

13. Second 15-Day Public Comment Period for Proposed Revised Regulation (August 21, 2020 – September 4, 2020)
 - a. Notice of Changes to Proposed Regulation
 - b. Listserv Notices
 - 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: August 20, 2020

To: Interested Parties

From: Jason Smyth, Supervising Senior Environmental Scientist

Subject: Notice of Changes to Proposed Regulations and Economic and Fiscal Impact Statement and Additional Documents Relied Upon 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 August 21, 2020 and end on September 4, 2020 at 11:59 pm. After considering comments received during the previous comment period that ran from July 15, 2020 to August 3, 2020, CalRecycle staff revised the proposed regulations. These revisions will add further clarity to the existing language.

The Third Draft Proposed Regulations for the 15-Day Comment Period, August 2020 are available on the Pharmaceutical and Sharps Waste Stewardship rulemaking website at: www.CalRecycle.ca.gov/laws/rulemaking/pharmasharps.

The revisions are depicted as follows:

- Text in single underline depicts first draft Proposed Regulation additions.
- Text in double underline depicts second draft Proposed Regulation additions.
- Text shown in ~~double strikethrough~~ depicts second draft Proposed Regulation deletions.
- Text in grey highlight (no underline or strikethrough) depicts third draft Proposed Regulation additions.
- Text in ~~grey highlight with single strikethrough~~ depicts third draft Proposed regulation deletions.

A version of the revised proposed regulations for non-sighted readers is also available at the link above.

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 August 21, 2020 to September 4, 2020.

- American Institute of Certified Public Accountants. Audit and Attest Standards, including Clarified Standards. <https://www.aicpa.org/research/standards/auditattest.html>
- American Institute of Certified Public Accountants. General Accepted Auditing Standards. <https://www.aicpa.org/Research/Standards/AuditAttest/DownloadableDocuments/AU-00150.pdf>
- Financial Accounting Standards Board. General Accepted Accounting Principles. <https://fasb.org/home>
- Mattress Recycling Council 2017 California Annual Report. <https://mattressrecyclingcouncil.org/wp-content/uploads/MRC-2017-California-Annual-Report-for-web.pdf>
- U.S. Government Accountability Office. Generally Accepted Government Auditing Standards. <https://www.gao.gov/yellowbook/overview>
- World Wide Web Consortium. 2008. Web Content Accessibility Guidelines 2.0. <https://www.w3.org/TR/WCAG20/>

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

CalRecycle revised the Economic and Fiscal Impact Statement (Form 399 and Appendix). During this 15-day written comment period, CalRecycle is making these documents available for comment on the Pharmaceutical and Sharps Waste Stewardship rulemaking website at: www.CalRecycle.ca.gov/laws/rulemaking/pharmasharps. Please submit written comments to pharmasharps@calrecycle.ca.gov.

Thank you for your interest and participation in this process.

[CalRecycle Home](#) » [Listservs](#) » [List Archive Search](#) » Message Details

List Archive Message Details

Pharmaceutical and Sharps Waste Stewardship

Message Details

Sent On

8/20/2020 6:32 PM

Priority

Normal

Frompharmasharps@calrecycle.ca.gov**Subject**


Notice of Changes to Proposed Regulations and Economic and Fiscal Impact Statement and Additional Documents Relied Upon 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 August 21, 2020 and end on September 4, 2020 at 11:59 pm. After considering comments received during the previous comment period that ran from July 15, 2020 to August 3, 2020, CalRecycle staff revised the proposed regulations. These revisions will add further clarity to the existing language.

The Third Draft Proposed Regulations for the 15-Day Comment Period, August 2020 are available on the Pharmaceutical and Sharps Waste Stewardship rulemaking website at: www.CalRecycle.ca.gov/laws/rulemaking/pharmasharps. The revisions are depicted as follows:

- Text in single underline depicts first draft Proposed Regulation additions.
- Text in double underline depicts second draft Proposed Regulation additions.
- Text shown in double ~~strikethrough~~ depicts second draft Proposed Regulation deletions.
- Text in grey highlight (no underline or strikethrough) depicts third draft Proposed Regulation additions.
- Text in ~~grey highlight with single strikethrough~~ depicts third draft Proposed regulation deletions.

A version of the revised proposed regulations for non-sighted readers is also available at the link above. 

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 August 21, 2020 to September 4, 2020.

- American Institute of Certified Public Accountants. Audit and Attest Standards, including Clarified Standards. <https://www.aicpa.org/research/standards/auditattest.html>
- American Institute of Certified Public Accountants. General Accepted Auditing Standards. <https://www.aicpa.org/Research/Standards/AuditAttest/DownloadableDocuments/AU-00150.pdf>
- Financial Accounting Standards Board. General Accepted Accounting Principles. <https://fasb.org/home>
- Mattress Recycling Council 2017 California Annual Report. <https://mattressrecyclingcouncil.org/wp-content/uploads/MRC-2017-California-Annual-Report-for-web.pdf>
- U.S. Government Accountability Office. Generally Accepted Government Auditing Standards. <https://www.gao.gov/yellowbook/overview>
- World Wide Web Consortium. 2008. Web Content Accessibility Guidelines 2.0. <https://www.w3.org/TR/WCAG20/>

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.

CalRecycle revised the Economic and Fiscal Impact Statement (Form 399 and Appendix). During this 15-day written comment period, CalRecycle is making these documents available for comment on the Pharmaceutical and Sharps Waste Stewardship rulemaking website at:

www.CalRecycle.ca.gov/laws/rulemaking/pharmasharps. Please submit written comments to pharmasharps@calrecycle.ca.gov.

Thank you for your interest and participation in this process.

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



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
Second 15-Day comment period, 8/21/2020 – 9/04/2020

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 as well as a revised Form 399. The notice, along with the Third Draft of the regulatory text, was mailed on August 20, 2020, 15 days prior to the close of the public comment period. The public comment period for the Third Draft of the regulatory text, additional documents relied upon, and revised Form 399 began on August 21, 2020 and ended on September 4, 2020.

SB 212 Second 15-Day Formal Public Comment Period (8/21/2020 – 9/4/2020)
 Comments and Responses on the Third Draft Proposed Regulatory Text, Sorted by Comment Number

Comment Letter Number	Commenter	CalRecycle Response Pages
033	Stat-Medicament-Disposal Corporation	1-3
034	Sharps Compliance, Incorporated	3-5
035	Stat-Medicament-Disposal Corporation	5-6
036	Covanta	6-7
037	Coalition for Prevention and Awareness in Los Angeles Metro (COPALM)	7-9
038	Pharmaceutical Product Stewardship Work Group (PPSWG)	9-12
039	National Stewardship Action Council (NSAC)	12-14
040	Med-Project USA	14-20
041	California Product Stewardship Council (CSPC)	20-21
042	Waste Management (WM) Curbside, LLC	21

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
033-001	Stat-Medicament Disposal Corporation	Larry Kenemore	18972.1	N	Without these definitions it is pretty difficult to determine exactly what and how this law is implemented. That is it is left to the whim of any government employee to make that determination or even exclude possible future new inventions that may already be on the horizon?	033-001. A change to the proposed regulatory text is not necessary. The definitions in section 18972.1 of the proposed regulatory text, in conjunction with the definitions set forth in section 42030 of the Public Resources Code, provide clarity. Together, these definitions are sufficient to interpret the legal requirements and determine how the law may be implemented. See comment responses 033-001A through 033-001F.
033-001A	Stat-Medicament Disposal Corporation	Larry Kenemore	18972.1	N	18972.1 Definitions are missing for: a. Covered entity	033-001A. A change to the proposed regulatory text is not necessary. The definition of "covered entity" in Public Resources Code section 42030(f)(1)(A-E) provides sufficient clarity and does not need to be restated in the proposed regulatory text.
033-001B	Stat-Medicament Disposal Corporation	Larry Kenemore	18972.1	N	18972.1 Definitions are missing for: b. Authorized Collector	033-001B. A change to the proposed regulatory text is not necessary. The definition of "authorized collector" in Public Resources Code section 42030(b) provides sufficient clarity and does not need to be restated in the proposed regulatory text.
033-001C	Stat-Medicament Disposal Corporation	Larry Kenemore	18972.1	N	18972.1 Definitions are missing for: c. Service Provider	033-001C. A change to the proposed regulatory text is not necessary. The phrase "service provider" has a common meaning and does not need further definition.
033-001D	Stat-Medicament Disposal Corporation	Larry Kenemore	18972.1	N	18972.1 Definitions are missing for: d. Program operator	033-001D. A change to the proposed regulatory text is not necessary. The definition of "program operator" in Public Resources Code section 42030(q) provides sufficient clarity and does not need to be restated in the proposed regulatory text.
033-001E	Stat-Medicament Disposal Corporation	Larry Kenemore	18972.1	N	18972.1 Definitions are missing for: e. Stewardship plan:	033-001E. A change to the proposed regulatory text is not necessary. The definition of "stewardship plan" in Public Resources Code section 42030(x) provides sufficient clarity and does not need to be restated in the proposed regulatory text.
033-001F	Stat-Medicament Disposal Corporation	Larry Kenemore	18972.1	N	18972.1 Definitions are missing for: Supplemental service	033-001F. A change to the proposed regulatory text is not necessary. The phrase "supplemental service" has a common meaning and does not need further definition.
033-002	Stat-Medicament Disposal Corporation	Larry Kenemore	18973.2 (j)(3)(D)	N	J(3)(D) add mechanism to accept requests for a Safe Drug Disposal Kiosk	033-002. 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 Kiosk, even though the commenter uses the phrase as a defined term. Please see comment response to 033-006.
033-003	Stat-Medicament Disposal Corporation	Larry Kenemore	18973.2 (j)(4)	N	(4) add accept requests for Safe Drug Disposal Kiosk	033-003. 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 Kiosk, even though the commenter uses the phrase as a defined term. Please see comment response to 033-006.

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
033-004	Stat-Medicament Disposal Corporation	Larry Kenemore	18973.2 (g)(6)(E)	N	18973.2 Stewardship Plan for Covered Drugs (g)(6)(E) Remove word "amount" and/or include weight	033-004. A change to the proposed regulatory text is not necessary. CalRecycle disagrees with the commenter's recommendation to specify the appropriate metrics. Pursuant to section 42033.2(b)(3) of the Public Resources Code, program operators are required to track the weight of covered products collected at authorized collection sites. 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.
033-005	Stat-Medicament Disposal Corporation	Larry Kenemore	18973.2 (g)(6)(C)	N	(6)(c) remove words "supplemental service" or have under definitions for "supplemental service" and "main service"	033-005. A change to the proposed regulatory text is not necessary. CalRecycle declines to further define or remove the phrase "supplemental service", which has a common meaning and does not need further definition. The phrase "supplemental service" is consistent with Public Resources Code section 42032.2(c), which uses the phrase "may supplement service."
033-006	Stat-Medicament Disposal Corporation	Larry Kenemore	18973.2 (g)(7)	N	There is no wording that would include a safe drug disposal kiosk that does not require a service schedule.	033-006. CalRecycle believes the comment is referring to section 18973.2(g)(7). A change to the proposed regulatory text is not necessary. The proposed regulations and statutory language use the term "authorized collection site". It is the program operator's responsibility to develop a service schedule that ensures collection receptacles do not reach capacity. The term "safe drug disposal kiosk" is not used in the proposed regulations or authorizing statute. Moreover, CalRecycle cannot provide a more specific response because the commenter has not defined safe drug disposal kiosk, even though the commenter uses the phrase as a defined term. 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). 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.
033-007	Stat-Medicament Disposal Corporation	Larry Kenemore	18973.2 (g)(7)	N	The wording of collection site does not include a safe drug disposal kiosk.	033-007. CalRecycle believes the comment is referring to section 18973.2(g)(7). A change to the proposed regulatory text is not necessary. The proposed regulations and statutory language use the term "authorized collection site". The term "kiosk" is not used in the proposed regulations or authorizing statute. Moreover, CalRecycle cannot provide a more specific response because the commenter has not defined safe drug disposal kiosk, even though the commenter uses the phrase as a defined term. 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). If

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
						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.
033-008	Stat-Medicament Disposal Corporation	Larry Kenemore	18973.2	N	There should be language differing drop box sites and safe drug disposal kiosks.	<p>033-008. A change to the proposed regulatory text is not necessary. The statutory language and proposed regulations do not contain the phrase “drop box sites” or “safe drug disposal kiosk”, so the department disregards the commenter’s recommendation.</p> <p>The proposed regulations and statutory language use the term “authorized collection site”. 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). 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.</p> <p>Moreover, CalRecycle cannot provide a more specific response because the commenter has not defined safe drug disposal kiosk or drop box site, even though the commenter uses the phrases as defined terms.</p>
034-001	Sharps Compliance, Incorporated	Lindsey Murrile-Hawkins	18973.2 (g)(6)(A)	N	<p>Pg. 11 L 33 Proposed regulation: “List of locations and/or description of mechanisms to provide ultimate users with preaddressed, prepaid mail-back materials or an alternative form of collection and disposal system,that would render the covered drug <i>inert</i>, if applicable.”</p> <p>Issue: The definition of “inert” has been removed and per the California Department of Public Health’s Medical Waste Management Program, pharmaceutical waste generated in California must be treated by incineration, or by an alternative treatment technology that has received approval from the Department. The technologies on the Department’s alternative medical waste treatment technologies list are the only alternative treatments approved for use in California and expressly prohibit use of charcoal/chemical-based decomposition products. Use of such products requires disposal in a pharmaceutical waste container which cannot be placed in municipal solid waste. Furthermore, 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>034-001. A change to the proposed regulatory text is not necessary. CalRecycle acknowledges the commenters concerns, however, Section 18973.2(g)(6)(A) of the proposed regulatory text, including the term “inert”, is a statutory requirement found in section 42032.2(a)(1)(G)(i) of the Public Resources Code. 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. Regardless of whether the department decided to remove reference in the proposed regulations to disposal systems that would render a covered drug “inert”, a program operator would still be required to permit an ultimate user who is a homeless, homebound, or disabled individual to request prepaid, pre-addressed mailing envelopes or an alternative form of a collection and disposal system that would render the covered drug “inert”, pursuant to section 42032.2(a)(1)(G)(i) of the Public Resources Code.</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</p>

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					Proposed Resolution: Remove references allowing use of disposal systems that render drugs inert since these products cannot be placed in municipal solid waste landfills and would have to be coupled with an additional container designed for pharmaceutical waste when routed for incineration. Additionally, the DOT would consider this a hazardous waste, given above, thus require containment compliant for hazardous waste transport and treatment.	and regulations regarding handling, collection, and transportation of such substances. CalRecycle may consult with other agencies regarding a proposed alternative form of collection and disposal that would render a drug inert, and will determine which agencies are appropriate based on the proposal.
034-002	Sharps Compliance, Incorporated	Lindsey Murrile-Hawkins	18973.3 (f)(2)(A)	N	Pg. 17 L 7 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. Issue: Who is responsible for determining how many mail-back containers each patient should have and who is responsible for keeping track to ensure patients have the correct amount? Proposed Regulation: Clarify who is responsible for the determination of distribution of containers and who is tracking the volume of sharps waste containers and mail-back materials to ensure ultimate users have an adequate number of containers.	034-002. 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 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 by the program operator that is responsible for meeting requirements under the authorizing statute and its implementing regulations.
034-003	Sharps Compliance, Incorporated	Lindsey Murrile-Hawkins	18973.3 (f)(5)	N	Pg. 18 L 1 Proposed Regulation: “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:” Issue: Would needle clippers meet the definition of supplemental collection method? If allowed, how should needle clippers be disposed of? According to the California Medical Waste Management Program , all sharps waste shall be placed in sharps containers, and, no home generated sharps may be placed into municipal waste containers or recycling containers. Proposed Regulation: Include language that specifically states whether needle clippers may be utilized by the ultimate user to discard sharps. If it is allowed, include additional language to outline appropriate disposal based upon California’s Department of Health Medical Waste Management Program requirements.	034-003. A change to the proposed regulatory text is not necessary. CalRecycle declines to make individual product determinations in the proposed regulations and defers to the appropriate agency that has such authority.
034-004	Sharps Compliance, Incorporated	Lindsey Murrile-Hawkins	18973.3 (i)(2)	N	Pg. 20 L 12 Proposed Regulation: “Materials to be utilized that are distributed in languages suited to local demographics, consistent with section 7295 of the Government Code. These materials shall include, but are not limited to, signage for hospitals, pharmacies, and other locations, as necessary. Signage or labeling for secure collection receptacles shall be designed with explanatory graphics which are readily understandable by all ultimate users.”	034-004. A change to the proposed regulatory text is not necessary. CalRecycle declines to define or specify what constitutes a substantial number of the population for language translation purposes or who is responsible for making this determination. This number may vary by jurisdiction and the department prefers to determine compliance on a case-by-case basis when reviewing stewardship plans.

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					<p>Issue: Who determines what a substantial number of the public is in accordance with section 7295 in terms of deciding which languages of each area to translate? Who is making the determination at the individual county level as to what languages the inserts need be translated in?</p> <p>Proposed Regulation: Include language that outlines the responsible party in determining the languages for each location which need additional translation services. Define what a substantial number of the population would be.</p>	Meeting this requirement may involve collaboration between multiple groups to establish what language translation options will meet the varying needs of California's non-English speaking demographics.
034-005	Sharps Compliance, Incorporated	Lindsey Murrile-Hawkins	18973.3 (i)(2)	N	<p>Pg. 20 L 18 Proposed Regulation: "Establishment of an internet website designed with functionality for mobile platforms, provided with language options suited to local demographics, consistent with section 7295 of the Government Code, and maintained to ensure all information is up to date and accurate. The internet website's digital content and navigability must be accessible to disabled individuals. The internet website shall include, but is not limited to, the following:"</p> <p>Issue: Who determines what a substantial number of the public is in accordance with section 7295 in terms of deciding which languages of each area to translate? Who is responsible for disseminating the information?</p> <p>Proposed Regulation: Clarify who determines the languages necessary for website creation, as well as who is responsible for disseminating the information.</p>	034-005. A change to the proposed regulatory text is not necessary. The program operator is responsible for meeting this component of the stewardship plan. A program operator must determine what constitutes a substantial number of the population for language translation purposes and for disseminating that information. Meeting this requirement may involve collaboration between multiple groups to establish what language translation options will meet the varying needs of California's non-English speaking demographics. The department prefers to evaluate compliance with this provision on a case-by-case basis.
035-001	Stat-Medicament Disposal Corporation	Larry Kenemore	General	N	Just for your information while rulemaking something to keep in mind	035-001. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. CalRecycle acknowledges the news release provided by the commenter.
035-Supp. 001	Stat-Medicament Disposal Corporation	Larry Kenemore	General	N	<p>NEWS RELEASE</p> <p>Providing a safe-in-home drug deactivation system for unused opioid disposal at release from the hospital post surgery, is an opportunity to reduce the community illegal opioid supply and have an impact on the opioid crisis!</p> <p>August 26, 2020</p> <p>Research was just completed to determine the impact of a SAFE-IN-HOME drug deactivation system provided to post-surgical patients on the rate of opioid prescription disposal.</p> <p>Of the hundreds of post-operative patients discharged after in-patient surgery at a large academic medical center, the study conducted August 20, 2018, through November 30, 2018 provides data as to In-Home safe-disposal of opioids.</p> <p>Patients were provided with an in-home drug deactivation system, and an instruction sheet along with their opioid prescription. Up to 4 weeks after dismissal, the patients were surveyed about quantity of opioids remaining, the use of the drug deactivation system or other disposal methods, and satisfaction with the drug disposal system if used. One hundred forty-nine of 200 (74.5%) patients were surveyed. One hundred six reported leftover opioids and 29 (27.3%) had disposed of these medications.</p>	035-Supp.001. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. See response to comment 035-001.

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					<p>At the time of survey, 23 (21.2%) participants with leftover opioids had used the drug disposal system to destroy their remaining supply and an additional 33 (31.1%) participants reported plans to use the disposal system on a future date.</p> <p>Of the 23 participants who used the drug disposal system, 22 (96.0%) reported that they were very satisfied with the disposal process.</p> <p>RESULTS: More than 79% of use In-Home Safe-Drug-Disposal, increasing by 650% drug removal over the current Take-Back program. Participants are willing to use an IN-HOME SAFE-DRUG-DISPOSAL SYSTEM and are satisfied with the process.</p> <p>Published in PubMed August 17, 2020</p> <p>INFORMATION PROVIDED BY: THE ONLY AWARD-WINNING IN-HOME SAFE-DRUG-DISPOSAL PROGRAM IN THE UNITED STATES Stat-Medicament-Disposal Corporation (A data driven organization) https://statmeddisposal.net larry5@statmeddisposal.net (855) 873-4965 Ext. 6</p>	
036-001	Covanta	David Cali	18973.2(g)(6)(A)	N	<p>Comment: 18973.2. STEWARDSHIP PLAN FOR COVERED DRUGS Page 11 of 43 Line 33</p> <p>"Section (A) List of locations and/or description of mechanisms to provide ultimate users with preaddressed, prepaid mail-back materials or an alternative form of collection and disposal system, that would render the covered drug inert, if applicable."</p> <p>Covanta encourages CalRecycle to replace 'inert' with 'non-retrievable'. The paragraph establishes a Drug Enforcement Administration compliant standard of operation by utilizing the term 'ultimate user' which is a defined under the Controlled Substances Act (21 U.S.C. 802(27)). The standard for disposal is also defined under the CF R's as 'non-retrievable' (Title 21 CFR §1317.90 (a)). Utilization of the already established DEA standard for compliant destruction offers compliant consistency, ensures collected medications are destroyed, and avoids unintended consequences such as diversion or harmful impacts to the environment.</p>	<p>036-001. A change to the proposed regulatory text is not necessary. CalRecycle acknowledges the commenters concerns, however, Section 18973.2(g)(6)(A) of the proposed regulatory text, including the term "inert", is a statutory requirement found in section 42032.2(a)(1)(G)(i) of the Public Resources Code. 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. Additionally, 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".</p> <p>The authorizing statute requires that a program operator's stewardship plan and program comply with all applicable federal and state laws and regulations. This applies to an alternative form of a collection and disposal system that would render a covered drug "inert" (section 42032.2(a)(1)(G)(i) of the Public Resources Code).</p>
036-Supp.001	Covanta	David Cali	18973.2(g)(6)(A)	N	<p><u>Third Party Analysis</u></p> <p>While Congress was investigating 'H.R.6 - SUPPORT for Patients and Communities Act', one alternative collection company discussed under oath to Congressman Latta that the disposal system can be reverse engineered utilizing vodka. The testimony can be seen here at the 4 hour 59 minute 20 second mark: https://youtu.be/9Jv6JLWCRpE?t=17960</p> <p>Certain alternative forms of collection and disposal systems have been thoroughly reviewed by the San Francisco Department of the Environment. The report summarizes the key findings on page two including absence of any federal agency approval including the DEA and lack of scientific evidence of product performance:</p>	<p>036-Supp.001. A change to the proposed regulatory text is not necessary. CalRecycle will assume that the commenter's position is that products that are currently available that render drugs "inert" are not effective. See response to comment 036-001.</p>

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					https://sfenvironment.org/sites/default/files/fliers/files/overviewmedicinedisposalproducts_21april2017.pdf By reducing the disposal standard to 'inert' versus re-enforcing the already established DEA standard of disposal of 'non-retrievable' creates a strong possibility of impacting community and environmental health.	
037-001	COPALM	Bryan Zaragoza Hurtado	18973.2	N	Provide a detailed outline and expand on strategies on safe disposal options for people experiencing homelessness, disabilities, or are homebound.	037-001. A change to the proposed regulatory text is not necessary. CalRecycle declines to provide additional guidance to program operators. The proposed regulatory text provides flexibility for a program operator to select and propose its own mechanisms to provide preaddressed, prepaid mail-back materials or an alternative form of collection and disposal system requested by ultimate users who are homeless, homebound, or disabled.
037-002a	COPALM	Bryan Zaragoza Hurtado	18973.2 (j)	N	Provide necessary resources and/or opportunities to collaborate with 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.	037-002a. 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.
037-002b	COPALM	Bryan Zaragoza Hurtado	18973.3 (i)	N	Provide necessary resources and/or opportunities to collaborate with 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.	037-002b. 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.
037-003a	COPALM	Bryan Zaragoza Hurtado	18973.2 (j)	N	Provide a detailed overview on different methods to reach retail pharmacies and to ensure participation.	037-003a. A change to the proposed regulatory text is not necessary. Retail pharmacies are independently required to make a reasonable effort to serve as an authorized collector, pursuant to Public Resources Code section 42032.2(b)(2). Additionally, CalRecycle will evaluate the education and outreach plan in each stewardship plan to ensure it adequately promotes and maximizes participation in the stewardship program.

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
037-003b	COPALM	Bryan Zaragoza Hurtado	18973.3 (i)	N	Provide a detailed overview on different methods to reach retail pharmacies and to ensure participation.	037-003b. A change to the proposed regulatory text is not necessary. Retail pharmacies are independently required to make a reasonable effort to serve as an authorized collector, pursuant to Public Resources Code section 42032.2(b)(2). Additionally, CalRecycle will evaluate the education and outreach plan in each stewardship plan to ensure it adequately promotes and maximizes participation in the stewardship program.
037-004a	COPALM	Bryan Zaragoza Hurtado	18973.2 (j)	N	Expanding on outreach plans with specific details on information dissemination strategies to reach the general public.	037-004a. A change to the proposed regulatory text is not necessary. CalRecycle will evaluate the education and outreach plan to ensure it adequately promotes and maximizes participation in the stewardship program. Communication platforms and mediums are constantly evolving. Mandating use of a specific platform or medium may hinder a program's success as it may not reflect future trends. Utilizing broad language in regulations such as "activities to promote awareness and maximize ultimate user participation" in section 18973.2(j)(1) will provide the program operator with the flexibility needed to design a successful education and outreach program.
037-004b	COPALM	Bryan Zaragoza Hurtado	18973.3 (i)	N	Expanding on outreach plans with specific details on information dissemination strategies to reach the general public.	037-004b. A change to the proposed regulatory text is not necessary. CalRecycle will evaluate the education and outreach plan to ensure it adequately promotes and maximizes participation in the stewardship program. Communication platforms and mediums are constantly evolving. Mandating use of a specific platform or medium may hinder a program's success as it may not reflect future trends. Utilizing broad language in regulations such as "activities to promote awareness and maximize ultimate user participation" in section 18973.3(i)(1) will provide the program operator with the flexibility needed to design a successful education and outreach program.
037-005	COPALM	Bryan Zaragoza Hurtado	18973.2 (j)	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.	037-005. 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.
037-006	COPALM	Bryan Zaragoza Hurtado	18973.2 (j)	N	Pharmacies including retailers be required to include printed safe disposal instructions and information for all medications prescribed.	037-006. 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.

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
037-007	COPALM	Bryan Zaragoza Hurtado	18973.2 (j)	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.	037-007. 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.
037-008	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.	037-008. 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.
038-001	PPSWG	Anne Vogel-Marr	18975(a)	N	<p>I. The Revised Language in Section 18975(a) of the Proposed Regulations Is No Longer Consistent with SB 212.</p> <p>The language in section 18975(a) of the Proposed Regulations has been modified such that the administrative civil penalty provision now provides that the Department “shall impose an administrative civil penalty if it determines that a covered entity, program operator, stewardship organization, or authorized collector <i>that</i> sells, offers for sale, or provides a covered product in California <i>has violated</i> this Article or Chapter 2 of Part 3 of Division 30 of the Public Resources Code.” (emphasis added).</p> <p>It is not clear from the record why CalRecycle has made the changes in the emphasized text of the Proposed Regulations copied above; however, the effect is that the Proposed Regulations are no longer consistent with the enforcement authority conferred upon the Department by SB 212 and arguably purport to impermissibly expand the scope of the Department’s enforcement authority. For this reason, the language is invalid as currently drafted and must be revised to align with the scope and intent of enforcement authority that has been conferred by SB 212. <i>PaintCare v. Mortensen</i>, 233 Cal.App.4th 1292, 1306 (2015) (“Regulations that are inconsistent with a statute, alter or amend it, or enlarge or impair its scope are void.”).</p> <p>The enabling language of SB 212 only authorizes the Department to impose an administrative penalty on a “covered entity, program operator, stewardship organization, or authorized collector <i>that sells, offers for sale, or provides a covered product</i> in violation of this chapter [2 to Part</p>	<p>038-001. For purposes of this response, “PRC” refers to the Public Resources Code.</p> <p>The department’s regulations are consistent with the authorizing statute, do not alter or amend it, or enlarge or impair its scope. 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>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</p>

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					<p>3 of Division 30 of the Public Resources Code].” Cal. Public Resources Code § 42035.2(a)(1) (emphasis added). In other words, it is the act of selling, offering or providing a non-compliant covered product that triggers the Department’s authority to initiate an enforcement proceeding assessing administrative penalties. The legislative history on this point corroborates this interpretation: it is only the act of selling a non-complaint product that triggers CalRecycle’s enforcement authority to assess administrative penalties against covered entities. See, Assembly Committee on Environmental Safety and Toxic Materials Bill Analysis, SB 212 – As Amended June 18, 2018. However, the Department’s proposed revisions could now be read as authorizing the assessment of civil penalties for any violation of SB 212 or the Proposed Regulations. This is a clear expansion of the enforcement authority conferred by SB 212, is in direct conflict with the text of SB 212 and, therefore, cannot stand as currently written. As such, section 18975(a) of the Proposed Regulations must be revised to align with SB 212, and should read as follows:</p> <p>(a) Pursuant to section 42035.2(a)(1) of the Public Resources Code, the department shall <u>may</u> impose an administrative civil penalty if it determines that any covered entity, program operator, stewardship organization, or authorized collector that sells, offers for sale, or provides a covered product in California has violated in violation of this Article or Chapter 2 of Part 3 of Division 30 of the Public Resources Code.</p>	<p>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) of the PRC 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</i> is one of the disciplinary actions “the department may take .. against a ... stewardship organization, program operator,” and other entities for failure to provide access to certain required information. For all of the foregoing reasons, 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 references the Assembly Committee on Environmental Safety and Toxic Materials Bill Analysis, SB 212 – (As Amended June 18, 2018). However, the legislative history does not corroborate the commenter’s position. Significant changes to the administrative civil penalties sections in SB 212 were made after the June 18, 2018 version of the bill. The June 18, 2018 version of SB 212 included penalties for \$1,000 and \$5,000 (which were changed) and did not include program operators in the list of entities against which the department can impose penalties. In the August 24, 2018 version of the bill, the legislature deliberately added program operators to the list of entities against which the department may impose penalties. There were no other amendments after this, and SB 212 was signed into law. By adding program operators to the list and keeping stewardship organizations in the list, the legislature intended to authorize the department to impose penalties on program operators and stewardship organizations.</p>

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
						<p>Deletion of the phrase “this Article” is not necessary because the department has authority to impose penalties for violations of the authorizing statute as well as its implementing regulations. 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> <p>The authorizing statute allows for imposition of penalties with the word “may”, and the department has chosen to use the word “shall” in its regulations.</p> <p>The following changes are unnecessary because there is no change in the meaning: deletion of the word “that” and replacement of the phrase “has violated” with “in violation”.</p>
038-002	PPSWG	Anne Vogel-Marr	18975.1	N	<p>II. Revised Administrative Procedures Applicable to Administrative Penalty Actions Proposed at Section 18975.1</p> <p>As raised in its comment letter submitted on August 3, 2020, PPSWG reiterates through this comment letter that it still has concerns with the new administrative procedures that the Department is proposing in Section 18975.1 of the Proposed Regulations, 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> The procedures in Chapter 4.5 of the APA incorporate the 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. This proposed process was consistent with the administrative procedures adopted by the Department for other stewardship programs that it administers. See, e.g., 14 C.C.R. §§ 18945.3 (proceedings to</p>	<p>038-002. 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 comports with minimum due process protections.</p>

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					<p>assess administrative civil penalties under the product stewardship program for carpets are subject to Chapter 5 of the APA), 18955.3(proceedings to assess administrative civil penalties under the architectural paint recovery program are subject to Chapter 5 of the APA), & 18971 (proceedings to assess administrative civil penalties under the used mattress recovery and recycling program are subject to Chapter 4.5 of the APA).</p> <p>For reasons unclear from the rulemaking file, however, the Department has removed all references to the APA in the 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 not only unprecedented, but also extremely scant and fail to address all aspects of an adjudicatory proceeding. Moreover, the proposed procedures 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 to incorporate the administrative procedures established under the APA for clarity, consistency with the Department procedures established under similar EPR programs, and to satisfy minimum due process protections conferred upon respondents to such an enforcement proceeding.</p>	
038-003	PPSWG	Anne Vogel-Marr	General	N	<p>III. Support for Comments Submitted By MED-Project USA Our understanding is that MED-Project USA will be or has submitted comments on the Proposed Regulations. PPSWG supports the comments submitted by MED-Project USA.</p>	038-003. 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 040-001 through 040-006 for CalRecycle's responses to Med-Project USA's comments.
039-001	National Stewardship Action Council	Heidi Sanborn	18972.1 (a)(10)	N	<p>1) Proposed Regulations are Now Consistent 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: <i>"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."</i></p>	039-001. 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 revisions to section 18972.1(a)(10)(C) of the proposed regulations.

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					<p>For purposes of establishing a foundational fact for the comment we are about to make, we'd stress that the authorizing statute simply <u>does not allow</u> 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 <u>prohibited by law</u>.</p> <p>We thank the department for striking the words "or is not reasonably feasible" from lines 5 and 6 of page 3 of the third draft of proposed regulations because they are inconsistent with the authorizing statute and could significantly weaken the program.</p>	
039-002	National Stewardship Action Council	Heidi Sanborn	18975	N	<p>2) Enforcement of Implementation Timeline and Programmatic Requirements</p> <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 believe that the statute and third draft of the regulations provide the department enough authority to enforce the law.</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 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>	039-002. 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.
039-003	National Stewardship Action Council	Heidi Sanborn	18975.2	N	<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>	039-003. This comment is general in nature and does not specify a change to the proposed regulatory text. CalRecycle will utilize its authority under the authorizing statute and its implementing regulations, as appropriate.
039-004	National Stewardship Action Council	Heidi Sanborn	18973.2 (g)(6)(A)	N	<p>3) 18973.2. Stewardship Plan for Covered Drugs Page 11 of 43 Line 33</p> <p>"Section (A) List of locations and/or description of mechanisms to provide ultimate users that are homebound or homeless with preaddressed, prepaid mail-back materials or an alternative form of collection and disposal system, that would render the covered drug inert, if applicable."</p> <p>NSAC encourages CalRecycle to replace 'inert' with 'non-retrievable'. The paragraph establishes a Drug Enforcement Administration compliant standard of operation by utilizing the term 'ultimate user' which is a defined under the Controlled Substances Act (21 U.S.C. 802(27)). The standard for disposal is also defined under the</p>	<p>039-004. A change to the proposed regulatory text is not necessary. CalRecycle acknowledges the commenters concerns, however, Section 18973.2(g)(6)(A) of the proposed regulatory text, including the term "inert", is a statutory requirement found in section 42032.2(a)(1)(G)(i) of the Public Resources Code. 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".</p> <p>The authorizing statute requires that the program operator's stewardship plan and program comply with all applicable federal and state laws and regulations. This applies to an alternative form of a</p>

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					<p>CFR's as 'non-retrievable' (Title 21 CFR §1317.90 (a)). Utilization of the already established DEA standard for compliant destruction offers compliant consistency, ensures collected medications are destroyed, and avoids unintended consequences such as diversion or harmful impacts to the environment.</p> <p>Certain alternative forms of collection and disposal systems have been thoroughly reviewed by the San Francisco Department of the Environment. The report summarizes the key findings on page two including absence of any federal agency approval including the DEA and lack of scientific evidence of product performance: https://sfenvironment.org/sites/default/files/fliers/files/overviewmedicinedisposalproducts_21april2017.pdf</p> <p>By reducing the disposal standard to 'inert' versus re-enforcing the already established DEA standard of disposal of 'non-retrievable' creates a strong possibility of impacting community and environmental health.</p>	collection and disposal system that would render a covered drug "inert" (section 42032.2(a)(1)(G)(i) of the Public Resources Code).
039-005	National Stewardship Action Council	Heidi Sanborn	General	N	We support the 3rd draft of the proposed regulations with the one recommended change of replacing "inert" with "non-retrievable". We are very appreciative that the department has addressed most of our concerns and are doing so in a very timely manner so Californian's can get the program they have been waiting for as soon as possible.	039-005. CalRecycle declines to replace "inert" with "non-retrievable," and the department 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.
040-001	MED-Project USA	Michael R. Van Winkle	18972.1 (a)(9)	N	<p>B. Section 18972.1(a)(9): The Department should define "Point of Sale" to include online retailers that Program Operators identify in their Stewardship Plans.</p> <p>The Department should revise the Proposed Regulations' definition of "Point of Sale" to provide an achievable standard. SB 212 requires Stewardship Plans (as defined in PRC § 42030(x)) 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." PRC 42032.2(d)(1)(F)(i). The Proposed Regulations set the scope of this statutory obligation by defining "Point of Sale" to mean "the point in time at which an ultimate user purchases a covered drug or sharp at a pharmacy or other retailer, including but not limited to an online retailer." Proposed Regulations §18972.1(a)(9).</p> <p>As MED-Project has previously indicated, standards requiring Program Operators to "Provide or Initiate[] Distribution of a Sharps Waste Container and Mail-back Materials" (as defined in Proposed Regulations § 18972.1(a)(10)) to cover the universe of Ultimate Users' "Covered Drug" (as defined in PRC § 42030(e)) and "Sharp" (as defined in PRC § 42030(u)) online transactions are impossible to satisfy. Information identifying all such online retailers (or sales, or transactions, etc.) is simply</p>	040-001. A change to the proposed regulatory text is not necessary. CalRecycle disagrees that it is impossible for a program operator to comply with the "point of sale" requirement over online sales, and the department declines to allow a program operator to identify in its proposed stewardship plan the list of online retailers that will distribute 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 the difficulty for a program operator to obtain information regarding the full scope of online sales, 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.

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					<p>not available. MED-Project has found no evidence of such information being available from the Department, from other governmental entities, or for purchase. This information is also not available from a Program Operator's participating "Covered Entities" (as defined in PRC § 42030(f)), which cannot identify all online retailers selling their own Covered Drugs and Sharps. Even if Program Operators could obtain this information from their participating Covered Entities, they would have no way of identifying the online retailers selling Covered Drugs and Sharps for Covered Entities participating in no Stewardship Plan or a different Stewardship Plan. With Program Operators unable to identify all online retailers, logically, they cannot Provide or Initiate Distribution of a Sharps Waste Containers and Mail-back Materials at the Point of Sale for all of them.</p> <p>To provide "Ultimate Users" (as defined in PRC § 42030(z)) a successful "Stewardship Plan" (as defined in PRC § 42030(y)), the Department should promulgate a Point of Sale definition that provides an attainable standard. Specifically, the Department should require Stewardship Plans to identify each online retailers they will work with to Provide or Initiate Distribution of a Sharps Waste Container and Mail-back Materials. This requirement will allow the Department to confirm each Program Operator has identified and is working with the online retailers necessary to provide Ultimate Users sharps containers and mail-back materials without requiring Program Operators to perform the impossible task of identifying in real time every online retailers selling to Ultimate users on the internet. As revised to make the Point of Sale definition workable, Proposed Regulations (as defined in PRC § 42030(z)) 18972.1(a)(9) should read: "'Point of sale' means the point in time at which an ultimate user purchases a covered drug or sharp at a pharmacy, or other retailer, including but not limited to an online retailer <u>if identified in a program operator's stewardship plan.</u></p>	
040-002	MED-Project USA	Michael R. Van Winkle	18972.1 (a)(10)(B)	N	For the reasons described in its February 17, 2020 and August 3, 2020 comments on prior iterations of the Proposed Regulations, MED-Project supports the Department revising the Proposed Regulations to provide five business days for the arrival of sharps waste containers and mail-back materials sent to an Ultimate User. Because it provides flexibility to account for common carrier delays, this revision will allow Program Operators to arrange for sharps waste containers and mail-back materials to be sent to an Ultimate User.	040-002. 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 support of the revision to five business days in section 18972.1(a)(10)(B) of the proposed regulations.
040-003	MED-Project USA	Michael R. Van Winkle	18972.1 (a)(10)	N	<p>B. Section 18972.1(a)(10): The definition of "Provides or Initiates Distribution of a Sharps Waste Container and Mail-back Materials" should provide flexibility for Program Operators to best serve Ultimate Users.</p> <p>To further promote the most effective services for Ultimate Users, the Department should provide Program Operators flexibility to use other</p>	040-003. CalRecycle declines to adopt the commenter's proposed changes. While the "reasonably feasible" language does add flexibility for program implementation, the department finds that this flexibility may encourage a program operator to claim that the options in sections 18972.1(a)(10)(A) and (B) are not reasonably feasible when that is not actually the case. Program operators cannot design distribution mechanisms for sharps waste containers and mail-back

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					<p>methods to Provide or Initiate Distribution of a Sharps Waste Container and Mail-back Materials when the Proposed Regulations' identified methods are "not reasonably feasible." Prior to the August 2020 draft, the Proposed Regulations provided that the definition of Provides or Initiates Distribution of a Sharps Waste Container and Mail-back Materials includes:</p> <p style="padding-left: 40px;">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 <i>or is not reasonably feasible</i>, and if the method identified in subpart (B) above is not allowed by law <i>or is not reasonably feasible</i>. 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>July 2020 Proposed Regulations § 18972.1(a)(11) (emphasis added). This language - allowing Program Operators to innovate when the identified methods are not reasonably feasible - provided Program Operators the flexibility to best serve Ultimate Users as circumstances change. For example, if some pharmacies refuse to participate in providing or arranging for the delivery of sharps containers and mail-back materials, the "reasonably feasible" language would allow Program Operators to develop other solutions serving Ultimate Users purchasing a Covered Drug or Sharp at those pharmacies. The Department would, of course, have the opportunity to approve any of these solutions to ensure they are convenient for Ultimate Users. See Proposed Regulations § 18972.1(a)(10)(C).</p> <p>The Department correctly explained the need for such flexibility in its Initial Statement of Reasons for this rulemaking, recognizing that "it is impossible for the department to predict which distribution mechanisms may be proposed by program operators, and thus allowing flexibility is crucial for providing ultimate users with the most effective disposal methods while also allowing program operators to implement their stewardship program in a less burdensome manner." CalRecycle, Initial Statement of Reasons for Pharmaceutical and Sharps Waste Stewardship Program Regulations 9 (Dec. 2019). For the very reasons the Department observed, it should reintroduce the "reasonably feasible" language into the definition of Provides or Initiates Distribution of a Sharps Waste Container and Mail-back Materials. For these same reasons, it should also refer to "initiating distribution" of a sharps waste container and mail-back materials in discussing the "other methods" of providing a sharps waste container and mail-back materials. The revised Proposed Regulations§ 18972.1(a)(10)(C) should state as follows:</p>	<p>materials that lower costs at the expense of consumer convenience. Similarly, in the event that both options (A) and (B) are found to be illegal, program operators must still uphold convenience for the ultimate user, which is why the department declines to add the phrase "or initiating distribution" as the commenter suggests. Instead, the department chooses to rely on the term "providing" in subpart (C) which emphasizes greater consumer convenience in any scenario where arranging for delivery of sharps containers at the point of sale or prior is found to be illegal.</p>

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					Other methods of providing <u>or initiating distribution</u> of 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, if the method identified in subpart (A) above is not allowed by law <u>or is not reasonably feasible</u> . and if the method identified in subpart (B) above is not allowed by law <u>or is not reasonably feasible</u> . 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.	
040-004a	MED-Project USA	Michael R. Van Winkle	18973.4 (n)	N	<p>Section 18973.4(n) & 18973.5(q): Requiring the Submission of Actual Expenses by March is Infeasible for Entities that Operate on a Calendar Year.</p> <p>The Department's Proposed Regulations include a new component in the annual reports that must be submitted for Covered Drug and Home-Generated Sharps Waste Stewardship Plans by March 31 of each year: "a list of all actual expenses incurred during the previous reporting period." Proposed Regulations, §§ 18973.4(n) & 18973.5(q).</p> <p>As MED-Project has previously noted, SB 212 limits the Department's authority to requiring additional information in the annual reports, above and beyond that which is already enumerated in the statute, to information that is "reasonably require[d]." Cal. Public Resources Code § 42033.2(b)(9). It is not reasonable to request that audited financials for the previous calendar year be prepared and submitted by March. Because SB 212 does not require or contemplate the submission of actual expenses to the Department on an annual basis, and because requiring such annual expense reporting for a previous calendar year by March is infeasible based on discussions with independent auditors, MED-Project requests that the new proposed language at sections 18973.4(n) and 18973.5(q) be stricken from the Proposed Regulations.</p> <p>Alternatively, if sections 18973.4(n) and 18973.5(q) are not stricken from the Proposed Regulations, MED-Project requests that an alternative deadline - of July 1 - be added to Proposed Regulations, which will provide Program Operators, and their accountants, with the time necessary to compile and prepare the actual expense reports that the Department is seeking.</p>	040-004a. CalRecycle declines the commenter's proposed change. 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. CalRecycle also declines to extend the deadline to submit program expenses to July 1, since including this information along with the annual report is essential for the department to be able to evaluate the annual report and annual program budget effectively. Finally, the authorizing statute requires that on or before March 31, a program operator submit an independent financial audit of the stewardship program as part of an annual program budget (see Public Resources Code, section 42033.2(c)(1)).
040-004b	MED-Project USA	Michael R. Van Winkle	18973.5 (q)	N	<p>Section 18973.4(n) & 18973.5(q): Requiring the Submission of Actual Expenses by March is Infeasible for Entities that Operate on a Calendar Year.</p> <p>The Department's Proposed Regulations include a new component in the annual reports that must be submitted for Covered Drug and Home-Generated Sharps Waste Stewardship Plans by March 31 of each year:</p>	040-004b. CalRecycle declines the commenter's proposed change. 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,

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					<p>"a list of all actual expenses incurred during the previous reporting period." Proposed Regulations, §§ 18973.4(n) & 18973.5(q).</p> <p>As MED-Project has previously noted, SB 212 limits the Department's authority to requiring additional information in the annual reports, above and beyond that which is already enumerated in the statute, to information that is "reasonably require[d]." Cal. Public Resources Code § 42033.2(b)(9). It is not reasonable to request that audited financials for the previous calendar year be prepared and submitted by March. Because SB 212 does not require or contemplate the submission of actual expenses to the Department on an annual basis, and because requiring such annual expense reporting for a previous calendar year by March is infeasible based on discussions with independent auditors, MED-Project requests that the new proposed language at sections 18973.4(n) and 18973.5(q) be stricken from the Proposed Regulations.</p> <p>Alternatively, if sections 18973.4(n) and 18973.5(q) are not stricken from the Proposed Regulations, MED-Project requests that an alternative deadline - of July 1 - be added to Proposed Regulations, which will provide Program Operators, and their accountants, with the time necessary to compile and prepare the actual expense reports that the Department is seeking.</p>	<p>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. CalRecycle also declines to extend the deadline to submit program expenses to July 1, since including this information along with the annual report is essential for the department to be able to evaluate the annual report and annual program budget effectively. Finally, the authorizing statute requires that on or before March 31, a program operator submit an independent financial audit of the stewardship program as part of an annual program budget (see Public Resources Code, section 42033.2(c)(1)).</p>
040-005	MED-Project USA	Michael R. Van Winkle	18975.2 (a)	N	<p>A. Section 18975.2(a) Impermissibly Seeks to Extend the Scope of the Department's Enforcement Authority and Should Be Revised Accordingly.</p> <p>Section 18975.2(a) of the Proposed Regulations has been revised to now read that if the Department finds that an entity "has failed to meet a material requirement of this Article or Chapter 2 of Part 3 of Division 30 of the Public Resources Code, the Department shall, in addition to imposing any civil penalties authorized under this Article and ... the Public Resources Code, take one or all of the [three enumerated actions authorized by SB 212]." (emphasis added).</p> <p>MED-Project objects to the language proposed by the Department in Section 18975.2(a) because it purports to impermissibly grant the agency with broader enforcement powers than the legislature has conferred in SB 212. The language in SB 212 is clear: the legislature only authorized the Department to take one of three enumerated punitive actions against an entity - revocation of a plan, resubmission of a plan or additional reporting - if a finding is made that the entity "has not met a material requirement of this chapter [2 to Part 3 of Division 30 of the Public Resources Code]." Cal. Public Resources Code § 42035.4 (emphasis added). By adding "or of this Article [4 of Chapter 11, Division 7 of Title 14 of the California Code of Regulations]", the Department has impermissibly extended the scope of its enforcement authority to cover alleged noncompliance with</p>	<p>040-005. 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>one of the myriad of additional substantive requirements that have been added to the Pharmaceutical and Sharps Waste Stewardship Program through these regulations. This is improper under the controlling California case law and therefore cannot stand. <i>PaintCare v. Mortensen</i>, 233 Cal.App.4th 1292, 1306 (2015) ("Regulations that are inconsistent with a statute, alter or amend it, or enlarge or impair its scope are void.").</p> <p>Based on the foregoing, Section 18975.2(a) of the Proposed Regulations must be amended to read:</p> <p>(a) If the department finds that a covered entity, program operator, stewardship organization, or authorized collector has failed to meet a material requirement of this Article or Chapter 2 of Part 3 of Division 30 of the Public Resources Code, the department shall, in addition to imposing any civil penalties authorized under this Article and Chapter 2 of Part 3 of Division 30 of the Public Resources Code, take one or all of the following actions:</p> <ol style="list-style-type: none"> (1) Revoke a previously approved stewardship plan, (2) Require resubmittal of the stewardship plan, and/or (3) Require additional reporting, relating to compliance with the material requirement(s) of this Article or Chapter 2 of Part 3 of Division 30 of the Public Resources Code, that was/were not met. 	
040-006	MED-Project USA	Michael R. Van Winkle	18975	N	<p>B. The Administrative Procedures Contained in Section 18975.2(b)-(t) Do Not Satisfy Minimum Due Process Requirements.</p> <p>The Department's Proposed Regulations at Section 18975.2(b) - (f) have not been revised to incorporate 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. MED-Project reiterates the comments provided in its August 3, 2020 comment letter: the Department should revert to the language initially proposed in its first draft proposed regulations issued on January 3, 2020, which incorporated the established procedures governing adjudicative hearings under the California Administrative Procedures Act ("APA"). As stated in our August 3, 2020 comment letter, Section 18975.2(b)-(f) should be revised accordingly, and as follows:</p> <p>(b) Before revoking a previously approved plan, requiring resubmittal of an approved stewardship plan, and/or requiring additional compliance reporting, the department shall issue a written notice to the respondent 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</p>	040-006. 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 comports with minimum due process protections.

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					<p>basis for the <u>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.</u></p> <p>...</p> <p>(d) A program operator <u>respondent</u> may submit to the department a <u>written</u> request for 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, 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>	
041-001	California Product Stewardship Council	Doug Kobold	18972.1 (a)(10)	N	<p>We want to specifically and enthusiastically endorse the changes reflected in this third draft relating to the definition that includes “provides or initiates distribution of a sharps waste container and mail-back materials” as reflected in 18972.1(a)(10). Prior drafts of the regulations would have allowed the sharps stewardship organization(s) to argue that distributing or initiating distribution at the point of sale wasn’t feasible, and instead propose another method. This could have resulted in significantly diminished convenience to the consumer. That was adjusted in the third draft and we support that change enthusiastically.</p> <p>The core of the sharps waste takeback 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 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</p>	041-001. 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 revisions to section 18972.1(a)(10)(C) of the proposed regulations.

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					important requirement. The changes to the third draft will ensure that the sharps waste takeback program operates as intended by SB 212.	
042-001	WM Curbside, LLC	Reggie B Pestano	18973.1 (i)	N	Page 7, Line Number 13. What are considered "significant changes"? They need to be defined to avoid confusion. "Minor" changes also need to be defined if they exist.	042-001. A change to the proposed regulatory text is not necessary. CalRecycle declines to define "minor" or "significant changes". 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 changes to an approved stewardship plan.
042-002	WM Curbside, LLC	Reggie B Pestano	18973.4 (n)	N	Page 27, Line Number 8. What type of expenses? Direct (disposal and transportation) or indirect (office expenses) or both.	042-002. A change to the proposed regulatory text is not necessary. Section 18973.4(n) of the proposed regulatory text references the budget categories in section 18973.6(b); as described in these budget categories, expenses include costs of collection, transportation and disposal of covered products and administrative costs.
042-003	WM Curbside, LLC	Reggie B Pestano	18973.5 (q)	N	Page 31, Line Number 49. What type of expenses? Direct (disposal and transportation) or indirect (office expenses) or both.	042-003. A change to the proposed regulatory text is not necessary. Page 31, line number 49 does not exist in the proposed regulatory text, the department assumes the commenter is referring to page 31, line number 29. Section 18973.5(q) of the proposed regulatory text references the budget categories in section 18973.6(b); as described in these budget categories, expenses include costs of collection, transportation and disposal of covered products and administrative costs.

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

Comment Letter Number:	Comments Submitted By:	Representative Organization: (If Applicable)
033	Larry Kenemore	Stat-Medicament-Disposal Corporation
034	Lindsey Murrile-Hawkins	Sharps Compliance, Incorporated
035	Larry Kenemore	Stat-Medicament-Disposal Corporation
036	David Cali	Covanta
037	Bryan Zaragoza Hurtado	Coalition for Prevention and Awareness in Los Angeles Metro (COPALM)
038	Anne Vogel-Marr	Pharmaceutical Product Stewardship Work Group
039	Heidi Sanborn	National Stewardship Action Council
040	Michael R. Van Winkle	Med-Project USA
041	Doug Kobold	California Product Stewardship Council
042	Reggie B Pestano	Waste Management Curbside, LLC



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**

Stat-Medicament-Disposal Corporation



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

August 25, 2020

CalRecycle

Proposed Regulations Third Draft

Gentlemen;

After review of the Proposed Third Draft of the regulations, below are our recommendations:

18972.1 Definitions are missing for:

- a. Covered entity 033-001A
- b. Authorized Collector 033-001B
- c. Service Provider 033-001C
- d. Program operator 033-001D
- e. Stewardship plan: 033-001E
- f. Supplemental service 033-001F

Without these definitions it is pretty difficult to determine exactly what and how this law is implemented. That is it is left to the whim of any government employee to make that determination or even exclude possible future new inventions that may already be on the horizon? 033-001

J(3)(D) add mechanism to accept requests for a Safe Drug Disposal Kiosk 033-002

(4) add accept requests for Safe Drug Disposal Kiosk 033-003

18973.2 Stewardship Plan for Covered Drugs

(g)(6)(E) Remove word “amount” and/or include weight 033-004

(6)(c) remove words “supplemental service” or have under definitions for “supplemental service” and “main service” 033-005

There is no wording that would include a safe drug disposal kiosk that does not require a service schedule. 033-006

The wording of collection site does not include a safe drug disposal kiosk. 033-007

There should be language differing drop box sites and safe drug disposal kiosks. 033-008

Regards

Larry Kenemore CEO

From: [Lindsey Murrile-Hawkins, BSN, RN, RN-BC](#)
To: [PharmaSharps](#)
Cc: [Regulatory Compliance](#)
Subject: Formal comments to Third Draft Proposed Regulations - SB 212
Date: Wednesday, August 26, 2020 11:05:18 AM
Attachments: [CA SB212 Third Draft Comment Period August 2020.pdf](#)
[SB212 AugustComments.pdf](#)

[[EXTERNAL]]

To Whom It Concerns:

Please accept the attached comments and recommended modifications to the Third Draft Proposed Regulations for 15-day Comment Period, August 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,

Lindsey Murrile-Hawkins, BSN, RN, RN-BC | Clinical Specialist, Regulatory Compliance

Sharps Compliance, Inc. | www.sharpsinc.com
d- 713-660-3572 | o- 800-772-5657 | f- 713-353-1281 | m- 281-714-1165

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.



August 26, 2020

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

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

To Whom It Concerns:

Please accept the attached comments and recommended modifications to the Third 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,

Lindsey Murrile-Hawkins, BSN, RN, RN-BC
Clinical Specialist, Regulatory Compliance
Sharps Compliance, Inc.

LHawkins@sharpsinc.com

www.sharpsinc.com

281-714-1165

www.sharpsinc.com

d 713.432.0300 | t 800.772.5657 | f 713.838.0508

9220 Kirby Drive, Suite 500, Houston, TX 77054



Formal Comments to Proposed Regulations, Third Draft SB212 Pharmaceutical and Sharps Stewardship Program

Comment Period: August 21, 2020 – September 4, 2020

034-001 **Pg. 11 L 33 Proposed regulation:** “List of locations and/or description of mechanisms to provide ultimate users with preaddressed, prepaid mail-back materials or an alternative form of collection and disposal system, that would render the covered drug *inert*, if applicable.”

Issue: The definition of “inert” has been removed and per the California Department of Public Health’s [Medical Waste Management Program](#), pharmaceutical waste generated in California must be treated by incineration, or by an alternative treatment technology that has received approval from the Department. The technologies on the Department’s alternative medical waste treatment technologies list are the only alternative treatments approved for use in California and expressly prohibit use of charcoal/chemical-based decomposition products. Use of such products requires disposal in a pharmaceutical waste container which cannot be placed in municipal solid waste. Furthermore, 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: Remove references allowing use of disposal systems that render drugs inert since these products cannot be placed in municipal solid waste landfills and would have to be coupled with an additional container designed for pharmaceutical waste when routed for incineration. Additionally, the DOT would consider this a hazardous waste, given above, thus require containment compliant for hazardous waste transport and treatment.

034-002 **Pg. 17 L 7 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.

Issue: Who is responsible for determining how many mail-back containers each patient should have and who is responsible for keeping track to ensure patients have the correct amount?

Proposed Regulation: Clarify who is responsible for the determination of distribution of containers and who is tracking the volume of sharps waste containers and mail-back materials to ensure ultimate users have an adequate number of containers.

034-003

Pg. 18 L 1 Proposed Regulation: “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:”

Issue: Would needle clippers meet the definition of supplemental collection method? If allowed, how should needle clippers be disposed of? According to the California [Medical Waste Management Program](#), all sharps waste shall be placed in sharps containers, and, no home generated sharps may be placed into municipal waste containers or recycling containers.

Proposed Regulation: Include language that specifically states whether needle clippers may be utilized by the ultimate user to discard sharps. If it is allowed, include additional language to outline appropriate disposal based upon California’s Department of Health Medical Waste Management Program requirements.

034-004

Pg. 20 L 12 Proposed Regulation: “Materials to be utilized that are distributed in languages suited to local demographics, consistent with section 7295 of the Government Code. These materials shall include, but are not limited to, signage for hospitals, pharmacies, and other locations, as necessary. Signage or labeling for secure collection receptacles shall be designed with explanatory graphics which are readily understandable by all ultimate users.”

Issue: Who determines what a substantial number of the public is in accordance with section 7295 in terms of deciding which languages of each area to translate? Who is making the determination at the individual county level as to what languages the inserts need be translated in?

Proposed Regulation: Include language that outlines the responsible party in determining the languages for each location which need additional translation services. Define what a substantial number of the population would be.

034-005

Pg. 20 L 18 Proposed Regulation: “Establishment of an internet website designed with functionality for mobile platforms, provided with language options suited to local demographics, consistent with section 7295 of the Government Code, and maintained to ensure all information is up to date and accurate. The internet website’s digital content and navigability must be accessible to disabled individuals. The internet website shall include, but is not limited to, the following:”

Issue: Who determines what a substantial number of the public is in accordance with section 7295 in terms of deciding which languages of each area to translate? Who is responsible for disseminating the information?

Proposed Regulation: Clarify who determines the languages necessary for website creation, as well as who is responsible for disseminating the information.

From: [Larry Kenemore Jr.](#)
To: [PharmaSharps](#)
Subject: Recent research Mayo Clinic In-Home Safe Drug Disposal
Date: Friday, August 28, 2020 2:09:07 PM
Attachments: [Research Report In-Home Safe Drug Disposal.png](#)

[[EXTERNAL]]



**FROM THE DESK OF LARRY KENEMORE
MEMBER:**
Board of Directors AEEA Arkansas Environmental Education Association
Rotary Club Siloam Springs Arkansas
Rotary Action Group(RAG) Addiction Prevention(AP)
ESRAG Environmental Sustainability Rotary Action Group
APNet Arkansas Prevention Network
NSAC National Stewardship Action Council
Project WET Trainer
Sierra Club Water Sentinels
Retired Paramedic City of San Diego Fire Department

035-001

**Gentlemen;
Just for your information while rulemaking something to keep in mind.
Larry Kenemore**

NEWS RELEASE

PROVIDING A SAFE IN-HOME DRUG DEACTIVATION SYSTEM FOR UNUSED OPIOID DISPOSAL AT RELEASE FROM THE HOSPITAL POST SURGERY, IS AN OPPORTUNITY TO REDUCE THE COMMUNITY ILLEGAL OPIOID SUPPLY AND HAVE AN IMPACT ON THE OPIOID CRISIS!

August 26, 2020

Research was just completed to determine the impact of a SAFE IN-HOME drug deactivation system provided to post-surgical patients on the rate of opioid prescription disposal.

Of the hundreds of post-operative patients discharged after in-patient surgery at a large academic medical center, the study conducted August 20, 2018, through November 30, 2018 provides data as to In-Home safe-disposal of opioids.

Patients were provided with a in-home drug deactivation system, and an instruction sheet along with their opioid prescription. Up to 4 weeks after dismissal, the patients were surveyed about quantity of opioids remaining, the use of the drug deactivation system or other disposal methods, and satisfaction with the drug disposal system if used.

One hundred forty-nine of 200 (74.5%) patients were surveyed. One hundred six reported leftover opioids and 29 (27.3%) had disposed of these medications.

At the time of survey, 23 (21.2%) participants with leftover opioids had used the drug disposal system to destroy their remaining supply and an additional 33 (31.1%) participants reported plans to use the disposal system on a future date.

Of the 23 participants who used the drug disposal system, 22 (96.0%) reported that they were very satisfied with the disposal process.

RESULTS: More than 79% use In-Home Safe-Drug-Disposal, increasing by 650% drug removal over the current Take-Back program. Participants are willing to use an IN-HOME SAFE-DRUG-DISPOSAL SYSTEM and are satisfied with the process.

Published in PubMed August 17, 2020

INFORMATION PROVIDED BY:

THE ONLY AWARD-WINNING IN-HOME SAFE-DRUG-DISPOSAL PROGRAM IN THE UNITED STATES

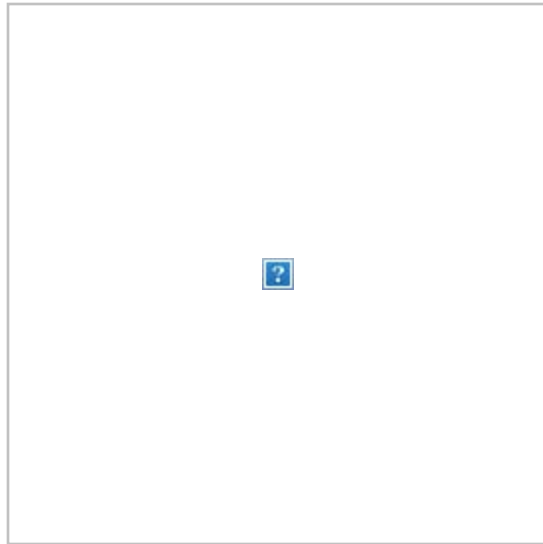
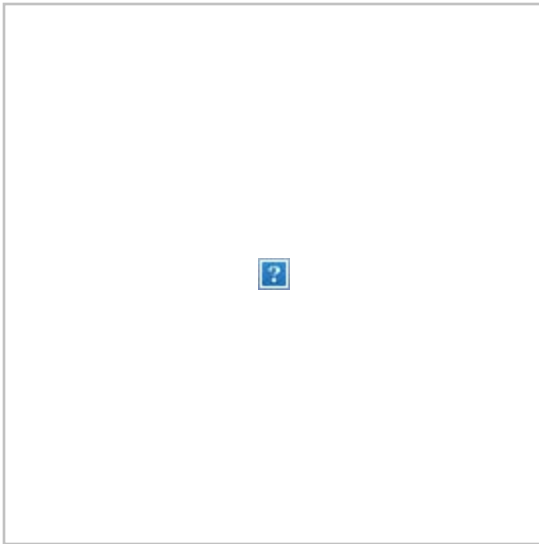
Stat-Medicament-Disposal Corporation (A data driven organization)

<https://statmeddisposal.net> larry5@statmeddisposal.net (855) 873-4965 Ext.6

**Inventor of the ONLY
Award-Winning
Safe-Drug-Disposal Program**

**[CLICK HERE TO
WATCH THE
BOTTLE](#)**

**[CLICK HERE TO
SEE THE ONLY
SAFE DRUG
DISPOSAL KIOSK](#)**



Larry Kenemore 207 Western Hills Dr. Siloam Springs Arkansas 72761

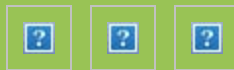
(913) 705-0983

EMAIL ldkjr100@gmail.com

OFFICE (855) 873-4965 Ext.6

CONFIDENTIALITY NOTICE

Copyright 2020 Larry Kenemore, FillAbox Corporation, Stat-Medicament-Disposal Corporation, Winrows Corporation, Greenebank Corporation. The contents of this email message and any attachments are intended solely for the addressee(s) and may contain confidential and/or privileged 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 mail 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.



From: [Cali, David](#)
To: [PharmaSharps](#)
Cc: [Moran, Daniel](#)
Subject: Comments / Senate Bill 212
Date: Tuesday, September 1, 2020 12:03:45 PM
Attachments: [image001.png](#)
[Covanta Comments CalRecycle.pdf](#)

[[EXTERNAL]]

Good afternoon,

Please find the attached comments regarding the implementation of Senate Bill 212.

Kind regards-

David Cali

Director, DEA Compliance - Healthcare Solutions



Cell: 1-571-205-2703

dcali@covanta.com

www.covanta.com

CONFIDENTIALITY AND PRIVACY NOTICE: Information transmitted in this email is proprietary to Covanta and is intended for use only by the individual or entity to which it is addressed. It may contain information that is private, privileged, confidential or exempt from disclosure under applicable law. If you are not the intended recipient or it appears that this mail has been forwarded to you without proper authority, you are notified that any use or dissemination of this information in any manner is strictly prohibited. In such cases, please inform the sender and delete this mail from your records.

September 1, 2020

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
pharmasharps@calrecycle.ca.gov

Re: Senate Bill 212 Proposed Regulations

Mr. Smyth,

On behalf of Covanta, we are honored to actively participate in offering the following comments regarding the implementation of Senate Bill 212. Covanta is the largest owner and operator of Waste-to-Energy facilities which annually convert approximately 21 million tons of waste into enough renewable energy to power more than one million homes and recycle over 600,000 tons of metal. Our destruction services include the receipt and secure destruction of thousands of tons of controlled substances, consumer generated pharmaceuticals via liners and envelopes and regulated medical waste.

Comment:

18973.2. STEWARDSHIP PLAN FOR COVERED DRUGS

Page 11 of 43 Line 33

“Section (A) List of locations and/or description of mechanisms to provide ultimate users with preaddressed, prepaid mail-back materials or an alternative form of collection and disposal system, that would render the covered drug inert, if applicable.”

Covanta encourages CalRecycle to replace ‘inert’ with ‘non-retrievable’. The paragraph establishes a Drug Enforcement Administration compliant standard of operation by utilizing the term ‘ultimate user’ which is defined under the Controlled Substances Act (21 U.S.C. 802(27)). The standard for disposal is also defined under the CFR’s as ‘non-retrievable’ (Title 21 CFR §1317.90 (a)). Utilization of the already established DEA standard for compliant destruction offers compliant consistency, ensures collected medications are destroyed, and avoids unintended consequences such as diversion or harmful impacts to the environment.

Covanta maintains over 25 years of experience destroying controlled substances and pharmaceutical waste. Over this time, Covanta has worked in collaboration with the DEA to determine the most compliant method of destruction. Covanta has determined that if a diversion event occurred that used a method other than incineration, there would likely be enforcement activity initiated by the DEA as the alternative disposal method does not achieve the regulatory standard for destruction.

036-001

Third Party Analysis

While Congress was investigating 'H.R.6 - SUPPORT for Patients and Communities Act', one alternative collection company discussed under oath to Congressman Latta that the disposal system can be reverse engineered utilizing vodka. The testimony can be seen here at the 4 hour 59 minute 20 second mark:

<https://youtu.be/9Jv6JLWCRpE?t=17960>

Certain alternative forms of collection and disposal systems have been thoroughly reviewed by the San Francisco Department of the Environment. The report summarizes the key findings on page two including absence of any federal agency approval including the DEA and lack of scientific evidence of product performance:

https://sfenvironment.org/sites/default/files/fliers/files/overviewmedicinedisposalproducts_21april2017.pdf

By reducing the disposal standard to 'inert' versus re-enforcing the already established DEA standard of disposal of 'non-retrievable' creates a strong possibility of impacting community and environmental health.

Thank you for your consideration.



David Cali
Director, DEA Compliance – Healthcare Solutions

From: [CoPALM](#)
To: [PharmaSharps](#)
Subject: CoPALM- Written Public Comment Period for the Third Draft Proposed Regulations
Date: Thursday, September 3, 2020 11:59:47 AM
Attachments: [CoPALM Rx-Third Public Comment SB212 \(1\).pdf](#)

[[EXTERNAL]]

Hello,

Attached is the written public comment for the third draft of the proposed regulations.

Thank you,

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



September 4, 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:

- Provide a detailed outline and expand on strategies on safe disposal options for people experiencing homelessness, disabilities, or are homebound. 037-001
- Provide necessary resources and/or opportunities to collaborate with 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. 037-002a
037-002b
- Provide a detailed overview on different methods to reach retail pharmacies and to ensure participation. 037-003a
037-003b

- Expanding on outreach plans with specific details on information dissemination strategies to reach the general public. 037-004a
037-004b
- 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. 037-005
- Pharmacies including retailers be required to include printed safe disposal instructions and information for all medications prescribed. 037-006

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. 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. 037-007
037-008

Sincerely,

Bryan Zaragoza Hurtado
CoPALM Chair

From: [Anne Vogel Marr](#)
To: [PharmaSharps](#)
Subject: Subject: PPSWG Comments on CalRecycle's Third Draft of the Proposed Pharmaceutical and Sharps Waste Stewardship Program Regulations
Date: Friday, September 4, 2020 5:11:23 AM
Attachments: [image001.png](#)
[image002.png](#)
[2020-09-04 PPSWG Comments on California Rulemaking.pdf](#)

[[EXTERNAL]]

September 4, 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 third draft proposed Pharmaceutical and Sharps Waste Stewardship Program regulations, which revise the second draft of the proposed regulations issued on July 14, 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



September 4, 2020

VIA EMAIL AT pharmasharps@calrecycle.ca.gov

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 Third 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”) third draft proposed Pharmaceutical and Sharps Waste Stewardship Program regulations (the “Proposed Regulations”), which revise the second draft of the proposed regulations issued on July 14, 2020.

038-001 **I. The Revised Language in Section 18975(a) of the Proposed Regulations Is No Longer Consistent with SB 212.**

The language in section 18975(a) of the Proposed Regulations has been modified such that the administrative civil penalty provision now provides that the Department “shall impose an administrative civil penalty if it determines that a covered entity, program operator, stewardship organization, or authorized collector *that* sells, offers for sale, or provides a covered product in California *has violated* this Article or Chapter 2 of Part 3 of Division 30 of the Public Resources Code.” (emphasis added).

It is not clear from the record why CalRecycle has made the changes in the emphasized text of the Proposed Regulations copied above; however, the effect is that the Proposed Regulations are no longer consistent with the enforcement authority conferred upon the Department by SB 212 and arguably purport to impermissibly expand the scope of the Department’s enforcement authority. For this reason, the language is invalid as currently drafted and must be revised to align with the scope and intent of enforcement authority that has been conferred by SB 212. *PaintCare v. Mortensen*, 233 Cal.App.4th 1292, 1306 (2015) (“Regulations that are inconsistent with a statute, alter or amend it, or enlarge or impair its scope are void.”).

The enabling language of SB 212 only authorizes the Department to impose an administrative 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 [2 to Part 3 of Division 30 of the Public Resources Code].” Cal. Public Resources Code § 42035.2(a)(1) (emphasis added). In other words, it is the act of selling, offering or providing a non-compliant covered product that triggers the Department’s authority to initiate an enforcement proceeding assessing administrative penalties. The legislative history on this point corroborates this interpretation: it is only the act of selling a non-complaint product that triggers CalRecycle’s enforcement authority to assess administrative penalties against covered entities. See, Assembly Committee on Environmental Safety and Toxic Materials Bill Analysis, SB 212 – As Amended June 18, 2018. However, the Department’s proposed revisions could now be read as authorizing the assessment of civil penalties for any violation of SB 212 or the Proposed Regulations. This is a clear expansion of the enforcement authority conferred by SB 212, is in direct conflict with the text of SB 212 and, therefore, cannot stand as currently written. As such, section 18975(a) of the Proposed Regulations must be revised to align with SB 212, and should read as follows:

(a) Pursuant to section 42035.2(a)(1) of the Public Resources Code, the department shall may impose an administrative civil penalty if it determines that any covered entity, program operator, stewardship organization, or authorized collector that sells, offers for sale, or provides a covered product in California has violated in violation of this Article or Chapter 2 of Part 3 of Division 30 of the Public Resources Code.

038-002 II. **Revised Administrative Procedures Applicable to Administrative Penalty Actions Proposed at Section 18975.1**

As raised in its comment letter submitted on August 3, 2020, PPSWG reiterates through this comment letter that it still has concerns with the new administrative procedures that the Department is proposing in Section 18975.1 of the Proposed Regulations, 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.* The procedures in Chapter 4.5 of the APA incorporate the 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. This proposed process was consistent with the administrative procedures adopted by the Department for other stewardship programs that it administers. See, e.g., 14 C.C.R. §§ 18945.3 (proceedings to assess administrative civil penalties under the product stewardship program for carpets are subject to Chapter 5 of the APA), 18955.3

(proceedings to assess administrative civil penalties under the architectural paint recovery program are subject to Chapter 5 of the APA), & 18971 (proceedings to assess administrative civil penalties under the used mattress recovery and recycling program are subject to Chapter 4.5 of the APA).

For reasons unclear from the rulemaking file, however, the Department has removed all references to the APA in the 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 not only unprecedented, but also extremely scant and fail to address all aspects of an adjudicatory proceeding. Moreover, the proposed procedures 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 to incorporate the administrative procedures established under the APA for clarity, consistency with the Department procedures established under similar EPR programs, and to satisfy minimum due process protections conferred upon respondents to such an enforcement proceeding.

038-003 **III. Support for Comments Submitted By MED-Project USA**

Our understanding is that MED-Project USA will be or has submitted comments on the Proposed Regulations. 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 Proposed Regulations and the implementation of SB 212.

Respectfully submitted,



Anne Vogel-Marr
Executive Director

From: [Heidi Sanborn](#)
To: [PharmaSharps](#)
Cc: [Jason Schmelzer](#); [Priscilla Quiroz](#)
Subject: NSAC Final Comment Letter on 3rd Draft SB 212 regulations
Date: Friday, September 4, 2020 11:33:06 AM
Attachments: [NSAC Comment Letter 3rd SB 212 regs FINAL 9-4-2020.pdf](#)

[[EXTERNAL]]

Dear CalRecycle Staff:

Thank you for working so hard on these regulations! We are very grateful.

See the letter attached and please feel free to contact me if you have any questions.

Have a great long weekend!

Heidi

Heidi Sanborn | Executive Director



Standing for environmental and social justice.

C: (916) 217-1109 | heidi@nsaction.us





**NATIONAL
STEWARDSHIP
ACTION COUNCIL**

ADVOCATING FOR A CIRCULAR ECONOMY

1822 21st Street, Suite 200
Sacramento, CA 95811
(916) 431-7804
nsaction.us

September 4, 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: Comments on Third Draft Proposed Regulations (August 2020)
Pharmaceutical and Sharps Waste Stewardship Program**

Dear Mr. Smyth,

The National Stewardship Action Council (NSAC) would like to thank you for the opportunity to submit comments on the most recent draft of proposed regulations to implement the Pharmaceutical and Sharps Waste Stewardship Program established by SB 212 (2018 - Jackson, Ting, and Gray).

In short, we support the changes in the third draft of the regulations with one minor but important change. We greatly appreciate the Department's addressing our concerns on the distribution of sharps containers raised in our prior comment letter.

Below, we have provided several comments on specific portions of the regulations.

1) Proposed Regulations are Now Consistent 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.

039-001 **We thank the department for striking the words “or is not reasonably feasible” from lines 5 and 6 of page 3 of the third draft** of proposed regulations because they are inconsistent with the authorizing statute and could significantly weaken the program.

2) 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 believe that the statute and third draft of the regulations provide the department enough authority to enforce the law.**

039-002

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.

039-003

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.

039-004

3) 18973.2. Stewardship Plan for Covered Drugs Page 11 of 43 Line 33

“Section (A) List of locations and/or description of mechanisms to provide ultimate users that are homebound or homeless with preaddressed, prepaid mail-back materials or an alternative form of collection and disposal system, that would render the covered drug **inert**, if applicable.”

NSAC encourages CalRecycle to replace ‘inert’ with ‘non-retrievable’. The paragraph establishes a Drug Enforcement Administration compliant standard of operation by utilizing the term ‘ultimate user’ which is defined under the Controlled Substances Act (21 U.S.C. 802(27)). **The standard for disposal is also defined under the CFR’s as ‘non-retrievable’** (Title 21 CFR §1317.90 (a)). Utilization of the already established DEA standard for compliant destruction offers compliant consistency, ensures collected medications are destroyed, and avoids unintended consequences such as diversion or harmful impacts to the environment.

Certain alternative forms of collection and disposal systems have been thoroughly reviewed by the San Francisco Department of the Environment. The report summarizes the key findings on page two including absence of any federal agency approval including the DEA and lack of scientific evidence of product performance:

https://sfenvironment.org/sites/default/files/fliers/files/overviewmedicinedisposalproducts_21april2017.pdf

By reducing the disposal standard to **'inert' versus** re-enforcing the already established DEA standard of disposal of **'non-retrievable'** creates a strong possibility of impacting community and environmental health.

Conclusion

039-005

We support the 3rd draft of the proposed regulations with the one recommended change of replacing “inert” with “non-retrievable”. We are very appreciative that the department has addressed most of our concerns and are doing so in a very timely manner so Californian’s can get the program they have been waiting for as soon as possible.

Sincerely,



Heidi Sanborn, Executive Director
National Stewardship Action Council

From: [Jim Wilson](#)
To: [PharmaSharps](#); [Smyth, Jason@CalRecycle](#); [MED-Project \(California\)](#)
Cc: [Michael Van Winkle](#); [Victoria Travis](#)
Subject: MED-Project USA Comments on the Third Draft of the Proposed Pharmaceutical and Sharps Waste Stewardship Program
Date: Friday, September 4, 2020 4:34:36 PM
Attachments: [image001.png](#)
[MED-Project Comments on Third Draft Pharmaceutical and Sharps Waste Stewardship Proposed Regulations 09.04.2020.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 third draft of the Proposed Pharmaceutical and Sharps Waste Stewardship Program Regulations issued on August 21, 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.

September 4, 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 Third 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”) third draft proposed Pharmaceutical and Sharps Waste Stewardship Program regulations (the “Proposed Regulations”), which revise the second draft of the proposed regulations issued on July 14, 2020. 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 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 Proposed Regulations. Thank you for considering these comments and MED-Project’s other comments throughout this rulemaking process.

I. DEFINITIONS

A. Section 18972.1(a)(9): The Department should define “Point of Sale” to include online retailers that Program Operators identify in their Stewardship Plans.

The Department should revise the Proposed Regulations’ definition of “Point of Sale” to provide an achievable standard. SB 212 requires Stewardship Plans (as defined in PRC § 42030(x)) 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.” PRC § 42032.2(d)(1)(F)(i). The Proposed Regulations set the scope of this statutory obligation by defining “Point of Sale” to mean “the point in time at which an ultimate user purchases a covered drug or sharp at a pharmacy or other retailer, including but not limited to an online retailer.” Proposed Regulations § 18972.1(a)(9).

As MED-Project has previously indicated, standards requiring Program Operators to “Provide or Initiate[] Distribution of a Sharps Waste Container and Mail-back Materials” (as defined in Proposed Regulations § 18972.1(a)(10)) to cover the universe of Ultimate Users’ “Covered Drug” (as defined in PRC § 42030(e)) and “Sharp” (as defined in PRC § 42030(u)) online transactions are impossible to satisfy. Information identifying all such online retailers (or sales, or transactions, etc.) is simply not available. MED-Project has found no evidence of such information being available from the Department, from other governmental entities, or for purchase. This information is also not available from a Program Operator’s participating “Covered Entities” (as defined in PRC § 42030(f)), which cannot identify all online retailers selling their own Covered Drugs and Sharps. Even if Program Operators could obtain this information from their participating Covered Entities, they would have no way of identifying the online retailers selling Covered Drugs and Sharps for Covered Entities participating in no Stewardship Plan or a different Stewardship Plan. With Program Operators unable to identify all online retailers, logically, they cannot Provide or Initiate Distribution of a Sharps Waste Container and Mail-back Materials at the Point of Sale for all of them.

To provide “Ultimate Users” (as defined in PRC § 42030(z)) a successful “Stewardship Program” (as defined in PRC § 42030(y)), the Department should promulgate a Point of Sale definition that provides an attainable standard. Specifically, the Department should require Stewardship Plans to identify each online retailer they will work with to Provide or Initiate Distribution of a Sharps Waste Container and Mail-back Materials. This requirement will allow the Department to confirm each Program Operator has identified and is working with the online retailers necessary to provide Ultimate Users sharps containers and mail-back materials without requiring Program Operators to perform the impossible task of identifying in real time every online retailer selling to Ultimate Users on the internet. As revised to make the Point of Sale definition workable, Proposed Regulations § 18972.1(a)(9) should read: “‘Point of sale’ means the point in time at which an ultimate user purchases a covered drug or sharp at a pharmacy, or other retailer,

including but not limited to an online retailer if identified in a program operator’s stewardship plan.

B. Section 18972.1(a)(10): The definition of “Provides or Initiates Distribution of a Sharps Waste Container and Mail-back Materials” should provide flexibility for Program Operators to best serve Ultimate Users.

040-002

For the reasons described in its February 17, 2020 and August 3, 2020 comments on prior iterations of the Proposed Regulations, MED-Project supports the Department revising the Proposed Regulations to provide five business days for the arrival of sharps waste containers and mail-back materials sent to an Ultimate User. Because it provides flexibility to account for common carrier delays, this revision will allow Program Operators to arrange for sharps waste containers and mail-back materials to be sent to an Ultimate User.

040-003

To further promote the most effective services for Ultimate Users, the Department should provide Program Operators flexibility to use other methods to Provide or Initiate Distribution of a Sharps Waste Container and Mail-back Materials when the Proposed Regulations’ identified methods are “not reasonably feasible.” Prior to the August 2020 draft, the Proposed Regulations provided that the definition of Provides or Initiates Distribution of a Sharps Waste Container and Mail-back Materials includes:

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.

July 2020 Proposed Regulations § 18972.1(a)(11) (emphasis added). This language – allowing Program Operators to innovate when the identified methods are not reasonably feasible – provided Program Operators the flexibility to best serve Ultimate Users as circumstances change. For example, if some pharmacies refuse to participate in providing or arranging for the delivery of sharps containers and mail-back materials, the “reasonably feasible” language would allow Program Operators to develop other solutions serving Ultimate Users purchasing a Covered Drug or Sharp at those pharmacies. The Department would, of course, have the opportunity to approve any of these solutions to ensure they are convenient for Ultimate Users. *See Proposed Regulations § 18972.1(a)(10)(C).*

The Department correctly explained the need for such flexibility in its Initial Statement of Reasons for this rulemaking, recognizing that “it is impossible for the department to predict which distribution mechanisms may be proposed by program operators, and thus allowing flexibility is

crucial for providing ultimate users with the most effective disposal methods while also allowing program operators to implement their stewardship program in a less burdensome manner.” CalRecycle, Initial Statement of Reasons for Pharmaceutical and Sharps Waste Stewardship Program Regulations 9 (Dec. 2019). For the very reasons the Department observed, it should reintroduce the “reasonably feasible” language into the definition of Provides or Initiates Distribution of a Sharps Waste Container and Mail-back Materials. For these same reasons, it should also refer to “initiating distribution” of a sharps waste container and mail-back materials in discussing the “other methods” of providing a sharps waste container and mail-back materials. The revised Proposed Regulations § 18972.1(a)(10)(C) should state as follows:

Other methods of providing or initiating distribution of 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, 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.

II. ANNUAL REPORTING

A. **Section 18973.4(n) & 18973.5(q): Requiring the Submission of Actual Expenses by March is Infeasible for Entities that Operate on a Calendar Year.**

The Department’s Proposed Regulations include a new component in the annual reports that must be submitted for Covered Drug and Home-Generated Sharps Waste Stewardship Plans by March 31 of each year: “a list of all actual expenses incurred during the previous reporting period.” Proposed Regulations, §§ 18973.4(n) & 18973.5(q).

As MED-Project has previously noted, SB 212 limits the Department’s authority to requiring additional information in the annual reports, above and beyond that which is already enumerated in the statute, to information that is “reasonably require[d].” Cal. Public Resources Code § 42033.2(b)(9). It is not reasonable to request that audited financials for the previous calendar year be prepared and submitted by March. Because SB 212 does not require or contemplate the submission of actual expenses to the Department on an annual basis, and because requiring such annual expense reporting for a previous calendar year by March is infeasible based on discussions with independent auditors, MED-Project requests that the new proposed language at sections 18973.4(n) and 18973.5(q) be stricken from the Proposed Regulations.

Alternatively, if sections 18973.4(n) and 18973.5(q) are not stricken from the Proposed Regulations, MED-Project requests that an alternative deadline – of July 1 – be added to Proposed

Regulations, which will provide Program Operators, and their accountants, with the time necessary to compile and prepare the actual expense reports that the Department is seeking.

040-005 **III. ADMINISTRATIVE PROCEDURES**

A. Section 18975.2(a) Impermissibly Seeks to Extend the Scope of the Department’s Enforcement Authority and Should Be Revised Accordingly.

Section 18975.2(a) of the Proposed Regulations has been revised to now read that if the Department finds that an entity “has failed to meet a material requirement *of this Article or* Chapter 2 of Part 3 of Division 30 of the Public Resources Code, the Department shall, in addition to imposing any civil penalties authorized *under this Article and* ... the Public Resources Code, take one or all of the [three enumerated actions authorized by SB 212].” (emphasis added).

MED-Project objects to the language proposed by the Department in Section 18975.2(a) because it purports to impermissibly grant the agency with broader enforcement powers than the legislature has conferred in SB 212. The language in SB 212 is clear: the legislature only authorized the Department to take one of three enumerated punitive actions against an entity – revocation of a plan, resubmission of a plan or additional reporting – if a finding is made that the entity “has not met a material requirement *of this chapter* [2 to Part 3 of Division 30 of the Public Resources Code].” Cal. Public Resources Code § 42035.4 (emphasis added). By adding “or of this Article [4 of Chapter 11, Division 7 of Title 14 of the California Code of Regulations]”, the Department has impermissibly extended the scope of its enforcement authority to cover alleged noncompliance with one of the myriad of additional substantive requirements that have been added to the Pharmaceutical and Sharps Waste Stewardship Program through these regulations. This is improper under the controlling California case law and therefore cannot stand. *PaintCare v. Mortensen*, 233 Cal.App.4th 1292, 1306 (2015) (“Regulations that are inconsistent with a statute, alter or amend it, or enlarge or impair its scope are void.”).

Based on the foregoing, Section 18975.2(a) of the Proposed Regulations must be amended to read:

(a) If the department finds that a covered entity, program operator, stewardship organization, or authorized collector has failed to meet a material requirement of ~~this Article or~~ Chapter 2 of Part 3 of Division 30 of the Public Resources Code, the department shall, in addition to imposing any civil penalties authorized under ~~this Article and~~ Chapter 2 of Part 3 of Division 30 of the Public Resources Code, take one or all of the following actions:

- (1) Revoke a previously approved stewardship plan,
- (2) Require resubmittal of the stewardship plan, and/or

(3) Require additional reporting, relating to compliance with the material requirement(s) ~~of this Article or~~ Chapter 2 of Part 3 of Division 30 of the Public Resources Code, that was/were not met.

040-006

B. The Administrative Procedures Contained in Section 18975.2(b)-(f) Do Not Satisfy Minimum Due Process Requirements.

The Department’s Proposed Regulations at Section 18975.2(b) – (f) have not been revised to incorporate 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. MED-Project reiterates the comments provided in its August 3, 2020 comment letter: the Department should revert to the language initially proposed in its first draft proposed regulations issued on January 3, 2020, which incorporated the established procedures governing adjudicative hearings under the California Administrative Procedures Act (“APA”). As stated in our August 3, 2020 comment letter, Section 18975.2(b)-(f) should be revised accordingly, and as follows:

(b) Before revoking a previously approved plan, requiring resubmittal of an approved stewardship plan, and/or requiring additional compliance reporting, the department shall issue a written notice to the respondent 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 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 respondent may submit to the department a written request for 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 Proposed Regulations going forward.

Sincerely yours,



Michael R. Van Winkle
Executive Director

From: [Doug Kobold](#)
To: [PharmaSharps](#)
Cc: [Jason Schmelzer](#); [Priscilla Quiroz](#); [Joanne Brasch](#); [Nate Pelczar](#)
Subject: CPSC Comment Letter for Third Draft of SB 212 Regulations
Date: Friday, September 4, 2020 4:36:03 PM
Attachments: [SB212 Reg Comments - Third Draft - CPSC Comments.pdf](#)

[[EXTERNAL]]

Jason & PharmaSharps Team,

Thank you for the opportunity to comment on the Third Draft of the SB 212 Regulations.
Excellent Job on this regs package!

Have a great holiday weekend!

Respectfully;

Doug Kobold | Executive Director

1535046002576_cpsc.png



1822 21st Street, Suite 100
Sacramento, CA 95811

O: [\(916\) 706-3420](tel:(916)706-3420) | C: [\(916\) 413-5262](tel:(916)413-5262)

Doug@calpsc.org

September 4, 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: Third Draft Proposed Regulations
Pharmaceutical and Sharps Waste Stewardship Program

Dear Mr. Smyth,

Thank you for the opportunity to submit comments on the third 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 look forward to the swift and successful implementation of this program.

As we near the end of the regulatory process, we'd like to thank you for an open and collaborative process. We have appreciated the opportunity to comment on multiple drafts of the regulations over the last roughly two years, from pre-rulemaking workshops to formal rulemaking proceedings. We think the department's process has produced a solid foundation upon which to implement the California statewide unused/unwanted medicines and used sharps/needles takeback programs.

041-001 We want to specifically and enthusiastically endorse the changes reflected in this third draft relating to the definition that includes "provides or initiates distribution of a sharps waste container and mail-back materials" as reflected in 18972.1(a)(10). Prior drafts of the regulations would have allowed the sharps stewardship organization(s) to argue that distributing or initiating distribution at the point of sale wasn't feasible, and instead propose another method. This could have resulted in significantly diminished convenience to the consumer. That was adjusted in the third draft and we support that change enthusiastically.

The core of the sharps waste takeback 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 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. The changes to the third draft will ensure that the sharps waste takeback program operates as intended by SB 212.

Again, thank you for CalRecycle's openness and collaboration throughout the rulemaking process. As one of the sponsors of SB 212 (Jackson, Ting, and Gray) we believe that the regulations will result in a program with the convenience needed by the consumer while also giving a clear path to compliance for producers.

Please feel free to contact me by phone at 916-413-5262 or by email at Doug@calpsc.org if you have any questions.

Respectfully,



Doug Kobold
Executive Director

From: [Pestano, Regalado](#)
To: [PharmaSharps](#)
Subject: 3rd Draft Comments
Date: Wednesday, September 9, 2020 2:13:58 PM
Attachments: [STEWARSHIP PROGRAM - COMMENTS 9-9-20.xlsx](#)

[[EXTERNAL]]

Attached are my 3rd draft comments. I only focus on the changes and did not repeat my comments from the 2nd draft.

Thanks.

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.

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

PAGE	LINE NUMBER	COMMENT/QUESTIONS	
7	13	What are considered "significant changes"? They need to be defined to avoid confusion. "Minor " changes also need to be defined if they exist.	042-001
27	8	What type of expenses? Direct (disposal and transportation) or indirect (office expenses) or both.	042-002
31	49	What type of expenses? Direct (disposal and transportation) or indirect (office expenses) or both.	042-003

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

Christopher Lester Comment and CalRecycle Response:

Summary: Christopher Lester, from San Francisco Department of the Environment, asked if a particular product would be considered a sharp under the authorizing statute and regulations. CalRecycle held a meeting with the stakeholder following the second 15-day comment period. A response to the comment is not necessary because the commenter's question did not relate to the proposed regulatory text and is not relevant. A change to proposed text is not necessary.

Jim Wilson Question and CalRecycle Response:

Summary: Jim Wilson, from MED-Project, asked if comments submitted during the first 15-day comment period and CalRecycle responses will be available to view. CalRecycle responded with the following: "Comments received during the comment period that concluded on August 3rd 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".

From: Lester, Christopher (ENV) <christopher.lester@sfgov.org>
Sent: Monday, August 24, 2020 6:08 PM
To: Smyth, Jason@CalRecycle <Jason.Smyth@CalRecycle.ca.gov>
Cc: Dunn, Cynthia@CalRecycle <Cynthia.Dunn@CalRecycle.ca.gov>; Kaminer, Irina@CalRecycle <Irina.Kaminer@calrecycle.ca.gov>; PharmaSharps <PharmaSharps@calrecycle.ca.gov>; Johnson, Margaret (ENV) <margaret.johnson@sfgov.org>
Subject: RE: Meds/sharps questions

Hi Jason,

Looks like I missed your call earlier this afternoon. Sorry we couldn't connect. And thanks for getting back to me so quickly.

Following up on the voice message I left, our question pertains to a specific sharps-type product we recently encountered and whether it will be covered under the SB 212 sharps mail-back program. Here are details:

The device is called [Dexcom G6](#), which is a continuous glucose monitoring (CGM) system. As part of the system, the patient uses a sharps-containing device – called an applicator – to apply the glucose sensor patch to their body. Paraphrasing language from the [FDA](#), the applicator contains an “introducer needle” that installs the “sensor probe” (microtube) under the skin, then retracts back into the applicator. CDPH advised that we should consider the applicator a sharp.

Our understanding is that a typical user will generate at least 1 applicator per month because it's one-time use and the sensor patch is changed monthly. Dexcom does not offer patients a mail-back option based on our research, so we anticipate this and similar devices becoming a substantial waste stream over time. One resident who brought the product to our attention had 45 applicators to get rid of and will continue generating them while using the system.

We'd appreciate CalRecycle's guidance on whether the applicator will be covered under the statewide sharps program. It's a prime candidate for an EPR approach in our view.

Regarding scheduling, we have availability tomorrow, Wednesday and next week as well:

- Tomorrow – 9:30 AM, anytime 3:30 PM and after
- Wednesday – 10 AM, anytime 12:30 to 2 PM, 4 PM and after

Thanks in advance for your help on this.

Sincerely,
Chris

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

SFEEnvironment.org | [Get Involved, Stay Connected](#)

Please consider the environment before printing this email.

From: Smyth, Jason@CalRecycle <Jason.Smyth@CalRecycle.ca.gov>
Sent: Monday, August 24, 2020 3:05 PM
To: Lester, Christopher (ENV) <christopher.lester@sfgov.org>
Cc: Dunn, Cynthia@CalRecycle <Cynthia.Dunn@CalRecycle.ca.gov>; Kaminer, Irina@CalRecycle <Irina.Kaminer@calrecycle.ca.gov>; PharmaSharps <PharmaSharps@calrecycle.ca.gov>
Subject: RE: Meds/sharps questions

This message is from outside the City email system. Do not open links or attachments from untrusted

Hi Chris,

Certainly! It sounds like you already have a sense of the questions. Can they be sent in advance so we can prepare?

The 15-day formal comment period for our third draft proposed regulations is active and causes some limitations on the types of conversations we can have prior to the end of the comment period (midnight 9/4). Let's aim for tomorrow or Wednesday afternoon if we think we can hold the conversation after reviewing the questions. Otherwise, does the week after 9/4 work for your needs?

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: Lester, Christopher (ENV) <christopher.lester@sfgov.org>
Sent: Monday, August 24, 2020 2:33 PM
To: Smyth, Jason@CalRecycle <Jason.Smyth@CalRecycle.ca.gov>
Subject: Meds/sharps questions

[[EXTERNAL]]

Hi Jason,

I hope you're well. Maggie and I have two medicine/sharps stewardship related questions we'd like to run by you.

Are you available for a quick call this week? I don't anticipate needing more than 15-20 minutes.

Thanks

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

SFEvironment.org | [Get Involved, Stay Connected](#)

Please consider the environment before printing this email.

From: PharmaSharps <PharmaSharps@calrecycle.ca.gov>
Sent: Monday, August 24, 2020 10:31 AM
To: 'Jim Wilson' <jwilson@med-project.org>
Cc: MED-Project (California) <California@med-project.org>; PharmaSharps <PharmaSharps@calrecycle.ca.gov>
Subject: RE: Public Review of Comments Posted on the Second Draft of the Proposed Pharmaceutical and Sharps Waste Stewardship Program Regulations

Good Morning Jim,

Comments received during the comment period that concluded on August 3rd 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.

Thank you for your participation in the rulemaking process.

The CalRecycle Pharmaceutical & Sharps Team

Website | <https://www.calrecycle.ca.gov/epr/pharmasharps>

Listserv | <https://www2.calrecycle.ca.gov/Listservs/Subscribe/73>

From: Jim Wilson <jwilson@med-project.org>
Sent: Saturday, August 22, 2020 10:49 AM
To: Smyth, Jason@CalRecycle <Jason.Smyth@CalRecycle.ca.gov>; PharmaSharps <PharmaSharps@calrecycle.ca.gov>
Cc: MED-Project (California) <California@med-project.org>
Subject: Public Review of Comments Posted on the Second Draft of the Proposed Pharmaceutical and Sharps Waste Stewardship Program Regulations

[[EXTERNAL]]

Dear Mr. Smyth,

MED-Project USA submitted 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. Will the submitted comments that were due to CalRecycle on August 3 be made available to the public on CalRecycle's website? If so, when do you anticipate the comments will be available for review?

Thank you,

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.