time between the passage of SB 212 and the deadline to implement the program. There is simply no excuse for a program operator to be unprepared to meet their responsibility under the law.

Similarly, we hope the department will utilize its authority in Section 18975.2 to enforce key aspects of the program. Subsection (a) requires the department to revoke a previously approved stewardship plan if the department finds that a material requirement of the article is not being met by a program operator.

Education & Outreach Program

Product stewardship programs cannot work if they are difficult to understand and navigate. The education and outreach portion of the stewardship plans needs to be robust, consistent, and accessible by all Californians. We strongly support the changes to the education and outreach portions of the regulations (Section 18973.2(j) for medicines and 18973.3(i) for sharps) because they significantly strengthen the regulations and provide clear direction to program operators.

The second draft proposed regulations require program operators to coordinate closely with other program operators or stewardship organizations on their efforts to promote awareness and participation in their stewardship programs, develop educational signage and materials in multiple languages depending on local need, develop internet websites and mobile platforms to provide vital information, establish a toll-free telephone number that provides service for the hearing- and speech-impaired and is also answered by a human representative, and metrics to evaluate and recalibrate efforts as needed. All of these components are necessary for an effective education and outreach program and we support their inclusion in the regulations.

025-003a

025-003b

While we understand that the plan development, submission, and approval process will ultimately determine what is in the actual education and outreach programs, we believe the regulations provide a strong foundation for success. We urge the department to be vigilant in terms of this portion of the product stewardship plan – if program operators don't get the education and outreach program correct then the entire effort will suffer.

025-004a

025-004b

In our comments on the first draft of proposed regulations we stated that we thought the prohibition against promoting disposal options inconsistent with the purposes of the program, contained in PRC 42031.6(b), should be re-stated in the regulations. We still believe this would be wise because of experiences on the local level where stewardship organization websites linked to information on disposal that was unquestionably in conflict with the purposes of the program.

Conclusion

Thank you again for the opportunity to comment on the second draft proposed regulations. We are supportive of the direction in which the department is moving and believe that the second draft contains many improvements and ensures that this important program will effectively serve all Californians.

Sincerely,



Doug Kobold, Executive Director
California Product Stewardship Council

**Emily Barnett, Intergovernmental Relations
Manager**
Central Contra Costa Sanitary District

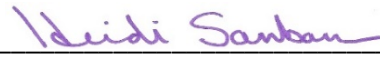
Adam C. Albert, Mayor
City of Thousand Oaks

Nate Miley, County Supervisor
County of Alameda

Jennifer Lombardi, General Manager
Mendo Recycle

Veronica Pardo, Regulatory Affairs Director
Resource Recovery Coalition of California

Amanda Griffis, Staff
Upper Valley Waste Management Agency



Heidi Sanborn, Executive Director
National Stewardship Action Council

Göran Eriksson, Mayor
City of Culver City

Alison Sherman, Recycling Coordinator
City of Torrance

Amanda Roa, Environmental Programs Manager
Delta Diablo

Tim Flanagan, General Manager
Monterey Regional Waste Management District

Sabrina Marson, Association Staff
Russian River Watershed Association

Leslie Lukacs, Executive Director
Zero Waste Sonoma

Cc: Senator Hanna Beth Jackson
Assemblymember Phil Ting
Assemblymember Adam Gray
Melissa Immel, Deputy Legislative Secretary & Chief of Legislative Operations / Gov. Newsom

From: [Anne Vogel Marr](#)
To: [PharmaSharps](#)
Subject: PPSWG Comments on California Rulemaking
Date: Monday, August 3, 2020 1:19:43 PM
Attachments: [image001.png](#)
[image002.png](#)
[2020-08-03 PPSWG Comments on California Rulemaking.pdf](#)
Importance: High

[[EXTERNAL]]

August 3, 2020

Jason Smyth
Materials Management and Local Assistance Division
California Department of Resources Recycling and Recovery
P.O. Box 4025
Sacramento, CA 95814

Dear Mr. Smyth:

The Pharmaceutical Product Stewardship Work Group (“PPSWG”) appreciates the opportunity to submit comments on the California Department of Resources Recycling and Recovery’s second draft proposed Pharmaceutical and Sharps Waste Stewardship Program regulations, which revise the original proposed regulations issued on January 3, 2020.

PPSWG appreciates the Department’s willingness to accept and consider public comments throughout the rulemaking process for the proposed regulations.

Respectfully submitted,

Anne Vogel-Marr

Anne Vogel-Marr

Executive Director

Pharmaceutical Product Stewardship Work Group

1800 M Street, NW, Suite 400 South | Washington, DC 20036

(t) 202/868-4438 **(f)** 202/530-0659 **(e)** avogelmarr@ppswg.org



CONFIDENTIALITY NOTICE: The contents of this email message and any attachments are intended solely for the addressee(s) and may contain confidential and/or privileged information and may be legally protected from disclosure. If you are not the intended recipient of this message or their

agent, or if this message has been addressed to you in error, please immediately alert the sender by reply email and then delete this message and any attachments. If you are not the intended recipient, you are hereby notified that any use, dissemination, copying, or storage of this message or its attachments is strictly prohibited.



Pharmaceutical Product Stewardship Work Group
1800 M Street, NW | Suite 400 South | Washington, DC 20036
Phone: (202) 495-3131 | Fax: (202) 530-0659
info@ppswg.org

VIA EMAIL AT pharmasharps@calrecycle.ca.gov

August 3, 2020

Jason Smyth
Materials Management and Local Assistance Division
California Department of Resources Recycling and Recovery
P.O. Box 4025
Sacramento, CA 95814

Re: PPSWG Comments on CalRecycle’s Second Draft of the Proposed Pharmaceutical and Sharps Waste Stewardship Program Regulations (California Code of Regulation, Title 14, Division 7, Chapter 11, Article 4, Sections 18972 to 18975.2)

Dear Mr. Smyth:

The Pharmaceutical Product Stewardship Work Group (“PPSWG”) appreciates the opportunity to submit comments on the California Department of Resources Recycling and Recovery’s (the “Department’s” or “CalRecycle’s”) second draft proposed Pharmaceutical and Sharps Waste Stewardship Program regulations, which revise the original proposed regulations issued on January 3, 2020 (the “Revised Proposed Regulations”).

I. Revised Administrative Procedures Applicable to Administrative Penalty Actions Proposed at Section 18975.1

026-001

PPSWG has concerns with the new administrative procedures that the Department is proposing in Section 18975.1, which would apply to proposed actions by the Department that could result in the assessment of tens of thousands, or even hundreds of thousands of dollars, in administrative penalties.

Under the original version of the proposed regulations issued on January 3, 2020, Section 18975.1 stated that proceedings held on a proposed administrative penalty action by the Department were subject to the procedures in Chapter 4.5 of the California Administrative Procedures Act (“APA”), Gov’t Code section 11455.10 *et seq.* As you likely know, the procedures in Chapter 4.5 apply to informal hearings conducted by state agencies, like CalRecycle, and incorporate minimum due process protections afforded to respondents under California law, including, namely those set forth in the Administrative Adjudicative Bill of Rights, Gov’t Code §§ 11425.10 – 11425.60.

For reasons unclear from the rulemaking file, the Department has removed all references to the APA in the Revised Proposed Regulations and Section 18975.1 now includes what appears to be a novel set of procedures that the Department has created for use in future proposed administrative penalty actions. The procedures now proposed in Section 18975.1 are extremely

scant and fail to address all aspects of an adjudicatory proceeding. Moreover, the procedures that the Department is now proposing do not comport with the minimum due process protections that are conferred upon respondents under California’s Administrative Adjudicative Bill of Rights, Cal. Gov’t Code §§ 11425.10 – 11425.60.

As such, the Section 18975.1(b)-(f) of the Revised Proposed Regulation should be revised as follows:

(b) The department shall commence an action to impose administrative civil penalties by serving an accusation upon the respondent that includes a notice informing the respondent of their right to a hearing. The accusation shall state the legal and factual basis for the imposition of penalties, including a description of how the department applied the criteria in Section 18975(b).

...

(d) A written request for a hearing to contest the proposed action shall be submitted to the department within thirty (30) days of receipt of the accusation. ~~The hearing request shall be in writing and shall state the basis for objecting to the department’s action. Upon a failure to submit a timely hearing request under this subdivision, the respondent shall be deemed to have waived its right to hearing and the department shall issue a penalty order to the respondent requiring payment of penalties at the levels described in the accusation.~~

~~(e) The hearing shall be held before the Director of the Department of Resources Recycling and Recovery. A party shall be afforded the opportunity to present evidence and testimony on all relevant issues. Any relevant evidence shall be admitted if it is the sort of evidence on which responsible persons are accustomed to rely in the conduct of serious affairs, regardless of the existence of any common law or statutory rule which might make improper the admission of the evidence over objection in civil actions. If a hearing is requested pursuant to subdivision (d), the hearing shall be held in accordance with the provisions governing adjudicative proceedings in Government Code Title 2, Division 3, Part 1, Chapter 4.5 (Section 11400 et seq.).~~

~~(f) The Director of the Department of Resources Recycling and Recovery shall issue a written decision within sixty (60) days from the date the hearing is concluded.~~

II. Support for Comments Submitted By MED-Project USA

026-002

Our understanding is that MED-Project USA is submitting comments on the Revised Proposed Regulations addressing the Revised Proposed Regulations' definitions, stewardship plan requirements, annual reporting and budgets, and administrative procedures. PPSWG supports the comments submitted by MED-Project USA.

* * * * *

Thank you for your consideration of these comments. Please feel free to contact me with any questions. We look forward to continuing to work with CalRecycle during the development of the Revised Proposed Regulations and the implementation of SB 212.

Respectfully submitted,



Anne Vogel-Marr
Executive Director

From: [DPW-EPD TaskForce](#)
To: [PharmaSharps](#)
Cc: [Coby Skye](#); [Carlos Ruiz](#); [Patrick Holland](#); mikemohajer@yahoo.com
Subject: COMMENTS ON SENATE BILL 212 SECOND DRAFT PROPOSED REGULATIONS FOR 15-DAY COMMENT PERIOD, JULY 2020
Date: Monday, August 3, 2020 4:15:24 PM
Attachments: [image001.png](#)
[SB 212 Regulations Second Draft for 15-day Comment Period July 2020 - LAC Task Force to CR Final.pdf](#)

[[EXTERNAL]]



TO: Jason Smyth, Senior Environmental Scientist
Materials Management and Local Assistance Division
California Department of Resources Recycling and Recovery

Please see attached letter dated August 3, 2020 from the Los Angeles County Solid Waste Management Committee/Integrated Waste Management Task Force to California Department of Resources Recycling and Recovery regarding Comments on Senate Bill 212: Pharmaceutical and Sharps Waste Stewardship Program Second Draft Proposed Regulations For 15-Day Comment Period, July 2020.

If you have any questions regarding the subject matter, please contact Mr. Mike Mohajer of the Task Force at MikeMohajer@yahoo.com or at (909) 592-1147. For questions regarding the Task Force, please contact Ms. Elizabeth Zaragoza at (626) 300-3234 or at ezaragoza@pw.lacounty.gov.



MARK PESTRELLA, CHAIR
MARGARET CLARK, VICE - CHAIR

LOS ANGELES COUNTY
SOLID WASTE MANAGEMENT COMMITTEE/
INTEGRATED WASTE MANAGEMENT TASK FORCE
900 SOUTH FREMONT AVENUE, ALHAMBRA, CALIFORNIA 91803-1331
P.O. BOX 1460, ALHAMBRA, CALIFORNIA 91802-1460
www.lacountyiswmtf.org

August 3, 2020

Jason Smyth, Senior Environmental Scientist
Materials Management and Local Assistance Division
California Department of Resources Recycling and Recovery
P.O. Box 4025
Sacramento, CA 95812-4025

Sent via PharmSharps@calrecycle.ca.gov

Dear Mr. Smyth:

**COMMENTS ON SENATE BILL 212 SECOND DRAFT PROPOSED REGULATIONS
FOR 15-DAY COMMENT PERIOD, JULY 2020**

The Los Angeles County Solid Waste Management Committee/Integrated Waste Management Task Force (Task Force) supports Senate Bill 212 (SB 212) Pharmaceutical and Sharps Waste Stewardship Program and is grateful for the opportunity to comment on this Second Draft (dated July 2020) in the Resources Recycling and Recovery Department of California's (CalRecycle) Formal Rulemaking process to finalize the Regulations Text.

<https://www.calrecycle.ca.gov/laws/rulemaking/pharmasharps>

As enacted in 2018, SB 212 requires "covered entities" to create a stewardship program, either individually or through a stewardship organization, and that the program plan must be approved by CalRecycle. The law expands upon much needed safe and convenient disposal options for home-generated pharmaceutical drug and sharps waste.

It is our understanding that after this Second Draft comment period, CalRecycle will proceed with final adoption of the regulations by the deadline of January 1, 2021.

As required by SB 212, the Stewardship Plans are due to CalRecycle by July 1, 2021, and Stewardship Organization(s) are to provide CalRecycle their first Annual Report by March 31, 2022.

The Task Force would like to offer the following comments regarding the subject Second Draft Proposed Regulations:

Article 4.

Section 18972.1(a)(11) Sharps waste container and mail-back materials at the point of sale, to the extent allowable by law.

In statute 42032.2(d)(1)(F)(i) it clearly states:

- (i) The program provides or initiates distribution of a sharps waste container and mail-back materials at the point of sale, **to the extent allowable by law.**

We respectfully request the removal of the language “or is not reasonably feasible”.
Second Draft Regulations:

(11) “Provides or initiates distribution of a sharps waste container” means one of the following:

- (A) To provide a sharps waste container and mail-back materials to the ultimate user, at the point of sale or prior, at no cost to the ultimate user; or,
- (B) To arrange, at the point of sale or prior, for a sharps waste container and mail-back materials to be sent to the ultimate user and arrive within four business days at no cost or inconvenience to the ultimate user; or
- (C) Other methods of providing a sharps waste container and mail-back materials, if the method identified in subpart (A) above is not allowed by law ~~or is not reasonably feasible~~, and if the method identified in subpart (B) above is not allowed by law ~~or is not reasonably feasible~~. These methods must be approved by the department in a stewardship plan and result in substantially the same level of convenience to the ultimate user as the methods identified in subparts (A) and (B) above.

027-001

There is no allowance in the statute for this primary convenience standard requirement to be compromised except for being limited by “to the extent allowable by law”. This convenience standard is of primary importance because the success of Extended Producer Responsibility (EPR) programs are greatly determined by convenience for end users. The inclusion of the language “or is not feasible” allows the stewardship organization an off-ramp that is not allowed by law and was specifically not included in the law. SB 212 was largely a negotiated compromise between industry and stakeholders and while industry insisted on a mail-back program only, stakeholders insisted on certain convenience standard provisions to ensure the success of the program.

Section 18972.2(j) and Section 189733(i) Education and Outreach.

027-002a The changes to the Education and Outreach sections for pharmaceuticals and sharps
027-002b enhances educational and outreach in provisions of materials, signage, labeling,
extensive internet and toll-free telephone number functionality, key metrics for evaluation,
and coordination. These additions add comprehension and clarification of these
provisions and will help to optimize awareness, increase user participation, and contribute
to their success.

Section 18975, 18975.1, and 18975.2 Enforcement.

027-003 These sections pertain to the Criteria to Impose an Administrative Civil Penalty,
Procedure for Imposing Administrative Civil Penalties, and the Procedure for Stewardship
Plan Revocation, Resubmittal, or Additional Compliance Reporting. These provisions
authorize CalRecycle to exercise sufficient corrective actions to achieve the success of
the SB 212's EPR programs. The importance of the pharmaceutical and sharps
management at end of life and the extensive stakeholder support for the development
and implementation of these programs warrant that any failure to comply ought to be
handled with sufficient penalties to ensure reasonable actions for success.

Conclusion.

Correcting convenience standards language regarding the sharps waste container and
mail-back materials at the point of sale as indicated in this letter, the strong changes for
medicines and sharps education and outreach, and CalRecycle's strong enforcement of
implementation timelines and programmatic requirements ought to ensure the success of
these vitally needed EPRs for pharmaceutical and sharps waste.

Pursuant to Chapter 3.67 of the Los Angeles County Code and the
California Integrated Waste Management Act of 1989 (Assembly Bill 939), the Task Force
is responsible for coordinating the development of all major solid waste planning
documents prepared for the County of Los Angeles and the 88 cities in
Los Angeles County with a combined population in excess of ten million. Consistent with
these responsibilities and to ensure a coordinated and cost-effective and environmentally
sound solid waste management system in Los Angeles County, the Task Force also
addresses issues impacting the system on a countywide basis. The Task Force
membership includes representatives of the League of California Cities-Los Angeles
County Division, County of Los Angeles Board of Supervisors, City of Los Angeles, waste
management industry, environmental groups, the public, and a number of other
governmental agencies.

Jason Smyth
August 3, 2020
Page 4

We respectfully request CalRecycle address these comments, concerns, and recommendations in the Regulations. If you have any questions regarding these comments, please contact Mr. Mike Mohajer, a member of the Task Force, at MikeMohajer@yahoo.com or at (909) 592-1147.

Sincerely,



Margaret Clark, Vice-Chair
Los Angeles County Solid Waste Management Committee/
Integrated Waste Management Task Force and
Mayor, City of Rosemead

EC:pg:ez

P:\eppub\Budget\IT\TASK FORCE\6-Letters\2020\July\SB 212 Regulations Second Draft for 15-day Comment Period July 2020 - LAC Task Force to CR Final.docx

cc: Senator Jackson
Assembly Member Gray
Assembly Member Ting
California State Association of Counties
CalRecycle, Matt Henigan, Deputy Director
League of California Cities – Los Angeles County Division
Each member of the Los Angeles County Board of Supervisors
Sachi A. Hamai, Los Angeles County Chief Executive Officer
San Gabriel Valley Council of Governments
South Bay Cities Council of Governments
Gateway Cities Council of Governments
Westside Cities Council of Governments
Each City Mayor and City Manager in the County of Los Angeles
Each City Recycling Coordinator in the County of Los Angeles
Each Member of the Los Angeles County Solid Waste Management
Committee/Integrated Waste Management Task Force

From: [Jim Wilson](#)
To: [PharmaSharps](#); [Smyth, Jason@CalRecycle](#); [MED-Project \(California\)](#)
Cc: [Michael Van Winkle](#); [Victoria Travis](#)
Subject: MED-Project USA Comments on the Second Draft of the Proposed Pharmaceutical and Sharps Waste Stewardship Program
Date: Monday, August 3, 2020 4:41:14 PM
Attachments: [image002.png](#)
[MED-Project Comments on Second Draft Pharmaceutical and Sharps Waste Stewardship Proposed Regulations 08.03.2020.pdf](#)

[[EXTERNAL]]

Dear Mr. Smyth,

PLEASE CONFIRM RECEIPT

MED-Project USA appreciates the opportunity to submit the attached comments to the California Department of Resources Recycling and Recovery ("CalRecycle") on CalRecycle's second draft of the Proposed Pharmaceutical and Sharps Waste Stewardship Program Regulations issued on July 14, 2020.

MED-Project appreciates CalRecycle's willingness to accept and consider public comments throughout the rulemaking process for the Proposed Regulations.

Sincerely,

Jim Wilson, P.E.

Sr. Director, Compliance and Risk Management

MED-ProjectTM

Medication Education & Disposal

(direct) 202/892-6502 (main) 833/633-7765 (e) jwilson@med-project.org | www.med-project.org

This e-mail transmission and any attachments that accompany it may contain information that is privileged, confidential or otherwise exempt from disclosure under applicable law and is intended solely for the use of the individual(s) to whom it was intended to be addressed. If you have received this e-mail by mistake, or you are not the intended recipient, any disclosure, dissemination, distribution, copying or other use or retention of this communication or its substance is prohibited. If you have received this communication in error, please immediately reply to the author via e-mail that you received this message by mistake and also permanently delete the original and all copies of this e-mail and any attachments from your computer.



MED-Project USA
1800 M Street, NW | Suite 400 S | Washington, DC 20036
Phone: (833) 633-7765 | Fax: (866) 633-1812

August 3, 2020

SENT VIA ELECTRONIC MAIL

Jason Smyth
Materials Management and Local Assistance Division
California Department of Resources Recycling and Recovery
P.O. Box 4025
Sacramento, CA 95814
Email: pharmasharps@calrecycle.ca.gov

Re: MED-Project USA Comments on CalRecycle’s Second Draft of the Proposed Pharmaceutical and Sharps Waste Stewardship Program Regulations (California Code of Regulation, Title 14, Division 7, Chapter 11, Article 4, Sections 18972 to 18975.2)

Dear Mr. Jason Smyth,

MED-Project USA appreciates the opportunity to submit comments on the California Department of Resources Recycling and Recovery’s (“Department’s” or “CalRecycle’s”) second draft proposed Pharmaceutical and Sharps Waste Stewardship Program regulations, which revise the original proposed regulations issued on January 3, 2020 (the “Revised Proposed Regulations”). MED-Project USA and its affiliated MED-Project companies (“MED-Project”) operate drug and sharps take-back programs in cities, counties, and states across the country, including in California. MED-Project plans to act as a “Program Operator” (as defined in PRC § 42030(q)) in California and has accordingly organized as a tax-exempt 501(c)(3) organization, as required under Section 42030(w) of the Pharmaceutical and Sharps Waste Stewardship Act (SB 212, Chapter 1004, Statutes of 2018) (“SB 212”).

MED-Project requires additional time to continue understanding the Revised Proposed Regulations given the nature and extent of revisions. Notwithstanding the unusually short comment period, MED-Project has prepared the following comments for CalRecycle to consider in promulgating regulations that are effective, practical, and clear. The comments provided below are organized in the same order as they appear in the Revised Proposed Regulations. Thank you for considering these comments.

I. DEFINITIONS

A. Section 18972.1(a)(10): MED-Project suggests further clarifying the term “Online Marketplace” and the Department’s use of the term “Covered Product” in the definition of “Point of Sale.”

1. The Department should clarify the term “Online Marketplace.”

MED-Project's February 17, 2020 public comments identified several issues regarding online sales under the version of the regulations released for public comment on January 3, 2020 (the “Jan. 2020 Proposal”). Although some of those issues still remain, MED-Project supports the Department’s “Point of Sale” definition in the Revised Proposed Regulations, which addresses online sales as sales occurring through an “online marketplace,” as compared to the broader Point of Sale definition referring to “online sales” in the Jan. 2020 Proposal. *See* Revised Proposed Regulations § 18972.1(a)(10) (“Point of sale’ means the point in time at which an ultimate user purchases a covered product at a pharmacy, other retailer, or online marketplace.”); Jan. 2020 Proposal § 18972.1(i). By establishing parameters for the scope of online activity subject to SB 212, this definition will better allow Program Operators to identify when they must “provide[] or initiate[] distribution of a sharps waste container and mail-back materials” *See* Cal. Pub. Res. Code (“PRC”) § 42032.2(d)(1)(F)(i). That was not possible under the Jan. 2020 Proposal, which defined Point of Sale so broadly that it included online sharps sales to an “Ultimate User” (as defined in PRC § 42030(z)) through any website worldwide. *See* Jan. 2020 Proposal § 18972.1(i).

028-001

028-002

In supporting the Department’s Point of Sale definition, MED-Project suggests that the Department further clarify the term “online marketplace” to better identify when sharps waste containers or mail-back materials must be provided. Without this clarification, the Department, Program Operators, “Covered Entities” (as defined in PRC § 42030(f)), and the public may have different expectations regarding what the Revised Proposed Regulations cover. The Department should make this clarification by:

028-003

- Cross-referencing the California Department of Tax and Fee Administration’s definition of “marketplace.” *See* 18 CCR § 1684.5(a)(9) (“Marketplace’ means a physical or electronic place, including, but not limited to, a store, booth, internet website, catalog, television or radio broadcast, or a dedicated sales software application, where a marketplace seller sells or offers for sale tangible personal property for delivery in this state regardless of whether the tangible personal property, marketplace seller, or marketplace has a physical presence in this state.”). Adding this cross reference to the definition of Point of Sale will remove ambiguity regarding the meaning of an online marketplace in a manner consistent with existing California regulations.
- Requiring “Stewardship Plans” (as defined in PRC § 42030(x)) to identify each online marketplace that they will work with to provide sharps waste containers or mail-back materials at the Point of Sale. This requirement will allow the Department to confirm each

028-004

028-005

“Stewardship Program” (as defined in PRC § 42030(y)) has identified and is working with the online marketplaces necessary to provide Ultimate Users sharps containers and mail-back materials.

These minor additions to the Revised Proposed Regulations would provide greater clarity for the Department, Program Operators, Covered Entities, and the public, while allowing the Department to ensure Ultimate Users have access to the services SB 212 and the Revised Proposed Regulations require. As revised with respect to this issue (see below for an additional comment), the Point of Sale definition would read: “‘Point of sale’ means the point in time at which an ultimate user purchases a covered product at a pharmacy, or other retailer, or online ‘marketplace’ as defined in 18 CCR § 1684.5(a)(9) and identified in a program operator’s stewardship plan.”

028-006

2. The Department should clarify the use of the term “Covered Product” in the Point of Sale definition.

Under SB 212, Stewardship Programs must meet the following requirement:

The program provides or initiates distribution of a sharps waste container and mail-back materials at the point of sale, to the extent allowable by law. Containers and mail-back materials shall be provided at no cost to the ultimate user. The program operator shall select and distribute a container and mail-back materials sufficient to accommodate the volume of sharps purchased by an ultimate user over a selected time period.

028-007

PRC § 42032.2(d)(1)(F)(i). The Revised Proposed Regulations similarly state that a Stewardship Plan for home-generated sharps waste must, among other things, describe how “stewardship plan implementation ... provides or initiates distribution of sharps waste containers and mail-back materials ... at no cost to ultimate users at the point of sale.” Revised Proposed Regulations § 18973.3(f)(2).

The Revised Proposed Regulations would define the term Point of Sale to mean “the point in time at which an ultimate user purchases a covered product at a pharmacy, other retailer, or online marketplace.” Revised Proposed Regulations § 18972.1(a)(10). “Covered Product” is defined in PRC § 42030(g) as a covered drug or home-generated sharps *waste* and, therefore, it is unclear why the Department used the phrase “*purchases* a covered product” in defining Point of Sale. MED-Project seeks clarification on CalRecycle’s intent in adding the phrase “purchases a covered product” in the definition of Point of Sale.

B. Section 18972.1(a)(11): The definition of “Provides or Initiates Distribution of a Sharps Waste Container” should provide for sharps waste container and mail-back materials to arrive within five business days.

MED-Project appreciates the Department recognizing that arranging at the Point of Sale for a sharps waste container or mail-back materials to arrive within three business days is impracticable. *See* Revised Proposed Regulations § 18972.1(a)(11) (requiring such materials to arrive within four business days). However, MED-Project continues to propose that the Department define “Provides or Initiates Distribution of a Sharps Waste Container” as providing for these materials to arrive within five business days. *See id.* As explained in MED-Project’s February 17, 2020 comments, Program Operators cannot guarantee common carrier delivery dates. In light of this reality, the Department should revise the Revised Proposed Regulations to require that Program Operators ship sharps waste containers and mail-back materials to arrive within five business days. This revision requires Program Operators to provide sharps waste containers and mail-back materials promptly, but decouples common carrier reliability from Program Operator compliance. Accordingly, Revised Proposed Regulations § 18972.1(a)(11) should require Program Operators: “[t]o arrange, at the point of sale or prior, for a sharps waste container and mail-back materials to be sent to the ultimate user and shipped to arrive within ~~three~~five business days at no cost or inconvenience to the ultimate user”

028-008

C. Section 18972.1(a)(13): The definition of “Significant Change” should not include “service providers,” ambiguous language, or subjective standards.

Program Operators need the flexibility to adapt their Stewardship Programs as markets for “Covered Drug” (as defined in PRC § 42030(e)) and “Home-Generated Sharps Waste” (as defined in PRC § 42030(l)) take-back services mature, legal requirements evolve, and Program Operators and the Department become more experienced in best serving Ultimate Users. At the same time, the Department’s change management processes must ensure that it has notice of proposed changes that affect Stewardship Program compliance with SB 212. While the Jan. 2020 Proposal carefully balanced the needs for flexibility and oversight, the Revised Proposed Regulations upset this balance and introduce ambiguity by defining “Significant Change” to include:

[A] change that is not consistent with an approved stewardship plan that the department determines has a material impact on the operation of a stewardship program, including, but not limited to: . . . Any changes of the service providers or facility(ies) used to transport, handle, or dispose of covered drugs or home-generated sharps waste collected through the stewardship program.

028-009

Revised Proposed Regulations § 18972.1(a)(13). To promote effective Stewardship Program operations and Department oversight, the Department should return to the Jan. 2020 Proposal’s definition of Significant Change. *See* Jan. 2020 Proposal § 18972.1(k).

Requiring prior Department approval for changes to service providers will be burdensome and, in some cases, infeasible for the Program Operator and Department. Stewardship Program transporters change with some frequency given the many transportation networks these programs involve (e.g., transport from a reverse distributor’s location to Disposal Facility X, Disposal Facility Y, etc.). Program Operators seeking, and the Department reviewing and approving, each of these changes will frustrate efforts to provide the most effective services. In addition to constraining Program Operator flexibility to provide the best collection services possible, this paperwork exercise will distract from more critical Program Operator and Department functions, especially given that the Department does not have jurisdiction over how Stewardship Programs transport or dispose of waste out of state. *See Daniels Sharpsmart, Inc. v. Smith*, 889 F.3d 608 (9th Cir. 2018) (upholding an injunction prohibiting California from applying the California Medical Waste Management Act to disposal activities occurring wholly outside California because California’s action likely violated the “dormant commerce clause” of the United States Constitution).

The Revised Proposed Regulations also introduce ambiguity into the definition of Significant Change by referring to “a change that is not consistent with an approved stewardship plan that the department determines has a material impact on the operation of a stewardship program” Revised Proposed Regulations § 18972.1(a)(13). What is “a change that is not consistent with an approved stewardship plan?” It appears to mean that some changes to a Stewardship Plan do not require Department approval because, even if they have a material impact on Stewardship Program operations or are enumerated in Revised Proposed Regulations § 18972.1(a)(13)(A)-(F), they are consistent with that Stewardship Plan. How Program Operators will determine which changes are consistent with their Stewardship Plans and which are not is unclear. The Jan. 2020 Proposal avoided these ambiguities. 028-010

Additionally, defining Significant Change as those the “department determines” have a material impact on Stewardship Program operations makes the definition subjective and unworkable. Under some interpretations of this requirement, the Department would have almost unfettered discretion to determine what changes are significant. That puts Program Operators in the difficult position of predicting how the Department will react to a specific change. The definition also creates a timing issue. A Program Operator must seek approval for a change “not consistent with an approved stewardship plan that the department determines has a material impact” on Stewardship Plan operations, but does not know whether a change is material until the Department determines it is – creating a “chicken or the egg” problem regarding whether Department approval is required. *See* Revised Proposed Regulations § 18972.1(a)(13). To address these issues and provide Program Operators meaningful notice of what constitutes a Significant Change, the Department should provide an objective definition for Significant Change by returning to the Jan. 2020 Proposal’s definition of that term. 028-011

II. STEWARDSHIP PLANS

A. Section 18973.2(d)(5): The Revised Proposed Regulations should require Program Operators to inform potential Authorized Collectors rejected from Stewardship Program participation why they were rejected and how they can again offer to participate, rather than provide for appeals.

Because the Revised Proposed Regulations would require Stewardship Plans to describe the reasons they exclude any potential “Authorized Collectors” (as defined in PRC § 42030(b)) from the Stewardship Program, and annual reports must identify rejected potential Authorized Collectors and the reasons for each rejection, Program Operators will only reject potential Authorized Collectors for reasons approved by the Department. *See* Revised Proposed Regulations §§ 18973.2(d)(4), 18973.4(c)(2)(E). Such reasons could include suspension of a pharmacy license, unwillingness to place a collection receptacle in compliance with United States Drug Enforcement Administration requirements, etc. Program Operators are not governmental entities with independent oversight bodies to which potential Authorized Collectors can appeal a rejection of their offer to participate in a Stewardship Program. Once a Program Operator has rejected a potential Authorized Collector for a Department-approved reason, an appeal by that potential Authorized Collector will not change the Program Operator’s decision, and SB 212 never contemplates such appeals.

028-012

Instead of requiring Stewardship Plans to describe how potential Authorized Collectors can appeal to a Program Operator that has already decided to reject them, the Proposed Regulations should require Program Operators to inform potential Authorized Collectors why they were rejected from Stewardship Program participation and how they can again offer to participate. This revised requirement would allow the potential Authorized Collectors to address the reasons they were rejected and give them a path towards Stewardship Program participation, rather than a fruitless appeal. For these reasons the Revised Proposed Regulations should be amended to read: “Description of how the program operator will notify any the process potential authorized collectors of the reasons they were rejected from can utilize to appeal a rejection, by the program operator, for inclusion in the stewardship program and how they can offer to participate in the future.”

B. Sections 18973.2(e)(2), 18973.3(d)(2): The Department should clarify the requirement for Covered Drug and Home-Generated Sharps Waste Stewardship Plan certifications.

The Revised Proposed Regulations introduce a brand new requirement for Stewardship Plans to provide:

Written certification, by an authorized representative of the program operator, that: the *stewardship plan*, including the collection, transportation, and disposal of covered drugs, *is in compliance with* all applicable local, state, and federal laws and regulations,

including, but not limited to United States Drug Enforcement Administration regulations.

Revised Proposed Regulations §§ 18973.2(e)(2) (emphasis added), 18973.3(d)(2) (analogous requirement for home-generated sharps waste). Certification requirements like these must be crystal clear so that Program Operators know what they are certifying and for what they may be held responsible. The Department should revise these certification requirements to remove ambiguity regarding their applicability and scope.

Currently, these certification requirements do not specify whether they apply as of the date the certification is made or, alternatively, act as a continuing certification for some undefined period. The Department should clarify that these certifications apply only as of the date the Program Operator submits the Stewardship Plan for Department approval. While MED-Project puts in place many mechanisms to operate and maintain compliant Stewardship Programs, it cannot certify as to those programs' future compliance status. The Department should amend the Revised Proposed Regulations to avoid any suggestion that the certifications are made on a continuing basis.

028-013

Furthermore, the Department should clarify the scope of these certifications. As drafted, the Revised Proposed Regulations are unclear regarding whether these certifications cover the Stewardship Plan itself or also the many participating Authorized Collectors, service providers, disposal facilities, etc. Because the certifications refer to the "stewardship plan" being "in compliance with all applicable local, state, and federal laws and regulations," it appears that these certifications apply only to the Stewardship Plan itself; *i.e.*, implementing the Stewardship Plan's text would provide for a Stewardship Program compliant with all applicable laws, regulations, and other legal requirements.

028-014

An interpretation of the Revised Proposed Regulations that the Program Operator is making a certification with regard to the compliance status of each participating Authorized Collector, service provider, disposal facility, etc. would require Program Operators to make certifications for parties and actions beyond Program Operators' knowledge and control. Program Operators can require by contract that all participating Authorized Collectors, service providers, disposal facilities, etc. comply with all applicable laws, regulations, and other legal requirements, but they cannot control these independent entities' compliance statuses, do not have real time knowledge thereof, and cannot make certifications on their behalves. Additionally, as a Stewardship Program includes hundreds of participating entities, requiring Program Operators to certify as to each participating Authorized Collectors', service providers', and disposal facilities' compliance status would be a tremendous undertaking requiring months of work, something never contemplated in SB 212. *See* PRC §§ 42032, 42032.2.

For the reasons described above, the Department should clarify the applicability and scope of Revised Proposed Regulations §§ 18973.2(e)(2) and 18973.3(d)(2), respectively, through the following revisions:

028-015a

028-015b

Section 18973.2(e)(2): Written certification, by an authorized representative of the program operator and made as of the date of Stewardship Plan submission pursuant to PRC § 42032(a)(1), that: ~~the stewardship plan, including the collection, transportation, and disposal of covered drugs, is in~~ compliance with all applicable local, state, and federal laws and regulations, including, but not limited to United States Drug Enforcement Administration regulations.

Section 18973.3(d)(2): Written certification, by an authorized representative of the program operator and made as of the date of Stewardship Plan submission pursuant to PRC § 42032(a)(1), that: ~~the stewardship plan, including the handling, transportation, and disposal of home-generated sharps waste, is in~~ compliance with all applicable local, state, and federal laws and regulations.

C. Sections 18973.2(j)(2), 18973.3(i)(2): The Revised Proposed Regulations should promote education and outreach to Ultimate Users without creating confusion regarding hospital waste streams.

Hospitals have independent obligations to manage medical waste under the California Medical Waste Management Act. *See* Cal. Health & Safety Code § 117600 *et seq.* Consistent with these independent obligations, SB 212’s definition of “Ultimate User” clearly excludes hospitals. *See* PRC § 42030(z) (“‘Ultimate User’ does not include . . . a medical waste generator, as defined in Section 117705 of the Health and Safety Code.”); Cal. Health & Safety Code 117705 (defining “medical waste generator” to include “hospitals”). Despite this exclusion, however, SB 212 requires Program Operators to “[p]romote [their] stewardship program[s] to ultimate users by providing signage for hospitals . . . as necessary.” *See* PRC § 42031.6(a)(1). The Revised Proposed Regulations also require Stewardship Programs to describe how they will include “signage for hospitals . . . as necessary.” Revised Proposed Regulations §§ 18973.2(j)(2), 18973.3(i)(2).

028-016a

028-016b

The Department should strike the reference to “hospitals” in Revised Proposed Regulations §§ 18973.2(j)(2) and 18973.3(i)(2). Providing Stewardship Program education and outreach in hospitals could confuse Ultimate Users being treated at the hospital, potentially causing them to mistakenly deposit medical waste in a Stewardship Program collection receptacle. Such departures from hospital procedures for managing medical waste could raise compliance and safety concerns. By excluding hospitals from the definition of Ultimate User, SB 212 helped keep Stewardship Program and hospital waste streams separate, consistent with existing California law. While the Department cannot change SB 212 requirements, it should not add requirements in the Revised Proposed Regulations that cause confusion regarding proper medical waste management in hospitals. Stewardship Program outreach should target Ultimate

Users, but not in a hospital setting where there are existing procedures for managing medical waste.

D. Sections 18973.2(j)(3), 18973.3(j)(3): Clarification is needed regarding website accessibility language added by the Department.

In the education and outreach provisions of the Revised Proposed Regulations at Sections 18973.2(j)(3) and 18973.3(j)(3), the Department has added language stating that the internet website established as part of a Stewardship Plan must have “digital content and navigability” that is “accessible to disabled individuals.” The terms “accessible” and “disabled individuals” do not have universally accepted meanings. Therefore, clarification is needed regarding the Department’s intent in this regard; e.g., adding a cross-reference to the accessibility standards that all Stewardship Plan websites should adhere to. 028-017a
028-017b

E. Sections 18973.2(k), 18973.3(j): Program Operators must comply with applicable federal and state antitrust requirements.

MED-Project supports the Revised Proposed Regulations removing language regarding Program Operators working with other Stewardship Programs to “most effectively” achieve statutory and regulatory goals, as that language could raise federal and state antitrust and related concerns among Program Operators, which are industry competitors as it relates to Covered Entity participation. *See* Jan. 2020 Proposal §§ 18973.2(k), 18973.3(j). However, the Department should revise these sections to remove language requiring Stewardship Plans to describe how the Program Operator will coordinate with other Program Operators “to avoid conflict, duplication” Revised Proposed Regulations §§ 18973.2(k), 18973.3(j). Such coordination to avoid “conflict” or “duplication” could raise federal and state antitrust and related concerns among Program Operators, which are industry competitors. Program Operators can coordinate to avoid confusion to the public and all program participants, but, as competitors, Program Operators will necessarily have conflict as they compete to provide the most effective collection and disposal services. For example, Program Operators will compete for certain participating Covered Entities and potential Authorized Collectors, and with regard to “Local Agency” (as defined in Revised Proposed Regulations § 18972.1(a)(7)) requests. *See* Revised Proposed Regulations § 18973.3(g). They will almost certainly provide duplicative services as each Program Operator works to independently satisfy statutory and regulatory Stewardship Program requirements. Because of the antitrust and related concerns associated with asking Program Operators to avoid “conflict” or “duplication,” the Department should remove references to these terms from the Revised Proposed Regulations. The new language in Revised Proposed Regulations §§ 18973.2(k) and 18973.3(j) should read: 028-018a
028-018b

Coordination Efforts. Description of how the program operator will coordinate with other program operators to avoid ~~conflict, duplication, and~~ confusion to the public and all program participants in the event that multiple stewardship programs for [covered drugs

or home-generated sharps waste] are in operation concurrently or new stewardship programs begin operating.

F. Section 18973.3(g)(2): CalRecycle should require local agencies to distribute requests equally among Program Operators and such requests should comply with SB 212 requirements.

Revised Proposed Regulations § 18973.3(g) establishes a process for Local Agency requests for removal of certain Home-Generated Sharps Waste that seems to contemplate only a single Program Operator. Because each Program Operator has an independent obligation to resolve these Local Agency requests, the Revised Proposed Regulations should establish a system requiring Local Agencies to distribute these requests equally among Program Operators. *See* PRC § 42032.2(d)(1)(F)(ii); Revised Proposed Regulations § 18973.3(g). If not equally distributed, these Local Agency requests could create competitive imbalances among Program Operators as they compete for Covered Entities. Additionally, without equally distributed requests, Program Operators could be incentivized to drive Local Agency requests to other Program Operators through barriers to submitting requests. To avoid these competitive imbalances, inefficiencies, and the associated decline in service for Local Agencies (and, thus, Ultimate Users), the Department should require Local Agencies to request from each approved Program Operator the reimbursement or removal of an equal amount of Home-Generated Sharps Waste, measured as reported in Revised Proposed Regulations § 18973.5(p)(2)(C), to the extent practicable. [Note that an internal cross reference in Section 18973.5(p)(2)(C) should be revised to refer to Section 18973.3(f)(8), rather than (f)(9)].

028-019

The Local Agencies are best situated to equally allocate these requests, rather than requiring the Department to referee among Program Operators or, alternatively, raising federal and state antitrust or related risks through Program Operator coordination in distributing these requests amongst themselves. To assist these Local Agencies, the “to the extent practicable” qualification recognizes that there may be subtle variations in the amount of qualifying home-generated sharps waste Program Operators remove from Local Agencies over the course of a year, as each load removed is unlikely to have an identical weight.

028-020

Additionally, the Revised Proposed Regulations should account for SB 212’s express limits on the scope of Local Agency requests. *See* PRC § 42032.2(d)(1)(F)(ii) (generally prohibiting Local Agencies from requesting reimbursement for disposal expenses relating to a municipal needle exchange program or medical waste generator, and limiting reimbursable costs to actual transportation and disposal costs). Consistent with SB 212, the Revised Proposed Regulations should also require that Local Agencies submit requests for reimbursement “with a declaration under penalty of perjury that the local agency has not knowingly requested reimbursement for expenses prohibited by this section.” *See id.* Although the Revised Proposed Regulations restate many other SB 212 requirements, they omit these Local Agency request requirements. As CalRecycle envisioned the Proposed Regulations as a “one-stop-shop” for SB 212 requirements, the Revised Proposed Regulations should reflect these SB 212 requirements.

028-021

As revised to address multiple Program Operators and SB 212 requirements for Local Agency requests, Revised Proposed Regulations § 18973.3(g)(2) should read:

Requests by local agencies, or an agent on behalf of a local agency, shall include an invoice and shall be submitted to the program operator, as necessary. Such requests shall comply with the requirements in PRC § 42032.2(d)(1)(F)(ii). Local agencies shall request from each approved program operator the reimbursement or removal of an equal amount of home-generated sharps waste, as reported in section 18973.5(p)(2)(C), to the extent practicable. Program Operators shall respond to requests by local agencies within 14 days of receipt of the request and identify the method to resolve the request by selecting either reimbursement or removal from household hazardous waste facility(ies).

028-022

G. Section 18973.3(g)(2)(B): The “and” added in the Revised Proposed Regulations is inconsistent with state law and should be deleted.

Section 18973.3(g)(2)(B) of the Revised Proposed Regulations was revised by the Department so that it now reads that a Program Operator that provides for the removal of home-generated sharps waste from a local household hazardous waste facility shall do so “as often as required according to section 117904 of the Health and Safety Code and/or by the local enforcement authority. Section 117904(d)(2) of the Health and Safety Code provides that sharps containers “shall not be held for more than seven days without the written approval of the enforcement agency.” Thus, Section 18973.3(g)(2)(B) was consistent with state law as originally draft; i.e., either the seven-day timeline set in Section 117904 controls *or* another timeline controls if authorized by the local enforcement agency. Thus, the “and” added by the Department in the Revised Proposed Regulations should be deleted.

028-023

H. New Section in 18973.3: Stewardship Plans should identify the online marketplaces at which the Program Operator will Provide or Initiate Distribution of a Sharps Waste Container at the Point of Sale.

As described in Section I.A of these comments, and consistent with MED-Project’s proposed definition of Point of Sale, the Department should require Stewardship Plans to identify the online marketplaces through which they are making a good faith effort to Provide or Initiate Distribution of a Sharps Waste Container at the Point of Sale. Requiring Stewardship Plans to identify these online marketplaces for the Department’s review and approval will allow the Department to confirm a Stewardship Plan is serving Ultimate Users purchasing sharps through an online marketplace to the extent the Proposed Regulations require and, given that Program Operators cannot compel online marketplace participation in efforts under SB 212, to the extent practicable. Identifying these online marketplaces in a Stewardship Plan will also give Program

028-024

Operators the certainty that, upon the Department’s approval of the Stewardship Plan, they are working with the online marketplaces necessary to satisfy the Revised Proposed Regulations’ requirements. This new section should require Home-Generated Sharps Waste Stewardship Plans to:

Provide a list of the online marketplaces for which the program operator will make a good faith effort to provide or initiate the distribution of a sharps waste container at the point of sale.

III. ANNUAL REPORTING AND BUDGETS

A. **Section 18973.4(c)(4): The granular level of detail that is still sought in the annual reports for each collection site is unreasonable and impracticable.**

MED-Project appreciates the minor changes that the Department made to the collection site-specific information that is required to be included in the annual reports for Covered Drugs at Revised Proposed Regulations § 18973.4(c)(4). However, MED-Project is still concerned with the granular level of detail that is being sought in the Revised Proposed Regulations. Section 18973.4(c)(4)(E) of the Revised Proposed Regulations currently states that the annual reports must include the following information *by collection site*:

Number of instances and corresponding amount of time the secure collection receptacle was not available to the public during business hours. For each instance, provide a description of why the secure collection receptacle was not available.

028-025

As explained in our February 17, 2020 Comment Letter, SB 212 limits the Department’s authority with respect to annual reports by stating that it may only require additional information, above and beyond what is required by the statute, if the information is “reasonably require[d].” PRC § 42033.2(b)(9). SB 212 does not require that annual reports contain this type of granular information regarding availability statistics kiosk-by-kiosk and, therefore, this provision of the Revised Proposed Regulations is subject to the reasonableness requirement in PRC § 42033.2(b)(9).

The additional information that is being sought by the Department here - the total number of instances *and* amount of time over the course of a 365-day reporting period that each and every kiosk across the state of California is “not available to the public during business hours” for any reason - is not only unreasonable, but also impracticable. There are approximately 2,100 business hours in a year, and there will likely be over 1,000 kiosks throughout the state of California under a MED-Project Stewardship Plan. Obtaining complete and accurate information on the total number of instances and total amount of time that a kiosk at each collection site in the state of California was closed or otherwise inaccessible to the public during business hours for any given reason (renovations, employee errors, etc.) is impossible as a practical matter.

028-026

Further, despite the justifiable concerns previously raised by MED-Project regarding the reasonableness and practicability of the granular level of detail required in Section 18973.4(c)(4)(E), the Department’s Revised Proposed Regulations add on *more requirements* to an already unreasonable and unworkable provision. Section 18973.4(c)(4)(E) now also requires that a Program Operator describes “*why*” each instance occurred at each kiosk throughout the state of California during the 365-day reporting year. The Department’s expectation on reporting here is patently unreasonable.

028-027

In order to make this reporting requirement workable from an operational perspective, MED-Project recommends that the reporting obligation in Section 18973.4(c)(4)(E) be limited to only include instances that the Program Operator is aware of, either because they were reported to the Program Operator by the collection site or because they were observed during a site inspection.

For the above described reasons, Section 18973.4(c)(4)(E) of the Revised Proposed Regulation should be revised to read:

(E) Number of instances and corresponding amount of time the secure collection receptacle was not available to the public during business hours: ~~For each instance, provide, including a description if provided, as reported to the Program Operator by a collection site and/or identified during a site inspection. of why the secure collection receptacle was not available.~~

028-028

B. Sections 18973.4(p), 18973.5(r): The new written certifications required by Program Operators in annual reports are either redundant or unreasonable and should be stricken.

The Department’s Revised Proposed Regulations include a brand new “written certification” requirement applicable to Program Operators in annual reports for both Covered Drugs and Home-Generated Sharps Waste. The new provisions in the Revised Proposed Regulations state that annual reports must include:

Written certification, by an authorized representative of the program operator, that: *the stewardship plan*, including the collection, transportation, and disposal of covered drugs [or home-generated sharps waste, respectively], *is in compliance with* all applicable local, state, and federal laws and regulations, including, but not limited to United States Drug Enforcement Administration regulations.

028-029a

028-029b

Revised Proposed Regulations §§ 18973.4(p) & 18973.5(r) (emphasis added).

The intent of the above-quoted text is unintelligible on its face in the context of an annual report. Is the Department’s intent to require that a Program Operator certifies that the Stewardship

Plan, *as written*, complies with all applicable laws, regulations, and other legal requirements? If so, the Program Operator would have already made that certification in the Stewardship Plan approval process and re-requiring that certification is redundant. *See* Revised Proposed Regulations §§ 18973.2(e)(2), 18973.3(d)(2). Alternatively, is the Department’s intent that the annual report include a certification that all *activities* occurring in the Stewardship Program during the reporting period comply with all applicable laws, regulations, and other legal requirements? If the Department’s intent is the latter, then MED-Project has serious concerns with the new provision, as MED-Project does not and will not have knowledge of all third-party activities (including those taken by Authorized Collectors, vendors and disposal facilities) that are taken throughout the reporting year and, therefore, such a certification is impossible. Even if it was possible, for the reasons described in Section II.B of these comments, preparing such certifications would take months given the hundreds of participating entities, an effort SB 212 never contemplates.

It is MED-Project’s position that the new written certification requirements imposed on Program Operators at Revised Proposed Regulations §§ 18973.4(p) and 18973.5(r) are either redundant of the certifications provided under Sections 18973.2(e)(2) and 18973.3(d)(2) and unnecessary given all the other disclosures that are required in plan and annual reporting submissions, or they are unreasonable, and thus, contrary to the legislative limitations imposed on the Department at PRC § 42033.2(b)(9). Thus, Sections 18973.4(p) and 18973.5(r) should be stricken in full. If the Department does not strike Sections 18973.4(p) and 18973.5(r), it should clarify them consistent with the comments in Section II.B.

C. Section 18973.4(q): The novel proposal of requiring Program Operators to collect and include third party certifications in annual reports is unreasonable and unworkable in practice.

As with the new written certification requirements applicable to Program Operators in Sections 18973.4(p) and 18973.5(r) of the Revised Proposed Regulations, the new third party certification requirement for annual reports added by the Department at Section 18973.4(q) is unreasonable and impossible to implement or enforce in practice.

MED-Project is not aware of any federal, state or local requirement that is similar in scope or nature. The reason is evident: it is impossible to expect or require that a regulated entity obtain and submit written certifications from dozens of third-party vendors attesting to their compliance with *all laws and regulations* over the course of a year, and on an annual basis, for submission to a regulatory authority.

028-030a

028-030b

MED-Project does not anticipate that it would be able to obtain such certifications from all vendors on an annual basis. For instance, what if a third-party vendor was technically out of compliance with a paperwork requirement and, therefore, could not in good faith prepare such a certification? Alternatively, what if a third-party vendor’s legal counsel advises the company should not furnish such a certification for liability purposes? What is the consequence of this? Would the Department seek to penalize MED-Project for the failure of a third party to prepare and

provide a submission that the company itself has no legal obligation to furnish? This novel concept is wholly unworkable and unreasonable in concept and application. Accordingly, Section 18973.4(q) should be struck in its entirety.

D. Section 18973.6: SB 212 does not confer the Department with the authority to require the inclusion of actual expenses in annual Stewardship Program budget submissions.

MED-Project appreciates the revisions that have been made by the Department to date on the Stewardship Program budget provisions of the Revised Proposed Regulations including, namely, consolidating the nine (9) separate subcategories of anticipated costs at section 18973.6(b) into five. However, MED-Project still feels that the scope of information sought by the Department in the annual budget submissions is inconsistent with the plain language of SB212, and thus, is in excess of the Department’s authority.

As stated in MED-Project’s February 17, 2020 comment letter, although the legislature expressly authorized the Department to request additional information above and beyond that which is required in the statute, subject to the limitation that the additional information is “reasonably require[d]”, no such authorization was granted to the Department in SB212 for annual budget submissions. *Compare* PRC § 42033.2(b)(9), *with* § 42033.2(c). As a matter of law, this distinction has meaning, and that meaning can only be read to mean that the legislature *did not* intend to allow the Department to promulgate regulations which would require additional information in program budgets above and beyond that which is enumerated by statute. *See Azusa Land Partners v. Dep’t of Indus. Relations*, 191 Cal. App. 4th 1, 20 (2010) (“[W]hen the Legislature has carefully employed a term in one place and has excluded it in another, it should not be implied where excluded”); *California Soc’y of Anesthesiologists v. Brown*, 204 Cal. App. 4th 390, 404 (2012) (“While every word of a statute must be presumed to have been used for a purpose, it is also the case that every word excluded from a statute must be presumed to have been excluded for a purpose”). And, as noted in MED-Project’s February 17th comments, this construction is consistent with SB212’s legislative history and the distinction in this regard from other stewardship programs administered by the Department is warranted because the Pharmaceutical and Sharps Waste Stewardship Program is not publicly funded.

028-031

Based on the foregoing, MED-Project continues to believe that Section 18973.6 of the Revised Proposed Regulations should be revised to require no more than is required by SB212, and as described in PRC § 42033.2(c). However, at a minimum, the requirement to include not only anticipated costs, but also actual expenses at Section 18973.6(f), should be stricken in its entirety.

~~(f) Beginning with the first annual program budget, include all actual expenses incurred during the previous program year. Expenses shall be summarized in accordance with the budget categories specified in section 18973.6(b).~~

IV. THE DEPARTMENT’S WHOLESALE REVISIONS TO THE ADMINISTRATIVE PROCEDURES CONTAINED IN SECTIONS 18975.1 AND 18975.2 ARE INTERNALLY INCONSISTENT, BEYOND THE STATUTORY AUTHORITY CONFERRED BY SB 212 AND OTHERWISE LEGALLY DEFECTIVE.

The Revised Proposed Regulations propose completely new language in Sections 18975 (Criteria to Impose an Administrative Civil Penalty), Section 18975.1 (Procedure for Imposing An Administrative Penalties) and Section 18975.2 (Procedure for Stewardship Plan Revocation, Resubmittal, or Additional Compliance Reporting). The rationale for why these wholesale revisions are being proposed now, at this juncture of the rulemaking process is not discernable from the materials currently available in the rulemaking file, and no explanation has been offered by the Department (in its July 14, 2020 Notice of Changes to Proposed Regulations or elsewhere). MED-Project has serious concerns with the new language being proposed by the Department and, for the reasons explained below, believes that the revised provisions are arbitrary, capricious, inconsistent with SB212, beyond the Department’s authority and otherwise unlawful, as they fail to satisfy minimum due process protections that attach to the proposed actions that may be taken under the subject provisions.

028-032

A. Sections 18975.1(a), 18975.2(b): The new proposed language in Sections 18975.1(a) and 18975.2(b) is internally inconsistent and contrary to SB212.

Section 18975.1 of the Revised Proposed Regulations is titled “Procedures for Imposing *Administrative Civil Penalties*”; however, the first sentence of Section 18975.1(a) now states that the “department shall issue a notice of violation (NOV) to the respondent if the department determines that the respondent has violated a *material requirement* of this Article or Chapter 2 of Part 3 of Division 30 of the Public Resources Code.” (emphasis added). It is unclear what the intended scope and meaning of this new proposed language is, given that it is internally inconsistent with Department’s own Revised Proposed Regulations, and is also in direct conflict with the authorizing legislation at PRC §§ 42035.2 and 42035.4.

028-033

First, SB212 is clear in that the Department is only authorized to “impose an administrative civil penalty on a[] covered entity, program operator, stewardship organization, or authorized collector that sells, offers for sale, or provides a covered product in violation of this chapter.” PRC § 2035.2(a)(1). In other words, the operative act that triggers the Department’s authority to assess a monetary penalty is the sale, offering or distribution of a *covered product*. If the alleged conduct *does not* involve the sale, offering or distribution of a covered product, but pertains to the alleged violation of a “*material requirement*” of the statute, then SB 212 unequivocally limits the Department’s authority to taking the following types of punitive action:

028-034

- (a) Revoke the program operator’s stewardship plan approval or require the program operator to resubmit the plan.
- (b) Require additional reporting relating to compliance with the material requirement of this chapter that was not met.

PRC § 42035.4(a)-(b).

Indeed, the limited scope of the Department’s authority in this regard was acknowledged in the written comments submitted on this rulemaking by the California Product Stewardship Council, the National Stewardship Action Council, Zero Waste Sonoma and the County of Santa Clara. *See*, Comments in Response to CalRecycle’s SB 212 45-Day Formal Rulemaking Comment Period, Letter 5: 2-14-2020 Nat’l Stewardship Action Council, CalPSC, County of Santa Clara, & Zero Waste Sonoma at page 12 (“The application of civil penalties is relatively limited by the statute and applies only to the sale of a covered product in violation of the chapter. This seems to limit the department’s recourse in addressing material programmatic deficiencies to revocation of the plan.”). Notwithstanding the limitations which are clearly imposed and commonly understood to apply to the Department, for unknown reasons the Revised Proposed Regulations now discuss issuing notices for alleged violations of a material requirement of the statute in the Section titled “Procedures for Imposing Administrative Civil Penalties”.

Second, Section 18975.1(a) is also internally inconsistent with the Revised Proposed Regulations, and these inconsistencies and ambiguities lead to an overall lack of clarity regarding the process and procedures that are intended to apply to the various types of proposed actions that may be taken by the Department. Under Section 18975.1(a), a “NOV” can be issued for an alleged violation of a “material requirement” of SB212. However, Section 18975.2(a) and (b) states that a “written notice” shall be issued if the Department determines that a Program Operator “had failed to meet a material requirement” of SB212. It is unclear which process is intended to actually apply to an allegation by the Department that a Program Operator has violated a “material requirement” of SB212: does Section 18975.1 or Section 18975.2 apply?

028-035

It is unclear why the language in the first sentence of section 18975.1(a) of the Revised Proposed Regulations was intentionally added. Nevertheless, the enforcement provisions and procedures that are now laid out in Sections 18975.1 and 18975.2 are internally inconsistent and indiscernible. Further, as currently written, Section 18975.1 can now be read as authorizing the Department to impose an administrative civil penalty on a Program Operator that violates a material requirement of SB212. This is categorically beyond the authority conferred by the legislature and therefore invalid on its face. As such,¹ Section 18975.1(a) should be deleted in its entirety, as follows:

028-036

~~(a) The department shall issue a notice of violation (NOV) to the respondent if the department determines that the respondent has violated a material requirement of this Article or Chapter 2 of Part~~

¹ It is also noteworthy, but less relevant, to point out that the legislature did not authorize the Department to issue a “Notice of Violation” for any of the types of activities that are actionable under the statute, nor is it logical to include such a process – which is viewed as a type of informal enforcement action – in the same provision of the regulation that applies to a formal enforcement action taken by the Department to assess an administrative penalty.

~~3 of Division 30 of the Public Resources Code. The NOV shall list and describe the nature of the violation(s). The department shall issue a NOV before commencing an action to impose administrative civil penalties.~~

B. Section 18975.1(a): SB212 does not confer CalRecycle with enforcement authority for alleged violations of a “material requirement” of CalRecycle’s regulations.

The Revised Proposed Regulations at Section 18975.1(a) have also been modified such that now, a “notice of violation (NOV)” may now be issued “if the department determines that the respondent has violated a material requirement *of this Article or* Chapter 2 of Part 3 of Division 30 of the Public Resource Code.” (emphasis added). Similarly, the new language in Section 18975.2(a) provides that CalRecycle “shall” take certain enumerated punitive action “if the Department finds that a program operator has failed to meet a material requirement *of this Article or* Chapter 2 of Part 3 of Division 30 of the Public Resources Code.” (emphasis added).

The breadth of enforcement authority the Department has conferred upon itself in the above-quoted language is in direct conflict with the plain language of SB 212 and unambiguously beyond the scope of the powers conferred by the legislature. SB212 states:

Upon a written finding that a covered entity, program operator, stewardship organization, or authorized collector has not met a material requirement *of this chapter*, ..., the department may take one or both of the following actions to ensure compliance with the requirements *of this chapter*, after affording the covered entity, stewardship organization, or authorized collector a reasonable opportunity to respond to, or rebut, the finding:

028-037

(a) Revoke the program operator’s stewardship plan approval or require the program operator to resubmit the plan.

(b) Require additional reporting relating to compliance with the material requirement of this chapter that was not met.

As such, the legislature only authorized CalRecycle to take certain forms of punitive action if it finds that there was noncompliance with a material requirement *of the statute*. Had the legislature also intended to authorize CalRecycle to act on an alleged violation of the implementing regulations that the Department is required to promulgate, it would have said so. *See California Soc’y of Anesthesiologists v. Brown*, 204 Cal. App. 4th 390, 404 (2012) (“While every word of a statute must be presumed to have been used for a purpose, it is also the case that every word excluded from a statute must be presumed to have been excluded for a purpose”); *PaintCare v. Mortensen*, 233 Cal.App.4th 1292, 1306-07 (2015) (an administrative agency cannot be

“inconsistent with a statute ... or enlarge ... its scope”). Accordingly, Section 18975.2(a) of the Revised Proposed Regulations must be amended to read:

(a) if the department finds that a program operator has failed to meet a material requirement of ~~this Article or~~ Chapter 2 of Part 3 of Division 30 of the Public Resources Code.

Additionally, if, notwithstanding MED-Project’s above comment in section IV.A, CalRecycle retains the current language in Section 18975.1(a) discussing noncompliance with a “material requirement” in the context of administrative penalties (despite the clear inconsistency with the corresponding language in SB 212), Section 18975.1(a) must also be revised to read:

(a) if the department determines that the respondent has violated a material requirement of ~~this Article or~~ Chapter 2 of Part 3 of Division 30 of the Public Resources Code.

C. Section 18975.2: The newly proposed procedures must be revised to satisfy minimum due process requirements.

The Department’s Revised Proposed Regulations also propose an entirely new section on the procedures that would apply to a proposed action by CalRecycle to revoke a Program Operator’s approved Stewardship Plan, require a Program Operator to resubmit a Stewardship Plan, or require additional reporting associated with compliance with the material requirements of SB 212. The previous version of Section 18975.2 proposed by the Department incorporated the established procedures governing adjudicative hearings under the California Administrative Procedures Act (“APA”), and this was consistent with analogous provisions adopted by CalRecycle for the other stewardship programs that it administers, see 14 C.C.R. §§ 18945.3, 18955.3 & 18971; however, for unknown reasons the Revised Proposed Regulations no longer adopt, cross-reference or otherwise conform with the APA. MED-Project believes that the new language proposed in Section 18975.2 is arbitrary, capricious and fails to comport with the minimum due process protections that attach to a proposed action that could result in the revocation of a formal government approval granting a business the right to operate in the state.

028-038

The procedures now proposed in Section 18975.2(b)-(e) are extremely scant and fail to address all aspects of an adjudicatory proceeding. Moreover, the procedures that the Department is now proposing do not comport with the minimum due process protections that are conferred upon respondents that are subject to such types of proposed agency action pursuant to California’s Administrative Adjudicative Bill of Rights, Cal. Gov’t Code §§ 11425.10 – 11425.60, or the basic process laid out in SB 212 at PRC § 42035.4. As such, the Section 18975.2(b)-(e) of the Revised Proposed Regulation should be revised as follows:

(b) Upon making the finding in subdivision (a), the department shall issue a written notice to the program operator of the department’s intent to revoke an approved stewardship plan, require resubmittal of an approved stewardship plan, require additional compliance reporting, or all three. The notice shall state the legal and factual

028-039

basis for the proposed action, including a summary of all findings made by the Department to support the proposed action, and inform the respondent of their right to a hearing.

...

(d) A program operator may submit to the department a written request for a hearing to contest the proposed action within thirty (30) days of receipt of the notice issued pursuant to subdivision (b). ~~The hearing request shall be in writing and shall state the basis for objecting to the department's action. Upon a failure to submit a timely hearing request under this subdivision, the program operator shall be deemed to have waived its right to hearing and the department may revoke an approved stewardship plan, require resubmittal of an approved stewardship plan, require additional compliance reporting, or all three.~~

(e) ~~The hearing shall be held before the Director of the Department of Resources Recycling and Recovery. A party shall be afforded the opportunity to present evidence and testimony on all relevant issues. Any relevant evidence shall be admitted if it is the sort of evidence on which responsible persons are accustomed to rely in the conduct of serious affairs, regardless of the existence of any common law or statutory rule which might make improper the admission of the evidence over objection in civil actions.~~ If a hearing is requested pursuant to subdivision (d), the hearing shall be held in accordance with the provisions governing adjudicative proceedings in Government Code Title 2, Division 3, Part 1, Chapter 4.5 (Section 11400 et seq.).

(f) ~~The Director of the Department of Resources Recycling and Recovery shall issue a written decision within sixty (60) days from the date the hearing is concluded.~~

* * * * *

Thank you again, in advance, for your consideration of MED-Project's comments. Please feel free to contact us with any comments or questions, and we look forward to continuing to work with the Department on the development and implementation of the Revised Proposed Regulations going forward.

Sincerely yours,



Michael R. Van Winkle
Executive Director

From: [Simaga, Cara](#)
To: [PharmaSharps](#)
Subject: Comments to Pharma/Sharps Draft Regulations
Date: Monday, August 3, 2020 4:46:41 PM
Attachments: [image001.png](#)
[Stericycle comments on proposed reg text Cover Letter 8.3.20.pdf](#)
[Stericycle comments on proposed reg text 8.3.20.pdf](#)

[[EXTERNAL]]

Hello,

Attached you will find Stericycle's comments to the Pharmaceutical and Sharps Waste Stewardship Program Proposed Regulations, Second Draft. Thank you in advance for your consideration, please reach out to me if you have any questions.

Sincerely,

Cara Simaga, CHMM

Director, Regulatory Affairs

M: +1 312-720-6213 | stericycle.com

COVID-19 Knowledge Center <https://www.stericycle.com/coronavirus>

For assistance with regulatory questions, please email ask-regulatory@stericycle.com

For questions on the pharmaceutical waste rule, please email EPANewRules@stericycle.com



CONFIDENTIALITY NOTICE: The information in this Email is confidential and may be privileged. This Email is intended solely for the named recipient or recipients. If you are not the intended recipient, any use, disclosure, copying or distribution of this Email is prohibited. If you are not the intended recipient, please inform us by replying with the subject line marked "Wrong Address" and then deleting this Email and any attachments. Stericycle, Inc. uses regularly updated anti-virus software in an attempt to reduce the possibility of transmitting computer viruses. We do not guarantee, however, that any attachments to this Email are virus-free. Nota de confidencialidad: La información que presenta este correo es confidencial, y puede ser de uso privilegiado. Este correo intenta ser enviado solo al destinatario, o a los destinatarios. Si usted no es el destinatario, no podrá usar, desglosar, copiar, o distribuir la información de este correo ya que está prohibido. Si usted no es el correcto destinatario, por favor infórmenos reenviándonos el mismo con el asunto "Dirección Incorrecta", y luego borre el correo y los adjuntos. Stericycle, Inc. usa regularmente actualizaciones de software anti-virus para así reducir posibles virus. De todas maneras, no garantizamos que los adjuntos estén libres de virus.

Letter 29 - Stericycle

Proposed Reg Section	PDF Doc Page#	Current / Proposed Language	Stericycle Comment or Suggested Changes
GENERAL OBSERVATIONS DEFINITIONS			
18972.1 029-001	Not Included in Proposed Language	Definitions of "Covered Drug" and "Home-Generated Sharps Waste"	We recommend including the definitions from the statute for ease of reference and clarity.
18972.1 029-002	2	"Inert" means the covered drug or mixture of covered drugs is rendered chemically inactive prior to disposal and complies with all applicable local, state and federal laws and regulations, including those of the United State Drug Enforcement Administration and California statutes and regulations governing disposal in a municipal solid waste landfill.	"Inert" is not a term used to define or describe treatment of waste to meet applicable local, state, and federal laws and regulations, including those of the United States Drug Enforcement Administration (DEA). DEA uses the term "non-retrievable" which means: "for the purpose of destruction, the condition or state to which a controlled substance shall be rendered following a process that permanently alters that controlled substance's physical or chemical condition or state through irreversible means and thereby renders the controlled substance unavailable and unusable for all practical purposes. The process to achieve a non-retrievable condition or state may be unique to a substance's chemical or physical properties. A controlled substance is considered "non-retrievable" when it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue. The purpose of destruction is to render the controlled substance(s) to a non-retrievable state and thus prevent diversion of any such substance to illicit purposes." (Source: 21 CFR 1300.05(b)) The reference to DEA in this definition should be removed, or, the definition should be eliminated as it is only used in one other place in the regulations and we recommend later in these comments to remove that section as well.
18972.1 029-003	3	"Significant change" means a change that is not consistent with an approved stewardship plan that the department determines has a material impact on the operation of a stewardship program, including, but not limited to: ... (E) Any changes of the service providers or facility(ies) used to transport, handle, or dispose of covered drugs or home-generated sharps waste collected through the stewardship program...	Stericycle had agreed with the prior definition of "significant change", however the new verbiage in this draft, in conjunction with new language in 18973.1(i) on page 7 has changed our opinion, especially due to the new wording in (E) regarding changes of service providers or facilities that transport, handle, or dispose of covered drugs or home-generated sharps waste. We will comment further below in our comment to 18973.1(i).
DOCUMENT APPROVALS: STEWARDSHIP PLAN, INITIAL PROGRAM BUDGET, ANNUAL REPORT, AND ANNUAL BUDGET			
18973.1(i) 029-004	7	Any significant changes to an approved stewardship plan shall be submitted in accordance with the requirements of section 18973, and shall follow the review process outlined in subdivisions (a) through (h) above.	This new language, in conjunction with new wording to the definition of "significant change" found in 18972.1 needs to be reconsidered. According to that definition, and this new language, changes of service providers or facilities that transport, handle, or dispose of covered drugs or home-generated sharps waste would need to follow the extensive review process for a stewardship plan, initial program budget, annual report, or annual budget. Though we agree that some changes would certainly warrant following this process, changes to service providers or facilities that transport, handle, or dispose of covered drugs or home-generated sharps should not require such an extensive review process, especially if the change is simply to a facility that has already been identified in the plan or that meets the requirements described in the plan. The plan should require a list of the facilities that the operator has partnered with for transportation and disposal and the operator should be able to choose and switch between those facilities at any time without having to resubmit their plan. The regulations should be flexible enough to allow plan operators to adapt to unforeseeable changes that are consistent with the intent of the plan and have no material impact on transportation and disposal, such as a facility that changes hands but remains in compliance with all requirements. As currently written, operations could be significantly delayed while waiting for a months-long approval process, which could jeopardize consumers' access to convenient disposal. Perhaps the option of having several that are pre-approved and having that spelled out that this would not be a significant change would be helpful for this section and ease the burden we are concerned about.

Proposed Reg Section	PDF Doc Page#	Current / Proposed Language	Stericycle Comment or Suggested Changes
STEWARDSHIP PLAN FOR COVERED DRUGS			
18973.2(g)(1) 029-005	10	Collection, Transportation, and Disposal System. Descriptions of the following: (1) Processes and policies that will be used to safely and securely collect, track, and properly manage covered drugs from collection through final disposal.	It is imperative that hosts be able to safely continue to operate kiosks without security risks potentially caused by sharing specific security practices beyond those in direct need of the information. Likewise, it is imperative that service technicians, transporters, and all other persons involved in the program can safely perform their work without security risks potentially caused by sharing specific security practices beyond those in direct need of the information. Therefore, we strongly recommend that the plan include only broad descriptions of this information. In addition, this information should be marked confidential to prevent release to the general public with potentially nefarious intent. Full details of this type should <u>not</u> be publicly available.
18973.2(g)(6)(A) 029-006	11	Mail-back services or an alternative form of collection and disposal system, pursuant to section 42032.2(c) of the Public Resources Code, to be provided to ultimate users, including, but not limited to, the following: (A) Locations where preaddressed, prepaid mail-back materials are distributed or an alternative form of collection and disposal system, pursuant to section 42032.2(c)(2) of the Public Resources Code, that would render the drug inert, is provided, if applicable.	Disposal systems that render drugs inert, but do not require the material to be mailed back, would create an issue with the reporting structure. Use of these types of systems does not provide a way to identify what was used, how they were used, the amounts disposed, or the final disposition. There is also question as to the effectiveness of these products as discussed in our cover letter to these comments.
18973.2(g)(7) 029-007	11	If applicable, any alternative form of collection and disposal system that complies with applicable local, state, and federal laws and regulations including, but not limited to, United States Drug Enforcement Administration regulations, that is used as a supplemental service for any county that does not meet the minimum authorized collection site threshold due to circumstances out of the program operator's control.	We recommend clarifying this section to refer to pharmaceutical take back events. Section 18973.2(g) should specifically reference take back events for drugs, as 18973.3(f) does for sharps. If 18973.2(g)(7) is referring to events, it should be clarified.
18973.2(g)(9) 029-008	11	Description of a service schedule that meets the needs of each authorized collection site. Process by which collection receptacles will be monitored, explanation of how service schedules are determined to ensure that collection receptacles do not reach capacity, and procedures to be followed if capacity is reached. The service schedule must meet the needs of each authorized collection site to ensure that collected covered drugs are transported to final disposal in a timely manner.	The phrase "timely manner" needs to be removed or better defined as the phrase could be interpreted in many ways. The timeframe of the request should be defined, we would suggest the timeframe begins when the first call is made to notify of a full collection container. We would also like to remind that transportation to disposal of collected covered drugs ultimately falls on the common carrier (UPS/ FedEx) and shipping times can vary should that be what this section is referring to.
18973.2(g)(10) 029-009	12	What corrective actions will be taken if a program operator discovers critical deviations from stewardship plan policies and procedures.	"Critical deviations" needs to be defined or explained as this term is too subjective. We would suggest defining "critical deviation" as follows: any occurrence where diversion of consumer-generated medication is confirmed and/or where consumer-generated medication is not destroyed in compliance with DEA regulations.
18973.2(g)(12) 029-010	12	Standard operating procedures that will address incidents related to safety and security including processes to ensure that the department and applicable local, state, and federal agencies are notified of the incident. This description shall also explain the actions that will be taken to change policies, procedures, and tracking mechanisms to alleviate the problems with safety and security and improve safety and security.	This section of the proposed regulations existed prior, however, the new language on notifications to the department, and applicable local, state, and federal agencies leads to the need to clarify what is meant by "incidents related to safety and security". Because notification to the aforementioned agencies is now required, we would suggested a focus on reporting of incidents specifically related to diversion of covered drugs as they could potentially include controlled substances. Incidents that require the involvement of law enforcement, result in serious injury, or involve likely diversion. could also be included in this new notification requirement.

Proposed Reg Section	PDF Doc Page#	Current / Proposed Language	Stericycle Comment or Suggested Changes
STEWARDSHIP PLAN FOR HOME-GENERATED SHARPS WASTE			
General Comment for this section 029-011	NA	Mail back programs defined in this section have been left open (meaning doesn't stipulate the use of United States Postal Service -USPS). Stericycle agrees with leaving the options open. However, if a system chooses to use the USPS it is recommended that there is language in the regulation that is clear that it must meet all criteria for USPS.	As stated in previous comments, we recommend that the department add language that if the mail back system is developed to be used and shipped under the United States Postal Service (USPS) that all requirements under USPS for mail back of sharps and medical waste must be met. The sharps system being used through the USPS must meet minimum criteria as outlined in the domestic mail manual and must have approved authorization for the package for shipment through USPS. If an alternative shipping vendor/method is selected, the stewardship program operator should be required to provide documentation that their shipping vendor approves the program and packaging.
18973.3(f)(5)(A) 029-012	17	Supplemental collection method(s) for home-generated sharps waste that may be provided, in addition to, but not in lieu of, the mail-back program. These methods may include, but are not limited to: (A)Secure receptacle collection. If a program operator proposes to implement a receptacle-based program using authorized and approved home-generated sharps consolidation points then the following information, as applicable, shall be included, but not be limited to:...(i-iv not copied here for brevity)	We recommend describing/defining what is meant by "secure receptacle". Unlike collection receptacles used for collecting controlled substances, we are not aware of any design standards for sharps collection receptacles. The department should consider adding language to describe secure design features.
18973.3(f)(5)(A)(iv) 029-013	17	Standard operating procedures that will address incidents related to safety and security, including processes to ensure that the department and applicable local, state, and federal agencies are notified of the incident. This description shall also explain the actions that will be taken to change policies, procedures, and tracking mechanisms to alleviate the problems with safety and security and improve safety and security.	This section of the proposed regulations existed prior, however, the new language on notifications to "the department, and applicable local, state, and federal agencies" would require clarification on "incidents related to safety and security". We are not aware of safety or security incidents that have occurred involving sharps collection receptacles that would warrant such notification. Furthermore, if local, state, and federal agencies have such reporting requirements already (though we are not aware of any other than spill reporting requirements by the Department of Transportation (DOT)), referencing those requirements here is duplicative of their regulations. We suggest requiring notification to the department only as they are the entity providing oversight to the program.
18973.3(f)(9) 029-014	18	Corrective actions that will be taken if a program operator discovers critical deviations from stewardship plan policies and procedures.	"Critical deviations" needs to be defined or explained as this term is too subjective. We have suggested in other comments in this document that this term reflect diversion related issues for covered drugs. When the term is used to describe sharps stewardship plans or policies, we would suggest referring to issues related to DOT or USPS regulations for packaging and/or containers.
ANNUAL REPORT FOR COVERED DRUGS			
18973.4(e) 029-015	23	Corrective actions taken if the program operator discovered critical deviations from stewardship plan policies and procedures and a description of each critical deviation.	"Critical deviations" needs to be defined or explained as this term is too subjective. We would suggest defining "critical deviation" as follows: any occurrence where diversion of consumer-generated medication is confirmed and/or where consumer-generated medication is not destroyed in compliance with DEA regulations.

Proposed Reg Section	PDF Doc Page#	Current / Proposed Language	Stericycle Comment or Suggested Changes
18973.4(h) 029-016	23 & 24	Safety and Security. Describe the general nature of any incidents with safety or security related to collection, transportation, or disposal of collected covered drugs. Explain what corrective actions were taken to address the issue and improve safety and security. Information about any incident(s) shall be made available to the department upon request, and shall include, but not be limited to:	Describing the process and incidents that occurred related to safety or security failures could be a potential risk. This would require this information (corrective actions and updates to safety and security plans) to have to go through the confidential documentation process to prevent information on security practices from being available to the public to minimize risk of diversion, which is a more lengthy process. Our recommendation would be to minimize the information that is required to be submitted with the annual report. This information should only be made available to the department upon request and in this way the program is in place, but does not have to be submitted to the agency directly and have to be maintained under confidentiality constraints. As stated in comments above, It is imperative that hosts be able to safely continue to operate kiosks without security risks potentially caused by sharing specific security practices beyond those in direct need of the information. Likewise, it is imperative that service technicians, transporters, and all other persons involved in the program can safely perform their work without security risks potentially caused by sharing specific security practices beyond those in direct need of the information. Therefore, we strongly recommend that the plan include only broad descriptions of this information. In addition, this information should be marked confidential to prevent release to the general public with potentially nefarious intent. Full details of this type should <u>not</u> be publicly available and/or be included in the annual report.
18973.4(h)(5) 029-017	24	Regulatory or law enforcement agencies involved and any litigation, arbitration, or other legal proceedings that result from each incident.	As noted in prior comments, the language of this section should be clarified to require the stewardship program operator to identify and track the number of incidents and legal issues under their scope. The authorized collectors may be involved in incidents of which the stewardship program operator are unaware of, or are outside the scope of responsibility of the program operator. There may also be circumstances where the authorized collector will not provide information to the program operator due to legal issues, liability, or other corporate reasons. The program operator may not have any control or visibility to a host collector issue. Our recommendation would be to have the authorized collection sites track and maintain information on only the issues they are having with regulatory or other law enforcement as we believe this requirement is outside of the scope of this legislation and regulation.
ANNUAL REPORT FOR HOME-GENERATED SHARPS WASTE.			
18973.5(e) 029-018	27	Corrective actions taken if the program operator discovered critical deviations from stewardship plan policies and procedures, and a description of each critical deviation.	"Critical deviations" need to be defined or explained as this term is too subjective. We would suggest defining "critical deviation" as follows: any occurrence where diversion of consumer-generated medication is confirmed and/or where consumer-generated medication is not destroyed in compliance with DEA regulations.
18973.5(h) 029-019	27	Safety and Security. Describe the general nature of any incidents with safety or security related to collection, transportation, or disposal of home-generated sharps waste. Explain the corrective actions taken to address the issue and improve safety and security. Information about any incident(s) shall be made available to the department, upon request, and shall include, but not be limited to:	Describing the process and incidents that occurred related to safety or security failures could be a potential risk. This would require this information (corrective actions and updates to safety and security plans) to have to go through the confidential documentation process to prevent information on security practices from being available to the public to minimize risk of diversion, which is a more lengthy process. Our recommendation would be to minimize the information that is required to be submitted with the annual report. This information should only be made available to the department upon request and in this way the program is in place, but does not have to be submitted to the agency directly and have to be maintained under confidentiality constraints. As stated in comments above, it is imperative that hosts be able to safely continue to operate programs without security risks potentially caused by sharing specific security practices beyond those in direct need of the information. Likewise, it is imperative that service technicians, transporters, and all other persons involved in the program can safely perform their work without security risks potentially caused by sharing specific security practices beyond those in direct need of the information. Therefore, we strongly recommend that the plan include only broad descriptions of this information. In addition, this information should be marked confidential to prevent release to the general public with potentially nefarious intent. Full details of this type should not be publicly available and/or be included in the annual report.

From: [Perla Gomez](#)
To: [PharmaSharps](#)
Cc: [Coby Skye](#); [Carlos Ruiz](#); [Christopher Sheppard](#); [Gerald Ley](#); [Elijah Carder](#)
Subject: COMMENTS ON SENATE BILL 212 SECOND DRAFT PROPOSED REGULATIONS FOR 15-DAY COMMENT PERIOD, JULY 2020
Date: Monday, August 3, 2020 5:07:09 PM
Attachments: [PUBLIC WORKS COMMENT LETTER SB212.pdf](#)

[[EXTERNAL]]

TO: Jason Smyth, Senior Environmental Scientist
Materials Management and Local Assistance Division
California Department of Resources Recycling and Recovery

Please find the attached letter dated August 3, 2020 from the County of Los Angeles Public Works to California Department of Resources Recycling and Recovery regarding Comments on Senate Bill 212: Pharmaceutical and Sharps Waste Stewardship Program Second Draft Proposed Regulations For 15-Day Comment Period, July 2020.

If you have any questions regarding the subject matter, please contact Mr. Carlos Ruiz at (626) 458-3501 or CARUIZ@pw.lacounty.gov, Monday through Thursday, 7 a.m. to 5:30 p.m.



MARK PESTRELLA, Director

COUNTY OF LOS ANGELES

DEPARTMENT OF PUBLIC WORKS

"To Enrich Lives Through Effective and Caring Service"

900 SOUTH FREMONT AVENUE
ALHAMBRA, CALIFORNIA 91803-1331
Telephone: (626) 458-5100
<http://dpw.lacounty.gov>

ADDRESS ALL CORRESPONDENCE TO:
P.O. BOX 1460
ALHAMBRA, CALIFORNIA 91802-1460

August 3, 2020

IN REPLY PLEASE

REFER TO FILE: **EP-1**

Mr. Jason Smyth, Senior Environmental Scientist
Materials Management and Local Assistance Division
California Department of Resources Recycling and Recovery
P.O. Box 4025
Sacramento, CA 95812-4025

Dear Mr. Smyth:

**COMMENTS ON THE JULY 2020 SECOND DRAFT
PROPOSED REGULATIONS FOR SENATE BILL 212
PHARMACEUTICAL AND SHARPS WASTE STEWARDSHIP PROGRAM**

Public Works appreciates the opportunity to comment on Senate Bill 212, Proposed Regulation Text, Second Formal Draft dated July 2020.

We respectfully request that the enclosed comments be considered and incorporated in the next version of the regulations. Public Works would be pleased to participate in future stakeholder opportunities related to the development of these regulations.

If you have any questions, please contact me or your staff may contact Mr. Carlos Ruiz at (626) 458-3501 or CARUIZ@pw.lacounty.gov, Monday through Thursday, 7 a.m. to 5:30 p.m.

Very truly yours,

MARK PESTRELLA
Director of Public Works

Handwritten signature of Carlos Ruiz in blue ink.

COBY J. SKYE
Assistant Deputy Director
Environmental Programs Division

CR:ak
P:\SEC\AK\EP4\IPW COMMENT LETTER SB212

Enc.

ENCLOSURE A – COMMENTS

Article 4. Section 18972.1 DEFINITIONS.

1. We request the removal of the language "or is not reasonably feasible" from the regulation text. Public Resources Code 42032.2(d)(1)(F)(i), establishes a convenience standard for the program:
 - (i) The program provides or initiates distribution of a sharps waste container and mail-back materials at the point of sale, **to the extent allowable by law** as this additional allowance is not within the scope defined by statute.

030-001

The draft regulations Section 18972.1 is currently inconsistent with this statute as the language includes the language "or is not reasonably feasible". By including a convenience standard, the success of the stewardship program may be undermined by allowing other considerations other than legal limitations.

- Proposed Regulatory Text and [Recommended Changes/Revisions:](#)

(C) Other methods of providing a sharps waste container and mail-back materials, if the method identified in subpart (A) above is not allowed by law ~~or is not reasonably feasible~~, and if the method identified in subpart (B) above is not allowed by law ~~or is not reasonably feasible~~. These methods must be approved by the department in a stewardship plan and result in substantially the same level of convenience to the ultimate user as the methods identified in subparts (A) and (B) above.

Section 18973.2(j) and Section 18973.3(i) EDUCATION AND OUTREACH.

030-002a

2. The Education and Outreach provisions of these sections are enhanced by the changes made for the current draft. The provisions for materials, signage, labeling, internet and toll-free telephone number functionality, key metrics for evaluation, and coordination will most likely help maximize awareness, user participation, and the success of the programs.

030-002b

From: [Lester, Christopher \(ENV\)](#)
To: [PharmaSharps](#)
Cc: [Johnson, Margaret \(ENV\)](#); [Jackson, Jen \(ENV\)](#)
Subject: SF Environment comment letter regarding SB 212 7.15.2020 Proposed Regulations
Date: Monday, August 3, 2020 7:53:22 PM
Attachments: [SF Environment SB 212 July 2020 Proposed Regulations Comment Letter 8.3.2020.pdf](#)

[[EXTERNAL]]

Hello CalRecycle Staff,

Please find attached the San Francisco Department of the Environment's comment letter regarding the 7/15/2020 Proposed Regulations for implementing the Pharmaceutical and Sharps Waste Stewardship Act (SB 212).

We appreciate the opportunity to provide written comment on these important regulations.

Thank you

Best,

Christopher Lester
Special Waste Disposal Analyst
San Francisco Department of the Environment
1455 Market Street, Ste. 1200
San Francisco, CA 94103
christopher.lester@sfgov.org
P: (415) 355-3705
Pronouns: he, him, his

[SFEnvironment.org](https://www.sfdem.org) | [Get Involved, Stay Connected](#)

Please consider the environment before printing this email.



SF Environment
Our home. Our city. Our planet.
A Department of the City and County of San Francisco

London N. Breed
Mayor

Deborah O. Raphael
Director

August 3, 2020

Mr. Jason Smythe
CalRecycle
1001 I Street
Sacramento, CA 95814

BY ELECTRONIC MAIL to PharmaSharps@CalRecycle.ca.gov

Re: Comments on July 15, 2020 Proposed Regulations for implementing the Pharmaceutical and Sharps Waste Stewardship Act (SB 212)

Dear Mr. Smythe:

The San Francisco Department of the Environment appreciates the opportunity to provide comments on CalRecycle’s July 15, 2020 Proposed Regulations for implementing the Pharmaceutical and Sharps Waste Stewardship Act (California Code of Regulations, Title 14, Division 7, Chapter 11, Article 4 commencing with Section 18972).

The Department is encouraged by the changes CalRecycle made in the current Proposed Regulations, as we believe the revisions address many of the comments we voiced in our February 14, 2020 letter. Notably, the revised Outreach and Education and Stewardship Plan Coordination requirements provide CalRecycle with an improved framework and toolset to help ensure the statewide medicine and sharps stewardship programs are implemented in a robust, accessible, and cohesive manner. 031-001

We also want to recognize and commend CalRecycle’s hard work and diligence advancing these important regulations amid such unprecedented times. We urge CalRecycle to maintain this commitment to meeting the statute’s rulemaking and implementation deadlines so these critical programs become available to Californians across the state as soon as possible. 031-002

We offer the following comments in response to changes made in the July 15, 2020 Proposed Regulations.

Comment #1: Process for Meeting Retail Pharmacy Chain Participation Requirement.

We welcome the addition of Section 18973.4 (c)(2)(D) that requires the Annual Report for Covered Drugs to include a description of “Efforts between the program operator and retail pharmacy chains to meet the requirement stated in” Section 42032.2(b)(2) of the statute (“Retail Pharmacy Chain Participation Requirement”). However, we are concerned that the Proposed Regulations do not require a similar description in the Stewardship Plan, prior to program implementation. Given the ongoing communication and coordination that will be needed for a program operator and a retail pharmacy chain(s) to comply with this requirement, establishing clear roles and a detailed process from the outset is especially critical. This 031-003

will help ensure compliance during initial program implementation and on an ongoing basis in response to changes in the number of participating authorized collectors in each county.

Although meeting this requirement is a shared responsibility between the program operator and retail pharmacy chains, the program operator is the logical entity to assign responsibility for monitoring convenience standard levels in each county and, as applicable, notifying a pharmacy chain(s) that they are obligated to serve as an authorized collector(s). To that end, we urge CalRecycle to add a new subparagraph to Section 18973.2(d) as follows: 031-004

(6) Pursuant to Section 42032.2(b)(2) of the Public Resources Code, description of the process for monitoring the minimum convenience standard threshold in each county, notifying retail chain pharmacies of their obligation to serve as an authorized collector(s), as applicable, and including them in the stewardship program.

Comment #2: Comprehensive Education and Outreach Program.

We strongly support proposed revisions to the Education and Outreach requirements for both the Covered Drugs and Home-Generated Sharps Stewardship Plan sections of the Proposed Regulations (Section 18973.2(j) and Section 18973.3(i), respectively). Providing a robust, accessible, and consistent outreach and education program is critical to a stewardship program's overall success. The revised language better aligns with this priority and the statute's requirement for a "comprehensive education and outreach program" while providing program operators concrete guidance. We also appreciate additions such as multi-language support for the website and toll-free telephone number, readily-understandable kiosk signage design, and other accessibility provisions. Collectively, these requirements will help ensure the diverse audience of ultimate users across California can easily access important program information and services. 031-005

Comment #3: Enhanced Stewardship Plan Coordination Requirements.

As stated in our February 14, 2020 comment letter, establishing minimum coordination requirements and prescriptive criteria for the coordination of multiple stewardship plans is extremely important to minimize the possibility of conflicting messages or instructions from different program operators. We believe the revised language in the Proposed Regulations is a step in the right direction, as it moves away from a "good faith effort" standard in favor of more explicit, outcome-based guidance. We suggest that CalRecycle further expand the plan coordination language to require a single system of program design and promotion and to specify elements of program promotion on which multiple program operators are required to collaborate. In addition, we urge CalRecycle to promote program operator collaboration and coordination to the extent feasible through the stewardship plan review and approval process. 031-006
031-007
031-008

Thank you for the opportunity to comment on the July 15, 2020 Proposed Regulations for implementing the Statewide Pharmaceutical and Sharps Waste Stewardship Act. We sincerely appreciate the thoughtful and responsive manner CalRecycle has conducted this rulemaking process. We look forward to continued collaboration on these vitally important programs.

Please do not hesitate to contact Christopher Lester of my staff at 415-355-3705 or by email at Christopher.Lester@sfgov.org if you have questions or need additional information on these comments or on our experience implementing the San Francisco Safe Drug Disposal Stewardship Ordinance.

Sincerely,

A handwritten signature in black ink, appearing to read "Jen Jackson", with a long horizontal flourish extending to the right.

Jen Jackson
Toxics Reduction and Healthy Ecosystems Program Manager

From: [CoPALM](#)
To: [PharmaSharps](#)
Subject: Public Comment for Pharmaceutical and Sharps Waste Stewardship Regulations
Date: Tuesday, August 18, 2020 10:12:37 AM
Attachments: [CoPALM Rx-Second Public Comment SB212.pdf](#)

[[EXTERNAL]]

Hello,

Although we missed our deadline for the 15-day written public comment period for the Second Draft Proposed Regulations for 15-Day Comment Period, we would still like to send our input for the newly proposed changes to the regulations.

Thank you so much,

Coalition for Prevention & Awareness in L.A. Metro (CoPALM)
T: (213) 365-7400 Ext. 5143 E: copalmla@gmail.com
www.CoPALM.org



August 17, 2020

Senate Bill 212 Rulemaking Team
California Department of Resources Recycling and Recovery (CalRecycle)
P.O. Box 4025
Sacramento, CA 95812-4025

Dear California Department of Resources Recycling and Recovery (CalRecycle),

On behalf of the Coalition for Prevention and Awareness in Los Angeles Metro (CoPALM), we express our gratitude for the opportunity to provide a public comment. First, we want to thank you for your newly revised version of Senate Bill 212 and listening to stakeholders' input. CoPALM is a coalition of prevention service providers and community organizations that represent neighborhoods such as Boyle Heights, Koreatown, and Hollywood. Your revisions have assured us of your willingness to consider the voices of those directly impacted by this legislation. While we strongly support Senate Bill 212 in its current form, our coalition proposes that the following recommendations be incorporated:

- 032-001a • Providing necessary resources and funding for nonprofit organizations and community-based programs to assist with information/resource dissemination, outreach, and to educate the community on implementing methods of proper safe disposal and identifying disposal locations.
- 032-001b •
- 032-002 • Pharmaceutical companies and manufacturers should be responsible for any costs associated with the above recommendations without increasing the retail price of prescription drugs for consumers.
- 032-003 • Pharmacies including retailers such as Walgreens and Rite-Aid be required to include safe disposal instructions and information on their instructions page for all medications prescribed.

Prescription medicine misuse has a tremendous public health impact on the communities that we serve. As a result, many nonprofit organizations have taken the responsibility of informing community members on prescription use/misuse and safe

032-004 disposal. For this reason, we feel that SB 212 should provide support to the
032-005 organizations currently engaging in this work. In addition, considering that many of our
low income community members already struggle to afford healthcare and prescription
medications costs, we do not believe they should be burdened with the costs of
implementing the recommendations in SB 212.

Sincerely,

Bryan Zaragoza Hurtado
CoPALM Chair

Additional Comments/Emails from Stakeholders During the First 15-day Comment Period:

Jason Schmelzer Comment and CalRecycle Response:

Description: Jason Schmelzer, from Shaw Yoder Antwih Schmelzer & Lange emailed, expressing an interest in discussing the formal comment response his clients, California Product Stewardship Council (CPSC) and National Stewardship Action Council (NSAC), had provided. Because the questions were the same as formal comments CPSC and NSAC submitted, CalRecycle answered the questions in its comment responses.

Leah Lindahl Question and CalRecycle Response

Summary: Leah Lindahl, from Healthcare Distribution Alliance, asked if CalRecycle would provide responses to comments provided during the 45-day comment period. CalRecycle answered with the following: “We will be including our responses to comments from both the 45-day and 15-day comment periods in the final rulemaking record as required by the Administrative Procedure Act”.

From: Jason Schmelzer <Jason@SYASLpartners.com>
Sent: Tuesday, August 4, 2020 9:54 AM
To: PharmaSharps <PharmaSharps@calrecycle.ca.gov>
Cc: Haworth, Becky@CalRecycle <Becky.Haworth@calrecycle.ca.gov>
Subject: RE: Pharma/Sharps Regs

Just me. I can do either a conference line or a MS Teams meeting. Totally up to you!

JASON SCHMELZER

Partner

Shaw Yoder Antwih Schmelzer & Lange
1415 L Street, Suite 1000, Sacramento, CA 95814
O: 916.446.4656
M: 916-549-0898
jason@SYASLpartners.com

From: PharmaSharps <PharmaSharps@calrecycle.ca.gov>
Sent: Tuesday, August 4, 2020 8:35 AM
To: Jason Schmelzer <Jason@SYASLpartners.com>
Cc: PharmaSharps <PharmaSharps@calrecycle.ca.gov>; Haworth, Becky@CalRecycle <Becky.Haworth@calrecycle.ca.gov>
Subject: RE: Pharma/Sharps Regs

Excellent. Any other attendees on your end? Will you be in front of a computer with a webcam? If so, we could use Microsoft Teams conferencing software and Becky can provide instructions for convenient setup. Otherwise we can rely on a simple conference call line.

Jason

From: Jason Schmelzer <Jason@SYASLpartners.com>
Sent: Tuesday, August 4, 2020 8:31 AM
To: Smyth, Jason@CalRecycle <Jason.Smyth@CalRecycle.ca.gov>
Cc: PharmaSharps <PharmaSharps@calrecycle.ca.gov>; Haworth, Becky@CalRecycle <Becky.Haworth@calrecycle.ca.gov>
Subject: Re: Pharma/Sharps Regs

Hi Jason,

Thanks for the quick response. 8:30am works perfectly fine for me on 8/5. Thank you!

Jason

Sent from my iPhone

On Aug 4, 2020, at 8:26 AM, Smyth, Jason@CalRecycle <Jason.Smyth@calrecycle.ca.gov> wrote:

Jason,

CalRecycle is in receipt of your comment letter pertaining to SB 212 rulemaking for the Pharmaceutical and Sharps Stewardship Act. Comments received during the formal comment period will be posted on CalRecycle's Pharmaceutical and Sharps Waste Stewardship [rulemaking page](#) as part of the final rulemaking record as required by the Administrative Procedure Act.

Becky Haworth of my team will be reaching out to you to schedule the call. We are looking into the earliest available time to meet, which may be 8:30am tomorrow 8/5. Is that a viable option on your end?

Best regards,

Jason Smyth, Supervisor
Pharmaceutical & Sharps Unit
California Department of Resources Recycling and Recovery (CalRecycle)
jason.smyth@calrecycle.ca.gov (916) 341-6676
<image001.jpg>

From: Jason Schmelzer <Jason@SYASLpartners.com>
Sent: Monday, August 3, 2020 7:47 PM
To: Smyth, Jason@CalRecycle <Jason.Smyth@CalRecycle.ca.gov>
Cc: Jason Schmelzer <Jason@SYASLpartners.com>
Subject: Pharma/Sharps Regs

[[EXTERNAL]]

Hi Jason,

Thanks again for the comment period (and extension). I was hoping to set a time where we could chat about the letter submitted by my clients (CPSC and NSAC). I don't think we'll need a bunch of time, maybe 30 minutes. Feel free to loop in whoever you need from your team.

The regulations look pretty fantastic. Your team has done a pretty incredible job actualizing the stature, so thank you for that. From my perspective there is only one major issue to discuss, and that is the portion of the regulations that deals with provision of the mail-back container and materials at the point of sale.

Thanks!

**JASON
SCHMELZER**

Partner

Shaw Yoder Antwih Schmelzer & Lange

1415 L Street, Suite 1000, Sacramento, CA 95814

O: 916.446.4656

M: 916-549-0898

jason@SYASLpartners.com

<SB212 Reg Comments - Second Draft - 2020.08.03.pdf>

From: Smyth, Jason@CalRecycle <Jason.Smyth@CalRecycle.ca.gov>
Sent: Thursday, July 16, 2020 9:13 AM
To: Lindahl, Leah <llindahl@hda.org>
Subject: RE: Notice of Changes to Proposed Regulations for the Pharmaceutical and Sharps Waste Stewardship Program

Leah,

We will be including our responses to comments from both the 45-day and 15-day comment periods in the final rulemaking record as required by the Administrative Procedure Act.

Best regards,

Jason Smyth, Supervisor
Pharmaceutical & Sharps Unit
California Department of Resources Recycling and Recovery (CalRecycle)
jason.smyth@calrecycle.ca.gov (916) 341-6676



From: Lindahl, Leah <llindahl@hda.org>
Sent: Wednesday, July 15, 2020 11:39 AM
To: Smyth, Jason@CalRecycle <Jason.Smyth@CalRecycle.ca.gov>
Subject: RE: Notice of Changes to Proposed Regulations for the Pharmaceutical and Sharps Waste Stewardship Program

[[EXTERNAL]]

Good Afternoon Jason,

Hope you're well. Just checking to see if we will receive comments from CalRecycle on the comment letter HDA provided on the first round of proposed regs? Just curious as to the decisions in regard to our comments.

Thank you,

Leah

Leah Lindahl
Senior Director, State Government Affairs, Western Region
Direct:(703) 885-0243
Mobile:(303) 829-4121



[Healthcare Distribution Alliance](http://www.hda.org)
PATIENTS MOVE US.

From: CalRecycle: Pharmaceutical and Sharps Waste Stewardship Listserv
<pharmasharps@calrecycle.ca.gov>
Sent: Tuesday, July 14, 2020 5:48 PM
To: Lindahl, Leah <llindahl@hda.org>
Subject: Notice of Changes to Proposed Regulations for the Pharmaceutical and Sharps Waste Stewardship Program

A 15-day written public comment period for the Proposed Regulations for the Pharmaceutical and Sharps Waste Stewardship Program will begin on July 15, 2020 and end on July 29, 2020 at 11:59 pm.

The revised proposed regulations are available on the Pharmaceutical and Sharps Waste Stewardship rulemaking website at: www.CalRecycle.ca.gov/laws/rulemaking/pharmasharps. Text shown in double underline (addition) and double ~~striketrough~~ (deletion) depict changes made after the 45-day public comment period. CalRecycle staff is only required to respond to comments related to the newly proposed changes to the regulations.

Please submit written comments to pharmasharps@calrecycle.ca.gov.

During this 15-day written comment period, CalRecycle is providing the opportunity to review additional technical documents that were relied upon for the development of the proposed regulations but not previously included in the Initial Statement of Reasons. These documents are available for viewing online at the links below and at our offices between 9:00am and 3:30pm from July 15, 2020 to July 29, 2020.

- United States Postal Service. 2018. *What Are the Guidelines for Mailing Priority Mail*. <https://faq.usps.com/s/article/What-are-the-Guidelines-for-Mailing-Priority-Mail>
- Division 7, Chapter 17.5, Section 7295 of the Government Code. https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=GOV§ionNum=7295.

To make an appointment to view these documents or submit comments by mail, please contact:

Jason Smyth
Materials Management and Local Assistance Division
California Department of Resources, Recycling and Recovery (CalRecycle)
P.O. Box 4025
Sacramento, CA 95814
Fax: (916) 319-7147
Email: pharmasharps@calrecycle.ca.gov

To unsubscribe from the Pharmaceutical and Sharps Waste Stewardship listserv, please go to <https://www2.calrecycle.ca.gov/listservs/Unsubscribe/73>.

~

Serial Number: Q2QAQY0E
Sent On: 07/14/2020 4:47 PM

~