

8. 45-Day Public Comment Period (1/3/20 – 2/19/20)

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



Department of
Resources Recycling and Recovery

Jared Blumenfeld
Secretary for
Environmental Protection

Scott Smithline
CalRecycle Director

NOTICE OF PROPOSED RULEMAKING

Title 14: Natural Resources

Division 7: Department of Resources Recycling and Recovery

Chapter 11: Product Stewardship

Article 4: Pharmaceutical and Sharps Waste Stewardship Program

Sections: 18972 to 18975.2

PROPOSED REGULATORY ACTION

The California Department of Resources Recycling and Recovery (CalRecycle) proposes to adopt California Code of Regulations, Title 14, Division 7, Chapter 11, Article 4 commencing with Section 18972. The proposed regulation is intended to clarify processes for implementing the Pharmaceutical and Sharps Waste Stewardship Act (referred to throughout as the "Act") [Chapter 1004, Statutes of 2018 (Jackson, Senate Bill 212)].

PUBLIC HEARING

A public hearing to receive public comments is scheduled for February 19, 2020. The hearing will be held at the:

Joe Serna Jr., Cal EPA Building
Sierra Hearing Room
1001 I Street, 2nd Floor
Sacramento, CA 95814

The hearing will begin at 1:00 p.m. on February 19, 2020, and will conclude after all testimony is given. Any person may present statements or arguments, orally or in writing, with respect to the proposed action. CalRecycle requests that persons making oral comments also submit a written copy of their testimony at the hearing. The hearing

room is wheelchair accessible. If you have any questions, please contact pharmasharps@calrecycle.ca.gov.

WRITTEN COMMENT PERIOD

Any interested person, or his or her authorized representative, may submit to CalRecycle written comments relevant to the proposed regulation. The written comment period for this rulemaking closes on February 17, 2020. CalRecycle will consider only comments received by that time. Comments may be submitted via the contact information below. CalRecycle will also accept written comments during the public hearing described above. Please submit your written comments to:

Jason Smyth
Materials Management and Local Assistance Division
California Department of Resources Recycling and Recovery
P.O. Box 4025
Sacramento, CA 95812-4025
Fax: (916) 319 – 7147
e-mail: pharmasharps@calrecycle.ca.gov

AUTHORITY AND REFERENCES

Public Resources Code Sections 40401, 42031.2, and 40502 provide authority for this regulation. The purpose of the proposed actions is to implement, interpret, and make specific the law related to pharmaceutical and sharps waste stewardship. The following is a list of references cited in this proposed regulation: sections 42030, 42031, 42031.2, 42031.4, 42031.6, 42032, 42032.2, 42033, 42033.2, 42033.4, 42033.5, 42033.6, 42034, 42034.2, 42034.4, 42035, 42035.2, 42035.4, 42035.6, 42035.8, 42036, 42036.2 and 42036.4, Public Resources Code.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

EXISTING LAWS AND REGULATIONS

The California Integrated Waste Management Act, Public Resources Code Section 40000 et. seq., gives the CalRecycle authority to provide for the protection of public health, safety, and the environment through waste prevention, waste diversion, and safe waste processing and disposal. Public Resources Code Sections 40502 requires CalRecycle to adopt rules and regulations to implement the California Integrated Waste Management Act.

POLICY STATEMENT OVERVIEW AND EFFECT OF PROPOSED RULEMAKING

Pharmaceutical and home-generated sharps waste present significant environmental and public health concerns for California and currently is not managed effectively. As outlined in a 2017 report from the California State Auditor, while greater than 90% of state residents live within a 20-minute drive of a pharmaceutical or home-generated sharps collection site, collection services in rural areas are limited, and approximately

four million Californians do not have reasonable access to disposal sites. Furthermore, information on these collection sites is not readily available to ultimate users. Not all pharmacies, law enforcement agencies, and household-hazardous waste facilities accept pharmaceuticals and/or home-generated sharps; among facilities that do, not all accept Drug Enforcement Administration controlled substances such as prescription opioids or auto-injectors such as Epi-Pens. Currently, options for proper disposal of pharmaceuticals and home-generated sharps waste are complex and confusing, and as a result, these products are often inappropriately disposed in the household garbage, toilets, or sinks.

The Act is meant to address the above problems by expanding access to proper disposal methods for pharmaceutical and home-generated sharps waste and a robust education and outreach campaign to promote proper disposal. The Act places the cost burden of the program on the covered entities of certain pharmaceuticals defined as “covered drugs” and home-generated sharps waste and requires them to manage the home-generated sharps waste collected at local household hazardous waste facilities, which is typically paid for by local governments through general fund, property tax, or ratepayer revenue.

The Act creates a statewide pharmaceutical and home-generated sharps waste stewardship program and requires a program operator, consisting of a covered entity or stewardship organization as defined Section 42030 of the Public Resources Code, to establish and submit to CalRecycle, either individually or collectively through participation in a non-profit stewardship organization, a stewardship plan for covered drugs, home-generated sharps waste, or both.

The proposed regulation is intended to clarify the Act by providing procedures for submittal and approval of Stewardship Plans, as well as reporting requirements and enforcement provisions. More specifically, this regulation includes provisions on the following topics:

1. Definitions
2. Criteria for determining a covered entity
3. Document submittals: stewardship plan, initial program budget, annual report, and annual budget
4. Document approvals: stewardship plan, initial program budget, annual report, and annual budget
5. Stewardship plan for covered drugs
6. Stewardship plan for home-generated sharps waste
7. Annual report for covered drugs
8. Annual report for home-generated sharps waste
9. Program budgets
10. Record keeping requirements
11. Administrative fee to Department of Resources Recycling and Recovery
12. Stewardship organization audits of covered entities or authorized collectors
13. Retailer, wholesaler, distributor product verification

14. Criteria to impose an administrative civil penalty
15. Procedure for imposing administrative civil penalties
16. Procedure for revoking requiring resubmittal, or additional reporting of an approved stewardship plan for failure to meet a material requirement of the statute

The clarification provided in the proposed regulation will assist in the efficient and effective implementation of the Act and, together, the Act and the proposed regulation will lower the cost burden on individuals and local governments for the management of covered drugs and home-generated sharps waste, and will also result in benefits to public health and the environment (discussed in further detail starting on page 7).

Staff held informal public workshops on January 30, 2019 and February 27, 2019 to solicit stakeholder input regarding statutory terms and processes that should be defined and clarified through rulemaking. The input gathered through these workshops, written correspondence, and additional stakeholder meetings was then used to prepare informal draft regulatory text. Staff conducted two additional informal public workshops on May 17, 2019 and June 17, 2019 and held a public comment period to solicit stakeholder feedback on the informal draft regulatory text. Staff then incorporated comments from stakeholders into the proposed regulation.

CONSISTENCY EVALUATION

CalRecycle performed a search of existing state regulations and finds that the proposed regulation is not inconsistent or incompatible with existing state laws or regulations. CalRecycle considered any other possible related regulations and determined that this is the only regulation dealing in this subject area, and CalRecycle is the only agency that can implement this proposed regulation.

PLAIN ENGLISH REQUIREMENTS

CalRecycle staff prepared the proposed regulation pursuant to the standard of clarity provided in Government Code Section 11349 and the plain English requirements of Government Code Sections 11342.580 and 11346.2(a)(1). The proposed regulation is considered non-technical and is written to be easily understood by those parties that will use them.

FORMS INCORPORATED BY REFERENCE

No documents or forms are incorporated by reference in the proposed regulation.

MANDATED BY FEDERAL LAW OR REGULATIONS

Federal law or regulations do not contain comparable requirements.

LOCAL MANDATE

CalRecycle has determined that the proposed regulation does not impose a mandate on local agencies or school districts.

FISCAL IMPACT

COSTS TO ANY LOCAL AGENCY OR SCHOOL DISTRICT REQUIRING REIMBURSEMENT

CalRecycle has determined the proposed regulation does not impact any costs to local agencies or school districts, which must be reimbursed pursuant to Section 6 of Article XIII B of the California Constitution and Part 7 (commencing with Section 17500) of Division 4 of the Government Code. However, at the local government level some current expenditures may be reduced, to the extent that costs related to disposal of home-generated sharps waste may be covered by a stewardship program.

COSTS OR SAVINGS TO ANY STATE AGENCY

In Fiscal Year 2019-20, CalRecycle and the Board of Pharmacy staff costs to develop the regulation and oversee its implementation will total \$1,518,100. Costs for the state are expected to increase in subsequent years as additional enforcement staff are hired to ensure that regulated entities are in compliance. Starting in 2023, the State's costs associated with the Act (including costs incurred prior to 2023) will be reimbursed by covered entities participating in stewardship programs. CalRecycle's costs to oversee implementation of the Act prior to reimbursement will be covered by a loan from CalRecycle's E-Waste program.

NON-DISCRETIONARY COSTS OR SAVINGS

CalRecycle has determined that the proposed regulation does not impose any non-discretionary costs or savings upon local agencies.

COSTS OR SAVINGS IN FEDERAL FUNDING TO THE STATE

CalRecycle has determined that the proposed regulation will not impact federal funding to the state.

HOUSING COSTS

Department staff have determined that the proposed regulation will not have a significant effect on housing costs.

SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS, INCLUDING ABILITY TO COMPETE

CalRecycle has made an initial determination that the proposed regulation will not have a significant statewide adverse economic impact directly affecting business, including

the ability of California businesses to compete with businesses in other states. While manufacturers of pharmaceuticals and sharps will be responsible for bearing nearly all direct costs of the regulation, these costs represent an insignificant proportion of the profits made on these products.

There are approximately 700 covered entities that will bear nearly all of the direct costs of the regulation, of which approximately 500 are pharmaceutical manufacturers and 200 are sharps manufacturers. CalRecycle estimates that the initial cost for the statewide pharmaceutical program is approximately \$9.8 million, or \$20,000 for each of the pharmaceutical manufacturers. These costs include administration, outreach and education, and installation of pharmaceutical kiosks at approximately 750 pharmacies statewide. The ongoing annual cost is estimated to be \$8.9 million, or \$18,000 per pharmaceutical manufacturer, which includes administration, outreach and education, collection and disposal of pharmaceuticals at kiosks, and installation of additional pharmaceutical kiosks each year.

CalRecycle estimates that the initial cost for the statewide sharps program is approximately \$13.2 million, or \$66,000 per sharps manufacturer. These costs include administration, outreach and education, mail-back containers, collection and disposal of sharps, and installation of sharps kiosks at approximately 850 pharmacies statewide. The ongoing annual cost is \$12.2 million, or \$61,000 per sharps manufacturer, which includes administration, outreach and education, mail-back containers and mail-back costs, collection and disposal of sharps, and installation of additional sharps kiosks each year to supplement the mandatory mail-back requirement.

However, CalRecycle anticipates that the financial impact on a covered entity as a result of the regulation will vary depending on its size. The manufacturers of pharmaceuticals and sharps that are responsible for funding the program are primarily large businesses but may also include some small businesses that manufacture niche products. While the regulation does not specify how the costs of the program should be allocated between the entities participating in a stewardship organization, it is anticipated that costs will be allocated in proportion to the quantity of covered pharmaceuticals or sharps the manufacturer sells in California. This assumption is consistent with producer responsibility programs in operation elsewhere which utilize a sales-based formula to determine each manufacturer's financial obligation. The result is that large manufacturers will pay a greater proportion of the implementation costs than the smaller manufacturers.

In 2012, the Pharmaceutical Research and Manufacturers of America (PhRMA), an industry association of prescription drug producers, sued the County of Alameda for passing an ordinance establishing a local stewardship program for prescription drugs similar to the one outlined in the Act. PhRMA argued that the Alameda County ordinance violated the Commerce Clause of the U.S. Constitution by affecting the costs for drug producers to operate in California versus other states. The U.S. District Court, Northern District of California sided with Alameda County by ruling that "the Ordinance serves a legitimate public health and safety interest, and that the relatively modest

compliance costs producers will incur should they choose to sell their products in the county do not unduly burden interstate commerce.” PhRMA appealed the ruling up to the U.S. Supreme Court, which declined to hear the case and thus let the District Court ruling stand.

This lawsuit demonstrated that the costs of operating a stewardship program are minimal compared with profits made on prescription drugs. PhRMA estimated that total annual compliance costs in Alameda County would be \$1.2 million, compared with \$965 million in retail pharmaceutical sales. The Department estimates a similar minimal impact for the statewide pharmaceutical program with \$8.9 million in cost versus \$22 billion in revenue. It is reasonable to assume that the impact of the sharps program would be minimal as well.

STATEMENT OF THE RESULTS OF THE ECONOMIC IMPACT ASSESSMENT

CREATION OR ELIMINATION OF JOBS WITHIN CALIFORNIA

Approximately 40 new jobs will be created statewide as a direct result of the regulation. This number includes 17 new jobs for CalRecycle and the State Board of Pharmacy, with the remainder being jobs in newly formed stewardship organizations. In order to calculate potential job loss, staff had to consider how much of the costs to operate the stewardship programs may be passed on to consumers through retail price increases. It is important to note that statute requires stewardship plans demonstrate adequate funding for all administrative and operational costs of the stewardship program, to be borne by participating covered entities. However, determining whether a change in retail prices for the thousands of covered products in the marketplace will occur as a result of the regulation or the number of the other factors that go into a manufacturer’s determination of product price will be exceedingly difficult, if not impossible. Therefore, although it is expected that manufacturers will not increase prices consistent with the law, staff ran the Regional Economic Models Inc. (REMI) economic model under three different assumptions regarding how much of program costs may be passed on to consumers in order to prepare as conservative an economic analysis as possible. Under the most conservative assumption that 100% of the program costs could be passed on to consumers, around 40 jobs are expected to be lost, resulting in a total net job loss of 0 due to the 40 new jobs that are created as discussed above.

CREATION OF NEW BUSINESSES OR ELIMINATION OF EXISTING BUSINESSES WITHIN CALIFORNIA

Covered entities are likely to form a number of stewardship organizations (501(c)(3) non-profit organizations, per statutory requirements) to administer the stewardship programs. A small expansion in waste hauling and disposal is also expected, which might lead to additional businesses being created, but is more likely to result in expansion of existing businesses.

EXPANSION OF BUSINESSES CURRENTLY DOING BUSINESS WITHIN THE STATE

CalRecycle anticipates a small expansion of waste hauling and disposal businesses within the state.

BENEFITS OF THE REGULATION

CalRecycle has determined that the proposed regulation will result in the following benefits to public health and the environment:

1. Reduction of needle-stick injuries. The regulation is anticipated to decrease the rate of needle stick injuries and reduce the associated costs by providing consumers with safe and convenient disposal methods for home-generated sharps waste.
2. Reduction of accidental poisonings. The regulation is anticipated to reduce the incidence of accidental poisoning of children and pets from unused medications by providing consumers with convenient disposal options and conducting education and outreach campaigns to encourage their use.
3. Reduction in abuse of prescription drugs. The stockpiling of dangerous and highly addictive prescription drugs such as opioids in household medicine cabinets is a known gateway to prescription drug abuse and this regulation may make a minor contribution to reducing prescription drug abuse.
4. Water quality. Most existing water treatment infrastructure is not designed to treat or remove pharmaceuticals that have been improperly disposed of down the sink or toilet. The regulation will likely reduce the amount of trace pharmaceutical contamination in both surface and ground water by diverting unused covered drugs toward proper disposal methods.

COST IMPACT ON REPRESENTATIVE PERSONS OR BUSINESSES

Although the Act states that all administrative and operational costs of the programs are to be borne by covered entities, the regulation cannot ensure that pharmaceutical and sharps manufacturers will not raise the retail price of products in order to pass on to consumers the increased costs of compliance with the Act as with any other cost of doing business. In order to most conservatively capture the range of potential impacts on individuals due to price increases, the REMI economic model was run with different levels of consumer-cost pass-through. Under the most conservative assumption that 100% of program costs are passed on to consumers, the costs per individual in California for the pharmaceutical program would be approximately 25 cents for initial program costs and 22 cents annually thereafter. And under this scenario, the costs for the sharps program would be approximately \$10.75 per sharps user initially, and \$13.30 annually thereafter.

BUSINESS REPORT

The Act mandates multiple reporting requirements. Program operators are required to annually submit an annual budget and annual report to CalRecycle for approval;

covered entities are required to annually submit product lists to the Board of Pharmacy; and retailers of covered products as well as wholesalers and distributors are required to monitor CalRecycle's website for compliant covered entities and notify CalRecycle if they sell covered products that are not from a compliant covered entity. The proposed regulation does not require additional reports beyond what is laid out in statute, but the regulation does add clarity and specificity to some of these reporting requirements. It is necessary for the health, safety and welfare of the people of the state that the regulations and reporting requirements apply to businesses.

SMALL BUSINESS

Retail pharmacies in California are considered small businesses as most employ fewer than 100 people. Retail pharmacies will be directly impacted by the regulation and will incur costs associated with recordkeeping, occasional reporting to CalRecycle, and distributing sharps containers, which are estimated to cost a combined total of \$100,000 per year split among all the pharmacies, or less than \$50 per pharmacy. One of the reasons these costs are relatively small is that retail pharmacies are anticipated to fulfill the recordkeeping requirements at the corporate level instead of incurring recordkeeping costs at each individual pharmacy.

ALTERNATIVES STATEMENT

CalRecycle considered alternatives to the proposed rules and determined that: 1) no alternative would be more effective in carrying out the purpose for which the action is proposed; 2) no alternative would be as effective and less burdensome to affected private persons, while at the same time protecting human health, safety, and the environment, and the integrity of public funds; and 3) no alternative would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provisions of law. Three specific alternatives are described below.

ALTERNATIVE 1

Alternative 1 is to clarify in regulation the phrase "provides or initiates distribution of a sharps waste container and mail-back materials at the point of sale" to mean that every customer is given a sharps container and mail-back materials at each individual sale sufficient to accommodate the volume of sharps purchased. However, some customers who purchase syringes (and associated medications) on a frequent and routine basis may prefer not to receive a sharps container every time they purchase sharps. For example, a self-injector may prefer to receive a 1-gallon sharps container which could accommodate the amount of sharps they use over the course of nine months and enable them to make multiple purchases of syringes without incurring the additional burden of receiving and transporting a sharps container during that period of time.

Alternative 1 may also create a burden on pharmacies that have limited floor space to store sharps containers. Alternative 1 is estimated to cost covered entities \$114 million per year, which exceeds the cost of the regulation (\$21.1 million per year) and is not anticipated to result in significantly more sharps collected from ultimate users.

Alternative 1 was not selected as it does not significantly increase the quantity of sharps waste that would be collected and is more costly than the proposed regulation.

ALTERNATIVE 2

The proposed regulation requires that education and outreach materials produced by a stewardship organization are held to at least the same accessibility standards used by CalRecycle on its internet website. These accessibility standards include provisions for visually or hearing-impaired individuals, availability of text translations for several different languages, and full Americans with Disabilities Act compliance. A lower cost alternative would not require all education and outreach materials to meet accessibility standards. Under Alternative 2, stewardship organizations would save thousands of dollars per year in printing, translation, and information technology costs, but the education and outreach campaigns would be less successful in reaching certain communities and target audiences. Consequently, Alternative 2 would result in less pharmaceutical and sharps waste collected and reduce the effectiveness of the law, which is why it was not selected.

ALTERNATIVE 3

The third alternative would be for CalRecycle to not adopt any regulation beyond what is required by subsection (f)(2) of Section 42030 of the Public Resources Code. While this alternative would avoid much of CalRecycle's time and effort spent on the regulatory process, the clarity provided by the regulation is essential to minimize confusion, facilitate effective program implementation, and ensure that ultimate users have adequate access to safe and convenient disposal options for their covered drugs and home-generated sharps waste.

CONTACT PERSON

Inquiries concerning the substance of the proposed action may be directed to:

Jason Smyth
Materials Management and Local Assistance Division
California Department of Resources Recycling and Recovery
P.O. Box 4025
Sacramento, CA 95812-4025
PHONE: (916) 341-6676
FAX: (916) 319-7147
e-mail: pharmasharps@calrecycle.ca.gov

Back-up contact person to whom inquiries concerning the proposed administrative action may be directed:

Cynthia Dunn
Materials Management and Local Assistance Division
California Department of Resources Recycling and Recovery

P.O. Box 4025
Sacramento, CA 95812-4025
PHONE: (916) 341-6449
FAX: (916) 319-7495
e-mail: pharmasharps@calrecycle.ca.gov

AVAILABILITY OF STATEMENT OF REASONS, TEXT OF PROPOSED REGULATION, AND RULEMAKING FILE

CalRecycle will have the entire rulemaking file, and all information that provides the basis for the proposed regulation, available for inspection and copying throughout the rulemaking process on its internet webpage at <https://www.calrecycle.ca.gov/laws/rulemaking/pharmasharps>. Copies of the rulemaking file may also be obtained by contacting Jason Smyth or Cynthia Dunn using the contact information listed above. As of the date this notice is published in the Notice Register, the rulemaking file consists of this notice, the proposed text of the regulation, the economic and fiscal impact statement, the documents relied upon for the proposed action, and the initial statement of reasons (ISOR).

AVAILABILITY OF CHANGED OR MODIFIED TEXT

CalRecycle may adopt the proposed regulation substantially as described in this notice. If CalRecycle makes modifications, which are sufficiently related to the originally proposed text, it will make the modified text -- with changes clearly indicated -- available to the public for at least 15 days before CalRecycle adopts the regulation as revised. Requests for the modified text should be made to the contact person named above. CalRecycle will transmit any modified text to all persons who testify at the public hearing; all persons who submit written comments at the public hearing; and all persons whose comments are received during the comment period, and all persons who request notification of the availability of such changes. CalRecycle will accept written comments on the modified regulation for 15 days after the date on which they are made available.

FINAL STATEMENT OF REASONS

The Final Statement of Reasons (FSOR) will be made available at the above listed internet webpage or by contacting the people named above.

List Archive Message Details

Pharmaceutical and Sharps Waste Stewardship

Message Details

Sent On

1/3/2020 9:12 AM

Priority

Normal

From

pharmasharps@calrecycle.ca.gov

Subject

Formal Rulemaking Begins for SB 212 – California’s Pharmaceutical and Sharps Waste Stewardship Program

Message

CalRecycle is required to adopt regulations to implement the Pharmaceutical and Sharps Waste Stewardship Act (Jackson, Senate Bill 212). The Proposed Regulations for the Pharmaceutical and Sharps Waste Stewardship Program clarify statutory requirements including definitions, procedures for the submittal and approval of stewardship plans, annual reports, program budgets, and enforcement provisions for program participants.

Notice of Proposed Rulemaking to implement SB 212 will be published in the California Regulatory Notice Register by the Office of Administrative Law (OAL) (https://oal.ca.gov/publications/notice_register/) on January 3, 2020. This notice begins the formal 45-day comment period of the rulemaking process. The notice, proposed regulatory language, and other relevant rulemaking materials can be found on the Pharmaceutical and Sharps Rulemaking page at: <https://www.calrecycle.ca.gov/laws/rulemaking/pharmasharps>.

Any interested person, or his or her authorized representative, may submit to CalRecycle written comments relevant to the proposed regulations. The written comment period for this rulemaking closes on February 17, 2020.

Please submit written comments to:

Jason Smyth
Materials Management and Local Assistance Division
California Department of Resources Recycling and Recovery
P.O. Box 4025
Sacramento, CA 95812-4025
Fax: (916) 319-7147
e-mail: pharmasharps@calrecycle.ca.gov

A public hearing to receive public comments is scheduled for February 19, 2020 at 1:00 pm. The hearing will be held at the:

Joe Serna Jr., Cal EPA Building
Sierra Hearing Room
1001 I Street, 2nd Floor
Sacramento, CA 95814

Information on the hearing agenda and other related materials, including webcast link for remote participants, can be found on the CalRecycle Public Notice page.

Thank you,

The CalRecycle Pharmaceutical & Sharps Stewardship Team

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

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

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

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Statement of Mailing Notice

(Section 86 of Title 1 of the California Code of Regulations)

Re: Proposed Regulations for the Pharmaceutical and Sharps Waste Stewardship Act
45-Day comment period

The Department of Resources Recycling and Recovery has complied with the provisions of Government Code Section 11346.4, subdivisions (a)(1) through (4), regarding the mailing of the notice of proposed regulatory action. The notice, along with the First Draft of the regulatory text, was mailed on January 3, 2020, 45 days prior to the close of the public comment period and the public hearing, which was held on February 19, 2020. Written comments for the First Draft of the regulatory text were accepted starting January 3, 2020 through February 19, 2020 (through the end of the public hearing).

SB 212 45-Day Formal Public Comment Period (1/3/2020 – 2/19/2020)
Comments and Responses on the First Draft Proposed Regulatory Text, Sorted by Comment Number

Comment Letter Number	Commenter	CalRecycle Response Pages
001	Sharps Compliance, Incorporated	1-5
002	Rural County Representatives of California	5-7
003	Russian Riverkeeper	7-8
004	The City of San Diego	8-9
005	California Product Stewardship Council, National Stewardship Action Council, County of Santa Clara, and Zero Waste Sonoma	9-25
006	San Francisco Department of the Environment	25-42
007	Coalition for Prevention and Awareness in Los Angeles Metro (COPALM)	42-44
008	California Retailers Association/National Association of Chain Drug Stores, and California Pharmacists Association (CRA, NACDS, & CPhA)	44-47
009	Healthcare Distribution Alliance (HDA)	47-53
010	Pharmaceutical Product Stewardship Work Group (PPSWG)	53-55
011	AdvaMed	55-58
012	Stat-Medicament-Disposal Corporation	58-61
013	InMar Intelligence	61-70
014	Stericycle	70-76
015	Med-Project USA	76-127
016	Lil' Drug Store Products, Inc. & Convenience Valet	127-128
017	Sanitation Districts of Los Angeles County	128-129
PH	February 19, 2020 Public Hearing Comments	129-135

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
001-001	Sharps Compliance, Incorporated	Wanda Lingner	18972.1 (j)	Y	<p>Pg. 2 Ln 16 Proposed regulation: “To provide a sharps waste container and mail-back materials to the ultimate user at the point of sale at no cost to the ultimate user;”</p> <p>Issue: Tangible provision of sharps waste containers at “point of sale” places all the burden on pharmacies who do not have the space nor personnel to handle distribution.</p> <p>Proposed Resolution: Though Pg. 2 Ln 23 allows for “other methods” such as, for example, a patient support program, we still suggest to change Ln 16 to: “To initiate provision of a sharps mail-back system to the ultimate user either upon the point of prescribing the drug or at point of sale.”</p>	<p>001-001. CalRecycle agrees that a change is necessary to section 18972.1(a)(11) of the proposed regulatory text, but prefers the following edit:</p> <p><u>(11) “Provides or initiates distribution of a sharps waste container” means one of the following:</u></p> <p><u>(1A) To provide a sharps waste container and mail-back materials to the ultimate user, at the point of sale or prior, at no cost to the ultimate user; or,</u></p> <p><u>(2B) To arrange, at the point of sale or prior, for a sharps waste container and mail-back materials to be sent to the ultimate user and arrive within four business days at no cost or inconvenience to the ultimate user; or,</u></p> <p><u>(3C) Other methods of providing a sharps waste container and mail-back materials, as approved by the department in a stewardship plan, 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 or (2) is not allowed by law or is not reasonably feasible. These methods must be approved by the department in a stewardship plan and which result in substantially the same level of convenience to the ultimate user as the methods identified in subparts (A) and (B) above.</u></p> <p>Due to a reorganization of subsection 18972.1, subsection 18972.1(j) has been changed to 18972.1(a)(11) in the proposed regulatory text.</p> <p>The requirements contained in section 18972.1(a)(11)(B) and (C) are sufficiently flexible to allow a program operator who does not want to overburden pharmacies to propose other methods to accomplish the requirements. CalRecycle also recognizes the potential benefit of distributing sharps containers prior to the point of sale (such as at the point of prescribing the drug), and thus has added “or prior” to options (A) and (B).</p>
001-002	Sharps Compliance, Incorporated	Wanda Lingner	18972.1 (j)	Y	<p>Pg. 2 Ln 19 Proposed regulation: “...mail-back materials to be sent to the ultimate user and arrive within 3 business days at no cost or inconvenience to the ultimate user.”</p> <p>Issue: No way to guarantee delivery of mail-back solution within 3 days without significant cost increase to the mail-back solution in order to have guaranteed 3-day delivery.</p> <p>Proposed Resolution: Change statement to either: “...mail-back materials to be shipped to the ultimate user within 3 business days at no cost or</p>	<p>001-002. CalRecycle agrees with the commenter’s request to extend the required delivery timeframe for sharps waste containers and mail-back materials, but prefers four business days.</p> <p>Four business days reflects the general delivery timetable for United States Postal Service Priority Mail, and further extending this timeframe to five business days would detract from ultimate user convenience with</p>

Comment Number	Commenter Affiliation	Commenter Name	Section	Section Revised (Y/N)	Comment (As submitted)	CalRecycle Response
					inconvenience to the ultimate user". Or, "...mail-back materials to be sent to the ultimate user and arrive within 3-5 business days..."	little additional benefit to program operators. See response to comment 015-002 for further discussion on this topic.
001-003	Sharps Compliance, Incorporated	Wanda Lingner	18972.1 (j)(2)	N	<p>Pg. 2 Ln 20 Proposed regulation: "...no cost or inconvenience to the ultimate user..."</p> <p>Issue: Inconvenience is a very subjective word and has no definition. What is an inconvenience for an 80-year-old housebound person is not going to be an inconvenience to an 18-year-old diabetic.</p> <p>Proposed Resolution: Either define "inconvenience" or have it read "...no cost to the ultimate user..."</p>	001-003. A change to the proposed regulatory text is not necessary. CalRecycle declines to define or further clarify the term "inconvenience." The purpose of the proposed "no cost or inconvenience to the ultimate user" language is to provide flexibility for a program operator to develop innovative solutions to meet the statutory requirement to provide or initiate distribution of sharps waste containers and mail-back materials at the point of sale or prior and without it being necessary for the ultimate user to take further steps outside of the point of sale. Due to the variability of ways that a program operator may choose to meet this statutory requirement, it is not possible to set an objective standard for "inconvenience" that would be appropriate to apply to all circumstances. The department will determine on a case-by-case basis whether these requirements have been met during its stewardship plan review process.
001-004	Sharps Compliance, Incorporated	Wanda Lingner	18972.1 (j)(3)	N	<p>Pg. 2 Ln 23 Proposed regulation: "...if (1) or (2) are not reasonably feasible, and which results in substantially the same level of convenience to the ultimate user"</p> <p>Issue: Again, this sentence has very subjective measurements of "reasonably feasible" and "substantially the same level of convenience". These can have very different meanings to different people.</p> <p>Proposed Resolution: "...as approved by the department in a stewardship plan if (1) or (2) are not available."</p>	001-004. A change to the proposed regulatory text is not necessary. It is not possible to set an objective standard for this that would be appropriate to apply to all circumstances. The department will determine on a case-by-case basis whether these requirements have been met during its plan review process.
001-005	Sharps Compliance, Incorporated	Wanda Lingner	18973.2 (g)(5) (C)	N	<p>Pg. 7 Ln 29 Proposed regulation: "Metrics that will be used to measure the amount of materials distributed and weight of material returned".</p> <p>Issue: There is no clear definition of exactly what metrics you will be wanting program operator to provide.</p> <p>Proposed Resolution: Define the metrics that will be required. This way the program operator will know, when developing their plan, what data they will be required to provide and how they will be able to provide that information.</p>	001-005. A change to the proposed regulatory text is not necessary. CalRecycle disagrees with the commenter's recommendation to specify the appropriate metrics. The proposed regulatory text provides flexibility for a program operator to select and propose its own metrics, applicable to unique collection systems in its stewardship program. This is why weight was changed to amount in the proposed text below. Separately, CalRecycle proposes the following edits to proposed regulatory text section 18973.2(g)(6)(C) for clarity and consistency with statute, noting that subsection (g)(5) has been changed to (g)(6) due to edits made elsewhere: <u>(C) Metrics that will be used to measure the amount of preaddressed, prepaid mail-back materials distributed or alternative form of collection and disposal system provided, and the metrics used to measure the amountweight of material returned.</u> Note that section 42033.2(b)(3) of the Public Resources Code requires program operators to track the weight of covered products collected at authorized collection sites.
001-006a	Sharps Compliance, Incorporated	Wanda Lingner	18973.2 (j)(2)	Y	<p>Pg. 8 Ln 31 Proposed regulation: "...materials to be utilized that are distributed in languages suited to local demographics" ...</p> <p>Issue: Given the number of different languages spoken in California, how will the program operator know what language translations will be required in each county? Is there a minimum population threshold that must be met before</p>	001-006a. CalRecycle disagrees with the commenter's proposed resolution and declines to include language pertaining to a minimum population number to trigger production of education and outreach materials. Various factors, beyond population size, should be considered when deciding on the production of materials. The proposed

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					<p>materials must be produced in that language? Additionally, who will be responsible for making such determinations and notifying program operators or stewardship organizations of languages, by county, required for materials?</p> <p>Proposed Resolution: There should be a minimum population number that would then trigger production of materials in the specified location. Additionally, CalRecycle should be responsible for providing the list of required languages by county to program operators and stewardship organizations.</p>	<p>regulatory text provides flexibility for a program operator to design its stewardship program in a way that best suits the needs of populations it serves. However, CalRecycle does agree that the proposed regulations should provide some greater specificity regarding languages suited to local demographics, and proposes the following edit to sections 18973.2(j) and 18973.3(i):</p> <p><u>(2) 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.</u></p> <p>Incorporating section 7295 of the Government Code provides additional clarity by pointing program operators to a comparable benchmark applicable to local agencies.</p>
001-006b	Sharps Compliance, Incorporated	Wanda Lingner	18973.3 (i)(2)	Y	<p>Pg. 8 Ln 31 Proposed regulation: "...materials to be utilized that are distributed in languages suited to local demographics" ...</p> <p>Issue: Given the number of different languages spoken in California, how will the program operator know what language translations will be required in each county? Is there a minimum population threshold that must be met before materials must be produced in that language? Additionally, who will be responsible for making such determinations and notifying program operators or stewardship organizations of languages, by county, required for materials?</p> <p>Proposed Resolution: There should be a minimum population number that would then trigger production of materials in the specified location. Additionally, CalRecycle should be responsible for providing the list of required languages by county to program operators and stewardship organizations.</p>	<p>001-006b. CalRecycle disagrees with the commenter's proposed resolution and declines to include language pertaining to a minimum population number to trigger production of education and outreach materials. Various factors, beyond population size, should be considered when deciding on the production of materials. The proposed regulatory text provides flexibility for a program operator to design its stewardship program in a way that best suits the needs of populations it serves. However, CalRecycle does agree that the proposed regulations should provide some greater specificity regarding languages suited to local demographics, and proposes the following edit to sections 18973.2(j) and 18973.3(i):</p> <p><u>(2) 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.</u></p> <p>Incorporating section 7295 of the Government Code provides additional clarity by pointing program operators to a comparable benchmark applicable to local agencies.</p>
001-007	Sharps Compliance, Incorporated	Wanda Lingner	18973.2 (j)(4)	N	<p>Pg. 9 Ln 15 Proposed regulation: "Metrics to evaluate performance of the comprehensive education and outreach program..."</p> <p>Issue: There is no definition of what exact metrics required to evaluate the performance of the education and outreach program.</p> <p>Proposed Resolution: Define the metrics that will be required. This way the program operator will know, when developing their plan, what data they will be required to provide and how they will be able to provide that information.</p>	<p>001-007. A change to the proposed regulatory text is not necessary. CalRecycle disagrees with the commenter's recommendation to specify the appropriate metrics. The proposed regulatory text provides flexibility for a program operator to select and propose metrics applicable to unique education and outreach programs within its stewardship program.</p>

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001-008	Sharps Compliance, Incorporated	Wade Scheel	18973.3 (f)	N	<p>Pg. 10 Ln 26 Proposed regulation: "...initiates distribution of sharps waste containers and mail-back materials..."</p> <p>Issue: the mailback sharps disposal system should be a single system, all inclusive. It should not entail a consumer being handed a sharps container and then separately obtaining shipping materials later, for several reasons:</p> <ol style="list-style-type: none"> 1. If transporting via USPS – the entire mailback system must be independently tested to meet the mailability requirements set by USPS, and, once approved, only those system components can be used. You cannot just place a full sharps container into any box that is laying around a home. 2. If transporting via common carrier then DOT requirements for packaging, marking, and labeling must be met before UPS or FedEx could transport a full sharps container. 3. Inconvenience of consumer is mentioned earlier in the proposed rules, and, wouldn't it be an inconvenience to have to obtain shipping materials at a separate time and location than the sharps container? <p>Proposed Resolution: change language to the following: "...initiates distribution of the mailback disposal system, at no cost..."</p>	001-008. A change to the proposed regulatory text is not necessary. CalRecycle agrees with the commenter that sharps waste containers and mail-back materials should be distributed together but does not agree that a change to the proposed regulatory text is warranted. The proposed regulatory text aligns with Public Resources Code section 42032.2(d)(1)(F)(i) which clearly states, "...distribution of sharps waste containers <i>and</i> (emphasis added) mail-back containers..." which is inclusive.
001-009	Sharps Compliance, Incorporated	Wanda Lingner	18973.3 (f)(6)(A)	N	<p>Pg. 11 Ln 21 Proposed regulation: "Secure Receptacle Collection"</p> <p>Issue: Having sharps collection receptacles raises several issues as follows:</p> <ol style="list-style-type: none"> 1. Safety issue of individuals transporting home sharps to a collection receptacle. 2. Loose sharps being placed into collection receptacles places unnecessary risks on transporter collecting from receptacles once full 3. Regulation calls for "not inconveniencing" ultimate user; however, requiring them to transport their full sharps container to a secondary location could be considered by many as an inconvenience. 4. No way to limit that only covered drugs would be placed into receptacle and not things like illicit drug syringes. <p>Proposed Resolution: Given 100% of California counties can be more efficiently and safely serviced by mail-back solutions, remove secure receptacle collection as a means of disposing covered sharps products.</p>	<p>001-009. A change to the proposed regulatory text is not necessary. CalRecycle disagrees with the commenter's proposal that supplemental secure collection receptacles for home-generated sharps waste be removed from the proposed regulatory text. A program operator wishing to provide this supplemental service must describe safety considerations in its proposed stewardship plan, pursuant to sections 18973.3(f)(1) and 18973.3(f)(5)(A)(iv) of the proposed regulatory text. Existing local stewardship programs for home-generated sharps waste, i.e. the counties of Alameda, Santa Clara, San Luis Obispo, and Santa Cruz, have successful and safe use of secure collection receptacles for home-generated sharps waste.</p> <p>As specified in section 18973.3(f)(5), a program operator is permitted to offer supplemental services "in addition to, but not in lieu of, the mail-back program"; the supplemental secure receptacle collection is an additional option available to a program operator that wishes to go above and beyond the minimum requirements of the statute. Therefore, secure collection receptacles would not inconvenience ultimate users and instead would potentially provide them additional options. While CalRecycle agrees it is impossible to ensure that only home-generated sharps waste is placed in supplemental secure collection receptacles, this issue does not affect the safety or legality of the receptacles, and it is simply a factor a program operator must consider when deciding whether to offer this supplemental program.</p>
001-010	Sharps Compliance, Incorporated	Wanda Lingner	18973.3 (f)(7)	N	<p>Pg. 12 Ln 13 Proposed regulation: "Take-back collection events"</p> <p>Issue: Take-back collection events are for medications but do not include syringes or sharps. Community take-back events would have a difficult time safely collecting and immediately disposing of collected sharps. Additionally, how do you mitigate the public bringing loose sharps or sharps that are</p>	001-010. A change to the proposed regulatory text is not necessary. CalRecycle disagrees with the commenter's proposal that supplemental methods for collection and disposal of home-generated sharps waste be removed from the proposed regulations. The proposed regulatory text provides flexibility for a program operator to select and design unique

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					inappropriately contained into FDA-cleared and DOT-approved sharps containers for transport? Proposed resolution: Given 100% of California counties can be more efficiently and safely serviced by mail-back solutions, remove take-back events as a means of disposing covered sharps products.	methods of collection in their stewardship program, including take-back collection events that are in compliance with all applicable local, state, and federal laws and regulations. As specified in section 18973.3(f)(5) of the proposed regulatory text, a program operator is permitted to offer these supplemental services “in addition to, but not in lieu of, the mail-back program;” these services would not be “alternatives” to the mail-back program, but rather would be additional options available to a program operator that wishes to go above and beyond the minimum requirements of the statute.
001-011	Sharps Compliance, Incorporate	Wanda Lingner	18973.3 (f)(7)	N	Pg. 12 Ln 15 Proposed regulation: “... metrics that will be used to measure the amount of sharps waste containers...” Issue: Issue: There is no definition of what metrics will have to be provided by the program operator. Proposed Resolution: Define the metrics that will be required. This way the program operator will know, when developing their plan, what data they will be required to provide and how they will be able to provide that information.	001-011. A change to the proposed regulatory text is not necessary. CalRecycle disagrees with the commenter’s recommendation to specify the appropriate metrics. The proposed regulatory text provides flexibility for a program operator to select and propose metrics applicable to unique forms of collection within its stewardship program.
001-012	Sharps Compliance, Incorporated	Wanda Lingner	18973.3 (f)(8)	N	Pg. 12 Ln 17 Proposed regulation: “...metrics that will be used to measure the amount of sharps waste containers and mail-back materials collected through supplemental collection methods...” Issue: We proposed that both alternative methods be removed as 100% of counties in California can be serviced more efficiently and safely by mail-back solutions. Additionally, there is the issue of how to collect meaningful metrics on these supplemental methods of collection – take-back events and collection receptacles. For example, use of receptacles does not allow for quantifying how many persons have placed their sharps into the receptacle, nor if they were even a covered product. The same holds true for take-back events. Proposed Resolution: Remove alternative sharps collection methods. If you do not remove these alternative methods, then you will need to define the required metrics that will produce meaningful data.	001-012. A change to the proposed regulatory text is not necessary. CalRecycle disagrees with the commenter’s proposal that supplemental methods for collection and disposal of home-generated sharps waste be removed from the proposed regulations. As specified in section 18973.3(f)(5) of the proposed regulatory text, a program operator is permitted to offer these supplemental services “in addition to, but not in lieu of, the mail-back program;” these services would not be “alternatives” to the mail-back program, but rather would be additional options available to a program operator that wishes to go above and beyond the minimum requirements of the statute. CalRecycle also disagrees that defining the required metrics for supplemental collection methods is necessary. While the department does acknowledge the logistical challenges regarding data collection from collection receptacles and take-back events, the specific elements of a supplemental collection system will be unknown until outlined in a proposed stewardship plan. Rather than defining specific metrics in regulation, upholding flexibility for both program operators and the department is a more effective solution.
001-013	Sharps Compliance, Incorporated	Wanda Lingner	18973.3 (i)(5)	N	Pg. 13 Ln 29 Proposed regulations: Metrics to evaluate performance of the comprehensive education and outreach program...”. Issue: There is no definition of what exact metrics are required to evaluate the performance of the education and outreach program. Proposed Resolution: Define the metrics that will be required. This way the program operator will know, when developing their plan, what data they will be required to provide and how they will be able to provide that information.	001-013. A change to the proposed regulatory text is not necessary. CalRecycle disagrees with the commenter’s recommendation to specify the appropriate metrics. The proposed regulatory text provides flexibility for a program operator to select and propose metrics applicable to unique collection systems within its stewardship program.
002-001	Rural County Representati	Staci Heaton	18973.3	N	CalRecycle should consider supplementing the definition of “ultimate user,” defined in Public Resources Code Section 42032 subdivision (z), in order to allow for Household Hazardous Waste program sponsors to also receive	002-001. A change to the proposed regulatory text is not necessary. CalRecycle declines to supplement the definition of “ultimate user” so that Household Hazardous Waste program sponsors could also receive

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	ves of California				home-generated sharps containers. SB 212 allows Household Hazardous Waste programs to accept filled sharps containers, however, providing empty approved sharps containers would be a valuable part of the Stewardship Plan for Home-Generated Sharps Program and provide convenient service for residents.	sharps waste containers. The statutory definition in Public Resources Code section 42030(z) is clear that an ultimate user must have lawfully obtained and possess covered product(s) "for his or her own use of for the use of a member of his or her household." Expanding this definition in regulation to include Household Hazardous Waste program sponsors would conflict with statute and is outside the department's authority.
002-002	Rural County Representatives of California	Staci Heaton	18973.2 (d)	N	Further, CalRecycle should describe criteria to determine "good faith negotiations" and "reasonable effort" by the program operator and potentially authorized collectors of drug and sharps waste.	002-002. A change to the proposed regulations is not necessary. CalRecycle disagrees with the commenter's proposal to add criteria for good faith negotiations in section 18972.1 as these statutory terms are sufficiently clear. It is not possible to set an objective standard for these terms that would be appropriate to apply to all circumstances. The department will determine on a case-by-case basis whether these requirements have been met during its stewardship plan and annual report review process.
002-003	Rural County Representatives of California	Staci Heaton	18973.2 (f)	Y	We recommend clarifying the Stewardship Plan is solely funded by participating covered entities. As currently written, Section 18973.2 subdivision (f) could be interpreted to mean that future program budgets and funding could be borne by consumers or others. Specifically, we request the following amendment, which is noted as follows: (f) Initial Program Budget and Program Funding. Demonstration of adequate funding for all administrative and operational costs of the stewardship program, to be borne by participating entities, for the first five calendar years of operation pursuant to section 18973.6.	002-003. CalRecycle agrees that additional clarity is needed but finds the following edit to section 18973.2(f) of the proposed regulatory text to be clearer than the commenter's proposed change: <u>(f) Initial Program Budget and Program Funding. Demonstration of adequate funding for all administrative and operational costs of the stewardship program, as well as the departmental administrative fees, to be borne by participating covered entities for the first five calendar years of operation, to be borne by participating covered entities pursuant to section 18973.6.</u>
002-004	Rural County Representatives of California	Staci Heaton	18973.2	N	As with the Stewardship Plan for Home-Generated Sharps Program, there needs to be provisions in the Stewardship Plan for Covered Drugs regarding Local Agency Requests. Pharmaceuticals can wind up in solid waste, wastewater or sanitation facilities, not to mention parks or other public places, and there should be a mechanism to ensure they are recovered by covered entities. The regulatory language should contemplate requests by local jurisdictions and applicable reimbursement requests. Further, local agencies that conduct testing of inert drugs, such as an aquatic toxicity test, should be reimbursed for this activity in the course of ensuring that pharmaceuticals are properly disposed and managed.	002-004. A change to the proposed regulatory text is not necessary. Public Resources Code section 42032.2(d)(1)(F)(ii) requires a program operator to either reimburse local agencies for disposal costs related to home-generated sharps waste or provide for the removal of the home-generated sharps waste from the local household hazardous waste facility. Statute does not extend a similar provision for covered drugs, and thus requiring a program operator to accommodate local agency requests relating to covered drugs or reimbursement requests for aquatic toxicity testing is outside the scope and authority of these regulations.
002-005a	Rural County Representatives of California	Staci Heaton	18973.2 (j)	N	CalRecycle should also encourage program operators or the Stewardship Organization(s) to financially contribute to a local agency's advertisements rather than create separate campaigns for education and outreach. Local entities, for example, provide public education through its Household Hazardous Waste (HHW) programs. Residents and consumers should receive consistent and comprehensive messaging.	002-005a. A change to the proposed regulatory text is not necessary. Statute requires a program operator to conduct a comprehensive education and outreach campaign and does not require it to contribute financially to a local agency's advertisements. Thus, adding such a requirement in regulation would be outside the scope and authority of these regulations.
002-005b	Rural County Representatives of California	Staci Heaton	18973.3 (i)	N	CalRecycle should also encourage program operators or the Stewardship Organization(s) to financially contribute to a local agency's advertisements rather than create separate campaigns for education and outreach. Local entities, for example, provide public education through its Household	002-005b. A change to the proposed regulatory text is not necessary. Statute requires a program operator to conduct a comprehensive education and outreach campaign and does not require it to contribute financially to a local agency's advertisements.

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					Hazardous Waste (HHW) programs. Residents and consumers should receive consistent and comprehensive messaging.	Thus, adding such a requirement in regulation would be outside the department's statutory authority.
002-006	Rural County Representatives of California	Staci Heaton	18973.3 (e)	Y	As stated above, we recommend clarifying the Stewardship Plan is funded by participating covered entities only. As currently written, Section 18973.3 subdivision (e) could be interpreted to mean that future program budgets and funding could be borne by consumers or others. Specifically, we request the following amendment, which is noted as follows: (e) Initial Program Budget and Program Funding. Demonstration of adequate funding for all administrative and operational costs of the stewardship program, to be borne by participating entities, for the first five calendar years of operation pursuant to section 18973.6.	002-006. CalRecycle agrees that additional clarity is needed and prefers the following edit to section 18973.3: <u>(e) Initial Program Budget and Program Funding. Demonstration of adequate funding for all administrative and operational costs of the stewardship program, as well as departmental administrative fees, to be borne by participating covered entities for the first five calendar years of operation, to be borne by participating covered entities pursuant to section 18973.6.</u>
002-007	Rural County Representatives of California	Staci Heaton	18973.3 (g)	N	Rural local agencies often have limited budgets and staffing and rely on timely reimbursements. We appreciate requiring program operators to issue payment within 45 days but encourage CalRecycle to expand the types of reimbursements that could be made to local jurisdictions beyond transportation and disposal costs. For example, HHW facilities should be eligible to receive funding for empty approved sharps containers as part of their program, as well as the use of specialized tools and other worker safety equipment to properly handle these containers.	002-007. A change to the proposed regulatory text is not necessary. Public Resources Code section 42032.2(d)(1)(F)(ii)(II) states that "reimbursement costs shall be limited to the actual costs of transportation from the household hazardous waste facility and for the actual costs of disposal." Expanding the types of reimbursements that could be made to local jurisdictions in regulation would conflict with statute and thus are outside of the department's authority.
002-008	Rural County Representatives of California	Staci Heaton	18973.3 (g)	N	CalRecycle should also clarify how program operators will remove home-generated sharps from HHW facilities. Many of these HHW programs have large (e.g. 30-gallon) containers to hold collected sharps, which should be eligible for free disposal rather than having to stockpile mail-away containers. Similarly, load-checking programs and illegal dumping cleanup efforts encounter improperly disposed sharps, posing a hazard to solid waste and municipal workers. These programs should have an opportunity to dispose collected sharps under the stewardship program.	002-008. A change to the proposed regulatory text is not necessary. It is not the department's role to mediate contract discussions between a program operator and household hazardous waste programs. However, the statute does not require home-generated sharps waste consolidated at a household hazardous waste facility to have been brought to the facility directly by an ultimate user, and also does not require that home-generated sharps waste be transferred to mail-back containers in order to be eligible for reimbursement or removal.
002-009	Rural County Representatives of California	Staci Heaton	18973.3 (i)	N	CalRecycle should also encourage program operators or the Stewardship Organization(s) to financially contribute to a local agency's advertisements rather than create separate campaigns for education and outreach. Residents and consumers should receive consistent and comprehensive messaging.	002-009. A change to the proposed regulatory text is not necessary. Statute requires a program operator to conduct a comprehensive education and outreach campaign and does not require it to contribute financially to a local agency's advertisements. Thus, adding such a requirement in regulation would be outside the department's statutory authority.
002-010	Rural County Representatives of California	Staci Heaton	General	N	Given that these Stewardship Organizations do not have Advisory Committees and open meetings like other Extended Producer Responsibility laws, it is vital that CalRecycle provide clear and consistent expectations as well as results for local agencies and ultimate users.	002-010. The commenter did not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. Statute provides clear and consistent expectations for a program operator and its stewardship program through requirements for stewardship plans, education and outreach, annual budgets, and other programmatic elements. It requires transparency for program results through requirements for annual reporting. CalRecycle proposes to clarify only those statutory elements that require clarity for implementation of the statute.
003-001	Russian Riverkeeper	Don McEnhill	18973.3 (g)	N	We are concerned about our ability to dispose of pharmaceutical and sharps waste we collect from homeless camps. Our Clean River Alliance program	003-001. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary.

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					works with homeless individuals in our clean camp and we conduct weekly trash pickups at over 75 camps along the Russian River. We are also called out to clean up abandoned camps or camps after residents are evicted. We often find discarded needles and pharmaceutical that we didn't purchase or generate. At this time, we can't figure out from the bill language - reading hastily as this just came across our desk today - allows our staff to legally dispose of this medical waste through the program this bill is creating. Currently we work with a local hospital who disposes of medical waste for us but it is tenuous and sometimes they do not accept it so we have to store it so it doesn't go into landfills. Please make sure we have some avenue of participating in this program with our homeless cleanup work	The proposed regulatory text and statute do not prohibit clean-up programs from coordinating with a local agency for disposal of home-generated sharps at a household hazardous waste facility.
004-001	The City of San Diego	Kirk Galarneau	18972.1 (b)	N	<p>Page 1, Section 18972.1. Definitions</p> <p>...</p> <p>(b)“Administrative and operational costs” means costs to implement and operate a stewardship program, including, but not limited to, collection, <u>consolidation</u>, transportation, processing, disposal, and education and outreach costs, as well as administrative costs of operating the stewardship organization and administrative fees charged by the department.</p>	<p>004-001. A change to the proposed regulatory text is not necessary. Costs related to “consolidation” could be considered “operational costs” or reasonably inferred from the phrase “including, but not limited to” within the proposed definition. However, CalRecycle separately proposes the following edits to section 18972.1 of the proposed regulatory text for clarity and consistency with statute:</p> <p><u>(b1) “Administrative and operational costs” means costs to implement and operate a stewardship program, including, but not limited to, collection, transportation, processing, disposal, and education and outreach costs, as well as administrative costs of operating the stewardship organization, pursuant to section 42034 of the Public Resources Code. and administrative fees charged by the department.</u></p> <p><u>(2) “Departmental administrative fees” are fees required to be paid pursuant to section 42034.2 of the Public Resources Code.</u></p>
004-002	The City of San Diego	Kirk Galarneau	18973.2	N	<p>Page 8, Section 18973.2. Stewardship Plan for Covered Drugs</p> <p>Local Agency Requests.</p> <p><u>(1) Description of the process for coordinating with local agencies, or an agent on behalf of a local agency, for the removal of covered drugs from local household hazardous waste facilities other local agency collection locations, either by reimbursement for consolidation, transportation, and disposal costs or removal of covered drugs.</u></p> <p><u>(2) Requests by local agencies, or an agent on behalf of a local agency, shall be submitted to the program operator as necessary. Program operators will respond to requests by local agencies in a timely manner and identify the method to resolve the request by selecting either reimbursement or removal from household hazardous waste facility(ies) or other local agency collection locations.</u></p> <p><u>(A) A program operator that selects to resolve a request through reimbursement to a local agency shall issue payment within 45 days of the local agency providing an invoice.</u></p> <p><u>(B) A program operator that provides for the removal of covered drugs from the local household hazardous waste facilities or other local agency collection</u></p>	<p>004-002. A change to the proposed regulatory text is not necessary. Public Resources Code section 42032.2(d)(1)(F)(ii) requires a program operator to either reimburse local agencies for disposal costs related to home-generated sharps waste or provide for the removal of the home-generated sharps waste from the local household hazardous waste facility. Statute does not extend a similar provision for covered drugs, and thus requiring a program operator to accommodate local agency requests relating to covered drugs is outside the scope and authority of these regulations.</p>

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					<p><u>locations shall do so as often as required according to section 118280 of the Health and Safety Code or by the local enforcement authority.</u></p> <p>Explanation of proposed revisions to Section 18973.2: The City of San Diego (City) has Safe Prescription Drug Drop-Off collection kiosks located as San Diego Police Department (SDPD) facilities and accepts prescription drugs at the City’s household hazardous waste facility. Reimbursement for the costs for the collection, consolidation, and disposal of covered drugs by local agencies could be specifically added to the proposed regulations similar to Section 18973.3.</p>	
004-003	The City of San Diego	Kirk Galarneau	18973.3 (g)	N	<p>Page 12, Section 18973.3 (g) Local Agency Requests (g) Local Agency Requests. (1) Description of the process for coordinating with local agencies, or an agent on behalf of a local agency, for the removal of home-generated sharps waste from local household hazardous waste facilities, either by reimbursement for <u>consolidation</u>, transportation, and disposal costs or removal of the home-generated sharps waste.</p> <p>Explanation of proposed revisions to Section 17983.3 (g): The City of San Diego (City) has sharps collection kiosks located as San Diego Police Department (SDPD) facilities for the collection of home-generated sharps waste. The kiosks are serviced weekly by our hazardous waste contractor. The sharps collection kiosk waste from the SDPD locations is transported back to the City’s permanent household hazardous waste facility for consolidation and accumulation prior to disposal. The City is charged a separate fee for the pickup and consolidation of sharps kiosk waste from the SDPD locations and is proposing the revisions above to recover those additional costs associated with the proper disposal of home-generated sharps. There may be other local agencies that collect sharps at other local agency supported locations in addition to or as an alternate to a permanent household hazardous waste facility. This section could be further expanded to include other agency locations in addition to household hazardous waste facilities.</p>	004-003. A change to the proposed regulatory text is not necessary. Public Resources Code section 42032.2(d)(1)(F)(ii)(II) states that “reimbursement costs shall be limited to the actual costs of transportation from the household hazardous waste facility and for the actual costs of disposal.” Expanding the types of reimbursements that could be made to local jurisdictions in regulation would conflict with statute and thus are outside of the department’s authority.
005-001	Nat'l Stewardship Action Council, CalPSC, County of Santa Clara, & Zero Waste Sonoma	Doug Kobold, Heidi Sanborn, William Grimes, Leslie Lukacs	18972.1 (i)	N	<p>Proposed Regulation Section: 18972.1(i), Page: 2, Subject: Definition: "point of sale"</p> <p>Our coalition is supportive of the definition contained in the proposed regulations. Defining “point of sale” effectively is vitally important to the implementation of the Sharps Stewardship Program.</p> <p>Section 42032.2 of the Public Resources Code (PRC) contains the requirements for stewardship plans. The requirements for drug stewardship plans are different from sharps stewardship plans for one reason – the sharps manufacturers requested a mail-back only program instead of the collection site approach used for drugs.</p>	<p>005-001. 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 proposed definition for “point of sale”. However, the department proposes the following edits to section 18972.1 of the proposed regulatory text for clarity and consistency with statute:</p> <p><u>(#10) “Point of sale” means the point in time at which an ultimate user purchases a covered product at a checkout system utilized by pharmacies, stores, or other retailer, or online marketplace outlets where a covered product is sold, including online sales.</u></p>

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					<p>One of the key requirements (42032.2(d)(1)(F)(i) is that the mail-back containers and materials are provided at the point of sale. The point of sale requirement is the convenience standard for the Sharps Stewardship Plan. Under this requirement, the purchase of sharps, whether in-store or online, automatically triggers provision of the mail-back container and materials to the consumer.</p> <p>Without this type of consumer convenience, the program will not be effective.</p>	
005-002A	Nat'l Stewardship Action Council, CalPSC, County of Santa Clara, & Zero Waste Sonoma	Doug Kobold, Heidi Sanborn, William Grimes, Leslie Lukacs	18972.1 (j)	N	<p>Proposed Regulation Section: 18972(j), Page: 2, Subject: Definition: "provides or initiates distribution of a sharps waste container"</p> <p>Our coalition is strongly supportive of (1) and (2) because the proposed language clearly meets the requirements of the requirements of PRC 42032.2 and will result in maximum consumer convenience, which is a key aspect of ensuring the efficacy of any Sharps Stewardship Plan.</p> <p>The ability to arrange for delivery of the mail-back container and materials at the point of sale instead of physically handing them to the consumer is contained in (2). We support the precise requirements in (2) that the mail-back container and materials be delivered to the consumer within "three business days at no cost or inconvenience to the ultimate user". If the mail-back container and materials are not physically handed to the consumer at the point of sale, then it needs to be delivered to the consumer within a specific time period and with no further action required of the consumer.</p> <p>PROPOSED ALTERNATIVE LANGUAGE:</p> <p>(j) "Provides or initiates distribution of a sharps waste container" means: (1) To provide a sharps waste container and mail-back materials to the ultimate user at the point of sale at no cost to the ultimate user; (2) To arrange, at the point of sale, for a sharps waste container and mail-back materials to be sent to the ultimate user and arrive within three business days at no cost or inconvenience to the ultimate user; or,</p>	<p>005-002A. A change to the proposed regulatory text is not necessary based on this comment. CalRecycle acknowledges the commenter's support of Section 18972.1(j)(1) and (2). However, CalRecycle proposes the following changes to section 18972.1, noting that 18972.1(j) has been renumbered to 18972.1(a)(11) in the proposed regulatory text:</p> <p>(j) "Provides or initiates distribution of a sharps waste container" means one of the following:</p> <p>(4A) To provide a sharps waste container and mail-back materials to the ultimate user, at the point of sale or prior, at no cost to the ultimate user; or,</p> <p>(2B) To arrange, at the point of sale or prior, for a sharps waste container and mail-back materials to be sent to the ultimate user and arrive within four three business days at no cost or inconvenience to the ultimate user; or,</p> <p>See response to comment 001-001 for discussion on the addition of the phrase "or prior," and see response to comment 015-002 for discussion on the change from three to four business days.</p>
005-002B	Nat'l Stewardship Action Council, CalPSC, County of Santa Clara, & Zero Waste Sonoma	Doug Kobold, Heidi Sanborn, William Grimes, Leslie Lukacs	18972.1 (j)(3)	Y	<p>PROPOSED ALTERNATIVE LANGUAGE:</p> <p>(3) Other methods of providing a sharps waste container and mail-back materials, as approved by the department in a stewardship plan, if (1) or (2) are not reasonably feasible if (1) and (2) are found to be illegal, and which result insubstantially the same level of convenience to the ultimate user.</p> <p><u>CONCERNS WITH (3) AND ALTERNATIVE LANGUAGE</u></p> <p>Our coalition has concerns with the wording of (3) and have recommended alternative language. This provision moves away from point of sale provision of the mail-back container in a manner that is not supported by PRC 42032.2(d)(1)(F)(i), which only allows "other methods" like those anticipated by (3) if providing containers is prohibited by law.</p>	<p>005-002B. Due to a reorganization of subsection 18972.1 of the proposed regulatory text, subsection 18972.1(j) has been changed to 18972.1(a)(11) in the proposed regulatory text. CalRecycle agrees that the "legal offramp" mentioned by the commenter should be incorporated into the definition. Any "other method" for distributing sharps waste containers and mail-back materials at the point of sale included in a stewardship plan will be reviewed for statutory compliance prior to approval. However, CalRecycle prefers the following edit to section 18972.1(a)(11) of the proposed regulatory text:</p> <p>(3C) Other methods of providing a sharps waste container and mail-back materials, as approved by the department in a stewardship plan, if the method identified in subpart (A4) above is not allowed by law or is not reasonably feasible, and if the method identified in subpart (B)</p>

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					<p>There is some history to this legal offramp in PRC 42032.2(d)(1)(F)(i). During the negotiations on SB 212 the sharps manufacturers contended that providing anything of value to the consumer at the point of sale was considered an illegal inducement to purchase their product. No evidence was provided to support this contention, so the exception was added to PRC 42032.2(d)(1)(F)(i) to provide for an offramp that could be utilized only if there was a conflict in law.</p> <p>The proposed regulations expand this offramp in a manner that is inconsistent with PRC 42032.2(d)(1)(F)(i) because it allows “other methods” for reasons of feasibility when the statute is clear that the only offramp is for illegality of the requirement that mail-back containers and materials be provided at the point of sale.</p> <p>Suggested insertion and deletion in 18972(j) - if (1) or (2) are not reasonably feasible, <i>if (1) and (2) are found to be illegal,</i> and which result in substantially the same level of convenience to the ultimate user.</p>	<p>above or (2) is not allowed by law or is not reasonably feasible. These methods must be approved by the department in a stewardship plan and which result in substantially the same level of convenience to the ultimate user as the methods identified in subparts (A) and (B) above.</p> <p>CalRecycle disagrees with the commenter that section 18972.1(a)(11)(C) of the proposed regulatory text is inconsistent with statute. The “legality” limitation noted by the commenter was not CalRecycle’s reason for subpart (C) of this section. The definition for “provides or initiates distribution of a sharps waste container” is meant to clarify what types of distribution mechanisms for sharps waste containers and mail-back materials comply with the requirement in Public Resources Code section 42032.2(d)(1)(F)(i) and ensures that convenience to the ultimate user is not compromised. Since section 18972.1(a)(11)(C) of the proposed regulatory text must “result in substantially the same level of convenience to the ultimate user as the methods identified in subparts (A) and (B) above,” this option provides program operators with greater flexibility in designing innovative distribution mechanisms while upholding the level of consumer convenience intended by statute. Any proposed “other method” will require CalRecycle approval as part of a proposed Stewardship Plan.</p>
005-003	Nat'l Stewardship Action Council, CalPSC, County of Santa Clara, & Zero Waste Sonoma	Doug Kobold, Heidi Sanborn, William Grimes, Leslie Lukacs	18972.2	Y	<p>Proposed Regulation Section: 18972.2, Page: 3, Subject: Criteria for Determining a Covered Entity</p> <p>Our coalition is supportive of the general notion that the department will start by looking to the manufacturers, and then will move down the list contained in PRC 42030(1)(B)-(E). We do, however, recommend that the proposed regulations give those on the list some indication of the process for moving down the list. Specifically, at what point and via what process will an entity identified in PRC 42030(1)(B)-(E) be notified that the department is moving down the list and what timeframes will apply for compliance? We would recommend that the department more clearly address the process by which a Covered Entity in PRC 42030(1)(B)-(E) will be required to weave in and out of an ongoing program based largely on actions outside of their control.</p>	<p>005-003. Compliance determinations are made on a case-by-case basis. The proposed regulations, by pointing to the tiered definition of “covered entity” in Public Resources Code section 42030(f)(1)(A) through (E), provide sufficient clarity to determine a covered entity. Entities that could be considered covered entities based on the statutory definition should endeavor to coordinate amongst appropriate entities within their respective supply chains to determine how the statutory requirements will be met. It is the responsibility of covered entities to self-identify through the submission of covered products lists to the Board of Pharmacy for verification pursuant to Public Resources Code section 42031(a) through (d).</p> <p>Based on our review of this issue, we have determined that section 18972.2 of the proposed regulatory text should be revised as follows to accurately reflect the statutory priorities:</p> <p>(a) The department shall consider all manufacturers of covered products that are sold, offered for sale, or dispensed in California, whether they are program operators or are represented by a stewardship organization, as the covered entities. (b) The department will use the priority set forth in subsections(1)(B)-(E) of subdivision (f) of section 42030 of the Public Resources Code to identify the covered entity for any covered products consistent with subdivision (f) of section 42030, which do not meet the</p>

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						<p>definition of subsection (1)(A) of subdivision (f) of section 42030 of the Public Resources Code.</p> <p>This revision was made because the deleted text did not add any necessary information to what is already stated in Public Resources Code 42030(f)(1)(A)-(E). Additionally, the term “dispensed” is not part of the statutory definition of “covered entity.”</p>
005-004	Nat'l Stewardship Action Council, CalPSC, County of Santa Clara, & Zero Waste Sonoma	Doug Kobold, Heidi Sanborn, William Grimes, Leslie Lukacs	18973.1 (b)	N	<p>Proposed Regulation Section: 18973.1(b), Page: 4, Subject: Document Approvals: Stewardship Plan, Initial Program Budget, annual report, and Annual Budget</p> <p>Subsection (b) describes the process by which plans, budgets, and annual reports will be deemed “complete” by the department. The proposed regulations provide for a reasonable process of submission by the covered entity, review by the department, and potential re-submission if a document is determined to be incomplete.</p> <p>Subsection (b) does not provide a clear end to the process of determining whether a document is complete. Our coalition believes that this process should be limited to one resubmission for completeness. If a program operator resubmits a document as outlined in subsection (b) and the department determines that the resubmitted document is still incomplete, then the document should be deemed disapproved by the department and the program operator should be out of compliance. We believe that the regulations should limit the back-and-forth required to simply get a complete document.</p> <p>PROPOSED ALTERNATIVE LANGUAGE:</p> <p>(b) The department shall determine if a document is complete and notify the submitting program operator within 30 days of receipt. If the department determines that the document is complete, the department’s 90-day review period for consideration of approval, conditional approval, or disapproval of the document will commence upon the original date of receipt. If the department determines that the document is incomplete, the department shall identify for the program operator the required additional information and the program operator shall resubmit the document within 30 days of the department’s notification that the document is incomplete. If the department determines upon resubmittal that the document is complete, the department’s 90-day review period for consideration of approval, conditional approval, or disapproval of the document will commence upon the original date of receipt of the resubmittal. <u><i>If the department determines upon resubmittal that the document is incomplete, the department shall disapprove the document and the covered entities operating under the stewardship plan are not in compliance until the program operator submits a document the department approves.</i></u></p>	<p>005-004. A change to the proposed regulatory text is not necessary. The statutory requirements in Public Resources Code sections 42031.4(a) and 42032(g) identify the implementation timeline and are sufficient to discourage excess back-and-forth. The proposed regulatory text provides flexibility if additional information needs to be submitted pursuant to Public Resources Code section 42032(c)(3). Completeness reviews are common in California’s (and CalRecycle’s) regulatory structure – there is no reason to limit additional submittals, and no need to specify that a plan is disapproved after a second submission is incomplete. A completeness review occurs first and is separate from the approval review. Statute requires an approved plan for covered products to be sold in compliance. If a covered entity or stewardship organization has not submitted a complete plan to start the review process, then by definition, it does not have an approved plan.</p>

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005-005	Nat'l Stewardship Action Council, CalPSC, County of Santa Clara, & Zero Waste Sonoma	Doug Kobold, Heidi Sanborn, William Grimes, Leslie Lukacs	18973.1 (e)	N	<p>Proposed Regulation Section: 18973.1(e), Page: 5, Subject: Document Approvals: Stewardship Plan, Initial Program Budget, annual report, and Annual Budget</p> <p>Similar to the comment we made above with respect to Section 18972.2 on "Criteria for Determining a Covered Entity", we believe that it would be positive for the regulations to more clearly identify which events will trigger the department to look to the entities listed in PRC 42030(1)(B)-(E). If the department disapproved a Stewardship Plan under this provision will they then look to the listed entities?</p>	005-005. A change to the proposed regulatory text is not necessary. Section 18973.1(e) has been changed to section 18973.1(h) in the proposed regulatory text due to changes made elsewhere. Pursuant to section 18973.1(h), if a plan is disapproved then the covered entities operating under that plan are out of compliance until the program operator submits a plan that is approved. CalRecycle will determine covered entities pursuant to Public Resources Code section 42030(f)(1)(A) through (E). See response to comment 005-003 for further discussion on this topic.
005-006	Nat'l Stewardship Action Council, CalPSC, County of Santa Clara, & Zero Waste Sonoma	Doug Kobold, Heidi Sanborn, William Grimes, Leslie Lukacs	18973.1 (f)	N	<p>Proposed Regulation Section: 18973.1(f), Page: 5, Subject: Document Approvals: Stewardship Plan, Initial Program Budget, annual report, and Annual Budget</p> <p>Subsection (f) is not clear in terms of whether a disapproved annual report or program budget results in the program operator and covered entities being out of compliance. Our coalition has proposed language to make it clear that disapproval of the annual report or program budget will result in a determination that the covered entities and program operators are not in compliance.</p> <p>PROPOSED ALTERNATIVE LANGUAGE:</p> <p>(f) If the department conditionally approves an annual report or program budget, the department shall identify the deficiencies and the program operator shall comply with the conditions within 60 days of the notice date unless the director determines that additional time is needed. If the program operator does not comply and the conditions are not met within 60 days of the notice date for a conditional approval, the department shall disapprove the annual report or program budget. <i>If the department disapproves the annual report or program budget, then the covered entities operating under the stewardship plan are not in compliance until the program operator submits a document the department approves</i></p>	005-006. A change to the proposed regulatory text is not necessary. Public Resources Code Section 42035.4 allows CalRecycle to revoke the approval of a program operator's stewardship plan, require resubmittal of the stewardship plan, or require additional reporting in the event that a covered entity, program operator, stewardship organization, or authorized collector does not meet a material requirement of statute. In the event that an annual report or program budget is disapproved due to not meeting a material requirement of the statute, CalRecycle has the statutory authority to take the appropriate enforcement actions, as outlined in the Statute and Sections 18975 through 18975.2 of these regulations.
005-007	Nat'l Stewardship Action Council, CalPSC, County of Santa Clara, & Zero Waste Sonoma	Doug Kobold, Heidi Sanborn, William Grimes, Leslie Lukacs	18973.2 (d)(2)	N	<p>Proposed Regulation Section: 18973.2(d)(2), Page: 6, Subject: Stewardship Plan for Covered Drugs</p> <p>Our coalition supports the requirement to report on efforts to bring authorized collectors into the program because it will be relevant to enforcement decisions if a plan does not meet the minimum convenience standard in PRC 43032.2(a)(1)(F).</p>	005-007. 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 for section 18973.2(d)(2); however, the department is making the following edits to this section: <u>(2) Pursuant to Section 42032.2(b)(1) of the Public Resources Code, list of potential authorized collectors, in the counties in which the program will operate, that were notified of the opportunity to serve as an authorized collector for the proposed stewardship program, and the method(s) by which each potential authorized collector was notified. The notification shall occur at least 120 days before the stewardship plan is submitted to the department.</u>

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005-008	Nat'l Stewardship Action Council, CalPSC, County of Santa Clara, & Zero Waste Sonoma	Doug Kobold, Heidi Sanborn, William Grimes, Leslie Lukacs	18973.2 (d)(3)	N	<p>Proposed Regulation Section: 18973.2(d)(3), Page: 6, Subject: Stewardship Plan for Covered Drugs</p> <p>We support the inclusion of this provision but think it should be modified just slightly. It is vitally important to the effective operation of this program that program operators conduct business in good faith. PRC 43032(b)(1)(3) allows authorized collectors to request entrance to the program and requires a program operator to include them within 90 days. Our coalition is concerned that stewardship organizations may erect unnecessary roadblocks to onboarding authorized collectors once the minimum convenience standard has been met. The regulations should include a requirement that the plan include a process specifically for onboarding authorized collectors under PRC 43032.2(b)(3).</p> <p>PROPOSED ALTERNATIVE LANGUAGE:</p> <p>(3) Description of the process in which good faith negotiations with potential authorized collectors is conducted-, <u>including a process designed specifically for requests from authorized collectors under Section 42032.2(b)(3) of the PRC.</u></p>	005-008. A change to the proposed regulatory text is not necessary. Sections 18973.2(d)(3) and (4) of the proposed regulatory text and the statutory text of section 42032.2(b)(3) are sufficient to require a program operator to describe its efforts to onboard potential authorized collectors that offer to participate in the stewardship program.
005-009	Nat'l Stewardship Action Council, CalPSC, County of Santa Clara, & Zero Waste Sonoma	Doug Kobold, Heidi Sanborn, William Grimes, Leslie Lukacs	18973.2 (d)(4)	Y	<p>Proposed Regulation Section: 18973.2(d)(4), Page: 6, Subject: Stewardship Plan for Covered Drugs</p> <p>We believe strongly that this portion of the regulations needs to intersect with the department's enforcement efforts and application of civil penalties. The requirement contained in PRC 43032.2(b)(1)(3) is, in our opinion, a vital component of any stewardship plan for covered drugs. The department needs to consider how it will enforce against a program operator that does not meet the requirements of the statute. Because the civil penalties are limited to specific circumstances the department should consider plan revocation in circumstances where the program operator violates key requirements of the program. We would also recommend an appeals process for any authorized collectors whose request under PRC 43032.3(b)(3) is rejected.</p>	<p>005-009. In regards to the comment on enforcement considerations, Public Resources Code sections 42035.2 and 42035.4 designate CalRecycle with the authority to impose administrative penalties and/or revoke an approved stewardship plan. CalRecycle will determine if the program operator is not meeting the requirements of statute and regulations and will consider civil penalties and/or stewardship plan revocation on a case-by-case basis. CalRecycle enforcement actions will depend on the circumstances and violations.</p> <p>Separately, CalRecycle agrees with the commenter's suggestion to incorporate an appeals process for a potential authorized collector who offers to participate in the stewardship program and is rejected. A requirement has been added to section 18973.2(d) of the proposed regulatory text as follows:</p> <p><u>(5) Description of the process potential authorized collectors can utilize to appeal a rejection, by the program operator, for inclusion in the stewardship program.</u></p>
005-010	Nat'l Stewardship Action Council, CalPSC, County of Santa Clara,	Doug Kobold, Heidi Sanborn, William Grimes,	18973.2 (g)(2)	N	<p>Proposed Regulation Section: 18973.2(g)(2)(A), Page: 7, Subject: Stewardship Plan for Covered Drugs</p> <p>Our coalition is supportive of the requirement that the Stewardship Plan include an explanation of how the collection network provides for a reasonable geographic spread. It is important that these county-based networks serve the population broadly and are not concentrated in a few specific areas.</p>	005-010. 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 this section.

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	& Zero Waste Sonoma	Leslie Lukacs				
005-011	Nat'l Stewardship Action Council, CalPSC, County of Santa Clara, & Zero Waste Sonoma	Doug Kobold, Heidi Sanborn, William Grimes, Leslie Lukacs	18973.2 (g)(8)	N	<p>Proposed Regulation Section: 18973.2(g)(8), Page: 8, Subject: Stewardship Plan for Covered Drugs</p> <p>Our coalition is supportive of the requirement that the Stewardship Plan provide a process by which bins will be maintained and do not reach capacity. The program cannot operate if the bins are full and consumers cannot access them for disposal.</p>	005-011. 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 for this section.
005-012	Nat'l Stewardship Action Council, CalPSC, County of Santa Clara, & Zero Waste Sonoma	Doug Kobold, Heidi Sanborn, William Grimes, Leslie Lukacs	18973.2 (g)(9)	N	<p>Proposed Regulation Section: 18973.2(g)(10), Page: 8, Subject: Stewardship Plan for Covered Drugs</p> <p>The draft regulations circulated by the department during the informal rulemaking workshops included a requirement for the stewardship organization to provide, where needed, training to authorized collectors to ensure compliance. We would support the inclusion of that provision in the proposed regulations.</p>	005-012. A change to the proposed regulatory text is not necessary. Sections 18973.2(g)(1) and 18973.3(f)(1) of the proposed regulations require a description of "processes and policies that will be used to safely and securely collect, track, and properly manage covered drugs from collection through final disposal." Training could be one element of effective processes and policies, but CalRecycle prefers to give a program operator the flexibility to propose processes and policies tailored to its specific collection mechanisms.
005-013	Nat'l Stewardship Action Council, CalPSC, County of Santa Clara, & Zero Waste Sonoma	Doug Kobold, Heidi Sanborn, William Grimes, Leslie Lukacs	18973.2 (i)	N	<p>Proposed Regulation Section: 18973.2(i), Page: 8, Subject: Stewardship Plan for Covered Drugs - Local Ordinance Repeals</p> <p>While we do not have recommended language, we would encourage the department to consider expansion of the regulations to more closely oversee the process by which local ordinances are repealed and counties migrate into the statewide program. Counties that currently have a drug or sharps take-back program in place through the establishment of a local ordinance will not simply repeal their ordinance and move into this statewide program. Any movement away from a local ordinance and into the statewide program established under SB 212 will likely come as the result of negotiations with an individual county.</p> <p>We know from our discussions with both the sharps and pharmaceutical industries that they want to convince counties with existing ordinances to repeal the local ordinance and move into the statewide program. We believe that any terms that are negotiated during need to be protected by the department. For example, a county with a local ordinance may require a certain level of service (drug bin density, education campaign, etc.) that is beyond the requirements in SB 212 as a condition of their repeal. If this occurs, and local ordinances are permanently repealed in favor of the statewide program, then the terms of that repeal need to be protected in perpetuity.</p>	005-013. A change to the proposed regulatory text is not necessary. The commenter is requesting that the regulations require local ordinances with more stringent requirements than SB 212 to be maintained if repealed. This is beyond the scope and authority of these regulations.

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005-014A1 of (A-H)	Nat'l Stewardship Action Council, CalPSC, County of Santa Clara, & Zero Waste Sonoma	Doug Kobold, Heidi Sanborn, William Grimes, Leslie Lukacs	18973.2 (j)	N	<p>Proposed Regulation Section: 18973.2(j) and 18973.3(i), Page: 8 and 13, Subject: Education and Outreach for both Drug and Sharps Stewardship Plan</p> <p>The importance of the education and outreach portion of both the drugs and sharps stewardship program cannot be understated. The drug and sharps stewardship program will only be successful if ultimate users understand that free and convenient collection and disposal is available. The world of covered products is vast (prescription medications, over-the-counter medications, and sharps) and the number of ultimate users is high. It's not an overstatement to suggest that every household in California will have, at some point, a product covered by this program that needs collection and disposal.</p> <p>From the department's regulatory perspective, we think it is important to remember the statute gives you a broad mandate to require a comprehensive education and outreach plan. Section 42031.6(a) of the Public Resources Code requires a "comprehensive education and outreach program intended to promote participation in the stewardship program". The PRC then goes on to provide a list of minimum requirements for the education and outreach program. But it's important to note that the rest of subsection (a) is just a list of "minimum requirements" for a broader mandate to establish a comprehensive education and outreach program designed to promote participation by virtually every household in California.</p> <p>Because there are so many ultimate users spread across such a wide geography, the education and outreach programs should be tailored for success. We would recommend that the department consider a more prescriptive approach to the regulations in this area. Specifically, we'd highlight the following ideas:</p> <ul style="list-style-type: none"> - Multiple Languages: Californian's speak a variety of languages and this education and outreach campaign needs to reflect this diversity. 	005-014A1. A change to the proposed regulatory text is not necessary. CalRecycle recognizes California's high level of geographic and demographic diversity. Proposed regulatory text section 18973.2(j)(2) requires program operators to distribute materials in languages suited to local demographics. See the response to comment 005-014B for further discussion on this topic.
005-014A2	Nat'l Stewardship Action Council, CalPSC, County of Santa Clara, & Zero Waste Sonoma	Doug Kobold, Heidi Sanborn, William Grimes, Leslie Lukacs	18973.3 (i)	N	<p>Proposed Regulation Section: 18973.2(j) and 18973.3(i), Page: 8 and 13, Subject: Education and Outreach for both Drug and Sharps Stewardship Plan</p> <p>The importance of the education and outreach portion of both the drugs and sharps stewardship program cannot be understated. The drug and sharps stewardship program will only be successful if ultimate users understand that free and convenient collection and disposal is available. The world of covered products is vast (prescription medications, over-the-counter medications, and sharps) and the number of ultimate users is high. It's not an overstatement to suggest that every household in California will have, at some point, a product covered by this program that needs collection and disposal.</p> <p>From the department's regulatory perspective, we think it is important to remember the statute gives you a broad mandate to require a comprehensive education and outreach plan. Section 42031.6(a) of the Public Resources Code</p>	005-014A2. A change to the proposed regulatory text is not necessary. CalRecycle recognizes California's high level of geographic and demographic diversity. Proposed regulatory text section 18973.3(i)(2) requires program operators to distribute materials in languages suited to local demographics.

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					<p>requires a “comprehensive education and outreach program intended to promote participation in the stewardship program”. The PRC then goes on to provide a list of minimum requirements for the education and outreach program. But it’s important to note that the rest of subsection (a) is just a list of “minimum requirements” for a broader mandate to establish a comprehensive education and outreach program designed to promote participation by virtually every household in California.</p> <p>Because there are so many ultimate users spread across such a wide geography, the education and outreach programs should be tailored for success. We would recommend that the department consider a more prescriptive approach to the regulations in this area. Specifically, we’d highlight the following ideas:</p> <ul style="list-style-type: none"> - Multiple Languages: Californian’s speak a variety of languages and this education and outreach campaign needs to reflect this diversity. 	
005-014B	Nat'l Stewardship Action Council, CalPSC, County of Santa Clara, & Zero Waste Sonoma	Doug Kobold, Heidi Sanborn, William Grimes, Leslie Lukacs	18973.2 (j)(2)	Y	<p>Modify: 18973.1(j)(2) Materials to be utilized that are distributed in languages suited to local demographics. <i>Consistent with Section 7295 of Government Code, educational materials required by this chapter shall be translated into any non-English language spoken by a substantial number of the ultimate users in each local demographic area.</i> These materials shall include, but are not limited to, signage for hospitals, pharmacies, and other locations, as necessary.</p>	<p>005-014B. Section 18973.1(j)(2) does not exist in the proposed regulatory text and CalRecycle believes the comment is referring to section 18973.2(j)(2). CalRecycle agrees with the commenter’s proposed change, but the department prefers the following edit:</p> <p><u>(2) 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.</u></p> <p>CalRecycle prefers the phrase “languages suited to local demographics, consistent with section 7295 of the Government Code” (which requires “materials explaining services available to the public [to] be translated into any non-English language spoken by a substantial number of the public...”). In regards to the new sentence beginning with “signage or labeling,” see response to comment 006-014.</p>
005-014C1	Nat'l Stewardship Action Council, CalPSC, County of Santa Clara, & Zero Waste Sonoma	Doug Kobold, Heidi Sanborn, William Grimes, Leslie Lukacs	18973.2 (j)	N	<ul style="list-style-type: none"> - Multiple Communication Platforms and Mediums: The plan should span internet, television, radio, and print media platforms because of the need to reach such a diverse audience of ultimate users. 	<p>005-014C1. 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.</p> <p>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</p>

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						program operator with the flexibility needed to design a successful education and outreach program.
005-014C2	Nat'l Stewardship Action Council, CalPSC, County of Santa Clara, & Zero Waste Sonoma	Doug Kobold, Heidi Sanborn, William Grimes, Leslie Lukacs	18973.3 (i)	N	- Multiple Communication Platforms and Mediums: The plan should span internet, television, radio, and print media platforms because of the need to reach such a diverse audience of ultimate users.	005-014C2. 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" will provide the program operator with the flexibility needed to design a successful education and outreach program.
005-014D	Nat'l Stewardship Action Council, CalPSC, County of Santa Clara, & Zero Waste Sonoma	Doug Kobold, Heidi Sanborn, William Grimes, Leslie Lukacs	18973.2 (j)(3)	Y	Add: 18973.1(j)(3)(F) Include multiple language translation functionality.	005-014D. Section 18973.1(j)(3)(F) is not a valid reference to the proposed regulatory text and CalRecycle believes the comment is requesting an insertion to section 18973.2(j)(3). CalRecycle agrees with the commenter's request that a website that is part of a required comprehensive education and outreach program must include the functionality to provide content in multiple languages. Proposed regulatory text section 18973.2(j)(3) is revised as follows: <u>(3) Establishment of an internet website designed with functionality for mobile platforms, provided with language options suited to local demographics, and maintained to ensure all information is up to date and accurate. 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:</u> CalRecycle intends to similarly edit section 18973.3(i)(2) in the stewardship plan requirements for home-generated sharps waste.
005-014E1	Nat'l Stewardship Action Council, CalPSC, County of Santa Clara, & Zero Waste Sonoma	Doug Kobold, Heidi Sanborn, William Grimes, Leslie Lukacs	18973.2 (j)	N	- Action: The plan should be about action. The plan should describe what efforts will be undertaken to broadly distribute the printed materials to the parties outlined in Section 42031.6(a)(2). The plan should also describe how the program operator plans to drive traffic to their internet website. We would recommend that the department consider these types of requirements throughout this portion of the regulations.	005-014E1. A change to the proposed regulatory text is not necessary. CalRecycle will evaluate the education and outreach plan during the stewardship plan review process to ensure it adequately promotes and maximizes participation in the stewardship program.
005-014E2	Nat'l Stewardship Action Council,	Doug Kobold, Heidi Sanborn,	18973.3 (i)	N	- Action: The plan should be about action. The plan should describe what efforts will be undertaken to broadly distribute the printed materials to the parties outlined in Section 42031.6(a)(2). The plan should also describe how the program operator plans to drive traffic to their internet website. We would	005-014E2. A change to the proposed regulatory text is not necessary. CalRecycle will evaluate the education and outreach plan during the stewardship plan review process to ensure it adequately promotes and maximizes participation in the stewardship program.

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	CalPSC, County of Santa Clara, & Zero Waste Sonoma	William Grimes, Leslie Lukacs			recommend that the department consider these types of requirements throughout this portion of the regulations.	
005-014F1	Nat'l Stewardship Action Council, CalPSC, County of Santa Clara, & Zero Waste Sonoma	Doug Kobold, Heidi Sanborn, William Grimes, Leslie Lukacs	18973.2 (j)	N	- Market Research: The education and outreach plan should be market tested for effectiveness before it is implemented, and then again periodically to ensure that it is performing as designed.	005-014F1. A change to the proposed regulatory text is not necessary. While conducting market research upfront could be beneficial, this activity would have to occur prior to the program operator submitting the stewardship plan to CalRecycle and thus is outside the scope of the stewardship plan regulations. A program operator may choose to consult third-parties or draw from existing experience in order to design its comprehensive education and outreach program, prior to gaining insights from the program data collected during the first year of operation. Additionally, sections 18973.2(j)(5) and 18973.3(i)(5) of the proposed regulatory text require a program operator to propose metrics to evaluate the performance of a comprehensive education and outreach program. These metrics effectively serve as continual "market research" that enables CalRecycle to evaluate the performance of the education and outreach program during the department's annual report review. Thus, additional requirements for periodic market research are unnecessary.
005-014F2	Nat'l Stewardship Action Council, CalPSC, County of Santa Clara, & Zero Waste Sonoma	Doug Kobold, Heidi Sanborn, William Grimes, Leslie Lukacs	18973.3 (i)	N	- Market Research: The education and outreach plan should be market tested for effectiveness before it is implemented, and then again periodically to ensure that it is performing as designed.	005-014F2. A change to the proposed regulatory text is not necessary. Sections 18973.2(j)(5) and 18973.3(i)(5) of the proposed regulatory text require a program operator to propose metrics to evaluate the performance of a comprehensive education and outreach program. While conducting market research upfront could be beneficial, this activity would have to occur prior to the program operator submitting the stewardship plan to CalRecycle and thus is outside the scope of the stewardship plan regulations. A program operator may choose to consult third-parties or draw from existing experience in order to design its comprehensive education and outreach program, prior to gaining insights from the program data collected during the first year of operation.
005-014G	Nat'l Stewardship Action Council, CalPSC, County of Santa Clara, & Zero Waste Sonoma	Doug Kobold, Heidi Sanborn, William Grimes, Leslie Lukacs	18973.2 (j)(5)	N	Modify: 18973.1(j)(5) Metrics to evaluate performance of the comprehensive education and outreach program, including, but not limited to, ultimate user awareness, program usage, and accessibility, <u>and market research. Market research shall be conducted every three (3) years to determine whether the education and outreach program is successfully reaching and educating at least 90% of the ultimate users about the program. Further, the director may require specific any performance measures, performance requirements or targets when approving the plan.</u>	005-014G. Section 18973.1(j)(5) does not exist in the proposed regulatory text and CalRecycle believes the comment is referring to section 18973.2(j)(5). A change to the proposed regulatory text is not necessary. Sections 18973.2(j)(5) and 18973.3(i)(5) of the proposed regulatory text require a program operator to propose metrics to evaluate the performance of a comprehensive education and outreach program. In accordance with these metrics, a program operator will then collect data throughout the year, such as ultimate user awareness of the stewardship program, and then present this data in its annual report. Thus, these metrics effectively serve as continual "market research" that

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						<p>enables CalRecycle to evaluate the performance of the education and outreach program during the department’s annual report review, and an additional requirement for market research to occur every three years is unnecessary.</p> <p>Furthermore, CalRecycle does not seek to require a specific performance benchmark for an education and outreach program in the proposed regulations. The department will evaluate stewardship plans for compliance with the requirement in Public Resources Code section 42031.6(a) that a proposed education and outreach program be “comprehensive,” and the department has the authority to reject an annual report or revoke a stewardship plan if education and outreach activities prove to be insufficient.</p>
005-014H1	Nat'l Stewardship Action Council, CalPSC, County of Santa Clara, & Zero Waste Sonoma	Doug Kobold, Heidi Sanborn, William Grimes, Leslie Lukacs	18973.2 (j)	N	Finally, we think that the regulations should restate the prohibition in Section 42031.6(b). This subsection states unequivocally that the education and outreach program under this program shall not promote disposal options that are inconsistent with the services offered under the program. This section was included in SB 212 because there have been instances where programs under local ordinances promoted flushing and trashing meds. The education and outreach component of any stewardship plan for drugs or sharps should only promote disposal options offered by the program. The statute is clear – the education and outreach program should “promote participation in the stewardship program”.	005-014H1. A change to the proposed regulatory text is not necessary. The statutory requirement is sufficiently clear and is in effect despite not being repeated in the proposed regulatory text.
005-014H2	Nat'l Stewardship Action Council, CalPSC, County of Santa Clara, & Zero Waste Sonoma	Doug Kobold, Heidi Sanborn, William Grimes, Leslie Lukacs	18973.3 (i)	N	Finally, we think that the regulations should restate the prohibition in Section 42031.6(b). This subsection states unequivocally that the education and outreach program under this program shall not promote disposal options that are inconsistent with the services offered under the program. This section was included in SB 212 because there have been instances where programs under local ordinances promoted flushing and trashing meds. The education and outreach component of any stewardship plan for drugs or sharps should only promote disposal options offered by the program. The statute is clear – the education and outreach program should “promote participation in the stewardship program”.	005-014H2. A change to the proposed regulatory text is not necessary. The statutory requirement is sufficiently clear and is in effect despite not being repeated in the proposed regulatory text.
005-015a	Nat'l Stewardship Action Council, CalPSC, County of Santa Clara, & Zero Waste Sonoma	Doug Kobold, Heidi Sanborn, William Grimes, Leslie Lukacs	18973.2 (k)	Y	<p>Proposed Regulation Section: 18973.2(k) and 18973.3(j), Page: 9 and 13, Subject: Stewardship Plan for Covered Drugs</p> <p>We are somewhat confused by these portions of the regulations. It would be helpful to understand how department believes that the statute allows for different stewardship organizations to combine their efforts to meet the requirements of SB 212. The Initial Statement of Reasons cites an obvious potential for conflict in the education, outreach, and instructions to ultimate users. However, we’d want to know from the department if they envision coordination in other areas. If this is specific just to the education and outreach portion of the regulations, maybe this requirement should be imbedded in those sections of the regulations.</p>	<p>005-015a. CalRecycle does not believe statute restricts coordination to outreach and education efforts. For example, Public Resources Code 42032.2(a)(1)(F)(i) does not specify that a stewardship plan needs to independently meet the requirement. However, CalRecycle agrees with the commenter that additional clarity is needed and section 18973.2(k) of the proposed regulatory text has been modified as follows:</p> <p><u>(k) Coordination Efforts. Description of how the program operator will make a good faith effort to work with the other stewardship program(s) in order to most effectively achieve the requirements of statute and regulations, coordinate with other program operators to avoid conflict, duplication, and confusion to the public and all program participants in the event that</u></p>

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						<p><u>multiple stewardship programs for covered drugs are in operation concurrently or new stewardship programs begin operating.</u></p> <p>The department has removed the phrase “good faith effort” from section 18973.2(k) of the proposed regulatory text, while leaving the language that requires a description of how a program operator will work with other program operators in the event that multiple stewardship programs are in operation concurrently. Coordination efforts will be evaluated for compliance with the statute and regulations, and thus the department prefers to provide greater specificity for this requirement by listing the types of implementation issues that the description should address, rather than relying on the term “good faith effort,” which is ambiguous in this context. Furthermore, these proposed edits clarify that the required description should account for not only existing stewardship programs, but also for the possibility of new stewardship programs arising in the future.</p>
005-015b	Nat'l Stewardship Action Council, CalPSC, County of Santa Clara, & Zero Waste Sonoma	Doug Kobold, Heidi Sanborn, William Grimes, Leslie Lukacs	18973.3 (j)	Y	<p>Proposed Regulation Section: 18973.2(k) and 18973.3(j), Page: 9 and 13, Subject: Stewardship Plan for Covered Drugs</p> <p>We are somewhat confused by these portions of the regulations. It would be helpful to understand how department believes that the statute allows for different stewardship organizations to combine their efforts to meet the requirements of SB 212. The Initial Statement of Reasons cites an obvious potential for conflict in the education, outreach, and instructions to ultimate users. However, we'd want to know from the department if they envision coordination in other areas. If this is specific just to the education and outreach portion of the regulations, maybe this requirement should be imbedded in those sections of the regulations.</p>	<p>005-015b. The department does not believe coordination must be restricted to outreach and education efforts. For example, Public Resources Code 42032.2(a)(1)(F)(i) does not specify that a stewardship plan needs to independently meet the requirement. However, CalRecycle agrees with the commenter that additional clarity is needed and section 18973.3(j) of the proposed regulatory text has been modified as follows:</p> <p><u>(j) Coordination Efforts. Description of how the program operator will make a good faith effort to work with the other stewardship program(s) in order to most effectively achieve the requirements of statute and regulations, coordinate with other program operators to avoid conflict, duplication, and confusion to the public and all program participants in the event that multiple stewardship programs for covered drugs are in operation concurrently or new stewardship programs begin operating.</u></p> <p>The department has removed the phrase “good faith effort” from section 18973.3(j) of the proposed regulatory text, while leaving the language that requires a description of how a program operator will work with other program operators in the event that multiple stewardship programs are in operation concurrently. Collaboration efforts will be evaluated for compliance with the statute and regulations, and thus the department prefers to provide greater specificity for this requirement by listing the types of implementation issues that the description should address, rather than relying on the term “good faith effort,” which is ambiguous in this context. Furthermore, these proposed edits clarify that the required description should account for not only existing stewardship programs, but also for the possibility of new stewardship programs arising in the future.</p>

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005-016	Nat'l Stewardship Action Council, CalPSC, County of Santa Clara, & Zero Waste Sonoma	Doug Kobold, Heidi Sanborn, William Grimes, Leslie Lukacs	18973.3(f)(2)(A)	N	<p>Proposed Regulation Section: 18973.3(f)(2), Page: 10, Subject: Stewardship Plan for Home-Generated Sharps Waste</p> <p>Our coalition is a strong supporter of the language in this portion of the regulations. The language, as drafted, correctly implements the requirement that sharps stewardship program "provide or initiate distribution" of the sharps container and mail-back materials at the point-of-sale. This is one of the defining provisions of the sharps mail-back program contained in SB 212 because it provides maximum convenience to the ultimate user.</p>	005-016. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. CalRecycle notes the commenter's statement.
005-017	Nat'l Stewardship Action Council, CalPSC, County of Santa Clara, & Zero Waste Sonoma	Doug Kobold, Heidi Sanborn, William Grimes, Leslie Lukacs	18973.3(f)(2)(A)	Y	<p>Proposed Regulation Section: 18973.3(f)(2)(A), Page: 10, Subject: Stewardship Plan for Home-Generated Sharps Waste</p> <p>The department may want to consider a scenario where a sharps stewardship organization may want to provide containers and mail-back materials sufficient for several purchases. For example, if an ultimate user is receiving their sharps via mail delivery a program operator may want to send them a container suitable for several months of sharps deliveries. This should be allowed so long as the containers, when full, are not too heavy or large for an ultimate user to lift and carry safely.</p>	<p>005-017. CalRecycle agrees with the commenter's rationalization that providing sharps waste containers and mail-back materials that are sufficient for several purchases could be an effective practice. The proposed regulatory text is revised as follows in section 18973.3(f)(2)(A):</p> <p><u>(A) 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.</u></p> <p>This edit also further aligns the proposed regulatory text with the language in Public Resources Code section 42032.2(d)(1)(F)(i).</p>
005-018	Nat'l Stewardship Action Council, CalPSC, County of Santa Clara, & Zero Waste Sonoma	Doug Kobold, Heidi Sanborn, William Grimes, Leslie Lukacs	18973.3(f)(6)(A)	N	<p>Proposed Regulation Section: 18973.3(f)(6)(A), Page: 11, Subject: Stewardship Plan for Home-Generated Sharps Waste</p> <p>We are supportive of this option for a sharps stewardship plan to supplement their mail-back collection efforts with secure receptacles. While this is not required by the statute, we believe that it would be beneficial to ultimate users to have receptacles as part of the program.</p>	005-018. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. CalRecycle notes the commenter's statement.
005-019	Nat'l Stewardship Action Council, CalPSC, County of Santa Clara, & Zero Waste Sonoma	Doug Kobold, Heidi Sanborn, William Grimes, Leslie Lukacs	18973.3(g)(2)	Y	<p>Proposed Regulation Section: 18973.3(g), Page: 12, Subject: Stewardship Plan for Home-Generated Sharps Waste - Local Agency Requests</p> <p>Section 42032.2(d)(1)(F)(ii) of the PRC was included to ensure that the mail-back program was designed for success. This provision requires a stewardship plan to address sharps waste that slips through their mail-back program by either picking up sharps from local agencies or reimbursing local agencies for their costs. This is an extremely important provision because it serves as a sort of insurance on the quality of the mail-back program and protects local agencies from dangerous waste that can harm their employees. We are supportive of the regulations as drafted, but would encourage a few minor changes:</p>	<p>005-019. CalRecycle agrees with the commenter's recommendation. Proposed regulatory text section 18973.3(g) is revised as follows:</p> <p><u>(2) Requests by local agencies, or an agent on behalf of a local agency, shall include an invoice and shall be submitted to the program operator as necessary. Program operators will respond to requests by local agencies within 14 days of receipt in a timely manner and identify the method to resolve the request by selecting either reimbursement or removal from household hazardous waste facility(ies).</u></p>

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					- 18973.3(g)(2): Instead of requiring that a program operator “respond to requests in a timely manner” we would suggest a specific response time requirement of 14 days.	
005-020	Nat'l Stewardship Action Council, CalPSC, County of Santa Clara, & Zero Waste Sonoma	Doug Kobold, Heidi Sanborn, William Grimes, Leslie Lukacs	18973.4 (c)	Y	<p>Proposed Regulation Section: 18973.4(c) and 18973.4(d), Page: 14 and 16, Subject: Annual Report for Covered Drugs</p> <p>Subsection (c) requires stewardship organizations to report on their “efforts to include authorized collectors beyond the minimum convenience standards” pursuant to the requirements of the PRC. Subsection (d) requires stewardship organizations to identify the reasons that “potential authorized collectors” were excluded from program participation. Our coalition would recommend that there be a specific requirement that the annual report contain a list of the authorized collectors that have requested to join the program under Section 42032.2(a)(1)(F), including how their request was ultimately addressed in the required timeframe, the date of full inclusion if the request is approved, and the specific justification for each rejection.</p>	<p>005-020. CalRecycle agrees that a change to the proposed regulatory text is necessary, however, CalRecycle prefers the following change to section 18973.4(c)(2) of the proposed regulatory text:</p> <p><u>(E) A list of potential authorized collectors that requested joining the stewardship program and were rejected, and the reason(s) for each rejection.</u></p> <p>If the potential entity is accepted as an authorized collector, the entity will be listed as a participating authorized collector in the stewardship program pursuant to section 18973.4(c)(4). Therefore, it is unnecessary to request an additional list of all potential authorized collectors who offer to participate as those entities will already be listed as authorized collectors. The revised section 18973.4(c)(2)(E) above addresses the commenter’s concern by requiring the program operator to provide a specific reason for each rejection into the program. Furthermore, pursuant to section 42032.2(b)(3) of the Public Resources Code, after the stewardship plan has been approved, the program operator is required to include the offering entity as an authorized collector in the stewardship program within 90 days of receiving the written offer to participate. If the program operator does not include the offering entity within 90 days, pursuant to section 18973.4(c)(2)(E), the program operator must list the offering entity and provide the specific reason(s) for rejecting the offer to participate in the stewardship program. Sections 18973.4(c)(2)(A), (B), and (E) of the regulatory text require descriptions of how requirements of Sections 42032.2(b)(1) and (3) of the Public Resources Code were met. Requirements regarding specific timeframes and dates of inclusion that are outlined in Sections 42032.2(b)(1) and (b)(3) of the Public Resources Code are explicitly and unambiguously stated in Statute and do not necessitate repetition in the regulations. The “date of full inclusion” if an authorized collector’s request to join the program is approved by the program operator must be included to show that a program operator has complied with the timeframe requirements outlined in Statute. If the department requires additional information from the program operator to ensure that all statutory and regulatory requirements have been met, the department can request such information pursuant to Section 18973.1(b) of the regulations. The department can also request additional compliance reporting under Section 18975.2 of the regulations.</p>
005-021	Nat'l Stewardship Action	Doug Kobold, Heidi	18973.4 (c)(4)	Y	Proposed Regulation Section: 18973.4(c)(4)(D), Page: 15, Subject: Annual Report for Covered Drugs	005-021. CalRecycle agrees with the commenter’s suggested reporting requirement. Proposed regulatory text section 18973.4(c)(4)(E) is revised as follows:

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	Council, CalPSC, County of Santa Clara, & Zero Waste Sonoma	Sanborn, William Grimes, Leslie Lukacs			We support the inclusion of this data point but would suggest that the department also require the reason for each instance where the collection site was not available to the public.	(ED) Total number of instances and corresponding number of business hours amount of time the secure collection site receptacle was not available to the public during business hours. For each instance, provide a description of why the secure collection receptacle was not available.
005-022a	Nat'l Stewardship Action Council, CalPSC, County of Santa Clara, & Zero Waste Sonoma	Doug Kobold, Heidi Sanborn, William Grimes, Leslie Lukacs	18973.4 (i)	Y	<p>Proposed Regulation Section: 18973.4(i) and 18973.5(i), Page: 17 and 19, Subject: Annual Report for Covered Drugs and Annual Report for Home-Generated Sharps Waste</p> <p>We support thorough reporting on the educational and outreach portion of the plan because of its importance in implementing an effective program. We think the regulations require broad reporting, but we'd recommend that the department add a component requiring the stewardship organizations to report any internal metrics used to measure the efficacy of their education and outreach program. This includes market research that is conducted on this program, and any measurements of performance such as website traffic, email open rates, and similar metrics.</p>	<p>005-022a. CalRecycle agrees with the commenter regarding the importance of implementing an effective education and outreach program. Section 18973.4(i) of the proposed regulatory text is revised as follows to provide the department information to assess the effectiveness of the education and outreach efforts.</p> <p><u>(i) Education and Outreach. Description and evaluation of the comprehensive education and outreach activities pursuant to section 18973.2(j), including, but not limited to, the following:</u></p> <p><u>(1) Electronic examples of promotional marketing materials.</u></p> <p><u>(2) Numerical results of the education and outreach metrics outlined in the stewardship plan, pursuant to section 18973.2(j)(5).</u></p> <p><u>(3) A discussion of what the metrics reveal about the performance of the comprehensive education and outreach program, including, but not limited to, ultimate user awareness, program usage, and accessibility.</u></p> <p>Specific elements such as market research requirements have been omitted. While conducting market research upfront could be beneficial, this activity would have to occur prior to the program operator submitting the stewardship plan to CalRecycle and thus is outside the scope of the stewardship plan regulations. A program operator may choose to consult third-parties or draw from existing experience in order to design its comprehensive education and outreach program, prior to gaining insights from the program data collected during the first year of operation. CalRecycle prefers allowing a program operator the flexibility to propose metrics that adequately measure its comprehensive education and outreach program, rather than specifying metrics such as email open rates that may not be applicable.</p>
005-022b	Nat'l Stewardship Action Council, CalPSC, County of Santa Clara, & Zero	Doug Kobold, Heidi Sanborn, William Grimes, Leslie Lukacs	18973.5 (i)	Y	<p>Proposed Regulation Section: 18973.4(i) and 18973.5(i), Page: 17 and 19, Subject: Annual Report for Covered Drugs and Annual Report for Home-Generated Sharps Waste</p> <p>We support thorough reporting on the educational and outreach portion of the plan because of its importance in implementing an effective program. We think the regulations require broad reporting, but we'd recommend that the department add a component requiring the stewardship organizations to report</p>	<p>005-022b. CalRecycle agrees with the commenter regarding the importance of implementing an effective education and outreach program. Section 18973.5(i) of the proposed regulatory text is revised as follows to provide the department information to assess the effectiveness of the education and outreach efforts.</p> <p><u>18973.5(i) Education and Outreach. Description and evaluation of the comprehensive education and outreach activities pursuant to section 18973.3(i), including, but not limited to, the following:</u></p>

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	Waste Sonoma				any internal metrics used to measure the efficacy of their education and outreach program. This includes market research that is conducted on this program, and any measurements of performance such as website traffic, email open rates, and similar metrics.	<p><u>(1) Electronic examples of promotional marketing materials.</u></p> <p><u>(2) Numerical results of the education and outreach metrics outlined in the stewardship plan, pursuant to section 18973.2(i)(5).</u></p> <p><u>(3) A discussion of what the metrics reveal about the performance of the comprehensive education and outreach program, including, but not limited to, ultimate user awareness, program usage, and accessibility.</u></p> <p>Specific elements such as market research requirements have been omitted. While conducting market research upfront could be beneficial, this activity would have to occur prior to the program operator submitting the stewardship plan to CalRecycle and thus is outside the scope of the stewardship plan regulations. A program operator may choose to consult third-parties or draw from existing experience in order to design its comprehensive education and outreach program, prior to gaining insights from the program data collected during the first year of operation. CalRecycle prefers allowing a program operator the flexibility to propose metrics that adequately measure its comprehensive education and outreach program, rather than specifying metrics such as email open rates that may not be applicable.</p>
005-023	Nat'l Stewardship Action Council, CalPSC, County of Santa Clara, & Zero Waste Sonoma	Doug Kobold, Heidi Sanborn, William Grimes, Leslie Lukacs	18973.5 (p)	Y	<p>Proposed Regulation Section: 18973.5(p), Page: 20, Subject: Annual Report for Home-Generated Sharps Waste</p> <p>We support this reporting requirement but suggest that it be expanded to include a list of any local agency requests where responses, pick-up, or payment was performed outside of the required timelines. Additionally, the annual report should include the details of any specific local agency request for pick-up or reimbursement was rejected.</p>	005-023. CalRecycle accepts the commenter's suggestion and modified section 18973.5(p) of the proposed regulatory text to include any local agency request rejection and the reasons for rejection and requests where responses, removal, or reimbursement was performed outside of the timelines specified in section 18973.3(g)(2).
005-024	Nat'l Stewardship Action Council, CalPSC, County of Santa Clara, & Zero Waste Sonoma	Doug Kobold, Heidi Sanborn, William Grimes, Leslie Lukacs	18975(a)	Y	<p>Proposed Regulation Section: 18975(a), Page: 24, Subject: Criteria to Impose a Civil Penalty</p> <p>The scope of this section seems limited to a "covered entity" when the statute allows the department to assess a civil penalty on a covered entity, program operator, stewardship organization, or authorized collector.</p> <p>We would underscore the general comment made in our cover letter. The application of civil penalties is relatively limited by the statute and applies only to the sale of a covered product in violation of the chapter. This seems to limit the department's recourse in addressing material programmatic deficiencies to revocation of the plan.</p>	005-024. CalRecycle agrees with the commenter's suggestion and has made the following change to the proposed regulatory text section 18975: <u>(a) The department shall impose an administrative penalty if it determines that any covered entity, program operator, stewardship organization, or authorized collector sells, offers for sale, or provides a covered product in violation of this Article or Chapter 2 of Part 3 of Division 30 of the Public Resources Code.</u>
006-001	San Francisco	Jen Jackson	18973.2 (d)(2)	Y	1. Description of Authorized Collector Recruitment Efforts. We request that CalRecycle add a new subparagraph to Section 18973.2(d) that requires the	006-001. CalRecycle agrees that a proposed change is necessary in order to describe how a program operator complied with Public

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	Department of the Environment				<p>program operator to describe what efforts will be made to recruit potential authorized collectors to participate in the stewardship program, as follows:</p> <p><i>(5) Description of the recruitment efforts that will be made for each potential authorized collector, including but not limited to mail, email, phone calls, and in-person site visits.</i></p>	<p>Resources Code section 42032.2(b)(1), but prefers the following addition to section 18973.2(d)(2) of the proposed regulatory text:</p> <p><u>(2) Pursuant to Section 42032.2(b)(1) of the Public Resources Code, list of potential authorized collectors, in the counties in which the program will operate, that were notified of the opportunity to serve as an authorized collector for the proposed stewardship program, and the method(s) by which each potential authorized collector was notified. The notification shall occur at least 120 days before the stewardship plan is submitted to the department.</u></p> <p>Public Resources Code section 42032.2(b)(1) states that a program operator shall notify potential authorized collectors of the opportunity to serve in the stewardship program “at least 120 days before submitting a stewardship plan to the department.” Since this activity occurs prior to submitting the stewardship plan for review and approval, CalRecycle prefers to incorporate this proposed change in section 18973.2(d)(2) of the proposed regulations. CalRecycle declines to incorporate specific forms of notification, as simply requiring a description of the methods used is sufficient for the department to evaluate whether potential authorized collectors were sufficiently notified. Additionally, note that statute does not explicitly require ongoing “recruitment efforts,” although a program operator must still accommodate requests from potential authorized collectors to join the stewardship program.</p>
006-002	San Francisco Department of the Environment	Jen Jackson	18973.2 (d)	Y	<p>2. Discussion of Chain Retail Pharmacy Participation. We request a new subparagraph be added to Section 18973.2(d) that requires the program operator to include an evaluation of the program operator's and retail pharmacy chain's efforts to meet the participation requirements of Section 42032.2(b)(2) of the statute. We suggest the following language:</p> <p><i>(6) Description of the program operator's and retail pharmacy chains' respective efforts to meet the requirements of Section 42032.2(b)(2) of the statute, including the "reasonable effort" and "minimum threshold" participation requirements, if applicable.</i></p>	<p>006-002. Public Resources Code section 42032.2(b)(2) is a requirement on retail pharmacies that must be fulfilled independent of the contents of a proposed stewardship plan, and thus this requirement does not fit in section 18973.2(d) of the proposed regulatory text. However, CalRecycle does find that the commenter's proposed edit applies to the annual report requirements, and section 18973.4(c)(2) of the proposed regulatory text has been edited as follows:</p> <p><u>(D) Efforts between the program operator and retail pharmacy chains to meet the requirement stated in subsection (2) of subdivision (b) of section 42032.2 of the Public Resources Code. Any known reason why potential authorized collectors were excluded from participation in the stewardship program.</u></p> <p>CalRecycle declines to incorporate the phrase “including the ‘reasonable effort’ and ‘minimum threshold’ participation requirements, if applicable” because these requirements are already encompassed by the reference to Public Resources Code section 42032.2(b)(2). See response to comment 006-009 for further discussion on these edits to the annual report section.</p>
006-003	San Francisco	Jen Jackson	18973.2 (d)	N	<p>3. Description of Authorized Collector "Opt-In" Process. We ask CalRecycle to add a new subparagraph to Section 18973.2(d) that requires the program</p>	<p>006-003. A change to the proposed regulations is not necessary. Section 18973.2(d)(4) of the proposed regulatory text and the statutory</p>

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	Department of the Environment				operator to establish a process by which potential authorized collectors will be included in the stewardship program - even if the convenience standard has been met - within 90 days as required in Section 42032.2(b)(3) of the statute: <i>(7) Processes that will be used to include all potential authorized collectors that offer to participate within 90 days of plan approval, as required by Section 42032.2(b)(3) of the statute. At minimum, this shall include a description of how potential authorized collectors shall submit written offers to participate and any conditions for excluding interested potential collectors.</i>	text of Public Resources Code section 42032.2(b)(3) are sufficient to require a program operator to describe its efforts to onboard potential authorized collectors that offer to participate in the stewardship program. Public Resources Code, section 42032.2(b)(3) does not require further clarification. CalRecycle disagrees that further explanation of how potential authorized collectors shall submit written offers is necessary because it is self-explanatory. It is not necessary to restate this section in the regulations. Section 18973.2(d)(4) of the proposed regulatory text that the commenter is commenting on already requires the program operator to describe conditions for excluding potential authorized collectors. The term "conditions" has been changed to "reasons" to more closely match statutory terminology.
006-004	San Francisco Department of the Environment	Jen Jackson	18973.2 (g)(1)	N	4. Supplemental Services to Maintain Convenience Standard. In our experience, it is likely that the number of authorized collector locations will vary frequently due to retail pharmacies opening and closing. Program operators should account for this by describing the supplemental services that will be provided in the interim until additional authorized collector locations are added to meet the convenience standard. We request that CalRecycle add the following as a new subparagraph under Section 18973.2(g)(2): <i>(C) Describe what supplemental collection services, such as mail-back services or an alternative form of collection and disposal system, will be provided to ultimate users if the minimum convenience standard is no longer met in a county due to one or more authorized collectors discontinuing participation for any reason.</i>	006-004. A change to the proposed regulatory text is not necessary. A related and sufficient provision is contained in section 18973.2(g)(7) of the Second Draft proposed regulatory text. Additionally, the definition for "significant change" in the proposed regulatory text includes a provision that addresses changes due to the convenience standard no longer being met. Note that this definition has been changed from section 18972.1(l) to 18972.1(a)(13) due to edits made elsewhere.
006-005a	San Francisco Department of the Environment	Jen Jackson	18973.2 (g)(9)	Y	5. Collection Records Training. We recommend revising the language in Section 18973.2(g)(9) and Section 18973.3(f)(6)(A)(iv) to reflect that program operators are responsible for training authorized collectors or home-generated sharps consolidation points, respectively, so they remain aware of their responsibility to maintain collection records and make them available to the department. Mere notification may not be sufficient because retail pharmacy staff often rotate or change locations. We suggest the following language: <i>(9) How each authorized collection site [or "home-generated sharps consolidation point" in Section 18973.3] will be trained so that it remains aware of its responsibilities to maintain and make available collection records to the department and all other applicable authorities upon request.</i>	006-005a. CalRecycle declines the proposed recommendation, but a change to the proposed regulatory text is necessary. Retail pharmacies and retail pharmacy chains are required to maintain and provide records to the department, pursuant to Public Resources Code section 42035.6. Since retail pharmacies are independently responsible for complying with this requirement, a program operator is not responsible for notifying retail pharmacies of their recordkeeping responsibilities. Thus, CalRecycle is deleting section 18973.2(g)(9) from the proposed regulatory text. CalRecycle also declines to require collection site training by the program operator. Sections 18973.2(g)(1) and 18973.3(f)(1) of the proposed regulations require a description of "processes and policies that will be used to safely and securely collect, track, and properly manage covered drugs from collection through final disposal." Training could be one element of effective processes and policies, but CalRecycle prefers to give a program operator the flexibility to propose processes and policies tailored to its specific collection mechanisms.

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						Finally, proposed regulatory text sections 18973.2(h) and 18973.3(f)(3) sufficiently clarify the recordkeeping requirements specific to collection, transportation, and disposal of covered products.
006-005b	San Francisco Department of the Environment	Jen Jackson	18973.3(f)(6)(A)(iv)	Y	<p>5. Collection Records Training. We recommend revising the language in Section 18973.2(g)(9) and Section 18973.3(f)(6)(A)(iv) to reflect that program operators are responsible for training authorized collectors or home-generated sharps consolidation points, respectively, so they remain aware of their responsibility to maintain collection records and make them available to the department. Mere notification may not be sufficient because retail pharmacy staff often rotate or change locations. We suggest the following language:</p> <p><i>(9) How each authorized collection site [or "home-generated sharps consolidation point" in Section 18973.3] will be trained so that it remains aware of its responsibilities to maintain and make available collection records to the department and all other applicable authorities upon request.</i></p>	<p>006-005b. CalRecycle declines the proposed recommendation, but a change to the proposed regulatory text is necessary. Retail pharmacies and retail pharmacy chains are required to maintain and provide records to the department, pursuant to Public Resources Code section 42035.6. Retail pharmacies are independently responsible for complying with the notification requirement; therefore, a program operator is not responsible for notifying retail pharmacies of their recordkeeping responsibilities.</p> <p>CalRecycle also declines to require home-generated sharps consolidation point training by the program operator. Section 18973.3(f)(1) of the proposed regulations require a description of “processes and policies that will be used to safely and securely collect, track, and properly manage home-generated sharps waste from collection through final disposal.” Training could be one element of effective processes and policies, but CalRecycle prefers to give a program operator the flexibility to propose processes and policies tailored to its specific collection mechanisms.</p> <p>Section 18973.3(f)(6)(A)(iv) from the First Draft has been deleted in the Second Draft proposed regulatory text, noting that section 18973.3(f)(6)(A) has been renumbered to section 18973.3(f)(5)(A) in the Second Draft.</p> <p>Proposed regulatory text sections 18973.2(h) and 18973.3(f)(3) sufficiently clarify the recordkeeping requirements specific to collection, transportation and disposal of covered products.</p>
006-006a	San Francisco Department of the Environment	Jen Jackson	18973.2(g)(10)	Y	<p>6. Collector Compliance Monitoring. We urge CalRecycle to modify the language in Section 18973.2(g)(10) and Section 18973.3(f)(6)(A)(v) to require the program operator to monitor compliance of authorized collectors or home-generated sharps consolidation points, respectively, on an ongoing basis. As currently drafted, the Proposed Regulations establish a reactive approach by referencing corrective actions that will be taken after non-compliance is discovered. We suggest the following change:</p> <p><i>(10) What ongoing steps will be conducted by the program operator to ensure authorized collectors [or "home-generated sharps consolidation points" in Section 18973.3] maintain compliance with all collection, transportation, and disposal standards related to the handling of covered drugs [or "home-generated sharps waste" in Section 18973.3].</i></p>	<p>006-006a. CalRecycle agrees that a change to the proposed regulatory text is necessary, but prefers the following edit to section 18973.2(g)(10) of the proposed regulatory text:</p> <p><u>(10) What corrective actions will be taken if a program operator discovers critical deviations from stewardship plan policies and procedures, an authorized collector or service provider is not maintaining compliance with all collection, transportation, and disposal standards related to the handling of covered drugs, including, but not limited to, United States Drug Enforcement Administration regulations.</u></p> <p>Describing “ongoing steps” instead of “corrective actions” in the proposed stewardship plan is not necessary as the annual report requirements effectively ensure continuous monitoring of collection and disposal infrastructure, but with greater specificity than in the commenter’s proposed edit. Additionally, this section references</p>

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						stewardship plan “policies and procedures” instead of “collection, transportation, and disposal standards” (as the commenter proposes) because “policies and procedures” encompass a broader range of stewardship program components.
006-006b	San Francisco Department of the Environment	Jen Jackson	18973.3(f)(6)(A)(v)	Y	<p>6. Collector Compliance Monitoring. We urge CalRecycle to modify the language in Section 18973.2(g)(10) and Section 18973.3(f)(6)(A)(v) to require the program operator to monitor compliance of authorized collectors or home-generated sharps consolidation points, respectively, on an ongoing basis. As currently drafted, the Proposed Regulations establish a reactive approach by referencing corrective actions that will be taken after non-compliance is discovered. We suggest the following change:</p> <p><i>(10) What ongoing steps will be conducted by the program operator to ensure authorized collectors [or "home-generated sharps consolidation points" in Section 18973.3] maintain compliance with all collection, transportation, and disposal standards related to the handling of covered drugs [or "home-generated sharps waste" in Section 18973.3].</i></p>	<p>006-006b. CalRecycle agrees that a change to the proposed regulatory text is necessary, but prefers the following edit. Note that section 18973.3(f)(6)(A)(v) has been deleted and section 18973.3(f)(9) has been added so that it applies to all home-generated sharps waste collection, transportation, and disposal activities, not just those that occur under supplemental collection methods:</p> <p>(f)(6)(A)(v) What corrective actions will be taken if a program operator discovers a home-generated sharps consolidation point or service provider is not maintaining compliance with all collection, transportation, and disposal standards related to the handling of home-generated sharps waste.</p> <p><u>(9) What corrective actions will be taken if a program operator discovers critical deviations from stewardship plan policies and procedures.</u></p> <p>Describing “ongoing steps” in the proposed stewardship plan is not necessary as the annual report requirements effectively ensure continuous monitoring of collection and disposal infrastructure, but with greater specificity than in the commenter’s proposed edit. Additionally, this section references stewardship plan “policies and procedures” instead of “collection, transportation, and disposal standards” because “policies and procedures” encompass a broader range of stewardship program components.</p>
006-007	San Francisco Department of the Environment	Jen Jackson	18973.2(g)(12)	Y	<p>7. Unplanned Incident Notification. In the event of an unplanned incident involving safety and security, various local, state and federal agencies would need to be notified, as determined by the nature of the incident. Accordingly, we urge CalRecycle to require program operators to include a process for notifying all required regulatory and/or law enforcement agencies in their standard operating procedures for an unplanned incident. We propose the following revisions to Section 18973.2(g)(12):</p> <p><i>(12) Standard operating procedures that address safety and security issues for an unplanned incident, including processes to ensure CalRecycle and any local, state and/or federal agencies required by law, rule or regulation are notified of the incident.</i></p>	<p>006-007. CalRecycle accepts the commenter’s proposed change to section 18973.2(g)(12) of the proposed regulatory text, but prefers the following phrasing for clarity and consistency with subsection (1)(H) of subdivision (a) of section 42032.2 of the Public Resources Code:</p> <p><u>(12): Standard operating procedures that will address incidents related to safety and security issues for an unplanned incident, including processes to ensure the department and applicable local, state, and federal agencies required by laws and regulations are notified of the incident. This description shall also explain the actions that will be taken to change policies, procedures, and tracking mechanisms to alleviate the problems with safety and security and improve safety and security.</u></p> <p>CalRecycle is not including references to an “unplanned incident” because the proposed regulatory language is meant to capture any incidents related to safety and security. The department intends to revise the stewardship plan requirements for home-generated sharps</p>

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						waste in a similar manner, as the comment also applies to the standard operating procedures for home-generated sharps waste.
006-008	San Francisco Department of the Environment	Jen Jackson	18973.4 (c)	N	<p>8. Annual Report: Supplemental Services to Maintain Convenience Standard. We ask that a new subparagraph be added to Section 18973.4(c)(3) that requires a program operator to describe any supplemental services that were provided to ultimate users in a county where the minimum convenience standard was not met due to one of more authorized collectors discontinuing participation. We suggest:</p> <p><i>(3)(B) What supplemental collection services were provided to ultimate users if the minimum convenience standard was not met in a county at any time during the reporting period.</i></p>	006-008. A change to the proposed regulatory text is not necessary. CalRecycle disagrees with the commenter's recommendation. Related and sufficient provisions are contained in sections 18973.4(c)(2)(C) and (c)(6) of the proposed regulatory text. Additionally, the definition for "significant change" in proposed regulations section 18972.1(a)(13) includes a provision that addresses changes to the stewardship plan due to the convenience standard no longer being met.
006-009	San Francisco Department of the Environment	Jen Jackson	18973.4 (c)(2)	Y	<p>9. Annual Report: Evaluation of Retail Pharmacy Chain Participation. Similar to comment #2 above, we recommend requiring an evaluation of the program operator's and retail pharmacy chain's efforts to meet the participation requirements of Section 42032.2(b)(2) of the statute in an Annual Report for Covered Drugs. We urge CalRecycle to add the following as two new subparagraphs under Section 18973.4(c):</p> <p><i>(7) An evaluation of the program operator's and retail pharmacy chain's respective efforts to meet the "reasonable effort to serve as an authorized collector" requirement in Section 42032.2(b)(2) of the statute.</i></p> <p><i>(8) An evaluation of retail pharmacy chain's efforts to serve as authorized collectors in any county required because the convenience standard minimum threshold is not being met.</i></p>	<p>006-009. CalRecycle agrees that a change to the proposed regulatory text is necessary so the department can evaluate compliance with Public Resources Code section 42032.2(b)(2). However, CalRecycle prefers to incorporate the following language as section 18973.4(c)(2)(D) of the proposed regulatory text for clarity and consistency:</p> <p><u><i>(D) Efforts between the program operator and retail pharmacy chains to meet the requirement stated in subsection(2) of subdivision (b) of section 42032.2 of the Public Resources Code. Any known reason why potential authorized collectors were excluded from participation in the stewardship program.</i></u></p> <p>This allows CalRecycle to evaluate the efforts made between a program operator and retail pharmacy chain to serve as an authorized collector to meet the minimum convenience standard threshold (as suggested in (7)), and evaluate the efforts by a retail pharmacy chain to meet participation requirements in counties where the minimum convenience standard threshold is not being met (as suggested in (8)).</p>
006-010	San Francisco Department of the Environment	Jen Jackson	18973.4 (c)(5)	Y	<p>10. Annual Report: Reporting Mail-Back Packaging by Type. Due to Board of Pharmacy regulations and federal DOT/USPS transportation rules, there are currently two types of dosage forms - inhalers and prefilled injector products (e.g. EpiPens®) - that require separate mail-back packaging from other covered drugs. Therefore, any stewardship program approved for covered drugs will have to provide at least three types of mail-back packaging. We request that Section 18973.4(c)(5) be revised to add mail-back packaging type to the information required in the Annual Report:</p> <p><i>(5) For each type of mail-back services utilized, provide, as applicable:</i></p>	<p>006-010. CalRecycle agrees with the commenter's recommendation.</p> <p>Proposed regulatory text section 18973.4(c)(5) is revised as follows: <u><i>(5) For each type of mail-back services utilized, include the following, including, but not limited to, as applicable:</i></u></p> <p><u><i>(A) Name and location of distribution facility</i></u></p> <p><u><i>(B) Amount of materials distributed</i></u></p> <p><u><i>(C) Mechanism of distribution</i></u></p> <p><u><i>(D) Amount of mail-back materials distributed, as required in the stewardship plan pursuant to section 18973.2(g)(6)(C)</i></u></p> <p><u><i>(E) Weight of material returned</i></u></p>

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						<p><u>(D) Amount of mail-back material returned, as required in the stewardship plan pursuant to section 18973.2(g)(6)(C)</u></p> <p>For stewardship programs that utilize multiple mail-back services, the additional language will provide a program operator clarity on the information required in their annual report.</p>
006-011a	San Francisco Department of the Environment	Jen Jackson	18973.4 (f)	N	<p>11. Annual Report: Collection Records Training. In accordance with our previous comment #5, program operators should be required to describe how authorized collection locations and home-generated sharps consolidation points were kept aware of their responsibility to maintain collection records and make them available to the department. We request a new subparagraph be added to Section 18973.4 and Section 18973.5, as follows:</p> <p><i>(p) Training and other activities undertaken by the program operator to ensure each authorized collection site [or "home-generated sharps consolidation point" in Section 18973.5] remained aware of its responsibility to maintain collection records and make them available to the department.</i></p>	<p>006-011a. A change to the proposed regulatory text is not necessary. CalRecycle disagrees with the commenter's recommendation. See response to comment 006-005a. Public Resources Code section 42033.2(b)(6) requires a program operator to provide information on whether policies and procedures for collection, tracking, and disposing of covered products were followed during the reporting period. While section 18973.4(f) of the proposed regulatory text requires a program operator to include updates that were made or will be made to the processes and procedures, the proposed regulatory text provides flexibility in recognizing that training and other activities may be tailored to a program operator's specific collection mechanisms.</p>
006-011b	San Francisco Department of the Environment	Jen Jackson	18973.5 (f)	N	<p>11. Annual Report: Collection Records Training. In accordance with our previous comment #5, program operators should be required to describe how authorized collection locations and home-generated sharps consolidation points were kept aware of their responsibility to maintain collection records and make them available to the department. We request a new subparagraph be added to Section 18973.4 and Section 18973.5, as follows:</p> <p><i>(p) Training and other activities undertaken by the program operator to ensure each authorized collection site [or "home-generated sharps consolidation point" in Section 18973.5] remained aware of its responsibility to maintain collection records and make them available to the department.</i></p>	<p>006-011b. CalRecycle disagrees with the commenter. See response to comment 006-005b. Public Resources Code section 42033.2(b)(6) requires a program operator to provide information on whether policies and procedures for collection, tracking, and disposing of covered products were followed during the reporting period. While section 18973.5(f) of the proposed regulatory text requires a program operator to include updates that were made or will be made to the processes and procedures, the proposed regulatory text provides flexibility in recognizing that training and other activities may be tailored to a program operator's specific collection mechanisms.</p>
006-012a	San Francisco Department of the Environment	Jen Jackson	18973.4 (e)	Y	<p>12. Annual Report: Collector Compliance Monitoring. In accordance with our previous comment #6, we request modifications to Section 18973.4(e) and Section 18973.5(e) to require a program operator to describe the ongoing steps they took to ensure collectors complied with all applicable laws and regulations. We propose the following changes:</p> <p><i>(e) Description of the ongoing steps the program operator took to ensure authorized collectors [or "home-generated sharps consolidation points" in Section 18973.5(e)] maintained compliance with all collection, transportation, and disposal standards related to the handling of covered drugs [or "home-generated sharps waste" in Section 18973.5(e)].</i></p>	<p>006-012a. CalRecycle agrees that a change to the proposed regulatory text is necessary, but prefers the following edit to section 18973.4(e): <u>(e) Corrective actions taken if the program operator discovered critical deviations from stewardship plan policies and procedures and a description of each critical deviation, that a service provider did not maintain compliance with all collection, transportation, and disposal standards, including, but not limited to, local, state, and federal laws and regulations and United States Drug Enforcement Administration regulations.</u></p> <p>Describing "ongoing steps" is not necessary as the annual report requirements effectively ensure continuous monitoring of collection and disposal infrastructure so that the processes and policies used to safely and securely collect, track, and properly manage covered drugs from collection through final disposal that are outlined in the stewardship plan are met.</p>

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006-012b	San Francisco Department of the Environment	Jen Jackson	18973.5 (e)	Y	<p>12. Annual Report: Collector Compliance Monitoring. In accordance with our previous comment #6, we request modifications to Section 18973.4(e) and Section 18973.5(e) to require a program operator to describe the ongoing steps they took to ensure collectors complied with all applicable laws and regulations. We propose the following changes:</p> <p><i>(e) Description of the ongoing steps the program operator took to ensure authorized collectors [or "home-generated sharps consolidation points" in Section 18973.5(e)] maintained compliance with all collection, transportation, and disposal standards related to the handling of covered drugs [or "home-generated sharps waste" in Section 18973.5(e)].</i></p>	<p>006-012b. CalRecycle agrees that a change to the proposed regulatory text is necessary, but prefers the following edit to section 18973.5(e):</p> <p><u>(e) Corrective actions taken if the program operator discovered critical deviations from stewardship plan policies and procedures and a description of each critical deviation, that a service provider did not maintain compliance with all collection, transportation, and disposal standards, including, but not limited to, local, state, and federal laws and regulations and United States Drug Enforcement Administration regulations.</u></p> <p>Describing "ongoing steps" is not necessary as the annual report requirements effectively ensure continuous monitoring of collection and disposal infrastructure so that the processes and policies used to safely and securely collect, track, and properly manage home-generated sharps waste from collection through final disposal that are outlined in the stewardship plan are met.</p>
006-013a	San Francisco Department of the Environment	Jen Jackson	18973.4 (h)(5)	N	<p>13. Annual Report: Unplanned Incident Reporting. As noted in comment #7 above, unplanned incidents involving safety and security will typically require notification of at least one regulatory and/or law enforcement agency. To confirm the appropriate authorities were notified, we urge CalRecycle to require identification of all entities that were notified of an unplanned incident in the program operator's Annual Report. We recommend adding the following as a new subsection under Section 18973.4(h) and Section 18973.5(h):</p> <p><i>(6) Any regulatory and/or law enforcement agencies that were notified of the incident, as required by all applicable laws and regulations</i></p>	<p>006-013a. A change to the proposed regulatory text is not necessary as a related and sufficient provision is included in section 18973.4(h)(5) as follows:</p> <p><u>(5) Regulatory or law enforcement agencies involved and any litigation, arbitration, or other legal proceedings that result from each incident</u></p>
006-013b	San Francisco Department of the Environment	Jen Jackson	18973.5 (h)(6)	N	<p>13. Annual Report: Unplanned Incident Reporting. As noted in comment #7 above, unplanned incidents involving safety and security will typically require notification of at least one regulatory and/or law enforcement agency. To confirm the appropriate authorities were notified, we urge CalRecycle to require identification of all entities that were notified of an unplanned incident in the program operator's Annual Report. We recommend adding the following as a new subsection under Section 18973.4(h) and Section 18973.5(h):</p> <p><i>(6) Any regulatory and/or law enforcement agencies that were notified of the incident, as required by all applicable laws and regulations</i></p>	<p>006-013b. A change to the proposed regulatory text is not necessary as a related and sufficient provision is included in section 18973.5(h)(5) as follows:</p> <p><u>(5) Regulatory or law enforcement agencies involved and any litigation, arbitration, or other legal proceedings that result from each incident</u></p>
006-014	San Francisco Department of the Environment	Jen Jackson	18973.2 (g)	Y	<p>14. Kiosk Signage Accessibility. Signage for the secure collection receptacles for covered drugs should be designed with explanatory graphics and other readily understood imagery to minimize participation barriers for the diverse audience of ultimate users throughout the state. Consistent with this goal, we request the following language be added to Section 18973.2(g):</p> <p><i>(13) Signage for the secure collection receptacles shall be designed with</i></p>	<p>006-014. CalRecycle agrees that an edit to the proposed regulatory text is necessary, but prefers making the following additions to section 18973.2(j)(2):</p> <p><u>(2) 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</u></p>

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					<i>explanatory graphics, imagery and other features so that they shall be readily understandable by all residents, including individuals with limited literacy..</i>	<u>labeling for secure collection receptacles shall be designed with explanatory graphics which are readily understandable by all ultimate users.</u> Secure collection receptacles need adequate signage or labeling to be readily understood by all ultimate users. However, for clarity and concision, CalRecycle declines to incorporate the phrase “imagery and other features,” as “imagery” is redundant with “graphics” and “other features” are vague and unnecessary for this purpose. Furthermore, CalRecycle prefers “all ultimate users” to “all residents,” and declines to incorporate the phrase “including individuals with limited literacy;” “ultimate users” is a more inclusive term than “residents,” and “individuals with limited literacy” are already encompassed by “all ultimate users.” In regards to the addition of Government Code section 7295, see response to comment 005-014B. Finally, CalRecycle notes that this edit is included in section 18973.2(j)(2) instead of 18973.2(g)(13) as it fits more appropriately as a component of an education and outreach plan.
006-015a	San Francisco Department of the Environment	Jen Jackson	18973.2 (j)	N	15. Expanded Outreach Activities. Section 42031.6(a) of the statute requires program operators to conduct "a comprehensive education and outreach program intended to promote participation in the stewardship program." To better align the language in Section 18973.2(j)(1) and Section 18973.3(i)(1) with this requirement, we propose the following changes: <i>(1) Activities and materials to promote awareness and maximize user participation in the stewardship program, which shall include: print and out of home media; television and radio; social media and online advertisements; and brochures or flyers.</i>	006-015a. 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” will provide the program operator with the flexibility needed to design a successful education and outreach program.
006-015b	San Francisco Department of the Environment	Jen Jackson	18973.3 (i)(1)	N	15. Expanded Outreach Activities. Section 42031.6(a) of the statute requires program operators to conduct "a comprehensive education and outreach program intended to promote participation in the stewardship program." To better align the language in Section 18973.2(j)(1) and Section 18973.3(i)(1) with this requirement, we propose the following changes: <i>(1) Activities and materials to promote awareness and maximize user participation in the stewardship program, which shall include: print and out of home media; television and radio; social media and online advertisements; and brochures or flyers.</i>	006-015b. 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” will provide the program operator with the flexibility needed to design a successful education and outreach program.
006-016a	San Francisco Department	Jen Jackson	18973.2 (j)(3)	Y	16. Website Multi-Language Support. A stewardship plan's internet website should be required to provide support in multiple languages that are commonly used in California to ensure the diverse audience of ultimate users throughout the state can access program information and services. We request that	006-016a. The department recognizes the significance of ensuring the stewardship organization’s digital content and information be accessible to a wide range of people and that all users with disabilities have the same access to and use of information. CalRecycle agrees with adding

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	of the Environment				<p>CalRecycle modify the internet website requirements described in Section 18973.2(j)(3) and Section 18973.3(i)(3) to specify the following:</p> <p><i>(F) The required internet website shall provide a functionally equivalent user experience - including content, access and navigability - in languages other than English that are commonly used in California. At minimum, these shall include the languages used by the Board of Pharmacy to satisfy the requirements of Title 16 California Code of Regulations Section 1707.5(b).</i></p>	<p>additional language to require the internet website be accessible, which will also provide a program operator with additional clarity to construct a comprehensive educational and outreach program.</p> <p>However, CalRecycle prefers the following edit to proposed regulatory text sections 18973.2(j)(3) and 18973.3(i)(3):</p> <p><u>(3) Establishment of an internet website designed with functionality for mobile platforms, provided with language options suited to local demographics, and maintained to ensure all information is up to date and accurate. 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:</u></p> <p>CalRecycle declines to add requirements from the California Code of Regulations section 1707.5(b) to the proposed regulatory text as it could compromise the department's flexibility to evaluate the stewardship plan's education and outreach program proposals by incorporating a very specific set of standards that apply to prescription drug usage. Rather, CalRecycle is incorporating section 7295 of the Government Code to provide a benchmark that is not overly restrictive.</p>
006-016b	San Francisco Department of the Environment	Jen Jackson	18973.3 (i)(3)	Y	<p>16. Website Multi-Language Support. A stewardship plan's internet website should be required to provide support in multiple languages that are commonly used in California to ensure the diverse audience of ultimate users throughout the state can access program information and services. We request that CalRecycle modify the internet website requirements described in Section 18973.2(j)(3) and Section 18973.3(i)(3) to specify the following:</p> <p><i>(F) The required internet website shall provide a functionally equivalent user experience - including content, access and navigability - in languages other than English that are commonly used in California. At minimum, these shall include the languages used by the Board of Pharmacy to satisfy the requirements of Title 16 California Code of Regulations Section 1707.5(b).</i></p>	<p>006-016b. The department recognizes the significance of ensuring the stewardship organization's digital content and information be accessible to a wide range of people and that all users with disabilities have the same access to and use of information. CalRecycle agrees with adding additional language to require the internet website be accessible, which will also provide a program operator with additional clarity to construct a comprehensive educational and outreach program.</p> <p>However, CalRecycle prefers the following edit to proposed regulatory text section 18973.3(i):</p> <p><u>(3) Establishment of an internet website designed with functionality for mobile platforms, provided with language options suited to local demographics, and maintained to ensure all information is up to date and accurate. 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:</u></p> <p>CalRecycle declines to add requirements from the California Code of Regulations section 1707.5(b) to the proposed regulatory text as it could compromise the department's flexibility to evaluate the stewardship plan's education and outreach program proposals by incorporating a very specific set of standards that apply to prescription drug usage.</p>

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						Rather, CalRecycle is incorporating section 7295 of the Government Code to provide a benchmark that is not overly restrictive.
006-017a	San Francisco Department of the Environment	Jen Jackson	18973.2(j)(3)	Y	<p>17. Website Accessibility. A stewardship plan's internet website should be held to at least the same accessibility standards required for a stewardship plan document and for CalRecycle's own website. We request that CalRecycle add the following as a new subparagraph under Section 18973.2(j)(3) and Section 18973.3(i)(3):</p> <p><i>(G) The required internet website shall comply with section 7405 of the Government Code and the Web Content Accessibility Guidelines 2.0, or a subsequent version.</i></p>	<p>006-017a. Additional language added to sections 18973.2(j)(3) and 18973.3(i)(3), as indicated in the response to comment 006-016a, requires a program operator to design an accessible website that conveys information and content to a wide range of individuals. Section 18973.3(i)(3) and section 18973.2(j)(3) of the proposed regulatory text have been revised as follows:</p> <p><u>Establishment of an internet website designed with functionality for mobile platforms, provided with language options suited to local demographics, and maintained to ensure all information is up to date and accurate. 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</u></p> <p>CalRecycle finds that applying Web Content Accessibility Guidelines 2.0 to a program operator's website may be overly restrictive and could compromise the depth of information available to all ultimate users.</p>
006-017b	San Francisco Department of the Environment	Jen Jackson	18973.3(i)(3)	Y	<p>17. Website Accessibility. A stewardship plan's internet website should be held to at least the same accessibility standards required for a stewardship plan document and for CalRecycle's own website. We request that CalRecycle add the following as a new subparagraph under Section 18973.2(j)(3) and Section 18973.3(i)(3):</p> <p><i>(G) The required internet website shall comply with section 7405 of the Government Code and the Web Content Accessibility Guidelines 2.0, or a subsequent version.</i></p>	<p>006-017b. Additional language added to sections 18973.2(j)(3) and 18973.3(i)(3), as indicated in the response to comment 006-016a, requires a program operator to design an accessible website that conveys information and content to a wide range of individuals. Section 18973.3(i)(3) and 18973.2(j)(3) of the proposed regulatory text have been revised as follows:</p> <p><u>Establishment of an internet website designed with functionality for mobile platforms, provided with language options suited to local demographics, and maintained to ensure all information is up to date and accurate. 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</u></p> <p>CalRecycle finds that applying Web Content Accessibility Guidelines 2.0 to a program operator's website may be overly restrictive and could compromise the depth of information available to all ultimate users.</p>
006-018a	San Francisco Department of the Environment	Jen Jackson	18973.2(j)(3)(E)	Y	<p>18. Toll-Free Telephone Number Specifications. The toll-free telephone number provided by a program operator should be required to provide support in "real-time" (i.e. on-demand and with a live customer service representative) and in languages other than English that are commonly used in California. To accomplish this, we ask CalRecycle to modify Section 18973.2(j)(4) and Section 18973.3(i)(4) to require the toll-free telephone number described to meet the following specifications:</p> <p><i>(A) Accept calls via human customer service representatives</i></p>	<p>006-018a. A change to the proposed regulatory text is necessary. In response to the commenter's proposal (A) and (C), the department recognizes the significance of ensuring the stewardship program's telephone service is accessible to a wide range of people and that hearing impaired and speech-impaired individuals have the same access to information and services available to others. However, CalRecycle prefers to list specific accessibility considerations for clarity rather than incorporate a general reference to the Americans With Disabilities Act.</p>

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					<p>(B) Provide translation support in the languages used by the Board of Pharmacy to satisfy the requirements of Title 16 California Code of Regulations Section 1707.5(b)</p> <p>(C) Comply with any requirements of the Americans With Disabilities Act, including but not limited to provisions for hearing-impaired individuals.</p>	<p>The proposed regulatory text section 18973.2(j)(4) is revised as follows: <u>(4) Establishment of a toll-free telephone number to: 1) accept requests for mail-back materials requests from ultimate users who are homeless, homebound, or disabled, for mail-back materials and 2) to provide disposal options, and other program information to ultimate users without access to the internet. for ultimate users who are homeless, homebound, or disabled in addition to accepting requests through an internet website. The toll-free telephone number shall offer language options suited to local demographics, accept calls via human representative, and provide services for hearing-impaired and speech-impaired individuals.</u></p> <p>In response to the commenter's proposal for (B), CalRecycle declines to add requirements from the California Code of Regulations section 1707.5(b) to the proposed regulatory text as it could compromise the department's flexibility to evaluate the stewardship plan's education and outreach program proposals by incorporating a very specific set of standards that apply to prescription drug usage. Rather, CalRecycle is incorporating section 7295 of the Government Code to provide a benchmark that is not overly restrictive.</p>
006-018b	San Francisco Department of the Environment	Jen Jackson	18973.3 (i)(4)	Y	<p>18. Toll-Free Telephone Number Specifications. The toll-free telephone number provided by a program operator should be required to provide support in "real-time" (i.e. on-demand and with a live customer service representative) and in languages other than English that are commonly used in California. To accomplish this, we ask CalRecycle to modify Section 18973.2(j)(4) and Section 18973.3(i)(4) to require the toll-free telephone number described to meet the following specifications:</p> <p>(A) Accept calls via human customer service representatives</p> <p>(B) Provide translation support in the languages used by the Board of Pharmacy to satisfy the requirements of Title 16 California Code of Regulations Section 1707.5(b)</p> <p>(C) Comply with any requirements of the Americans With Disabilities Act, including but not limited to provisions for hearing-impaired individuals.</p>	<p>006-018b. A change to the proposed regulatory text is necessary. In response to the commenter's proposal (A) and (C), the department recognizes the significance of ensuring the stewardship program's telephone service is accessible to a wide range of people and that hearing impaired and speech impaired individuals have the same access to information and services available to others. However, CalRecycle prefers to list specific accessibility considerations for clarity rather than incorporate a general reference to the Americans With Disabilities Act.</p> <p>The proposed regulatory text section 18973.3(i) is revised as follows: <u>(4) Establishment of a toll-free telephone number to: 1) serve as an option for ultimate users to request sharps waste containers, and 2) to obtain information about the program including, but not limited to what is outlined in section 18973.3(i)(3)(A)-(E). The toll-free telephone number shall offer language options suited to local demographics, accept calls via human representative, and provide services for hearing-impaired and speech-impaired individuals.</u></p> <p>CalRecycle declines to add requirements from the California Code of Regulations section 1707.5(b) to the proposed regulatory text as it could compromise the department's flexibility to evaluate the stewardship plan's education and outreach program proposals by incorporating a very specific set of standards that apply to prescription drug usage. Rather, CalRecycle is incorporating section 7295 of the Government Code to provide a benchmark that is not overly restrictive.</p>

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006-019	San Francisco Department of the Environment	Jen Jackson	18973.3(f)(2)(B)	Y	<p>19. Mail-Back Package Information. We ask CalRecycle to revise the language in Section 18973.3(f)(2)(B) to specify that "all necessary information" for proper home-generated sharps disposal shall be included in the mail-back materials:</p> <p><i>(B) Mail-back materials shall include all necessary information for proper home-generated sharps disposal.</i></p>	<p>006-019. CalRecycle agrees with the commenter's proposal but prefers the following edit to proposed regulatory text section 18973.3(f)(2) to address the issue of mismatched language between statute and the proposed regulations:</p> <p><u>(B) For any sharps, the packaging, an insert or instructions, or separate information provided to the ultimate user shall include all necessary information on proper sharps waste disposal. Mail-back materials shall include information for proper home-generated sharps disposal.</u></p>
006-020	San Francisco Department of the Environment	Jen Jackson	18973.3(i)	N	<p>20. Training for Point-of-Sale Staff. Given the statute's requirement to provide or initiate distribution of sharps mail-back containers and materials at the point of sale, sharps retailers play a critical role in the program's success. To ensure that the necessary staff are aware of the program and able to provide ultimate users guidance on how to access mail-back services, we request the following subsection be added to Section 18973.3(i):</p> <p><i>(6) Activities and materials to ensure that retail staff involved with distributing or initiating distribution of sharps waste containers and mail-back materials are aware of the program and can assist ultimate users with accessing program services.</i></p>	<p>006-020. CalRecycle rejects the comment. Rather than specifying retail staff training in the proposed regulations, CalRecycle prefers to maintain flexibility for a program operator to propose a distribution mechanism that complies with applicable statutory and regulatory requirements and adheres to the levels of ultimate user convenience specified in the definition of "provides or initiates distribution of a sharps waste container and mail-back materials" (section 18972.1(a)(11) of the proposed regulatory text). CalRecycle prefers the following edit to 18973.3(i) to match statutory language:</p> <p>(1) Activities to promote awareness and maximize ultimate user participation in the stewardship program, <u>including, but not limited to provision of educational and outreach materials for persons authorized to prescribe drugs, pharmacies, pharmacists, ultimate users, and others, as necessary.</u></p>
006-021a	San Francisco Department of the Environment	Jen Jackson	18973.4(i)	Y	<p>21. Outreach Metric Reporting. Section 18973.2(j)(5) and Section 18973.3(i)(5) of the Proposed Regulations require program operators to establish metrics for evaluating the outreach and education program. However, there is no corresponding requirement to provide or discuss the metrics in the Annual Report. We ask CalRecycle to revise Section 18973.4(i) and Section 18973.5(i) to add the following requirements:</p> <p><i>(i) Education and Outreach. Description and evaluation of the comprehensive education and outreach activities pursuant to Section 18973.2(i) [or "Section 18973.3(i)" for Section 18973.5], including:</i></p> <p><i>(1) Electronic examples of promotional marketing materials</i></p> <p><i>(2) Numerical results of the outreach and education metrics established in the approved stewardship plan</i></p> <p><i>(3) A discussion of what the metrics and other results reveal about ultimate user awareness, program usage, and accessibility</i></p>	<p>006-021a. CalRecycle agrees with the commenter's recommendation. This additional information is necessary for the department to determine whether the education and outreach program was conducted comprehensively, pursuant to Public Resources Code section 42031.6.</p> <p>Proposed regulatory text section 18973.4(i) is revised as follows:</p> <p><u>(i) Education and Outreach. Description and evaluation of the comprehensive education and outreach activities pursuant to section 18973.2(j), including, but not limited to, the following:</u></p> <p><u>(1) eElectronic examples of promotional marketing materials=</u></p> <p><u>(2) Numerical results of the education and outreach metrics outlined in the stewardship plan, pursuant to section 18973.2(j)(5).</u></p> <p><u>(3) A discussion of what the metrics reveal about the performance of the comprehensive education and outreach program, including, but not limited to, ultimate user awareness, program usage, and accessibility.</u></p>

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006-021b	San Francisco Department of the Environment	Jen Jackson	18973.5 (i)	Y	<p>21. Outreach Metric Reporting. Section 18973.2(j)(5) and Section 18973.3(i)(5) of the Proposed Regulations require program operators to establish metrics for evaluating the outreach and education program. However, there is no corresponding requirement to provide or discuss the metrics in the Annual Report. We ask CalRecycle to revise Section 18973.4(i) and Section 18973.5(i) to add the following requirements:</p> <p><i>(i) Education and Outreach. Description and evaluation of the comprehensive education and outreach activities pursuant to Section 18973.2(i) [or "Section 18973.3(i)" for Section 18973.5], including:</i></p> <p><i>(1) Electronic examples of promotional marketing materials</i></p> <p><i>(2) Numerical results of the outreach and education metrics established in the approved stewardship plan</i></p> <p><i>(3) A discussion of what the metrics and other results reveal about ultimate user awareness, program usage, and accessibility</i></p>	<p>006-021b. CalRecycle agrees with the commenter's recommendation. This additional information is necessary for the department to determine whether the education and outreach program was conducted comprehensively, pursuant to Public Resources Code section 42031.6.</p> <p>Proposed regulatory text section 18973.5 is revised as follows:</p> <p><u>(i) Education and Outreach. Description and evaluation of the comprehensive education and outreach activities pursuant to section 18973.3(i), including, but not limited to, the following:</u></p> <p><u>(1) eElectronic examples of promotional marketing materials</u></p> <p><u>(2) Numerical results of the education and outreach metrics outlined in the stewardship plan, pursuant to section 18973.3(i)(5).</u></p> <p><u>(3) A discussion of what the metrics reveal about the performance of the comprehensive education and outreach program, including, but not limited to, ultimate user awareness, program usage, and accessibility.</u></p>
006-022	San Francisco Department of the Environment	Jen Jackson	18973.5 (i)	N	<p>22. Annual Report: Training for Point of Sale Staff. In accordance with comment #20 above, we recommend adding an additional subparagraph to Section 18973.5(i) that requires the program operator to discuss the training and other activities conducted to ensure point-of-sale staff can assist ultimate users with accessing program services. We propose the following language:</p> <p><i>(4) A discussion of the program operator's efforts to train retail staff involved with distributing or initiating distribution of sharps waste containers and mail-back materials to ensure staff can assist ultimate users with accessing program services.</i></p>	<p>006-022. CalRecycle disagrees with the commenter. Public Resources Code section 42033.2(b)(8) requires information on how a program operator complied with all elements in its stewardship plan during the reporting period. Sections 18973.5(f) of the proposed regulatory text require a program operator to include information on any changes to processes and procedures that were used to assist in the distribution of sharps waste containers and mail-back materials, which could include training retail staff or hiring a contractor to do so.</p> <p>See response to comment 006-020, that addresses the commenter's related recommendation in the associated stewardship plan section 18973.3(f)(2) of the proposed regulatory text. Rather than requiring a discussion of a program operator's efforts to train retail staff in the proposed regulations, CalRecycle prefers to maintain flexibility for a program operator to propose a distribution mechanism that complies with statute and adheres to the levels of ultimate user convenience specified in the definition of "provides or initiates distribution of a sharps waste container and mail-back materials" (section 18972.1(k) of the proposed regulatory text).</p>
006-023a	San Francisco Department of the Environment	Jen Jackson	18973.2 (k)	Y	<p>23. Minimum Requirements for Plan Coordination. We appreciate language in Section 18973.2(k) and Section 18973.3(j) requiring program operators to describe the "good faith" efforts that will be made to work with other program operators. However, we are concerned that the proposed language does not provide adequate safeguards to prevent ultimate users from being negatively impacted by conflicting messaging or instructions from multiple stewardship organizations. We strongly recommend revising the language in these sections</p>	<p>006-023a. Section 18973.2(k) of the proposed regulatory text has been revised as follows:</p> <p><u>(k) Coordination Efforts. Description of how the program operator will make a good faith effort to work with the other stewardship program(s) in order to most effectively achieve the requirements of statute and regulations, coordinate with other program operators to avoid conflict, duplication, and</u></p>

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					<p>to be more detailed and to establish certain minimum requirements for plan coordination. We suggest modifying the language in Section 18973.2(k) and Section 18973.3(j) as follows:</p> <p><i>(k) In the event that there is more than one stewardship plan approved for covered drugs [or "home-generated sharps waste" for Section 18973.3(j)], a program operator shall coordinate with all other program operators to most effectively achieve the requirements of the statute and regulations. At minimum, each program operator shall:</i></p> <p><i>(A) Accept all covered products in the secure receptacles and mail-back packages provided by their stewardship plan to the extent allowed by law or regulation.</i></p> <p><i>(B) Coordinate with other program operators to develop and implement a single system of promotion, including a single toll-free telephone number and single internet website to promote to ultimate users the opportunity to dispose of covered products.</i></p> <p><i>(C) If program operators cannot come to agreement on a single system of promotion, CalRecycle shall develop a single system of promotion on behalf of program operators, which program operators shall be required to fund and implement.</i></p>	<p><u>confusion to the public and all program participants in the event that multiple stewardship programs for covered drugs are in operation concurrently or new stewardship programs begin operating.</u></p> <p>The department has removed the phrase "good faith effort" from section 18973.2(k) of the proposed regulatory text, while leaving the language that requires a description of how a program operator will work with other program operators in the event that multiple stewardship programs are in operation concurrently. Coordination efforts will be evaluated for compliance with the statute and regulations, and thus the department prefers to provide greater specificity for this requirement by listing the types of implementation issues that the description should address, rather than relying on the term "good faith effort," which is ambiguous in this context. Furthermore, these proposed edits clarify that the required description should account for not only existing stewardship programs, but also for the possibility of new stewardship programs arising in the future. CalRecycle acknowledges the potential issue of conflicting messaging and instructions that may inhibit an ultimate user's experience. However, including prescriptive requirements (as the Commenter proposes in subparts (A) through (C)) for multiple program operators to coordinate program implementation is outside the scope and authority of these regulations.</p>
006-023b	San Francisco Department of the Environment	Jen Jackson	18973.3(j)	Y	<p>23. Minimum Requirements for Plan Coordination. We appreciate language in Section 18973.2(k) and Section 18973.3(j) requiring program operators to describe the "good faith" efforts that will be made to work with other program operators. However, we are concerned that the proposed language does not provide adequate safeguards to prevent ultimate users from being negatively impacted by conflicting messaging or instructions from multiple stewardship organizations. We strongly recommend revising the language in these sections to be more detailed and to establish certain minimum requirements for plan coordination. We suggest modifying the language in Section 18973.2(k) and Section 18973.3(j) as follows:</p> <p><i>(k) In the event that there is more than one stewardship plan approved for covered drugs [or "home-generated sharps waste" for Section 18973.3(j)], a program operator shall coordinate with all other program operators to most effectively achieve the requirements of the statute and regulations. At minimum, each program operator shall:</i></p> <p><i>(A) Accept all covered products in the secure receptacles and mail-back packages provided by their stewardship plan to the extent allowed by law or regulation.</i></p> <p><i>(B) Coordinate with other program operators to develop and implement a single system of promotion, including a single toll-free telephone number and single internet website to promote to ultimate users the opportunity to dispose of covered products.</i></p> <p><i>(C) If program operators cannot come to agreement on a single system of</i></p>	<p>006-023b. Section 18973.3(j) of the proposed regulatory text is revised as follows: <u>(j) Coordination Efforts. Description of how the program operator will make a good faith effort to work with the other stewardship program(s) in order to most effectively achieve the requirements of statute and regulations, coordinate with other program operators to avoid conflict, duplication, and confusion to the public and all program participants in the event that multiple stewardship programs for covered drugs are in operation concurrently or new stewardship programs begin operating.</u></p> <p>The department has removed the phrase "good faith effort" from section 18973.3(j) of the proposed regulatory text, while leaving the language that requires a description of how a program operator will work with other program operators in the event that multiple stewardship programs are in operation concurrently. Collaboration efforts will be evaluated for compliance with the statute and regulations, and thus the department prefers to provide greater specificity for this requirement by listing the types of implementation issues that the description should address, rather than relying on the term "good faith effort," which is ambiguous in this context. Furthermore, these proposed edits clarify that the required description should account for not only existing stewardship programs, but also for the possibility of new stewardship programs arising in the future.</p>

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					<i>promotion, CalRecycle shall develop a single system of promotion on behalf of program operators, which program operators shall be required to fund and implement.</i>	CalRecycle acknowledges the potential issue of conflicting messaging and instructions that may inhibit an ultimate user's experience. However, including prescriptive requirements for multiple program operators to coordinate program implementation is outside the scope and authority of these regulations.
006-024	San Francisco Department of the Environment	Jen Jackson	18973.3 (g)	N	<p>24. Process for Handling Local Agency Requests Among Multiple Program Operators. The Proposed Regulations are silent on how local agency reimbursement requests will be handled if there is more than one approved stewardship plan for home-generated sharps waste. It is important that CalRecycle establish prescriptive coordination requirements for program operators to ensure local agency requests are fulfilled in a timely manner. We request that CalRecycle add the following subparagraph as an additional requirement of Section 18973.3(g):</p> <p><i>(3) Description of the processes that will be used to receive, process, and fulfill local agency requests in the event that there is more than one approved program operator. At minimum, the processes shall address:</i></p> <ul style="list-style-type: none"> <i>(A) Submittal of local agency requests</i> <i>(B) Operator to operator coordination of removal service</i> <i>(C) Local agency reimbursement</i> <i>(D) Apportioning costs</i> <i>(E) If program operators cannot come to agreement on the coordination processes for handling local agency requests, CalRecycle shall develop processes on behalf of program operators, which program operators shall be required to implement</i> 	006-024. A change to the proposed regulatory text is not necessary. Public Resources Code section 42032.2(d)(1)(F)(ii) states that "upon request, the program provides for reimbursement to local agencies for disposal costs related to home-generated sharps waste, unless the program operator provides for the removal of the home-generated sharps waste from the local household hazardous waste facility." No matter how many stewardship programs for home-generated sharps waste are in operation, a program operator is required by statute to honor local agency requests for reimbursement or removal. Section 18973.3(g)(1) of the proposed regulatory text requires a description of the process for coordinating with local agencies, and section 18973.3(j) of the proposed regulatory text requires a description of efforts to coordinate with other program operators. Further prescriptive requirements are unnecessary and could compromise program operator flexibility to propose methods of coordination with local agencies and resolve potential disputes. CalRecycle does not seek to mediate disputes between program operators and local agencies.
006-025	San Francisco Department of the Environment	Jen Jackson	18973.5 (p)	Y	<p>25. Annual Report: Rejected Local Agency Requests. We urge Cal Recycle to revise Section 18973.5(p) so that a program operator is required to list any Local Agency Requests that were rejected in the Annual Report - if applicable - and indicate the reason(s) why each Request was rejected. We suggest adding the following subsection:</p> <p><i>(3) Any local agency requests that were rejected and the reason(s) each request was rejected</i></p>	<p>006-025. CalRecycle agrees with the commenter's recommendation. A requirement has been added to proposed regulatory text section 18973.5(p) as follows:</p> <p><u><i>(3) Any requests that were rejected and the reason(s) each request was rejected.</i></u></p> <p>This information will enable the department to verify whether a program operator's rejection of the local agency request was valid, pursuant to Public Resources code sections 42032.2(d)(1)(F)(ii)(I) through (IV).</p>
006-026	San Francisco Department of the Environment	Jen Jackson	18973	N	<p>26. Plan Submission After Initial 6 Month Window. Section 42032(a)(1) of the statute requires program operators to submit stewardship plans for approval within 6 months of CalRecycle adopting regulations. There is no other language in the statute or Proposed Regulations that addresses plan submission after this initial 6-month window has elapsed. This is a significant omission that could effectively prohibit submission of new stewardship plans after 6 months and/or limit revision of existing stewardship plans to the "Significant Change" process outlined in the statute. We urge CalRecycle to modify the Proposed Regulations to clarify that new stewardship plans can be</p>	006-026. CalRecycle disagrees that the statute and the proposed regulations do not address stewardship plan submissions outside of the initial 6-month time period following the adoption of the regulations. Nothing in the statute prohibits a covered entity, individually or as part of a stewardship organization, from submitting a stewardship plan at any point in time. The processes and procedures for stewardship plan review and approval as described in the statute and proposed regulations would apply to any stewardship plan submitted (including revisions, if necessary), so there is no need for separate requirements.

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					accepted after the initial 6-month window and establish processes, deadlines, and other guidance for plan submission, review, and approval.	
006-027	San Francisco Department of the Environment	Jen Jackson	18973	N	27. Plan Submission by a New Covered Entity. Similar to comment #26 above, the statute and Proposed Regulations are silent on what happens when a new covered entity begins selling one or more covered products in California more than 6 months after regulations are adopted. The current language seems to provide a covered entity no option other than joining an existing approved plan. We encourage CalRecycle to add language that establishes processes, deadlines, and other guidance to provide new covered entities clarity and flexibility in meeting the requirements of the statute.	006-027. CalRecycle disagrees that the statute and the proposed regulations do not address stewardship plan submissions outside of the initial 6-month time period following the adoption of the regulations. Nothing in the statute prohibits a covered entity, individually or as part of a stewardship organization, from submitting a stewardship plan at any point in time. The processes and procedures for stewardship plan review and approval as described in the statute and proposed regulations would apply to any stewardship plan submitted, so there is no need for separate requirements.
006-028	San Francisco Department of the Environment	Jen Jackson	18972.1	Y	28. Add New Definition for "Inert." The term "Inert" is used in the statute in Section 42032.2(a)(1)(G)(i) as the treatment goal for CalRecycle approval of an Alternative Collection and Disposal System for covered drugs. The Proposed Regulations must include a definition for the term to provide explicit requirements that an Alternative Collection and Disposal System shall meet for approval. We propose the following definition to ensure that any approved Alternative Collection and Disposal System meets Drug Enforcement Administration regulations and California's requirements for landfill: <i>"Inert" means the covered drug or mixture of covered drugs is rendered chemically inactive prior to disposal and complies with all applicable local, state and federal laws and regulations, including those of the United State Drug Enforcement Administration and California statutes and regulations governing disposal in a municipal solid waste landfill.</i>	006-028. CalRecycle concurs with the comment and accepts the commenter's addition to the proposed regulatory text.
006-029	San Francisco Department of the Environment	Jen Jackson	18972.1	N	29. Add New Definition for "Local Stewardship Program." "Local stewardship program" is used in Section 42036.2 of the statute and in the Proposed Regulations in reference to local programs for collection and disposal of covered drugs or covered home-generated sharps waste that are mandated by an ordinance that took effect before April 18, 2018. A definition for this term is needed to (1) clarify that local jurisdictions with an ordinance for a single type of covered product (e.g. covered drugs but not home-generated sharps waste) can participate in a statewide stewardship program for the other type of covered product without dissolving their existing local stewardship program; and (2) to provide that specific types of local programs, not mandated by a local ordinance, are not included. We request that CalRecycle add the following definition: <i>A "local stewardship program" means a program for the collection and disposal of either covered drugs or home-generated sharps waste, or both, which is mandated by a local ordinance or by any other state or federal statute. A local stewardship program, for the purposes of this chapter, does not include any voluntary program or activity related to collection and disposal of covered drugs or home-generated sharps waste. Nothing in this chapter shall require a local jurisdiction to dissolve a local stewardship program for covered drugs in order</i>	006-029. A change to the proposed regulatory text is not necessary. The commenter's proposed definition for 'local stewardship program' may falsely identify certain local programs just because they were mandated by a local ordinance. Instead, whether or not a particular program fits within the statutory exclusion would be a case-by-case determination.

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					<i>to participate in a statewide program for home-generated sharps waste, or vice versa.</i>	
006-030	San Francisco Department of the Environment	Jen Jackson	18972.1	Y	<p>29. Add New Definition for "Repeal." "Repeal" is used in the statute in Section 42036.2(a) and in the Proposed Regulations in reference to the requirements and procedures for California counties which passed a local stewardship ordinance prior to April 2018 to participate in a CalRecycle-approved stewardship program for covered drugs or home-generated sharps waste. In order to clarify that a repeal must be complete such that the local program is "dissolved" as described in Section 42032.2(c) of the statute, we suggest the following new definition:</p> <p><i>"Repeal" means to revoke or annul a law or ordinance in its entirety such that any program mandated by the law or ordinance is permanently dissolved. For the purposes of this chapter, an amendment or modification of an existing law or ordinance and/or its implementing regulations does not constitute a Repeal unless the changes fundamentally alter the program to the extent that it no longer meets the definition of "local stewardship program" in this chapter.</i></p>	<p>006-030. The department agrees with the commenter's recommendation of providing a definition for "repeal."</p> <p>CalRecycle prefers including the following definition in the proposed regulatory text section 18972.1:</p> <p><u>(12) "Repeal" means to revoke or annul a law or ordinance in its entirety such that any program mandated by the law or ordinance is permanently dissolved. For the purposes of this Article, a modification of an existing law or ordinance does not constitute to a repeal unless the changes fundamentally alter the program to the extent that it no longer meets the definition of a "stewardship program" as defined in subdivision (y) of section 42030 of the Public Resources Code.</u></p> <p>CalRecycle defers to the definition of "stewardship program", per Public Resources Code section 42030(y), rather than use the definition of "local stewardship program" recommended in comment 006-029.</p>
007-001a	COPALM	Melanie To	18973.2 (j)(4)	Y	<p>We propose that the following recommendations be incorporated:</p> <ul style="list-style-type: none"> Development of a safe disposal hotline in addition to the disposal locator websites for individuals without access to the internet. Hotline services should be provided in multiple languages. 	<p>007-001a. CalRecycle agrees with the commenter's recommendation to provide program information to individuals without access to the internet, including disposal options through the toll-free telephone number. Proposed regulatory text section 18973.2(j)(4) is revised as follows:</p> <p><u>(4) Establishment of a toll-free telephone number to: 1) accept requests for mail-back materials requests from ultimate users who are homeless, homebound, or disabled, for mail-back materials, and 2) to provide disposal options, and other program information to ultimate users without access to the internet, for ultimate users who are homeless, homebound, or disabled in addition to accepting requests through an internet website. The toll-free telephone number shall offer language options suited to local demographics, accept calls via human representative, and provide services for hearing-impaired and speech-impaired individuals.</u></p>
007-001b	COPALM	Melanie To	18973.3 (i)(4)	Y	<p>We propose that the following recommendations be incorporated:</p> <ul style="list-style-type: none"> Development of a safe disposal hotline in addition to the disposal locator websites for individuals without access to the internet. Hotline services should be provided in multiple languages. 	<p>007-001b. CalRecycle agrees with the commenter's recommendation to provide program information to individuals without access to the internet, including disposal options through the toll-free telephone number. Proposed regulatory text, section 18973.3(i), is revised as follows:</p> <p><u>(4) Establishment of a toll-free telephone number to: 1) serve as an option for ultimate users to request sharps waste containers, and 2) to obtain information about the program including, but not limited to what is outlined in section 18973.3(i)(3)(A)-(E). The toll-free telephone number shall offer language options suited to local demographics, accept calls</u></p>

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						<u>via human representative, and provide services for hearing-impaired and speech-impaired individuals.</u>
007-002a	COPALM	Melanie To	18973.2 (j)	N	<p>We propose that the following recommendations be incorporated:</p> <ul style="list-style-type: none"> Providing necessary resources and funding for nonprofit organizations to assist with information dissemination, outreach, and to educate the community on proper safe disposal and disposal locations. 	007-002a. 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.
007-002b	COPALM	Melanie To	18973.3 (i)	N	<p>We propose that the following recommendations be incorporated:</p> <ul style="list-style-type: none"> Providing necessary resources and funding for nonprofit organizations to assist with information dissemination, outreach, and to educate the community on proper safe disposal and disposal locations. 	007-002b. 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.
007-003	COPALM	Melanie To	18973.2 (d)(1)	N	<p>We propose that the following recommendations be incorporated:</p> <ul style="list-style-type: none"> Locating drop-off boxes in secured, public spaces that are easily accessible for everyone, including the homeless. 	007-003. A change to the proposed regulatory text is not necessary. A stewardship program for covered drugs is likely to include retail pharmacies serving as authorized collection sites, which would host secure collection receptacles for collecting covered drugs from ultimate users. However, retail pharmacies are private businesses that have autonomy over their business hours and how their space is utilized. Thus, CalRecycle declines to incorporate a requirement that secure collection receptacles be placed solely in “public spaces” that are easily accessible to all ultimate users. CalRecycle will review a proposed stewardship plan for compliance with the statute and regulations, which uphold convenience for ultimate users, such as through the convenience standard in Public Resources Code section 42032.2(a)(1)(F) and provisions for the homeless in Public Resources Code section 42032.2(a)(1)(G)(i).
007-004a	COPALM	Melanie To	18973.4 (i)	Y	<p>We propose that the following recommendations be incorporated:</p> <ul style="list-style-type: none"> Thorough evaluation and assessment to measure the effectiveness of education and outreach efforts. 	<p>007-004a. CalRecycle agrees with the commenter and recognizes the importance of an effective comprehensive education and outreach program. Section 18973.4(i) of the proposed regulatory text is revised as follows to provide the department information to assess the effectiveness of the education and outreach efforts.</p> <p><u>(i) Education and Outreach. Description and evaluation of the comprehensive education and outreach activities pursuant to section 18973.2(j), including, but not limited to, the following:</u></p>

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						<p><u>(1) eElectronic examples of promotional marketing materials=</u></p> <p><u>(2) Numerical results of the education and outreach metrics outlined in the stewardship plan, pursuant to section 18973.2(i)(5).</u></p> <p><u>(3) A discussion of what the metrics reveal about the performance of the comprehensive education and outreach program, including, but not limited to, ultimate user awareness, program usage, and accessibility.</u></p>
007-004b	COPALM	Melanie To	18973.5 (i)	Y	<p>We propose that the following recommendations be incorporated:</p> <ul style="list-style-type: none"> • Thorough evaluation and assessment to measure the effectiveness of education and outreach efforts. 	<p>007-004b. CalRecycle agrees with the commenter and recognizes the importance of an effective comprehensive education and outreach program. Section 18973.5(i) of the proposed regulatory text is revised as follows to provide the department information to assess the effectiveness of the education and outreach efforts.</p> <p><u>(i) Education and Outreach. Description and evaluation of the comprehensive education and outreach activities pursuant to section 18973.3(i), including, but not limited to, the following:</u></p> <p><u>(1) eElectronic examples of promotional marketing materials=</u></p> <p><u>(2) Numerical results of the education and outreach metrics outlined in the stewardship plan, pursuant to section 18973.3(i)(5).</u></p> <p><u>(3) A discussion of what the metrics reveal about the performance of the comprehensive education and outreach program, including, but not limited to, ultimate user awareness, program usage, and accessibility.</u></p>
007-005	COPALM	Melanie To	18973.2 (j)	N	<p>We propose that the following recommendations be incorporated:</p> <ul style="list-style-type: none"> • Pharmacies be required to include safe disposal instructions and information on their instructions page for all medications prescribed. 	<p>007-005. 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.</p>
007-006	COPALM	Melanie To	18973.2 (f)	N	<p>We propose that the following recommendations be incorporated:</p> <ul style="list-style-type: none"> • 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. 	<p>007-006. 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 are contained in both Public Resources Code section 42034 and proposed regulatory text sections 18973.2(f) and 18973.3(e). 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.</p>
008-001A	CRA, NACDS, & CPhA	Rachel Michelin, Steve Anderson,	18972.1 (j)	Y	<p>Definition of "provides or initiates distribution of a sharps waste container" Section 18972.1 (j)</p>	<p>008-001A. CalRecycle agrees that additional clarity is needed. Due to a reorganization of subsection 18972.1, subsection 18972.1(j) has been changed to 18972.1(a)(11) in the proposed regulatory text. Section 18972.1(a)(11) is edited as follows:</p>

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		Rajan Vaidya			The definition of providing a sharps waste container seems to require that a sharps waste container must be provided to a consumer at the point of sale. Our members have strong concerns about the ability of pharmacies to have on-hand and in-stock the number of containers necessary to achieve this goal.	<p>(11) “Provides or initiates distribution of a sharps waste container” means one of the following:</p> <p>(1A) To provide a sharps waste container and mail-back materials to the ultimate user, at the point of sale or prior, at no cost to the ultimate user; or,</p> <p>(2B) To arrange, at the point of sale or prior, for a sharps waste container and mail-back materials to be sent to the ultimate user and arrive within fourthree business days at no cost or inconvenience to the ultimate user; or,</p> <p>(3C) Other methods of providing a sharps waste container and mail-back materials, as approved by the department in a stewardship plan, if the method identified in subpart (A1) above is not allowed by law or is not reasonably feasible, and if the method identified in subpart (B) above or (2) is are not allowed by law or is not reasonably feasible. These methods must be and approved by the department in a stewardship plan and which result in substantially the same level of convenience to the ultimate user as the methods identified in subparts (A) and (B) above.</p> <p>The requirements contained in section 18972.1(a)(11)(B) and (C) are sufficiently flexible to allow a program operator who does not want to overburden pharmacies to propose other methods to accomplish the requirements. Additionally, since section 18972.1(a)(11)(C) of the proposed regulations must “result in substantially the same level of convenience to the ultimate user as the methods identified in subparts (A) and (B) above,” this option provides program operators with greater flexibility in designing innovative distribution mechanisms while upholding the level of consumer convenience intended by statute.</p>
008-001B	CRA, NACDS, & CPhA	Rachel Michelin, Steve Anderson, Rajan Vaidya	18972.1 (j)	N	In addition, pharmacies are concerned that too many containers will be distributed. Manufacturers or program operators and pharmacies should have the flexibility to work together on a solution that works best for their partnerships while ensuring compliance with the program requirements.	008-001B. A change to the proposed regulatory text is not necessary as it is sufficient to accommodate the needs of ultimate users without resulting in superfluous distribution. A program operator would be able to work with pharmacies to determine the most effective volume of containers to distribute, and ultimate users are able to deny an offer for a free sharps container due to still having space in an existing one. However, a program operator should not deny requests for sharps containers or restrict point-of-sale offers on the grounds of previous distribution volume.
008-002A	CRA, NACDS, & CPhA	Rachel Michelin, Steve Anderson,	18973.2 (d)	N	Outreach to pharmacies to encourage participation Section 18973.2 (d) Our members are concerned as to how each manufacturer or program operator on their behalf will be reaching out to potential pharmacies to participate in the	008-002A. A change to the proposed regulatory text is not necessary. A program operator is required to notify potential authorized collectors of the opportunity to serve as an authorized collector for the proposed stewardship program. The proposed regulations include provisions for a

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		Rajan Vaidya			drug and sharps waste stewardship program. We would like to see more explicit requirements for outreach and specific detail required as to how the manufacturer or program operator handles this outreach.	program operator to list potential authorized collectors that were notified, describe the process in which negotiations is conducted, and describe the conditions for excluding any potential authorized collectors in section 18973.2(d)(2), (3), and (4). Mandating more explicit requirements to the provisions in the proposed regulatory text will limit a program operator's flexibility when negotiating with potential authorized collectors to meet minimum convenience standards. The proposed regulatory language addresses the requirement that a program operator negotiate with potential authorized collectors while providing the department the information necessary to determine that potential authorized collectors are not being excluded from participating when interest is expressed.
008-002B	CRA, NACDS, & CPhA	Rachel Michelin, Steve Anderson, Rajan Vaidya	18973.2 (d)	N	In addition, we believe it is important for the new stewardship program to support and / incorporate those collection efforts already being administered by pharmacies either under county specific requirements or through their own company efforts. Collaboration and inclusion of all types of collection sites and efforts will be key to the success of the program.	008-002B. A change to the proposed regulatory text section 18973.2(d) is not necessary. A program operator may incorporate pharmacies administering collection efforts on their own as participating authorized collectors in order to meet minimum convenience standards and reasonable geographic spread. Further, Public Resources Code section 42032.2(b)(3) specifies that after a stewardship plan is approved, a pharmacy who requests to participate in the stewardship program must be included. However, per Public Resources Code section 42036.2(a), SB 212 does not apply to collection efforts being administered under county-specific requirements enacted through an ordinance effective before April 18, 2018, unless the ordinance is repealed in that jurisdiction. Therefore, this aspect of the commenter's recommendation is outside the scope and authority of these regulations.
008-003	CRA, NACDS, & CPhA	Rachel Michelin, Steve Anderson, Rajan Vaidya	18973.2 (g)	N	Collection site maintenance Section 18973.2 (g) Many pharmacies have expressed frustration with their collection receptacles reaching capacity and the lack of a timely response or consistent maintenance of the collection bins. Each program operator should be required to have a contact number for authorized collectors to utilize to notify the operator of the full receptacle. It is important for Cal Recycle to develop general standards for timeliness related to responses by operators to pharmacy requests.	008-003. A change to the proposed regulatory text is not necessary. A program operator is required to describe the process used to monitor collection receptacles to ensure they do not reach capacity and to identify the procedures followed if capacity is reached. Further, specific information is required in section 18973.4(c)(4) that will provide the department data on collection receptacle maintenance and service schedule adequacy. Any further specificity would impair flexibility for the program operator to work with pharmacies to design effective communication channels and may not improve convenience to the ultimate user.
008-004	CRA, NACDS, & CPhA	Rachel Michelin, Steve Anderson, Rajan Vaidya	18974	N	Recordkeeping requirements for pharmacies Section 18974 Current language included in Section 18974 that requires pharmacies to maintain and provide access for CalRecycle to records should be clarified so that a pharmacy chain corporate representative can maintain records for all pharmacies under their jurisdiction. The records that CalRecycle is requiring are not kept at the individual pharmacy level for chain pharmacies. These records are generally held at the regional or corporate level. For small independent pharmacies, this requirement may be too cumbersome to comply and might require some time or flexibility to gather and generate the information required by the Department. Pharmacies would like to retain any	008-004. A change to the proposed regulatory text is not necessary. Language in section 18974 does not specify that the required records must be maintained on location, nor does it preclude a pharmacy chain corporate representative from maintaining and providing access to these records. The proposed regulatory language requires pharmacies and pharmacy chains to provide access to the records while allowing flexibility in how and where the records are maintained. Reasonable effort will be made with pharmacies to coordinate a point of contact for the purpose of routine records examination.

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					records electronically and would appreciate a template or some additional direction from the Department to assure compliance.	
008-005	CRA, NACDS, & CPhA	Rachel Michelin, Steve Anderson, Rajan Vaidya	18974.3	Y	<p>Retailer product verification Section 18974.3</p> <p>While we appreciate the modifications that CalRecycle has made to the retailer product verification requirements, we are still concerned that each individual pharmacy will not have the capability to check a specified website every time they stock or sell a new drug or new drug dosage form. We do understand the importance of participation by pharmacies and pharmacy chains in assisting CalRecycle ensure that manufacturers that are selling in the California market are participating in the required stewardship program. We ask that Cal Recycle specify that the requirement to consult the website will be at least on an annual basis and also how the pharmacy will inform the Department if they learn of a non-compliant product.</p>	<p>008-005. CalRecycle disagrees with the commenter’s recommendation for the website to be monitored at least annually. Reporting entities are required to monitor the website regularly to determine which covered entities and program operators are in compliance with the law. Considering the frequency of the introduction of covered products into the market place, limiting reviews to a minimum of “at least annually” provides an opportunity for a covered product to be sold, offered for sale, or distributed by a covered entity that is not operating under an approved stewardship plan.</p> <p>However, the department finds additional clarity is needed in the proposed regulatory text to specify that a distributor, wholesaler, pharmacy, and retailer is required to monitor CalRecycle’s website to identify noncompliant covered entities, not non-compliant covered products. If a covered entity is listed on the website as being compliant, then all covered products that a distributor, wholesaler, pharmacy, and retailer sells, offers for sale, or dispenses under that covered entity are determined to be in compliance. The proposed regulatory text revisions for section 18974.3(a) and (b) are as follows:</p> <p><u>(a) Each distributor, wholesaler, pharmacy, and retailer that sells, offers for sale, or dispenses a covered product shall: sSuccessfully log onto the department’s internet web-site to determine if that covered products to be sold, offered for sale, or dispensed are in compliance with the law, by verifying that the covered entities providing the covered product(s) are in compliance with the law.</u></p> <p><u>(b) Should a distributor, wholesaler, pharmacy, other retailer, or a designated responsible party for any of the foregoing identify a noncompliant covered product or stewardship organization, the distributor, wholesaler, pharmacy, other retailer, or designated responsible party for any of the foregoing shall report the discovery to the department’s Enforcement Unit within 30 days.</u></p>
009-001A	HDA	Leah Lindahl	18972.2	Y	<p>1. 18972.2 Criteria for Determining a Covered Entity:</p> <p>The proposed regulatory text fails to provide any additional clarity around the term “Covered Entity,” instead placing much of the guidance on the legislative text which was specifically noted during the legislative process as needing additional clarity. As provided within comments during the informal rulemaking process, the current language creates uncertainty as to which entity is ultimately responsible and could result in a multi-layer fee where the manufacturer, wholesaler, repackager, licensee, importer, etc. fund the disposal of a single product.</p>	<p>009-001A. CalRecycle declines to further clarify the term “covered entity” because the statutory definition is sufficient to determine the priority in which a covered entity is identified. The tiered definition allows CalRecycle to determine the appropriate covered entity within a complex and dynamic supply chain on a case-by-case basis.</p> <p>To ensure multi-layer fees are not assessed by a stewardship organization, potential covered entities should coordinate within their respective supply chains to determine how the statutory requirements will be met. As this is determined, the covered entity must either join a</p>

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						<p>stewardship organization or submit its own stewardship plan to CalRecycle for approval.</p> <p>Based on our review of this issue, we have determined that section 18972.2 of the proposed regulatory text should be revised as follows to accurately reflect the statutory priorities:</p> <p>(a) The department shall consider all manufacturers of covered products that are sold, offered for sale, or dispensed in California, whether they are program operators or are represented by a stewardship organization, as the covered entities. (b) The department will use the priority set forth in subsections(1)(B)-(E) of subdivision (f) of section 42030 of the Public Resources Code to identify the covered entity for any covered products consistent with subdivision (f) of section 42030, which do not meet the definition of subsection (1)(A) of subdivision (f) of section 42030 of the Public Resources Code.</p> <p>This revision was made because the deleted text did not add any necessary information to what is already stated in Public Resources Code 42030(f)(1)(A)-(E). Additionally, the term “dispensed” is not part of the statutory definition of “covered entity.”</p>
009-001B	HDA	Leah Lindahl	18972.2	N	<p>Additionally, the language also fails to offer a definition as to what constitutes a “manufacturer.” HDA request the proposed regulations provide further clarity that any manufacturer who avails itself of the California market should be the responsible entity required to participate in the stewardship program. In other words, if a manufacturer’s product is for sale within the state of California, they are therefore “in” the state and responsible for participating in the Pharmaceutical and Sharps Waste Stewardship Program. It is clear that the legislative intent was that all manufacturers must participate in the stewardship program. Therefore, it is imperative that a manufacturer not be permitted to avoid participation simply by claiming that they do not have a facility in the state and are therefore not “in” the state. Based on current case law, the state of California clearly has jurisdiction over pharmaceutical manufacturers whose products are dispensed in California to comply with the proposed statewide take back program.</p>	<p>009-001B. A change to the proposed regulatory text is not necessary. The term “manufacturer” has a common meaning and does not need further definition. Furthermore, the statutory definition makes clear that the operative facts for whether an entity is a “covered entity” is whether or not it sells covered products “in or into the state,” not whether or not the entity is located within the state. CalRecycle disagrees with the commenter’s assertion that a manufacturer can avoid participating by claiming they do not have a facility in the state and is therefore not “in” the state. Regardless of complex market dynamics, an entity in the supply chain for a covered product must either propose a stewardship plan or join a stewardship organization to manage that covered product in compliance with SB 212. It is the responsibility of covered entities to self-identify through the submission of covered products lists to the Board of Pharmacy for verification pursuant to Public Resources Code section 42031(a) through (d).</p>
009-Supp.-001B	HDA	Leah Lindahl	18972.2	N	<p>add: (b) The department will consider any manufacturer with products offered for sale in the state of California as being “in” the state.</p> <p>Commented [HDA1]: HDA appreciates the inclusion of this provision, stipulating that any manufacturer who avails itself of the California market should be the responsible entity required to participate in the stewardship program. Due to the vague nature of the legislative text, we request the rules further stipulate that a manufacturer is “in” the states if any of their products are offered for sale within California.</p>	<p>009-Supp.-001B. A change to the proposed regulatory text is not necessary. See response to comment 009-001B.</p>

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009-001C	HDA	Leah Lindahl	18972.2	N	Additionally, HDA requests that regulations stipulate a clear process by which CalRecycle will identify the manufacturer and how the department would utilize the tiered definition should the manufacturer not be identifiable.	009-001C. A change to the proposed regulatory text is not necessary. CalRecycle declines to further clarify the terms “manufacturer” and “covered entity” because the statutory definition of “covered entity” is sufficient to determine the priority in which a covered entity is identified. Compliance determinations are made on a case-by-case basis. Entities that could be considered covered entities based on the statutory definition should endeavor to coordinate amongst appropriate entities within their respective supply chains to determine how the statutory requirements will be met. It is the responsibility of covered entities to self-identify through the submission of covered products lists to the Board of Pharmacy for verification pursuant to Public Resources Code section 42031(a) through (d).
009-Supp.-001C	HDA	Leah Lindahl	18972.2	N	After (d) (which was the Proposed Regulations original (b)) add: The department, in collaboration with the California Board of Pharmacy, will develop and implement procedures to communicate with manufacturers of covered products or the selected stewardship organization and ensure their understanding their compliance responsibilities. Only when there is sufficient evidence that such efforts have failed the department will then utilize the priority set forth in subsections(1)(B)-(E) of subdivision (f) of section 42030 of the Public Resources Code. Commented [HDA3]: HDA continues to request the CalRecycle establish a clear process by which the department will identify the manufacturer and how the department would utilize the tiered definition should the manufacturer not be identifiable.	009-Supp.-001C. A change to the proposed regulatory text is not necessary. See response to comment 009-001C.
009-001D	HDA	Leah Lindahl	18972.2	N	HDA also requests that a clear definition is developed as to what constitutes a “Manufacturer” and offers the below definition for consideration: “Manufacturer” means a person, company, corporation or other entity engaged in the manufacture of (a) a covered drug as defined in subsection (e)(1) of section 42030 of the Public Resources Code sold, offered for sale, or dispensed in the state pursuant to a United States Food and Drug Administration (FDA) approved New Drug Application (NDA), an approved Abbreviated New Drug Application (ANDA), or an over-the-counter drug monograph, or (b) hypodermic needles sold, offered for sale, or dispensed in the state pursuant to an FDA pre-market approval (PMA), or 510k. Manufacturer does not include the activities of a repackager, relabeler, private label distributor or wholesale distributor.	009-001D. A change to the proposed regulatory text is not necessary. CalRecycle declines to further clarify the definition of “manufacturer.” This is a commonly used term that needs no further definition (Note: the proposed definition defines a manufacturer as an entity engaged in the manufacture of ...” As for the exclusion of entities such as repackagers, they cannot be automatically excluded as proposed because the statutory definition may include them if the manufacturer of the covered drug does not themselves sell the drug in or into the state.
009-Supp.-001D	HDA	Leah Lindahl	18972.2	N	add: (c) “Manufacturer” means a person, company, corporation or other entity engaged in the manufacture of (a) a covered drug as defined in subsection (e)(1) of section 42030 of the Public Resources Code sold, offered for sale, or dispensed in the state pursuant to a United States Food and Drug Administration (FDA) approved New Drug Application (NDA), an approved Abbreviated New Drug Application (ANDA), or an over-the-counter drug monograph, or (b) hypodermic needles sold, offered for sale, or dispensed in the state pursuant to an FDA pre-market approval (PMA), or 510k.	009-Supp.-001D. A change to the proposed regulatory text is not necessary. See response to comment 009-001D.

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					<p>Manufacturer does not include the activities of a repackager, relabeler, private label distributor or wholesale distributor.</p> <p>Commented [HDA2]: HDA further requests CalRecycle include a clear definition as to what constitutes a “Manufacturer” as this term can have varying meanings depending on the context. HDA recommends the incorporated definition for consideration. Lack of a clear definition within the law and rules allows for open interpretation of the law and could potentially include other entities outside of the actual manufacturer.</p>	
009-002A	HDA	Leah Lindahl	18974.3	N	<p>2. 18974.3. Retailer, Wholesaler, Distributor Product Verification:</p> <p>We appreciate CalRecycle’s efforts to provide more clarity on how wholesalers and others will verify products being sold in or into California. HDA recommends the regulations stipulate that reporting entities should review the website at least annually and provide a listing of apparent non-compliant manufacturers or covered entities to the department in a format that has been agreed upon by the industry and the department.</p>	<p>009-002A. Reporting entities are required to monitor the website regularly to determine which covered entities and program operators are in compliance with the law. Considering the frequency of the introduction of covered products into the market place, limiting reviews to a minimum of “at least annually” provides an opportunity for a covered product to be sold, offered for sale, or distributed by a covered entity that is not operating under an approved stewardship plan. However, the department revised sections 18974.3(a) and (b) of the proposed regulatory text to specify that a distributor, wholesaler, pharmacy, and retailer is required to monitor CalRecycle’s website to identify noncompliant covered entities, not non-compliant covered products. If a covered entity is listed on the website as being compliant, then all covered products that a distributor, wholesaler, pharmacy, and retailer sells, offers for sale, or dispenses under that covered entity are determined to be in compliance.</p> <p>Regarding the commenter’s recommendation that a listing of non-compliant covered entities be provided to the department in an agreed upon format, a change to the proposed regulatory text is not necessary. Public Resources Code section 42035.6(d) indicates that CalRecycle may post a notice on the department’s Internet web site of non-compliant covered entities but does not require this. To the extent that CalRecycle publishes a list on non-compliant entities, there is no need to specify a format of what that list will look like.</p>
009-Supp.-002A	HDA	Leah Lindahl	18974.3	N	<p>modify: (a) Successfully log onto the department’s Internet Web site <u>at least annually</u> to verify that <u>a covered entity</u> of covered products to be sold, offered for sale, or dispensed are in compliance with the law.</p> <p>Commented [HDA4]: To ensure conformity and clarity, HDA recommends the department require reporting to be conducted at least annually. Further, under Article 6. Section 42305, the list provided by the department will contain “stewardship organizations, including entities with an approved stewardship plan, and covered entities, authorized collection sites, retail pharmacies, and retail pharmacy chains provided in the stewardship plans that are in compliance with this chapter” not a listing of covered products.</p>	<p>009-Supp.-002A. See response to comment 008-005 and 009-002A.</p>

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					<p>modify: (b) Should a distributor, wholesaler, pharmacy, other retailer, or a designated responsible party identify a noncompliant covered product, the distributor, wholesaler, pharmacy, other retailer, or designated responsible party shall report, <u>in an agreed upon format</u>, the discovery to the department's Enforcement Unit.</p> <p>Commented [HDA5]. HDA requests the department work with industry to determine how these reports should be conducted and to establish a standardized format for these reports.</p>	
009-002B	HDA	Leah Lindahl	18974.3	N	HDA also requests the department, in coordination with the board, notify licensees and reporting entities when a non-compliant entity has been identified.	009-002B. A change to the proposed regulatory text is not necessary. Pursuant to Public Resources Code section 42035, distributors, wholesalers, pharmacies, and pharmacy chains are required to monitor the department website for covered entities that are compliant. If a covered entity or stewardship organization is not listed, then it may be out of compliance. Further, the department may post a notice in association with the list the department maintains pursuant to Public Resources Code section 42035 of those entities no longer in compliance.
009-Supp.-002B	HDA	Leah Lindahl	18974.3	N	<p>add: (c) <u>Should the Department determine a covered entity or stewardship organization is not in compliance, the Department in collaboration with the Board shall notify all licensees of the non-compliance.</u></p> <p>Commented [HDA6]: HDA requests the Department notify licensed or reporting entities when they identify a non-compliant stewardship organization or covered entity.</p>	009-Supp.-002B. See response to comment 009-002B.
009-002C	HDA	Leah Lindahl	18974.3	N	HDA further recommends the regulations provide clarity that these reporting entities shall be held harmless for any assessment of penalties placed on the actual manufacturer for lack of participation in the stewardship program.	009-002C. A change to the proposed regulatory text is not necessary. Pursuant to Public Resources Code 42035.2, the department may impose an administrative penalty on a covered entity, program operator, stewardship organization, or authorized collector, as appropriate that violates the authorizing statute and its implementing regulations. These entities cannot be held harmless.
009-003A	HDA	Leah Lindahl	18975	N	<p>3. 18975. Criteria to Impose An Administrative Civil Penalty</p> <p>HDA requests the proposed regulations establish a process by which the department will inform covered entities when it will utilize the priority set forth in subsections(1)(B)-(E) of subdivision (f) of section 42030 of the Public Resources Code to identify the covered entity for any covered products, which do not meet the definition of subsection (1)(A) of subdivision (f) of section 42030 of the Public Resources Code.</p>	009-003A. A change to the proposed regulatory text is not necessary. Entities that could potentially be considered covered entities based on the statutory definition should endeavor to coordinate amongst appropriate entities within their respective supply chains to determine how the statutory requirements will be met. For instance, this may require the establishment of contractual or other terms that clarify the party responsible for participating in a stewardship program or reporting annually to the Board of Pharmacy.
009-Supp.-003A	HDA	Leah Lindahl	18975	Y	<p>After (a)</p> <p>add: (b) <u>The department will establish a process to alert potential covered entities when it will utilize the priority set forth in subsections(1)(B)-(E) of subdivision (f) of section 42030 of the Public Resources Code to identify the covered entity for any covered products, which do not meet the definition of subsection (1)(A) of subdivision (f) of section 42030 of the Public Resources</u></p>	009-Supp.-003A. See response to comment 009-003A regarding notification about the process of determining a covered entity. CalRecycle agrees that there should be a process to notify covered entities of a compliance issue, but prefers the following addition to section 18975.1 of the proposed regulatory text: <u>(a) The department shall issue a notice of violation (NOV) to the respondent if the department determines that the respondent has</u>

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					<p>Code and ensure the potential covered entities are aware of the regulations and responsibility before assessing any administrative penalty.</p> <p>Commented [HDA7]: HDA requests the department establish a process to alert covered entities when there has been a compliance issue. These entities should have the ability to understand their requirements before any potential assessment can be levied.</p>	<p><u>violated a material requirement of this Article or Chapter 2 of Part 3 of Division 30 of the Public Resources Code. The NOV shall list and describe the nature of the violation(s). The department shall issue a NOV before commencing an action to impose administrative civil penalties.</u></p>
009-003B	HDA	Leah Lindahl	18975	N	<p>Further, we request the proposed regulations stipulate that any identified covered entity shall not be penalized or assessed any fines due to non-compliance of a previously reported non-compliant covered entity.</p>	<p>009-003B. A change to the proposed regulatory text is not necessary. Limiting in regulations the Department's ability to take an enforcement action could result in unintended consequences.</p>
009-Supp.-003B	HDA	Leah Lindahl	18975	N	<p>add: (c) Should the department utilize the priority set forth in subsections(1)(B)-(E) of subdivision (f) of section 42030 of the Public Resources Code to identify the covered entity for any covered products, which do not meet the definition of subsection (1)(A) of subdivision (f) of section 42030 of the Public Resources Code, the subsequent participation entity shall be held harmless for the assessment of penalties on the non-compliant covered entity.</p> <p>Commented [HDA8]: HDA would like to ensure that should the Department utilize the tiered definition of covered entity, the penalties assessed on the previously reported non-compliant entity will not be applicable to subsequent entities.</p>	<p>009-Supp.-003B. See response to comment 009-003B.</p>
009-004	HDA	Leah Lindahl	None	N	<p>4. Submittal of Product Lists</p> <p>The proposed regulatory text does not provide any additional guidance on the reporting of product lists to the Board of Pharmacy. HDA and our member companies believe the current structure outlined in the legislative text establishes an inefficient and ineffective way to collect information to identify which entities should be participating in the stewardship program, resulting in the board receiving incredibly voluminous and duplicative information to analyze and interpret.</p> <p>Due to the vague definition of "Covered Entity" there is no mechanism for which an entity identified under the tiered definition can determine if the prior entity has provided a report to the state board, therefore each entity identified will be responsible to submit information on the products they sell or offer for sale within the state. Due to the structure of the pharmaceutical supply chain, these reports will be largely duplicative since a single product will flow through each of the listed entities prior to the point of dispensing.</p> <p>HDA and our member companies request the Board of Pharmacy establish regulations on this issue which specifically require reporting from the actual manufacturer of the product, these manufacturers can be identified through the above suggested definition. HDA and our members further request a uniform format for reporting to the state board include the following data sets: Name of Supplier, Description of Drug, and National Drug Code (NDC). Every drug product approved for marketing by the FDA, including prescription and over-</p>	<p>009-004. A change to the proposed regulatory text is not necessary. The commenter's recommendation falls under the purview of the State Board of Pharmacy, not CalRecycle, and is therefore outside the scope of these regulations.</p>

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					the-counter, is assigned a unique 10-digit, 3-segment NDC number. This number identifies the labeler, product, and trade package size and is utilized throughout the product's lifecycle. The regulations should also stipulate that entities shall be held harmless for any assessment of penalties on the manufacturer or preceding covered entity for lack of reporting.	
009-005	HDA	Leah Lindahl	None	N	Similar to the concerns expressed above, the requirement to provide a list and description of any drugs or sharps that are "not covered" would be incredibly difficult to ascertain, specifically due to the vague definitions provided in the law. Many of the "not covered" products listed do not include a specific or standard definition for such products, leaving open the interpretation as to what constitutes "not covered" products and what should and should not be reported. Utilizing a clear definition of "Manufacturer" and the NDC for reporting requirements should alleviate the need to report a full list of "not covered" products, unless the state board is seeking to clarify a specific question or product being submitted. We request the reporting of "not covered" products only be required upon request from the board under specific situations or to help identify specific product classes and not required on an annual basis.	009-005. A change to the proposed regulatory text is not necessary. The commenter's recommendation relates to regulations that may be adopted by the State Board of Pharmacy, not CalRecycle, and is therefore outside the scope of these regulations.
010-001a	PPSWG	Anne Vogel-Marr	18973.4(j)(2)	Y	<p>Section 18973.4(j)(2) of the Proposed Regulations states, without further elaboration, that the annual reports submitted to CalRecycle for a covered drug stewardship plan must include a "[l]ist of covered products." Section 18973.5(k) states, somewhat similarly, that the annual reports for a home-generated sharps waste stewardship plan must include an "[u]pdated list of covered products." These provisions should be revised for clarity and to ensure they are consistent with the corresponding statutory language in SB 212.</p> <p>The corresponding provision in SB 212 states that annual report submissions must include, among other things, "the updated and reverified list provided pursuant to paragraph (2) of subdivision (a) of Section 42031 of covered products that each covered entity subject to the stewardship plan sells or offers for sale." Cal. Pub. Res. Code § 42033.2(b)(2) (emphasis added). Section 42031(a)(2), in turn, requires that covered entities (or a stewardship organization on behalf of a group of covered entities) update and submit a list of covered products to the Board of Pharmacy on or before January 15 of each calendar year. This statutory language does not impose any new obligations on regulated entities during the annual reporting process; i.e., there is no obligation to prepare a new, updated or re-verified list of covered products during the roughly two month period between the January 15th Board of Pharmacy submission deadline and the March 31st annual reporting deadline. Rather, the intent was to simply – and only – require that a copy of the covered products list submitted to the Board of Pharmacy on January 15th be included in the annual report submitted to CalRecycle on March 31st.</p> <p>The corresponding language in the Proposed Regulations, as currently drafted, could be construed as imposing additional obligations on regulated entities to undertake another exercise in preparing an updated and/or reverified list of covered products to include in the March 31st annual report submissions. This</p>	<p>010-001a. CalRecycle agrees that additional clarity is needed regarding the submittal of covered product lists in the annual report and concurs with the commenter's interpretation of corresponding statutory requirements. The department accepts the commenter's edit to the proposed regulations.</p> <p>Proposed regulations section 18973.4(j)(2): <u>(2) A copy of the list of covered products submitted to the Board of Pharmacy pursuant to subsection (2) of subdivision (a) of section 42031 of the Public Resources Code.</u> List of covered products</p>

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					is inconsistent with SB 212. As such, Sections 18973.4(j)(2) and 18973.5(k) of the Proposed Regulations should be revised for clarity and consistency with the legislature’s intent. Specifically, Sections 18973.4(j)(2) and 18973.5(k) should be amended to read: “The annual report shall contain the following ... a copy of the list of covered products submitted to the Board of Pharmacy pursuant to subsection (a)(2) of section 42031 of the Public Resources Code.”	
010-001b	PPSWG	Anne Vogel-Marr	18973.5 (k)	Y	<p>Section 18973.4(j)(2) of the Proposed Regulations states, without further elaboration, that the annual reports submitted to CalRecycle for a covered drug stewardship plan must include a “[l]ist of covered products.” Section 18973.5(k) states, somewhat similarly, that the annual reports for a home-generated sharps waste stewardship plan must include an “[u]pdated list of covered products.” These provisions should be revised for clarity and to ensure they are consistent with the corresponding statutory language in SB 212.</p> <p>The corresponding provision in SB 212 states that annual report submissions must include, among other things, “the updated and reverified list provided pursuant to paragraph (2) of subdivision (a) of Section 42031 of covered products that each covered entity subject to the stewardship plan sells or offers for sale.” Cal. Pub. Res. Code § 42033.2(b)(2) (emphasis added). Section 42031(a)(2), in turn, requires that covered entities (or a stewardship organization on behalf of a group of covered entities) update and submit a list of covered products to the Board of Pharmacy on or before January 15 of each calendar year. This statutory language does not impose any new obligations on regulated entities during the annual reporting process; i.e., there is no obligation to prepare a new, updated or re-verified list of covered products during the roughly two month period between the January 15th Board of Pharmacy submission deadline and the March 31st annual reporting deadline. Rather, the intent was to simply – and only – require that a copy of the covered products list submitted to the Board of Pharmacy on January 15th be included in the annual report submitted to CalRecycle on March 31st.</p> <p>The corresponding language in the Proposed Regulations, as currently drafted, could be construed as imposing additional obligations on regulated entities to undertake another exercise in preparing an updated and/or reverified list of covered products to include in the March 31st annual report submissions. This is inconsistent with SB 212. As such, Sections 18973.4(j)(2) and 18973.5(k) of the Proposed Regulations should be revised for clarity and consistency with the legislature’s intent. Specifically, Sections 18973.4(j)(2) and 18973.5(k) should be amended to read: “The annual report shall contain the following ... a copy of the list of covered products submitted to the Board of Pharmacy pursuant to subsection (a)(2) of section 42031 of the Public Resources Code.”</p>	<p>010-001b. CalRecycle agrees that additional clarity is needed regarding the submittal of covered product lists in the annual report and concurs with the commenter’s interpretation of corresponding statutory requirements. The department accepts the commenter’s edit to the proposed regulations.</p> <p>Proposed regulations section 18973.5(k) is revised as follows: <u>(k) A copy of the list of covered products submitted to the Board of Pharmacy pursuant to subsection (2) of subdivision (a) of section 42031 of the Public Resources Code.</u> Updated list of covered products</p>
010-002	PPSWG	Anne Vogel-Marr	General	N	MED-Project USA is separately submitting comments today on the Proposed Regulations. PPSWG supports the MED-Project USA comments.	010-002. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. CalRecycle acknowledges PPSWG’s support for comments submitted

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						by Med-Project USA. Please see 015-001 through 030G for CalRecycle's responses to Med-Project USA's comments.
011-001	AdvaMed	Fielding Greaves	18972.1 (j)	Y	The definition of "provides or initiates distribution of sharps waste container" should be amended to change the number of business days from three to fifteen to promote cost-effectiveness. Long term sustainability of the program will require efforts to contain costs to avoid significant market responses that could impact access. Requiring express mail on every sharps container shipment could cause costs for the mail-back component of the program to rapidly escalate. Under a 15-day requirement, most containers will probably arrive far earlier than the 15th day but this will contain the costs of the program that will ultimately benefit patients and help to ensure the program's long-term success.	011-001. CalRecycle disagrees with the commenter's proposal. While the department acknowledges that program costs are an important consideration, a 15-day timeframe for container delivery places a significant burden on ultimate users, many of whom may self-inject multiple times a day and thus could amass an inconvenient and unsafe number of sharps before their container arrives. CalRecycle considers four business days as a reasonable timeframe that upholds convenience for the ultimate user without being overly burdensome on a program operator. Please see response to comment 015-002 for further discussion of this topic.
011-002a	AdvaMed	Fielding Greaves	18973.2 (e)	Y	Agency determinations should take into account late responses or non-responses from agencies. SB 212 was drafted with the understanding that state agencies may not respond in a timely manner that would allow the operator to meet other deadlines. In such a situation, the plan operator should be able to self-certify that they believe the plan is in compliance with all applicable laws. The regulation should be amended to include the following: "If any state agency failed to respond in a timely manner, the plan shall include a statement that the plan is self-certifying and list any agency that was solicited but failed to respond by the submission date."	011-002a. Public Resources Code section 42032(b)(4) states the following: "If, 90 days after submitting a plan to an applicable agency, a program operator has not received a response from the applicable agency, the program operator may submit a certification to the department that the stewardship plan is consistent with all other applicable laws and regulations." CalRecycle agrees that this provision should be incorporated into the regulations to clarify that a certification may be included in a proposed stewardship plan. However, in order to maintain consistency with statute, certification is only acceptable if the program operator has not received a response within 90 days, not within a "timely manner" as stated in the commenter's proposed edit. The following is the department's proposed change to sections 18973.2(e) and 18973.3(d) of the proposed regulatory text: <u>(e) State Agency Determinations and Compliance Certifications.</u> <u>(1) State agency determinations, pursuant to 42032.2(a)(1)(C) of the Public Resources Code. Determinations of compliance from the State Board of Pharmacy and any other state agency that reviewed the plan for compliance. If a determination of noncompliance was initially issued, the stewardship plan shall include both the initial determination of noncompliance and the superseding determination of compliance. If any state agency failed to respond to a request for review within 90 days of receipt of the stewardship plan, the program operator shall include documentation of this request along with a written certification, signed by an authorized representative of the program operator, that: 1) the stewardship plan is consistent with all laws and regulations relevant to that agency's authority; and 2) the applicable state agency failed to respond within 90 days of receipt of the stewardship plan.</u>

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						<u>(2) Written certification, by an authorized representative of the program operator, that: the stewardship plan, including the collection, transportation, and disposal of covered drugs, is in compliance with all applicable local, state, and federal laws and regulations, including, but not limited to United States Drug Enforcement Administration regulations.</u>
011-002b	AdvaMed	Fielding Greaves	18973.3 (d)	Y	Agency determinations should take into account late responses or non-responses from agencies. SB 212 was drafted with the understanding that state agencies may not respond in a timely manner that would allow the operator to meet other deadlines. In such a situation, the plan operator should be able to self-certify that they believe the plan is in compliance with all applicable laws. The regulation should be amended to include the following: "If any state agency failed to respond in a timely manner, the plan shall include a statement that the plan is self-certifying and list any agency that was solicited but failed to respond by the submission date."	<p>011-002b. Public Resources Code section 42032(b)(4) states the following: "If, 90 days after submitting a plan to an applicable agency, a program operator has not received a response from the applicable agency, the program operator may submit a certification to the department that the stewardship plan is consistent with all other applicable laws and regulations."</p> <p>CalRecycle agrees that this provision should be incorporated into the regulations to clarify that a certification may be included in a proposed stewardship plan. However, in order to maintain consistency with statute, certification is only acceptable if the program operator has not received a response within 90 days, not within a "timely manner" as stated in the commenter's proposed edit. CalRecycle has replaced the word "may" with "shall" in the proposed language to clarify that certification is necessary for CalRecycle to approve a proposed stewardship plan in the event that a program operator does not obtain a response from an applicable state agency.</p> <p>The following is the department's proposed change to section 18973.3(d) of the proposed regulatory text:</p> <p><u>(1) Agency determinations pursuant to 42032.2(d)(1)(B) of the Public Resources Code. Determinations of compliance from the State Board of Pharmacy and any other state agency that reviewed the plan for compliance. If a determination of noncompliance was initially issued, the stewardship plan shall include both the initial determination of noncompliance and the superseding determination of compliance. If any state agency failed to respond to a request for review within 90 days of receipt of the stewardship plan, the program operator shall include documentation of this request along with a written certification, signed by an authorized representative of the program operator, that: 1) the stewardship plan is consistent with all laws and regulations relevant to that agency's authority; and 2) the applicable agency failed to respond within 90 days of receipt of the stewardship plan.</u></p>
011-003	AvaMed	Fielding Greaves	18973.3 (f)(2)(A)	N	Manufacturers should determine the appropriate volume of containment appropriate. The statutory language currently provides an undefined metric for containers over a specified period of time. Manufacturers are in the best position to understand the volume of containment needed to accommodate a product used over a period of time, understanding that the volume must be sufficient to fully contain all product used appropriately over the period of time.	011-003. A change to the proposed regulatory text is not necessary. CalRecycle disagrees with the commenter's proposal. While the department acknowledges the potential issues with over-distribution of sharps containers, the existing language is sufficient to accommodate the needs of ultimate users without resulting in superfluous distribution. A program operator is free to work with manufacturers to determine the

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					The regulation should be amended to include the following after 18973.3(f)(2)(a) "...over a selected period of time as determined by the manufacturer or plan operator." This amendment will prevent inappropriate requests for containment that could lead to waste. The amendment also will prevent over containerization that would prevent excess containers from being deposited in recycling bins or filled with non-program materials. Excess containers increase the use of plastic and make it likely that municipal recycling facility workers will need to shut down lines and clear empty containers that a consumer attempts to recycle from lines as workers would be aware that these containers and their expected contents should not continue down the line with common recyclable materials. In the event of lost, damaged or otherwise non-usable containers, patients could make requests for additional containers.	most effective volume of container to distribute, and ultimate users are free to deny an offer for a free sharps container due to still having space in an existing one. However, a program operator should not deny requests for sharps containers or restrict point-of-sale offers on the grounds of previous distribution volume.
011-004	AdvaMed	Fielding Greaves	18972.1 (i)	N	Include "online sales" in definition of "point of sale" as "to the extent feasible" to recognize the reality of existing business models. In SB 212, the requirements to provide sharps containers to ultimate users was contemplated in lieu of an actual point of sale acquisition of a container at a brick and mortar point of sale. Sharps manufactures and program operators could not possibly have perfect information about every transaction over the Internet. Additionally, it may be difficult to cooperate with every online website that provides sharps and makes the inclusion of the online sales in the scope of "point of sale" practically impossible in all respects. The inclusion of online sales should be eliminated or limited "to the extent feasible." Alternatively, CalRecycle would need to identify the authority to compel a retailer to notify the purchaser of covered products about the program and how to contact a program operator.	011-004. A change to the proposed regulatory text is not necessary. Due to a reorganization of subsection 18972.1, subsection 18972.1(i) has been renumbered to 18972.1(a)(10) in the proposed regulatory text. The commenter's proposed change to the point of sale definition would allow for online sales to occur in some cases without the distribution of a sharps waste container. It is the responsibility of the covered entities for sharps to understand their distribution network and work with a program operator to provide or initiate distribution of sharps waste containers and mail-back materials at every point of sale, pursuant to Public Resources Code section 42032.2(d)(1)(F)(i). In accordance with the definition of "provides or initiates distribution of a sharps waste container" in section 18972.1(a)(11) of the proposed regulatory text, a program operator is free to propose innovative methods of distributing sharps waste containers and mail-back materials at the point of sale in its stewardship plan. Thus, adding "to the extent feasible" to the definition of "point of sale" is unnecessary. With regards to identifying the authority to compel a retailer to notify the ultimate user, statute does not compel a retailer to notify the ultimate user. However, retailers will likely often be notifying ultimate users about the program when, for example, distributing sharps waste containers or education and outreach materials, as applicable to a particular stewardship plan or situation. Moreover, a covered entity that sells sharps in California without the sharps being subject to an approved stewardship plan would be considered out of compliance.
011-005	AdvaMed	Fielding Greaves	General	N	Eliminate paraphrasing of the plain text of the statute in SB 212 where the substantive meaning is clear and unambiguous. In several instances throughout the draft regulation, the language diverges from the language of SB 212 via paraphrasing, either intentionally or unintentionally. The differences may seem subtle or more than subtle but in many cases the language or precise phrase was negotiated or drafted to effectuate a specific outcome. The resulting divergence can produce confusion and uncertainty.	011-005. A change to the proposed regulatory text is not necessary. One goal of the proposed regulations is to provide convenience to the regulated community; for example, listing all necessary components of a stewardship plan in the regulations minimizes confusion for a program operator that would otherwise have to constantly compare the statute with the regulations when developing its plan. Incorporating statutory requirements into the regulations involves adjusting phrasing in certain instances; however, the department strives to provide regulatory language that is clear and consistent with statute and has welcomed

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						public comments on any instances of perceived ambiguity. Since the commenter did not provide any specific instances of ambiguous paraphrasing, no changes to the proposed regulations are needed.
012-001	Stat-Medicament Disposal Corporation	Larry Kenemore	18973.2	N	There appears to be lacking any regulations as far as a Safe-Drug-Disposal program inclusion. This program was outlined and recommended in the ODNDPCP 2015 Report under Pillar #3.	012-001. A change to the proposed regulatory text is not necessary. The commenter has not defined or explained a Safe-Drug-Disposal program, so CalRecycle cannot comment on it specifically. Public Resources Code section 42032.2 includes provisions for "alternative forms of collection and disposal." Any proposed alternatives must comply with all applicable laws and regulations and will be evaluated for compliance with SB 212 during the department's stewardship plan review process.
012-002	Stat-Medicament Disposal Corporation	Larry Kenemore	18973.2 (d)(2)	N	18973.2(d)(2) Under current DEA Regulations it does not appear that a Stewardship Plan that operates ONLY a Safe-Drug-Disposal program would be classified as an authorized collector as that type of program does not collect Pharmaceuticals.	012-002. A change to the proposed regulatory text is not necessary. Comments on current DEA regulations should be directed to that agency. Moreover, the commenter has not defined or explained a Safe-Drug-Disposal program. The comment is unclear because a plan cannot operate as an authorized collector. If the commenter is requesting that the proposed regulations include a "Safe-Drug-Disposal program" under the definition of "authorized collector," CalRecycle notes that this term "authorized collector" is already defined in Public Resources Code section 42030(b). Thus, adding a "Safe-Drug-Disposal" program would be outside the scope and authority of these regulations. Separately, as stated in Public Resources Code section 42032.2(a)(1)(F), a stewardship plan for covered drugs is only considered complete if it provides for a handling, transport, and disposal system that complies with all statutory requirements, including secure collection receptacles placed at authorized collection sites.
012-003	Stat-Medicament Disposal Corporation	Larry Kenemore	18973.2 (g)(2)(A)	N	18973.2(g)(2)(A) Wording needs to included for Safe-Drug-Disposal and removes the words collection. And should include wording for a Safe-Drug-Disposal program to include all mailing addresses with a municipality and any public space that requests a Safe Drug Disposal Kiosk.	012-003. A change to the proposed regulatory text is not necessary. Public Resources Code section 42032.2 includes provisions for "alternative forms of collection and disposal." Any proposed alternatives will be evaluated for compliance with SB 212 and other applicable laws and regulations during the department's stewardship plan review process. Moreover, CalRecycle cannot specifically respond because the commenter has not defined Safe-Drug-Disposal or Safe-Drug-Disposal Kiosk, even though these are used as defined terms. The referenced section of the proposed regulations does not contain the word "collection," so the department disregards the proposed deletion.
012-004	Stat-Medicament Disposal Corporation	Larry Kenemore	18973.2 (g)(8)	N	18973.2(g)(8) Wording needs to include that a Safe-Drug-Disposal program provide a minimum of two (2) Safe-Drug-Disposal bottles per mailing address and that Kiosks include delivers of two (2) Safe-Drug-Disposal bottles.	012-004. A change to the proposed regulatory text is not necessary. Public Resources Code section 42032.2 includes provisions for "alternative forms of collection and disposal." Any proposed alternatives will be evaluated for compliance with SB 212 and other applicable laws and regulations during the department's stewardship plan review process. The commenter has not defined Safe-Drug-Disposal (which appears to be a defined term), and CalRecycle cannot make specific comments on

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						Safe-Drug-Disposal. CalRecycle does not endorse specific products and instead wishes to maintain flexibility for a program operator to design a stewardship plan that fulfills all statutory and regulatory requirements.
012-005a	Stat-Medicament Disposal Corporation	Larry Kenemore	18973.2	N	18972.2(g)(10) should include language that Safe-Drug-Disposal programs provide in-school training within each District within a Municipality either by in-person or webinar for Students.	012-005a. Section 18972.2(g)(10) does not exist in the proposed regulatory text and CalRecycle believes the comment is referring to section 18973.2(j). A change to the proposed regulatory text is not necessary. A program operator could choose to provide educational materials to schools as part of a comprehensive education and outreach program (see Public Resources Code section 42031.6(a) and sections 18973.2(j)(2) and 18973.3(i)(2) of the proposed regulations). Safe-Drug-Disposal appears to be a defined term which the commenter has not defined, so CalRecycle cannot comment on Safe-Drug-Disposal. For purposes of the rest of the response, CalRecycle will assume that Safe-Drug-Disposal is a specific product. CalRecycle does not endorse specific products and instead wishes to maintain flexibility for a program operator to design a stewardship plan that fulfills all statutory and regulatory requirements.
012-005b	Stat-Medicament Disposal Corporation	Larry Kenemore	18973.3	N	18972.2(g)(10) should include language that Safe-Drug-Disposal programs provide in-school training within each District within a Municipality either by in-person or webinar for Students.	012-005b. Section 18972.2(g)(10) does not exist in the proposed regulatory text and CalRecycle believes the comment is referring to section 18973.3(i). A change to the proposed regulatory text is not necessary. A program operator could choose to provide educational materials to schools as part of a comprehensive education and outreach program (see Public Resources Code section 42031.6(a) and sections 18973.2(j)(2) and 18973.3(i)(2) of the proposed regulations). Safe-Drug-Disposal appears to be a defined term which the commenter has not defined, so CalRecycle cannot comment on Safe-Drug-Disposal. For purposes of the rest of the response, CalRecycle will assume that Safe-Drug-Disposal is a specific product. CalRecycle does not endorse specific products and instead wishes to maintain flexibility for a program operator to design a stewardship plan that fulfills all statutory and regulatory requirements.
012-006a	Stat-Medicament Disposal Corporation	Larry Kenemore	18973.2 (j)	N	18973.2(j) and 18703.3(i) We think that market research is not necessary under a Safe-Drug-Disposal program. A Safe-Drug-Disposal program reaches every mailing address within a municipality and a properly defined Safe-Drug-Disposal program will provide “actual” stats as to the effectiveness of such a program that is inherent in this type of program.	012-006a. A change to the proposed regulatory text is not necessary. “Market research” is not a requirement listed in sections 18973.2(j) and 18973.3(i)(2) of the proposed regulations, but a program operator is free to propose market research as a part of its comprehensive education and outreach program. The department will evaluate any such proposals during the stewardship plan review process. The commenter has not defined Safe-Drug-Disposal program, which appears to be a defined term. CalRecycle cannot comment on a program which has not been defined.
012-006b	Stat-Medicament Disposal Corporation	Larry Kenemore	18973.3 (i)	N	18973.2(j) and 18703.3(i) We think that market research is not necessary under a Safe-Drug-Disposal program. A Safe-Drug-Disposal program reaches every mailing address within a municipality and a properly defined Safe-Drug-	012-006b. A change to the proposed regulatory text is not necessary. “Market research” is not a requirement listed in sections 18973.2(j) and 18973.3(i)(2) of the proposed regulations, but a program operator is free to propose market research as a part of its comprehensive education

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					Disposal program will provide “actual” stats as to the effectiveness of such a program that is inherent in this type of program.	and outreach program. The department will evaluate any such proposals during the stewardship plan review process. Moreover, the commenter has not defined Safe-Drug-Disposal program, which appears to be a defined term. CalRecycle cannot comment on a program which has not been defined.
012-007a	Stat-Medicament Disposal Corporation	Larry Kenemore	18973.2 (k)	N	18973.2(k) and 18973.3(j) It would be possible to combine a Safe-Drug-Disposal program with the standard Take-Back-Program and provide stats on both along with the education and outreach. Such as a municipality could use a Safe-Drug-Disposal for homes and Take-Back-Drop boxes for businesses or vice-versa and should be allowed through these regulations.	012-007a. A change to the proposed regulatory text is not necessary. Public Resources Code section 42032.2 includes provisions for “alternative forms of collection and disposal.” Any proposed alternatives must comply with all applicable laws and regulations and will be evaluated for compliance with SB 212 during the department’s stewardship plan review process. As stated in Public Resources Code section 42032.2(a)(1)(F), a stewardship plan for covered drugs is only considered complete if it provides for a handling, transport, and disposal system that complies with all statutory requirements, including secure collection receptacles placed at authorized collection sites. Making authorized collection sites optional or substituting them for another program” Is outside the scope and authority of these regulations. Moreover, the commenter has not defined or explained a Safe-Drug-Disposal program, so CalRecycle cannot comment on it specifically.
012-007b	Stat-Medicament Disposal Corporation	Larry Kenemore	18973.3 (j)	N	18973.2(k) and 18973.3(j) It would be possible to combine a Safe-Drug-Disposal program with the standard Take-Back-Program and provide stats on both along with the education and outreach. Such as a municipality could use a Safe-Drug-Disposal for homes and Take-Back-Drop boxes for businesses or vice-versa and should be allowed through these regulations.	012-007b. A change to the proposed regulatory text is not necessary. Public Resources Code section 42032.2 includes provisions for “alternative forms of collection and disposal.” Any proposed alternatives must comply with all applicable laws and regulations and will be evaluated for compliance with SB 212 during the department’s stewardship plan review process. As stated in Public Resources Code section 42032.2(d)(1)(D), a stewardship plan for home-generated sharps is only considered complete if it provides for a handling, transport, and disposal system that complies with all statutory requirements, including secure collection receptacles placed at authorized collection sites. The department does not have statutory authority to make authorized collection sites optional or substitute them for another program. Moreover, the commenter has not defined or explained a Safe-Drug-Disposal program, so CalRecycle cannot comment on it specifically.
012-008a	Stat-Medicament Disposal Corporation	Larry Kenemore	18973.4 (c)	N	18973.4 c and 18973.4(d) We recommend that reports from Drug-Take-Back programs provide the “actual weight” of the Pharmaceuticals “NOT” the containers-bottles-blister packages as has been the past practice. This has mis-lead the public in the past by 60-70%.	012-008a. A change to the proposed regulatory text is not necessary. CalRecycle disagrees with the commenter’s recommendation. While CalRecycle acknowledges the potential ambiguity issues with collection statistics, maintaining flexibility for a program operator to propose metrics that balance accurate reporting with the logistical challenges of data collection is a more effective solution. The following edits to section

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						18973.4(c)(4)(B) of the proposed regulatory text were made but not in response to the comment: (B) Weight of material collected <u>(B) Amount of covered drugs collected, as required in the stewardship plan pursuant to section 18973.2(g)(4)</u>
012-008b	Stat-Medicament Disposal Corporation	Larry Kenemore	18973.4 (c)(4)	N	18973.4 c and 18973.4(d) We recommend that reports from Drug-Take-Back programs provide the “actual weight” of the Pharmaceuticals “NOT” the containers-bottles-blister packages as has been the past practice. This has mis-lead the public in the past by 60-70%.	012-008b. A change to the proposed regulatory text is not necessary. CalRecycle disagrees with the commenter’s recommendation. While CalRecycle acknowledges the potential ambiguity issues with collection statistics, maintaining flexibility for a program operator to propose metrics that balance accurate reporting with the logistical challenges of data collection is a more effective solution. The following changes to section 18973.4(c)(4)(B) of the proposed regulatory text were made but not in response to the comment. (B) Weight of material collected <u>(B) Amount of covered drugs collected, as required in the stewardship plan pursuant to section 18973.2(g)(4)</u>
013-001	Inmar Intelligence	Domingo Isasi	General	N	I. General Comments An overall consideration is that program operations should key on well-established commercial channels and practice. An attempt to develop a reverse distribution process outside commercial norms could be unduly burdensome to stewardship programs and program operators, and introduces unnecessary complexity and costs.	013-001. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. General comment noted. It is the responsibility of a program operator to develop and implement a stewardship program and determine the methods that will be used to collect, transport, and dispose of covered products in accordance with all applicable laws and regulations.
013-002	Inmar Intelligence	Domingo Isasi	18973(e)	N	Similarly, to ensure the full engagement of all stakeholders, CalRecycle should affirm, through appropriate regulatory coverage, that confidential business information will be protected from disclosure outside the state government.	013-002. A change to the proposed regulatory text is not necessary. Public Resources Code section 42036.4 states proprietary information submitted to the department under this chapter shall be protected by all parties and shall be exempt from public disclosure under the California Public Records Act. The department and other parties may only disclose proprietary information in an aggregated form that does not directly or indirectly identify financial, production, or sales data of an individual covered entity or stewardship organization. This section in statute addresses concerns about “records, invoices, and other information made available when conducting audits, compliance reviews, or inspections. Please see response to comment 013-007C for an explanation regarding the process for protecting confidential business information from disclosure.
013-003	Inmar Intelligence	Domingo Isasi	18973.2 (k)	Y	The program includes a reasonable “good faith” efforts concept that should apply to negotiations with collectors, as well as among all parties engaged to	013-003. CalRecycle is responding to the comment assuming that “The program...” in the first sentence means “The proposed regulations...”.

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					<p>make the program function effectively. This would include “all covered entities, stewardship organizations, program operators, ...” as stated in Proposed Regulation (“PR”) 18972. The proposed regulations also require that in the event of “multiple stewardship programs,” program operators must work together to most effectively achieve the requirements of the statute and regulations. PR 18973.2(k). Through good faith efforts, many duplicative and potentially inefficient aspects of the program can be eliminated.</p>	<p>CalRecycle acknowledges the commenter’s support of applying “good faith efforts” to achieve efficient implementation of concurrent stewardship programs for covered drugs and/or home-generated sharps waste. However, the department proposes the following edits to section 18973.2(k) of the proposed regulatory text:</p> <p><u>(k) Coordination Efforts. Description of how the program operator will make a good faith effort to work with the other stewardship program(s) in order to most effectively achieve the requirements of statute and regulations, coordinate with other program operators to avoid conflict, duplication, and confusion to the public and all program participants in the event that multiple stewardship programs for covered drugs are in operation concurrently or new stewardship programs begin operating.</u></p> <p>The proposed edits above remove ambiguity as to how good faith efforts are achieved, clarify that coordination should occur with program operators and not stewardship programs, and clarify the purpose of the coordination efforts, which are for program operators to avoid conflict, duplication, and confusion to the public.</p> <p>Separately, Public Resources Code section 42032.2(b)(1) requires “good faith negotiations” between program operators and potential authorized collectors. CalRecycle declines extending specific “good faith” requirements to “all parties engaged to make the program function effectively” because dealings between parties should implicitly be conducted in “good faith”.</p>
013-004	Inmar Intelligence	Domingo Isasi	18972.1	N	<p>II. Comments</p> <p>1 Unless otherwise noted, emphasis is added. 1 Statutory citations are Cal. Pub. Resources Code Div. 30, Pt. 3, Ch. 2 (the “Act”).</p> <p>18972.1. DEFINITIONS. (a) Except as otherwise noted, the definitions of this Article supplement and are governed by the definitions set forth in Chapter 2, (commencing with section 42030) Part 3, Division 30 of the Public Resources Code. (b) “Administrative and operational costs”¹ means costs to implement and operate a stewardship program, including, but not limited to, collection, transportation, processing, disposal, and education and outreach costs, as well as administrative costs of operating the stewardship organization and administrative fees charged by the department.</p> <p><u>Comment:</u> In PR 18972.1, the terms “administrative and operational costs” (§§ 42032.2; 42034),² and “administrative fees” (§ 42034.2) should be defined and referred to separately. They are treated separately in SB 212.</p>	<p>013-004. CalRecycle agrees that the departmental administrative fees should be defined separately than the administrative and operational costs of implementing the stewardship program, and the department proposes the following edits to section 18972.1 of the proposed regulatory text:</p> <p><u>(1) “Administrative and operational costs” means costs to implement and operate a stewardship program, including, but not limited to, collection, transportation, processing, disposal, and education and outreach costs, as well as administrative costs of operating the stewardship organization, pursuant to section 42034 of the Public Resources Code, and administrative fees charged by the department.</u></p> <p><u>(2) “Departmental administrative fees” are fees required to be paid pursuant to section 42034.2 of the Public Resources Code.</u></p>

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013-005	Inmar Intelligence	Domingo Isasi	18972.1 (g)	N	<p>(g) “Minutes, books, and records” means accurate and up-to-date information regarding a program operator’s activities.</p> <p><u>Comment:</u> See General Comments, above. Audit and recordkeeping requirements should be consistent with commercial norms to allow program operators to comply with largely uniform standards nationwide.</p>	013-005. A change to the proposed regulatory text is not necessary. Public and private corporation financial reports are commonly required to be prepared according to U.S. Generally Accepted Accounting Principles (GAAP), which is the recognized set of standards for the preparation of general purpose financial statements in the United States and are, therefore, consistent with uniform standards nationwide. The requirements outlined in section 18973.6(g) of the proposed regulatory text provide an applicable financial framework of universally accepted standards that ensures the financial information provided to independent auditors is relevant, comparable with other organizations, and verifiable by a third party.
013-006	Inmar Intelligence	Domingo Isasi	18972.1 (k)	Y	<p>(k) “Significant change” to an approved stewardship plan includes, but is not limited to:</p> <p>(1) An addition or discontinuation of a collection method, whether a mail-back program, collection receptacle program, or an alternative method of collection.</p> <p>(2) Any changes to a stewardship program that are required by local, state, or federal laws and regulations.</p> <p>(3) Any changes to a stewardship program necessitated by the repeal of a local ordinance for either covered drugs or home-generated sharps waste.</p> <p>(4) Any changes regarding achievement of convenience standards.</p> <p>(5) Any changes in the facility(ies) to be used to process or dispose of a covered drug or home-generated sharps waste collected through the stewardship program not identified in the approved plan.</p> <p><u>Comment:</u> The “significant change” definition should include a limiting provision to avoid requiring reporting administrative or operational changes that do not have a material impact on program services. This would avoid creating an undue administrative burden on both the Department and program operators.</p>	<p>013-006. CalRecycle agrees that a “significant change” to a stewardship plan does not include reporting a change that does not have a material impact on program services. The proposed regulatory text section 18972.1 is revised as follows, noting that section 18972.1(k) has changed to 18972.1(a)(13) due to edits made elsewhere:</p> <p><u>(k13) “Significant change” means a change that is not consistent with an approved stewardship plan that has a material impact on a stewardship program includes, including, but is not limited to:</u></p> <p><u>(4A) An addition or discontinuation of a collection method, whether a mail-back program, collection receptacle program, or an alternative method of collection.</u></p> <p><u>(2B) Any changes to a stewardship program that are required by local, state, or federal laws and regulations.</u></p> <p><u>(3C) Any changes to a stewardship program necessitated by the repeal of a local ordinance for either covered drugs or home-generated sharps waste.</u></p> <p><u>(4D) Any changes regarding achievement of convenience standards.</u></p> <p><u>(5E) Any changes in the service providers or facility(ies) facility(ies) to be used to transport, handle, process or dispose of a covered drugs or home-generated sharps waste collected through the stewardship program not identified in the approved plan.</u></p> <p><u>(F) Any changes necessitated by a substantial change in program funding.</u></p>
013-007A	Inmar Intelligence	Domingo Isasi	18973	Y	<p>18973. DOCUMENT SUBMITTALS: STEWARDSHIP PLAN, INITIAL PROGRAM BUDGET, ANNUAL REPORT, AND ANNUAL BUDGET.</p>	013-007A. CalRecycle agrees with the commenter’s recommendation and the proposed regulatory text is revised as follows, noting that this requirement has been moved from the “document submittals” section to

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					<p>(a) <u>A corporate officer</u>, acting on behalf of the program operator, shall submit to the department contact information of the corporate officer responsible for submitting and overseeing <u>the document</u>, including, but not limited to:</p> <p style="text-align: center;">* * *</p> <p>(e) Any submittals to the department that the program operator believes are confidential in nature shall include a cover letter explaining the justification of confidentiality. Records supplied to the department pursuant to this Article that are, at the time of submission, claimed to be proprietary, confidential, or a trade secret shall be subject to the provisions in Title 14, California Code of Regulations, Division 7, Chapter 1, Article 4 (commencing with section 17041).</p> <p><u>Comment:</u> The language of Paragraph (a), above should be revised to provide that “[a] corporate officer, or a designee, acting on behalf of the program operator, shall submit” Program operators should have the flexibility to arrange for the submission of stewardship plans, budgets, or reports in an efficient manner consistent with their business practices.</p>	<p>sections corresponding with stewardship plans, annual reports, and program budgets:</p> <p>18973.2(a) A <u>Contact information of the corporate officer, or designee, acting on behalf of the program operator, shall submit to the department contact information of the corporate officer</u> responsible for submitting and overseeing the <u>document</u>, stewardship plan on behalf of the program operator, including, but not limited to:</p> <p style="margin-left: 40px;">(1) <u>Contact name and title</u></p> <p style="margin-left: 40px;">(2) <u>Name of program operator</u></p> <p style="margin-left: 40px;">(3) <u>Mailing and physical address(es)</u></p> <p style="margin-left: 40px;">(4) <u>Phone number</u></p> <p style="margin-left: 40px;">(5) <u>Email address</u></p> <p style="margin-left: 40px;">(6) <u>Internet website address</u></p> <p>The program operator will continue to be considered the responsible party regarding document content and compliance requirements.</p>
013-007B	Inmar Intelligence	Domingo Isasi	18973	N	<p>18973. DOCUMENT SUBMITTALS: STEWARDSHIP PLAN, INITIAL PROGRAM BUDGET, ANNUAL REPORT, AND ANNUAL BUDGET.</p> <p>(a) <u>A corporate officer</u>, acting on behalf of the program operator, shall submit to the department contact information of the corporate officer responsible for submitting and overseeing <u>the document</u>, including, but not limited to:</p> <p style="text-align: center;">* * *</p> <p>(e) Any submittals to the department that the program operator believes are confidential in nature shall include a cover letter explaining the justification of confidentiality. Records supplied to the department pursuant to this Article that are, at the time of submission, claimed to be proprietary, confidential, or a trade secret shall be subject to the provisions in Title 14, California Code of Regulations, Division 7, Chapter 1, Article 4 (commencing with section 17041).</p> <p>Paragraph (a) refers to the “document.” Will there be a template, matrix, or format available, including the format(s) consistent with local ordinances?</p>	013-007B. A change to the proposed regulatory text is not necessary. CalRecycle declines to specify a format for submittals that would limit a program operator’s flexibility in determining how the organization of the documents are structured.
013-007C	Inmar Intelligence	Domingo Isasi	18973	N	<p>18973. DOCUMENT SUBMITTALS: STEWARDSHIP PLAN, INITIAL PROGRAM BUDGET, ANNUAL REPORT, AND ANNUAL BUDGET.</p> <p>(a) <u>A corporate officer</u>, acting on behalf of the program operator, shall submit to the department contact information of the corporate officer responsible for submitting and overseeing <u>the document</u>, including, but not limited to:</p> <p style="text-align: center;">* * *</p>	013-007C. A change to the proposed regulatory text is not necessary. Typically, stewardship plans are public documents and are posted on the department’s website so that the public is aware of the programs that the department is approving. To the extent that a plan may have confidential information, those portions of the plan may be redacted from what is publicly made available, but they are potentially subject to a Public Records Act request. Consistent with Public Resources Code section 40062 and Title 14, Division 7, Chapter 1 of the California Code

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					<p>(e) Any submittals to the department that the program operator believes are confidential in nature shall include a cover letter explaining the justification of confidentiality. Records supplied to the department pursuant to this Article that are, at the time of submission, claimed to be proprietary, confidential, or a trade secret shall be subject to the provisions in Title 14, California Code of Regulations, Division 7, Chapter 1, Article 4 (commencing with section 17041).</p> <p>Paragraph (e) would require that any confidential submittals “shall include a cover letter explaining the justification of confidentiality.” The Act (§ 42036.4) does not contain an “explaining” and “justification” requirement, but rather emphasizes the importance of protecting proprietary information. This prohibition on release is more stringent than other statutory exemptions under the California Public Record Act. PR 18973(e), as proposed, would require a program operator to go beyond the requirements of the Act, and does not emphasize that confidential information should be protected. The legislature emphasized the critical importance of protecting this information in the stewardship bill itself, noting that the protection is necessary “to ensure that the competitive market in the state for the manufacture and sale of drugs and sharps is not compromised.” Stats 2018 ch 1004 Sec. 2. Consistent with practice under the federal Freedom of Information Act, submitters of confidential information should simply be required to mark the pages that contain proprietary information with a restrictive legend. At the time that the Department receives a public records act request seeking such information, the submitter should have advance notice of any potential disclosure, and at that time provide the additional detailed factual and legal justification for withholding information as appropriate under the Act. As currently drafted, PR 18973(e) is inconsistent with the statutory requirement.</p>	<p>of Regulations under Article 4, Public Records (Section 17041 et seq.), when a public records act request is made, there is a process for determining if the claimed confidential records are in fact confidential. This process involves notifying the entity claiming confidentiality for them to provide an explanation of the basis for that claim. The requirement in these regulations is designed to streamline that process and potentially allow a faster determination. If the initial explanation is sufficient, no further action would be needed from the covered entity to maintain confidentiality. If the initial explanation is not sufficient to verify the claim of confidentiality, CalRecycle would provide a program operator notice of a public records act request pursuant to Title 14, Division 7, Chapter 1 of the California Code of Regulations, Section 17046 in order to provide additional explanation. The information required to be submitted under this law is in no way automatically confidential without justification just because it is labelled as such.</p>
013-008A	Inmar Intelligence	Domingo Isasi	18973.1	Y	<p>18973.1. DOCUMENT APPROVALS: STEWARDSHIP PLAN, INITIAL PROGRAM BUDGET, ANNUAL REPORT, AND ANNUAL BUDGET.</p> <p>(a) A program operator submitting a stewardship plan, initial program budget, annual report, or annual budget shall provide to the department, upon request and by the requested deadline, clarifying information that is necessary to assist the department in its consideration of approval.</p> <p><u>Comments:</u> PR 18973.1 does not address § 42032(b)(4), which provides that “If, 90 days after submitting a plan to an applicable agency, a program operator has not received a response from the applicable agency, the program operator may submit a certification to the department that the stewardship plan is consistent with all other applicable laws and regulations.” The PR should recognize this and indicate that the certification allows for a reasonable belief a plan is consistent with the statutory and regulatory provisions.</p>	<p>013-008A. CalRecycle disagrees that section 18973.1 should contain language contained in section 42032(b)(4) of the Public Resources Code due to the way CalRecycle has decided to organize the regulatory text. CalRecycle has, however, included this language in sections 18973.2(e)(1) and 18973.3(d)(1). CalRecycle has replaced the word “may” with “shall” in the proposed language to clarify that certification is necessary for CalRecycle to approve a proposed stewardship plan in the event that a program operator does not obtain a response from an applicable state agency. Statute requires CalRecycle to approve stewardship plans and ensure compliance with all applicable laws and regulations (Public Resources Code sections 42032.2(a)(1)(E), 42032.2(d)(1)(D), and 42035.8). But, CalRecycle cannot make determinations of compliance regarding regulations that are outside of CalRecycle’s authority. Therefore, in order to implement the Statute and approve stewardship plans, CalRecycle must rely on either a supporting response from an applicable state agency or certification of compliance by the program operator. CalRecycle disagrees with the Commenter’s proposed language and proposes to use language that is consistent with statute. A “reasonable belief that a plan is consistent with the statutory</p>

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						<p>and regulatory provisions” differs from a certification that a plan <i>is</i> compliant with applicable laws and regulations.</p> <p>The following is the department’s proposed change to sections 18973.2(e) and 18973.3(d) of the proposed regulatory text:</p> <p><u>(e) State Agency Determinations and Compliance Certifications.</u></p> <p><u>(1) State agency determinations, pursuant to 42032.2(a)(1)(C) of the Public Resources Code. Determinations of compliance from the State Board of Pharmacy and any other state agency that reviewed the plan for compliance. If a determination of noncompliance was initially issued, the stewardship plan shall include both the initial determination of noncompliance and the superseding determination of compliance. If any state agency failed to respond to a request for review within 90 days of receipt of the stewardship plan, the program operator shall include documentation of this request along with a written certification, signed by an authorized representative of the program operator, that: 1) the stewardship plan is consistent with all laws and regulations relevant to that agency’s authority; and 2) the applicable state agency failed to respond within 90 days of receipt of the stewardship plan.</u></p> <p><u>(2) Written certification, by an authorized representative of the program operator, that: the stewardship plan, including the collection, transportation, and disposal of covered drugs, is in compliance with all applicable local, state, and federal laws and regulations, including, but not limited to United States Drug Enforcement Administration regulations.</u></p>
013-008B	Inmar Intelligence	Domingo Isasi	18973.1	N	<p>18973.1. DOCUMENT APPROVALS: STEWARDSHIP PLAN, INITIAL PROGRAM BUDGET, ANNUAL REPORT, AND ANNUAL BUDGET.</p> <p>(a) A program operator submitting a stewardship plan, initial program budget, annual report, or annual budget shall provide to the department, upon request and by the requested deadline, clarifying information that is necessary to assist the department in <u>its consideration of approval.</u> To the extent that other agencies are involved, the PR should confirm that CalRecycle will coordinate all such internal state or federal review and provide the final approval.</p>	<p>013-008B. A change to the proposed regulatory text is not necessary. CalRecycle declines to become an intermediate between a program operator and other applicable state agencies. As stated in Public Resources Code section 42032(b)(1), “Before submitting a stewardship plan to the department pursuant to this section, a program operator shall submit its proposed stewardship plan to the state board for review, and to any other applicable state agencies with areas of authority relative to the stewardship plan.” It is the responsibility of a program operator to coordinate the submittal of a stewardship plan with other state agencies for compliance determinations. If compliance is not met according to an agency’s determination, it is up to the program operator to amend the stewardship plan in order comply with local, state, and federal laws and regulations and submit an updated proposed stewardship plan to the applicable agency.</p>
013-009A	Inmar Intelligence	Domingo Isasi	18973.2 (k),	N	<p>18973.2. STEWARDSHIP PLAN FOR COVERED DRUGS.</p>	<p>013-009A. CalRecycle acknowledges the commenter’s support of the proposed regulatory text sections 18973.2(k), 18973.3(j), 18973.4(c)(2),</p>

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					<p>A stewardship plan for covered drugs shall comply with all applicable local, state, and federal laws and regulations, including, but not limited to, regulations adopted by the United States Drug Enforcement Administration. The stewardship plan shall include the following:</p> <p style="text-align: center;">* * *</p> <p>(k) Description of how the program operator will make <u>a good faith effort to work with the other stewardship program(s)</u> in order to most effectively achieve the requirements of the statute and regulations, in the event that multiple stewardship programs for covered drugs are in operation concurrently.</p> <p><u>Comment:</u> Pursuant to 18973.2(k) any program operator(s) should be allowed to exercise good faith efforts to collaborate on the above requirements to present the most cost-effective approach on a statewide basis.</p> <p>The overall program includes a reasonable “good faith” efforts concept (see, e.g.; PR 18973.2(k); PR 18973.3(j); PR 18973.4(c)(2), and (n); PR 18973.5(o)) that can apply to negotiations with collectors, as well as among all parties engaged to make the program function effectively. This would include “all covered entities, stewardship organizations, program operators,” PR 18972. These good faith efforts could easily eliminate, for example, duplicative collection sites. The proposed rule also requires that in the event of “multiple stewardship programs,” program operators must work together to most effectively achieve the requirements of the statute and regulations. PR 18973.2(k).</p> <p>Through good faith efforts, many duplicative and potentially inefficient aspects of the program can be eliminated. In fact, the more good faith cooperation to implement the program statewide, the more credibility and effectiveness it can achieve, both with covered entities, as well and the citizens it is designed serve. Thus, the current statute and PR correctly allow for manufacturers to utilize a cooperative approach to complying with convenience standards.</p> <p>Experience with other programs (e.g., federal small business contracting), indicates that “good faith” efforts is not readily definable, but the following are indicative of good faith attempts to maximize program goals: (1) whether a program operator has developed alternative utilization plan consistent with opportunities; (2) whether relevant plans, specifications, or terms and conditions for cooperation are available sufficiently in advance to enable potential cooperation among program operators and an informed response to requests for participation; (3) whether the terms and conditions of any cooperation agreements reasonably compare to the ordinary course of the commercial business standards; and (4) any other information that is relevant or appropriate to determining whether a program operator or stewardship organization has demonstrated a good faith effort to cooperate.</p>	<p>18973.4(n), and 18973.5(o). However, the department is proposing edits to these subsections of the proposed regulatory text, including removal of the phrase “good faith effort.” See response to comment 013-003 for further discussion on this topic.</p> <p>Separately, CalRecycle declines defining the concept of “good faith,” as doing so would limit the department’s flexibility to evaluate the wide variety of possible descriptions and implementations of “good faith” concepts that a program operator may submit in a stewardship plan or annual report.</p>
013-009B	Inmar Intelligence	Domingo Isasi	18973.2 (k)	N	18973.2. STEWARDSHIP PLAN FOR COVERED DRUGS.	013-009B. A change to the proposed regulatory text is not necessary. The convenience standards listed in Public Resources Code section

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					<p>A stewardship plan for covered drugs shall comply with all applicable local, state, and federal laws and regulations, including, but not limited to, regulations adopted by the United States Drug Enforcement Administration. The stewardship plan shall include the following: ** *</p> <p>(k) Description of how the program operator will make <u>a good faith effort to work with the other stewardship program(s)</u> in order to most effectively achieve the requirements of the statute and regulations, in the event that multiple stewardship programs for covered drugs are in operation concurrently. Accordingly, convenience standards could be met by any program operator(s) individually or collaboratively, or any stewardship organization(s).</p> <p>Conversely, in ensuring cooperation in meeting convenience standards, the Department should not permit new entrants to rely entirely on the network(s) established by other program operators without a commensurate financial contribution and otherwise demonstrating their ability to meet the CalRecycle program responsibility requirements (see discussion under PR 18973.6, infra).</p>	<p>42032.2(a)(1)(F) can be met by a program operator either individually or collaboratively. It is the responsibility of the program operators to negotiate the terms and conditions when collaborating. Should CalRecycle determine that a program operator is not implementing or complying with its approved stewardship plan, a determination of noncompliance could be made, resulting in an enforcement action.</p>
013-010A	Inmar Intelligence	Domingo Isasi	18973.6	N	<p>18973.6. PROGRAM BUDGETS</p> <p>The initial stewardship program budget that covers the first five calendar years of operation and annual program budgets shall contain <u>at a minimum, the following information:</u></p> <p>(a) <u>Anticipated costs to implement the stewardship program...</u>** *</p> <p><u>Comment:</u> There is an important and meaningful difference between the performance-based nature of the services provided by program operators, which is funded by the covered entities, and a cost-reimbursement program under which the Department would fund the cost of the drug take back functions. This difference should be clearly distinguished and bears on how PR 18973.6 and related audit requirements should be developed.</p> <p>Here, the covered entity bears the full risk of unexpected performance cost increases, and thereby exercises its best business judgment in meeting the performance standards (including, but not limited to, PR 18973.2(a) – (m)). By contrast, if the Department were reimbursing the cost of the program, the risk of cost growth would have an impact on state funds, and thus the level of auditing could justifiably be increased. Under the statutory structure of the California drug take back program, however, the risk is allocated to covered entities. The Department’s concern thus is not with the cost of the program, but rather in determining whether a covered entity/program operator is meeting the performance goals. A program operator’s technical and management proposal should address collection, transportation, processing, disposal, education, and other performance metrics,</p>	<p>013-010A. A change to the proposed regulatory text is not necessary. Section 18973.6 enables CalRecycle to review specific financial information relative to implementation and ongoing operation of the stewardship program to determine that the program is being funded in a “prudent and responsible manner” as stated in Public Resources Code section 42033.2(c)(2).</p> <p>A capabilities statement or similar document will not provide CalRecycle with sufficient detail to ensure that the program is being funded in a prudent and responsible manner.</p>

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					<p>but the underlying cost of the program is the risk and responsibility of the program operator.</p> <p>Approving an initial plan and subsequent annual reporting is a function of assessing the responsibility of the program operator evidenced by its technical and management plan. This is best determined based on such factors as a capabilities statement, including a discussion of corporate experience, size, locations, and a current financial statement.</p>	
013-010B	Inmar Intelligence	Domingo Isasi	18973.6	Y	<p>Total program aggregated costs can be projected and provided, such as: administrative costs, collection and disposal costs, and communication costs. These costs could be subject to audit verification at an aggregated level for purposes of independent financial audit pursuant to PR 18973.6(e), which would also be consistent with the aggregate approach of § 42036.4.</p> <p>For evaluation purposes, a program operator's proposal could include the aggregated totals for the following categories, for example, to capture program cost consistent with the Act (§§ 42033.2, 42033.4, and 42034.4):</p> <ul style="list-style-type: none"> •Administrative costs: contracted and employed personnel; direct and overhead costs; fees (legal, local and state business licensing); taxes; property and rental costs; general equipment and supplies. •Collection and disposal costs: collection, transportation, and disposal of drugs; purchase, maintenance, and replacement of collection receptacles; compensation of authorized collectors, if separate from personnel costs; and production, distribution, and postage of mailers. •Communication costs: advertising; marketing; web site creation and maintenance; and operation of a toll-free phone number. 	<p>013-010B. Based on stakeholder feedback, CalRecycle has modified the categories listed in section 18973.6(b). Due to insertion of a new subsection 18973.6(a), the subsection has been changed from 18973.6(a) to 18973.6(b).</p> <p>CalRecycle agrees that consolidation of collection, transportation, and disposal into one budget category is appropriate for a budget for this program. This category will also capture processing costs. CalRecycle has consolidated the budget categories in section 18973.6(b) of the proposed regulatory text.</p> <p>The revised separate line items in section 18973.6(b) are necessary for CalRecycle to determine adequate funding for the proposed activities of a stewardship program. CalRecycle retains the ability to request detailed costs data on each individual category.</p> <p>CalRecycle disagrees with the proposed recommended aggregated categories because they would not demonstrate the sufficient financial detail needed for CalRecycle to evaluate that the program is functioning in a financially prudent and responsible manner as required in Public Resources Code 42033.2(c)(2).</p> <p>Both the commenter's proposed categories and CalRecycle's proposed budget categories are consistent with section 42036.4 of Public Resources Code. That section of statute is directly referring to disclosure of proprietary information in an aggregated manner that disallows the identification of a covered entity or stewardship organization. The section refers to the manner by which CalRecycle can disclose proprietary information and does not limit the manner in which CalRecycle can collect the information.</p>
013-011A	Inmar Intelligence	Domingo Isasi	18974	N	<p>18974. RECORD KEEPING REQUIREMENTS</p> <p>Each party required to comply with Chapter 2 (commencing with section 42030, Part 3, Division 30 of the Public Resources Code) shall:</p> <p><u>(a) Maintain records to support the requirements in this Article. Covered entities, stewardship organizations, program operators, retail pharmacies and retail pharmacy chains must maintain records to support compliance</u></p>	<p>013-011A. A change to the proposed regulatory text is not necessary. CalRecycle declines to further limit the types of records to be retained beyond what is required in section 18974 of the proposed regulatory text. The purpose is to enable the department to execute its oversight responsibilities and ensure the accuracy and consistency of information when conducting audits, compliance reviews, and site inspections.</p>

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					<p>with the regulations. Retail pharmacies or retail pharmacy chains will maintain and provide access to records required by this Article for three years.</p> <p><i>Comment:</i> PR 18974 should be defined in terms of a program operator maintaining “reasonable commercial records” to support its meeting the performance standards of the program.</p>	
013-011B	Inmar Intelligence	Domingo Isasi	18974	N	<p>18974. RECORD KEEPING REQUIREMENTS</p> <p>Each party required to comply with Chapter 2 (commencing with section 42030, Part 3, Division 30 of the Public Resources Code) shall:</p> <p><u>(a) Maintain records to support the requirements in this Article. Covered entities, stewardship organizations, program operators, retail pharmacies and retail pharmacy chains must maintain records to support compliance with the regulations. Retail pharmacies or retail pharmacy chains will maintain and provide access to records required by this Article for three years.</u></p> <p>PR 18974 should also include a new subsection providing that “records, invoices, and other information made available under this provision shall be maintained as confidential and proprietary or otherwise exempt from disclosure outside the state government.”</p>	013-011B. A change to the proposed regulatory text is not necessary. To the extent that an annual report may contain proprietary or confidential information, those portions of the report may be redacted from what is publicly made available, but they are potentially subject to a Public Records Act request. Consistent with Public Resources Code section 40062 and Title 14, Division 7, Chapter 1 of the California Code of Regulations under Article 4, Public Records (Section 17041 et seq.), when a public records act request is made, there is a process for determining if the claimed confidential records are in fact confidential. This process involves notifying the entity claiming confidentiality for them to provide an explanation of the basis for that claim. The requirement in these regulations is designed to streamline that process and potentially allow a faster determination. If the initial explanation is sufficient, no further action would be needed from the covered entity to maintain confidentiality. If the initial explanation is not sufficient to verify the claim of confidentiality, CalRecycle would provide a program operator notice of a public records act request pursuant to Title 14, Division 7, Chapter 1 of the California Code of Regulations, Section 17046 in order to provide additional explanation. The information required to be submitted under this law is in no way automatically confidential without justification just because it is labelled as such.
014-001	Stericycle	Wade Scheel	18972.1 (k)	N	<p>Section: 18972.1(k)</p> <p>Stericycle agrees with this definition.</p>	014-001. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. CalRecycle notes the commenter’s statement.
014-002	Stericycle	Wade Scheel	18972.1	N	<p>Section: 18972.1</p> <p>Definition of Home-generated Sharps Waste.</p> <p>Recommend including the definition and limiting definition of home-generated sharps waste, as defined by section 117671 of the Health and Safety Code.</p>	014-002. A change to the proposed regulatory text is not necessary. The definition of “home-generated sharps waste” in Public Resources Code section 42030(l) provides sufficient clarity and does not need to be restated in the proposed regulatory text.
014-003	Stericycle	Wade Scheel	18973.2 (g)	N	<p>Section 18973.2(g) Collection, transportation, and disposal system</p> <p><i>(1) Describe the processes and policies that will be used to safely and securely collect, track, and properly manage unwanted covered drugs from collection to disposal, and how all entities participating will operate under and comply with all applicable state and federal laws and regulations.</i></p> <p>We would recommend that this be generic in nature but that there not be a requirement to fully detail out the plan for security.</p> <p>Allow this information on general policies and procedures to be marked confidential to prevent release to the general public with potentially nefarious intent. Full details of this type should not be publicly available.</p>	014-003. A change to the proposed regulatory text is not necessary. Typically, stewardship plans are public documents and are posted on the Department’s website so that the public is aware of the programs that the Department is approving. If certain security procedures for the handling, transportation and disposal system of covered drugs contain confidential information, those portions of the plan may be redacted from what is publicly made available, but they are potentially subject to a Public Records Act request. Consistent with Public Resources Code section 40062 and Title 14, Division 7, Chapter 1 of the California Code of Regulations under Article 4, Public Records (Section 17041 et seq.), when a public records act request is made, there is a process for determining if the claimed confidential records are in fact confidential.

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						This process involves notifying the entity claiming confidentiality for them to provide an explanation of the basis for that claim. The requirement in these regulations is designed to streamline that process and potentially allow a faster determination. If the initial explanation is sufficient, no further action would be needed from the covered entity to maintain confidentiality. If the initial explanation is not sufficient to verify the claim of confidentiality, CalRecycle would provide a program operator notice of a public records act request pursuant to Title 14, Division 7, Chapter 1 of the California Code of Regulations, Section 17046 in order to provide additional explanation. The information required to be submitted under this law is in no way automatically confidential without justification, just because it is labelled as such.
014-004	Stericycle	Wade Scheel	18973.2 (g)(6)	N	18973.2(g) Collection, transportation, and disposal system <i>(6) Any alternative form of collection and disposal system that complies with applicable local, state, and federal laws and regulations including, but not limited to, United States Drug Enforcement Administration regulations that is used as a supplemental service for any county that does not meet the minimum authorized collection site threshold due to circumstances out of the program operator's control, if applicable.</i> Recommend clarifying this section to refer to pharmaceutical Take Back Events.	014-004. Note that the subsection of the regulations the commenter is referring to changed to 18973.2(g)(7) in the proposed regulatory text. A change to the proposed regulatory text is not necessary. Public Resources Code section 42032.2(c) states that an alternative form of a collection and disposal system for covered drugs may be established as a supplemental service for a county that did not meet the minimum number of authorized collection sites due to circumstances beyond the program operator's control. The proposed regulatory text contains sufficient specificity without compromising flexibility for a program operator to propose innovative methods of alternative forms of collection and disposal systems in its stewardship plan, with take-back events being a possible option.
014-005	Stericycle	Wade Scheel	18973.2 (g)(8)	N	18973.2(g) Collection, transportation, and disposal system <i>(8) Process in which collection receptacles will be monitored, how service schedules are determined to ensure that collection receptacles do not reach capacity, and procedures to be followed if capacity is reached</i> The restrictions found under 21 CFR 1317.75(c) "Once a substance has been deposited into a collection receptacle, the substance shall not be counted, sorted, inventoried, or otherwise individually handled", make it very difficult to monitor the fill level of kiosks. Stericycle agrees with the proposed language, which allows for an overall explanation of the procedures used to schedule frequent services and manage kiosks that have reached capacity.	014-005. 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 agreement with this section, noting that the department has made the following edits for clarity and consistency with subsection (1)(G)(iii)(I) of subdivision (a) of section 42032.2 of the Public Resources Code: <u>(98) Description of a service schedule that meets the needs of each authorized collection site. Process by which collection receptacles will be monitored, explanation of how service schedules are determined to ensure that collection receptacles do not reach capacity, and procedures to be followed if capacity is reached. The service schedule must meet the needs of each authorized collection site to ensure that collected covered drugs are transported to final disposal in a timely manner.</u>
014-006	Stericycle	Wade Scheel	18973.3 (f)	N	18973.3(f)(8) Mail back programs defined in this section have been left open (meaning doesn't stipulate the use of United States Postal Service -USPS). Stericycle agrees with leaving the options open. However, if a system chose to use the USPS it is recommended that there is language in the regulation that is clear that it must meet all criteria for USPS.	014-006. A change to the proposed regulatory text is not necessary. Section 18973.3(d)(2) of the proposed regulatory text requires the program operator to certify that the stewardship plan for home-generated sharps waste is compliant with " all applicable local, state, and federal laws and regulations." A program operator wishing to utilize any shipping/vendor method (e.g. USPS) for transporting sharps containers would describe its efforts to comply with that shipping/vendor

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					<p>Recommend that the Department add language that if the mail back system is developed to be used and shipped under USPS that all requirements under USPS for mail back of sharps and medical waste must be met. The sharps system being used through the USPS must meet minimum criteria as outlined in the domestic mail manual and must have approved authorization for the package for shipment through USPS.</p> <p>If an alternative shipping vendor/method is selected, the stewardship program operator should be required to provide documentation that their shipping vendor approves the program and packaging.</p>	method's requirements as well as all applicable laws and regulations in its proposed stewardship plan.
014-007	Stericycle	Wade Scheel	18973.3 (f)(6)(A)	N	<p>18973.3 (f)(6)(A) <i>Supplemental collection method(s) for home-generated sharps waste that may be provided, in addition to, but not in lieu of, the mail-back program. These methods may include but are not limited to: (A) Secure receptacle collection. If a program operator proposes to implement a receptacle-based program to supplement its mail-back program and home-generated sharps consolidation points are authorized and approved by the city, county, or state enforcement authority that provides oversight of the Medical Waste Management Act, then the following information, as applicable, shall be included, but not limited to:</i></p> <p>Stericycle approves of the revised language regarding the requirements for secure collection receptacles to be authorized and approved by relevant regulatory agencies. However, the collection of sharps via receptacles presents substantial safety risks for the host collection sites, general public, kiosk service, vendors, disposal vendors, and host collection staff. Stericycle would recommend that language be added to specify the specific locations/settings where receptacles would be allowed and how the sharps receptacles will be located/marked/labeled to prevent cross-contamination with unwanted medication kiosks.</p>	014-007. A change to the proposed regulatory text is not necessary. A program operator is permitted to provide for safe and secure collection receptacles for home-generated sharps waste as part of an approved stewardship plan. Please note that section 18973.3(f)(6)(A) has been renumbered to section 18973.3(f)(5)(A) due to changes elsewhere in the text. Section 18973.3(f)(5)(A) of the proposed regulatory text requires the program operator to describe several elements of the supplemental program, such as processes and policies related to safety and security. The stewardship program as a whole must also comply with all applicable laws and regulations, such as the Medical Waste Management Act. Further specificity regarding the locations and labeling of secure collection receptacles is unnecessary and may compromise flexibility for a program operator to design and implement a supplemental program.
014-008	Stericycle	Wade Scheel	18973.4 (h)	Y	<p>Proposed Regulation Section: 18973.4, Page: 16, Comment or Suggested Changes: Describing the process and incidents that occurred related to safety or security failures could be a potential risk. This would require this information (corrective actions and updates to safety and security plans) to have to go through the confidential documentation process to prevent information on security practices from being available to the public to minimize risk of diversion, which is a more lengthy process. Recommendation would be to minimize the information that is required to be submitted with the annual report. This information should only be made available to the Agency upon request and in this way the program is in place but does not have to be submitted to the agency directly and have to be maintained under confidentiality constraints.</p>	014-008. While CalRecycle acknowledges the commenter's safety and security concerns surrounding certain annual reporting requirements, a program operator is free to assert confidentiality on any sensitive information submitted to the department. To the extent that an annual report may contain proprietary or confidential information, those portions of the report may be redacted from what is publicly made available, but they are potentially subject to a Public Records Act request. Consistent with Public Resources Code section 40062 and Title 14, Division 7, Chapter 1 of the California Code of Regulations under Article 4, Public Records (Section 17041 et seq.), when a public records act request is made, there is a process for determining if the claimed confidential records are in fact confidential. This process involves notifying the entity claiming confidentiality for them to provide an explanation of the basis for that claim. The requirement in these regulations is designed to streamline that process and potentially allow a faster determination. If the initial explanation is sufficient, no further action would be needed

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						<p>from the covered entity to maintain confidentiality. If the initial explanation is not sufficient to verify the claim of confidentiality, CalRecycle would provide a program operator notice of a public records act request pursuant to Title 14, Division 7, Chapter 1 of the California Code of Regulations, Section 17046 in order to provide additional explanation. The information required to be submitted under this law is in no way automatically confidential without justification, just because it is labelled as such.</p> <p>Public Resources Code sections 42033.2(b)(6) and (7) require the annual report to describe “whether policies and procedures ... were followed” and “whether any safety or security problems occurred.” The proposed regulatory text contains comparable requirements, and allow the specific details surrounding safety or security issues to be “made available to the department upon request.” However, the department proposes the following edits in order to further clarify this requirement:</p> <p>Proposed regulations sections 18973.4(h) and 18973.5(h): <u>(h) Safety and Security. Describe the general nature of any incidents with safety or security related to collection, transportation, or disposal of collected covered drugs. Explain what corrective actions were taken to address the issue and improve safety and security. The following information about any incident(s) shall be made available to the department upon request, and shall include, but not be limited to, the following:</u></p> <ul style="list-style-type: none"> <u>(1) Location and date</u> <u>(2) Description of specific incident</u> <u>(3) Cause(s) of specific incident</u> <u>(4) Parties involved</u> <u>(5) Regulatory or law enforcement agencies involved and any litigation, arbitration, or other legal proceedings that result from each incident</u>
014-009	Stericycle	Wade Scheel	18973.4 (h)	Y	Proposed Regulation Section: 18973.4, Page: 17, Comment or Suggested Changes: the language of this section should be clarified to require the stewardship program operator identify and track the number of incidents and legal issues under their scope. The Authorized Collectors may be involved in incidents of which the stewardship program operator are unaware of, or are outside the scope of responsibility of the program operator. There may also be circumstances where the authorized collector will not provide information to the program operator due to legal issues, liability or other corporate reasons. The program operator may not have any control or visibility to a host collector issue. Recommendation would be to have the authorized collection sites track and	014-009. Public Resources Code section 42033.2(b)(7) requires a program operator to report “whether any safety or security problems occurred during collection, transportation, or disposal of collected covered products during the reporting period and, if so, what changes have been or will be made to policies, procedures, or tracking mechanisms to alleviate the problem and to improve safety and security.” If a safety or security problem occurs, conveying certain information about the problem is essential to understanding whether proposed changes to policies, procedures, or tracking mechanisms will be sufficient to alleviate the problem in the future.

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					maintain information on only the issues they are having with regulatory or other law enforcement.	<p>The information required upon request in sections (1)-(5) of 18973.4(h) and 18973.5(h) of the proposed regulations are perfectly reasonable for a program operator to collect for safety or security issues directly related to its operations. It is up to the program operator to ensure that its authorized collectors will provide it with sufficient information to comply with the statutory requirement.</p> <p>However, the department proposes the following edit to further clarify which information is required to be included in the annual report and which is made available to the department upon request:</p> <p>Proposed regulations sections 18973.4(h) and 18973.5(h): <u>(h) Safety and Security. Describe the general nature of any incidents with safety or security related to collection, transportation, or disposal of collected covered drugs. Explain what corrective actions were taken to address the issue and improve safety and security. The following information about any incident(s) shall be made available to the department upon request, and shall include, but not be limited to, the following:</u></p> <p><u>(1) Location and date</u></p> <p><u>(2) Description of specific incident</u></p> <p><u>(3) Cause(s) of specific incident</u></p> <p><u>(4) Parties involved</u></p> <p><u>(5) Regulatory or law enforcement agencies involved and any litigation, arbitration, or other legal proceedings that result from each incident</u></p>
014-010	Stericycle	Wade Scheel	18973.5 (h)	Y	<p>Proposed Regulation Section: 18973.5, Page: 19, Comment or Suggested Changes: Describing the process and incidents that occurred related to safety or security failures could be a potential risk. This would require this information (corrective actions and updates to safety and security plans) to have to go through the confidential documentation process to prevent information on security practices from being available to the public to minimize risk of diversion, which is a more lengthy process. Recommendation would be to minimize the information that is required to be submitted with the annual report. This information should only be made available to the Agency upon request and in this way the program is in place, but does not have to be submitted to the agency directly and have to be maintained under confidentiality constraints.</p>	<p>014-010. While CalRecycle acknowledges the commenter's safety and security concerns surrounding certain annual reporting requirements, a program operator is free to assert confidentiality on any sensitive information submitted to the department. To the extent that an annual report may contain proprietary or confidential information, those portions of the report may be redacted from what is publicly made available, but they are potentially subject to a Public Records Act request. Consistent with Public Resources Code section 40062 and Title 14, Division 7, Chapter 1 of the California Code of Regulations under Article 4, Public Records (Section 17041 et seq.), when a public records act request is made, there is a process for determining if the claimed confidential records are in fact confidential. This process involves notifying the entity claiming confidentiality for them to provide an explanation of the basis for that claim. The requirement in these regulations is designed to</p>

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						<p>streamline that process and potentially allow a faster determination. If the initial explanation is sufficient, no further action would be needed from the covered entity to maintain confidentiality. If the initial explanation is not sufficient to verify the claim of confidentiality, CalRecycle would provide a program operator notice of a public records act request pursuant to Title 14, Division 7, Chapter 1 of the California Code of Regulations, Section 17046 in order to provide additional explanation. The information required to be submitted under this law is in no way automatically confidential without justification, just because it is labelled as such.</p> <p>Public Resources Code sections 42033.2(b)(6) and (7) require the annual report to describe “whether policies and procedures ... were followed” and “whether any safety or security problems occurred.” The proposed regulatory text contains comparable requirements, and allows for the specific details surrounding safety or security issues to be “made available to the department upon request.” However, the department proposes the following edit in order to further clarify this requirement:</p> <p>Proposed regulations section 18973.5(h): <u>(h) Safety and Security. Describe the general nature of any incidents with safety or security related to collection, transportation, or disposal of collected covered drugs. Explain what corrective actions were taken to address the issue and improve safety and security. The following information about any incident(s) shall be made available to the department upon request, and shall include, but not be limited to, the following:</u></p> <p><u>(1) Location and date</u></p> <p><u>(2) Description of specific incident</u></p> <p><u>(3) Cause(s) of specific incident</u></p> <p><u>(4) Parties involved</u></p> <p><u>(5) Regulatory or law enforcement agencies involved and any litigation, arbitration, or other legal proceedings that result from each incident</u></p>
014-011	Stericycle	Wade Scheel	18973.6 (a)	Y	<p>Proposed Regulation Section: 18973.6, Page: 21, Comment or Suggested Changes: Recommend three groupings/categories for budgetary reporting purposes: 1) Collection/Transportation/Disposal 2) Administration 3) Outreach and Education; Program budgets for covered drugs and sharps can be separate, although consolidating collection/transportation/disposal costs is necessary because these are often combined or intermixed from service vendors and may be difficult to extract separately.</p>	<p>014-011. CalRecycle has considered the commenter’s recommendation and has modified the categories listed in section 18973.6(b). Due to insertion of a new subsection 18973.6(a), the subsection has been changed from 18973.6(a) to 18973.6(b).</p> <p>CalRecycle agrees that consolidation of collection, transportation, and disposal into one budget category is appropriate for a budget for this program. This category will also capture processing costs. CalRecycle</p>

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						<p>has consolidated the budget categories in section 18973.6(b) of the proposed regulatory text.</p> <p>CalRecycle disagrees with the proposed recommended categories because they would not demonstrate the sufficient financial detail needed for CalRecycle to evaluate that the program is functioning in a financially prudent and responsible manner as required in section 42033.2(c)(2). It is also necessary for covered drug and home-generated sharps program budgets to be separated as the programs have different individual components and different minimum convenience standards.</p> <p>The commenter's categories do not include information related to funding for incentives such as grants, loans, and sponsorships, should they be part of program implementation. Capital costs are also missing from the proposed categories. These categories of information are needed for CalRecycle to evaluate initial program start-up costs and review year-to-year expenditure trends related to infrastructure and heavy-duty equipment.</p>
015-001	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18972.1 (i)	N	<p>A. Proposed Regulations § 18972.1(i)'s Definition of "Point of Sale" Should Only Include Online Sales As Practicable</p> <p>SB 212 provides that a "Home-Generated Sharps Waste" (as defined in California Public Resources Code ("PRC") § 42030(1)) "Stewardship Program" (as defined in PRC § 42030(y)) shall "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§ 4032.2(d)(1)(F)(i); see also Proposed Regulations§ 18973.3(f)(2) (Home-Generated Sharps Waste "Stewardship Plans" (as defined in PRC § 42030(x)) must, among other things, describe "[h]ow stewardship plan implementation provides or initiates distribution of sharps waste containers and mail-back materials ... at no cost to ultimate users at the point of sale ... "). The Department's Proposed Regulations broadly define "point of sale," as used in the above referenced provisions, to mean "the ultimate user checkout system utilized by pharmacies, stores, or other retail outlets where a covered product is sold, including online sales." Proposed Regulations § 18972.1(i). It is critical to note that "Program Operators" (as defined in PRC § 42030(q)) are not a party to the sharps transactions that are the subject of the above provisions. Additionally, MED-Project is not aware of any type of list (public or private) that identifies all retailers (including online retailers) that sell sharps to "Ultimate Users" (as defined in PRC § 42030(z)). Therefore, it is impossible for a Program Operator to be aware of every sharps transaction involving an Ultimate User that is occurring over the internet, regardless of the online retailer's physical location (China, India, etc.) and it is therefore also impossible for a Program Operator to initiate the distribution of a sharps waste container and mail-back materials at the point of sale for any and all online transactions. Reasonable limitations must be set in the Proposed</p>	<p>015-001. A change to the proposed regulatory text is not necessary. The commenter's two proposed changes to the point of sale definition would both allow for online sales to occur in some cases without the distribution of a sharps waste container. While CalRecycle acknowledges the difficulties of tracking online sharps sales, it is the responsibility of the covered entities for sharps that are sold online to understand their distribution network and work with a program operator to distribute sharps containers at every point of sale. Furthermore, this program emphasizes ultimate user convenience and should not rely on retailers or ultimate users to identify points of sale to program operators.</p>

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					<p>Regulations to make implementation of a Home-Generated Sharps Waste Stewardship Program practicable. To this end, the definition of "Point of Sale" in the Proposed Regulations at § 18972.1(i) should be revised as follows: "Point of sale' means the ultimate user checkout system utilized by pharmacies, stores, or other retail outlets where a covered product is sold, and shall also including online sales to the extent practicable." Alternatively, to ensure that the implementation of a Home-Generated Sharps Waste Stewardship Program is practicable as applied to online sales, the definition of "Point of Sale" should only include online sales that retailers or Ultimate Users identify to Program Operators. This revision would give Program Operators a means to identify and service online sales subject to the Stewardship Program. Accordingly, Proposed Regulations § 18972.1(i) should be revised to read: "Point of sale' means the ultimate user checkout system utilized by pharmacies, stores, or other retail outlets where a covered product is sold, including online sales that pharmacies, stores, and other retail outlets and/or ultimate users identify to program operators."</p>	
015-002	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18972.1 (j)(2)	Y	<p>B. Proposed Regulations§ 18972.1(j)(2) Should Recognize Fluctuations in Mail Delivery Timelines in Defining "Provides or Initiates Distribution of a Sharps Waste Container"</p> <p>By defining "provides or initiates distribution of a sharps waste container" to include arranging to send Ultimate Users sharps containers and mail-back materials, Proposed Regulations § 18972.1(j)(2) provides Program Operators needed flexibility to implement Home-Generated Sharps Waste Stewardship Programs in compliance with all applicable laws, regulations, and other legal requirements on the scale that SB 212 requires. The requirement that such sharps waste containers and mail-back materials "arrive within three business days," however, undermines this well-intentioned approach and should be revised. Common carriers do not always meet estimated delivery dates. The United States Postal Service estimates that Priority Mail will arrive within 1-3 days, but provides no guarantee. See United States Postal Service, https://faq.usps.com/s/article/What-are-the-Guidelines-for-MailingPriority-Mail (last visited Feb. 13, 2020). With the United States Postal Service unable to confirm arrival dates, Program Operators cannot do so. Even if arrival dates were guaranteed, requiring delivery within three business days is unreasonable. The Proposed Regulations could be understood as counting the three business day arrival requirement from the sharps sale date. By contrast, USPS calculates Priority Mail delivery timelines from the day after an item is mailed-at a minimum, one day later than the sale date. See <i>id</i> Because these timelines are offset, even if USPS meets its estimated 1-3 day delivery timeline, delivery may arrive four days after a sharps sale. For these reasons, Program Operators arranging to send Ultimate Users sharps containers and mail-back packages risk exceeding the Proposed Regulations' three business day arrival requirement through no fault of their own. This risk will discourage Program Operators from using the most effective measures to serve Ultimate Users, contrary to the Department's intent in adopting Proposed Regulations §18972.1(j)(2). See CalRecycle Initial Statement of Reasons for</p>	<p>015-002. CalRecycle acknowledges the difficulties of guaranteeing that a sharps container be delivered to an ultimate user and arrive within three business days, and proposes extending this deadline in the proposed regulations to four business days to accommodate delays in delivery times. Four business days is a reasonable timeframe that still upholds convenience for the ultimate user without being overly burdensome on a program operator.</p> <p>Due to a reorganization of subsection 18972., subsection 18972.1(j) has been changed to 18972.1(a)(11) in the proposed regulatory text. CalRecycle proposes the following edits to section 18972.1(a)(11)(B) of the proposed regulatory text:</p> <p style="text-align: center;"><u>(B2) To arrange, at the point of sale or prior, for a sharps waste container and mail-back materials to be sent to the ultimate user and arrive within fourthree business days at no cost or inconvenience to the ultimate user; or,</u></p> <p>In addition to the change from three business days to four, CalRecycle also notes the addition of "or prior" to the point of sale requirement, which gives a program operator additional flexibility in stewardship program design. CalRecycle declines the commenter's suggestion to change the word "arrive" to the phrase "shipped to arrive" because the meaning of this phrase is adequately encompassed by the phrase "sent to the ultimate user," and thus incorporating it is unnecessary and would only add confusion.</p>

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					Pharmaceutical and Sharps Waste Stewardship Program at 9 (Dec. 2019) ("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."). To preserve Program Operator flexibility to serve Ultimate Users effectively, the Department should require that Program Operators ship sharps waste containers and mail-back materials to arrive within five business days. This revision would mandate that Program Operators design processes to provide sharps waste containers and mail-back materials promptly, but avoid attaching compliance consequences to common carrier reliability. The revised Proposed Regulations § 18972.1(j)(2) should require Program Operators: "[t]o arrange, at the point of sale, for a sharps waste container and mail-back materials to be sent to the ultimate user and <u>shipped to</u> arrive within three five business days at no cost or inconvenience to the ultimate user."	
015-003	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973(b)	N	<p>Proposed Regulations § 18973(b) Should Require that a Stewardship Plan, Annual Reports, and Stewardship Program Budget Submissions Comply with All Applicable Legal Requirements for Private Entities Related to Accessibility</p> <p>To ensure that a Stewardship Plan, annual reports, and Stewardship Program budgets are accessible, the Proposed Regulations provide that "[d]ocuments are required to be in compliance with sections 7405 of the Government Code, and the Web Content Accessibility Guidelines 2.0, or a subsequent version, published by the Web Accessibility Initiative of the World Wide Web Consortium at a minimum Level AA success criteria to allow for posting on the department's website." Proposed Regulations § 18973(b). Although more definitive than prior iterations of the Proposed Regulations, this language raises due process concerns by tying compliance to third party standards. To ensure public notice of accessibility requirements, the Proposed Regulations should require that Stewardship Program Operators comply with all applicable legal requirements for private entities related to accessibility, such as the Americans with Disabilities Act. Fundamentally, the public must have notice of regulatory requirements. Dynamically incorporating the Web Content Accessibility Guidelines 2.0 ("WCAG 2.0") and subsequent versions into the Proposed Regulations could deprive the public, and specifically Program Operators, of this notice. Under the Proposed Regulations, it is possible that Program Operators may not have public notice of proposed or adopted changes to WCAG 2.0 -changes the Proposed Regulations would make binding legal requirements. This outcome would raise due process and other legal concerns. The Department should strike references to WCAG 2.0 and subsequent versions in the Proposed Regulations to avoid these issues. As previously noted in MED-Project comments, the Proposed Regulations should instead require that Program Operators comply with all applicable legal requirements for private entities related to accessibility, such as the Americans with Disabilities Act. See MED-Project LLC Comments</p>	015-003. A change to the proposed regulatory text is not necessary. For purposes of this response, CalRecycle will assume that the commenter's concern is that the Web Content Accessibility Guidelines 2.0 may change, and the public will not have notice of these changes. Public Resources Code section 42032(i) states that "the department shall make all stewardship plans submitted pursuant to this section available to the public, except proprietary information in the plans protected pursuant to Section 42036.4." CalRecycle intends to make stewardship plans, annual reports, and program budgets public by posting these documents on the department's website, in order to provide transparency regarding the implementation of stewardship programs. However, in order to make these documents available online, the department must adhere to legally mandated accessibility standards which apply to state government entities. Thus, the proposed regulations require that documents, as defined in Section 18973, submitted to the department also adhere to this standard. If this standard were to change in the future, CalRecycle would revise the regulations and provide proper notice in accordance with the Administrative Procedures Act.

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					Regarding CalRecycle's Informal Draft Regulatory Text Implementing California SB 212, July 1, 2019 at p. 9.	
015-004	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.1 (a)	N	<p>Requests for Clarifying Information Under Proposed Regulations § 18973.1(a) Should Be Reasonable In Scope and Timeline</p> <p>The Proposed Regulations would give the Department authority to require, "upon request and by the requested deadline, clarifying information that is necessary to assist the department in its consideration of approval." Proposed Regulations § 18973.1(a). MED-Project previously commented that the Department should add a reasonableness element to this provision. See MED-Project LLC Comments Regarding CalRecycle's Informal Draft Regulatory Text Implementing California SB 212, July 1, 2019 at p.17. The Department should revise the Proposed Regulations to apply a reasonableness element to both the scope of clarifying information requests and the required response timeline. As revised, Proposed Regulations § 18973.1(a) should read: "A program operator submitting a stewardship plan, initial program budget, annual report, or annual budget shall provide to the department, upon <u>reasonable</u> request and by the requested <u>a reasonable deadline</u>, clarifying information that is necessary to assist the department in its consideration of approval."</p>	<p>015-004. A change to the proposed regulatory text is not necessary. Section 18973.1(a) of the proposed regulations already limits the department's requests to information that is "necessary to assist the department in its consideration of completeness and/or approval," and thus adding a qualifier of "reasonableness" to the requests is unnecessary.</p> <p>Additionally, adding a "reasonableness" qualifier to the requested deadline for additional information is unnecessary. It is not possible to set an objective standard for the additional information that would be appropriate to apply to all circumstances. Thus, this deadline will be tailored to the specific information requested, with the understanding that the department must conclude its review for completeness within 30 days and its review for approval within 90 days. If the department does not have the information it needs to make these determinations, then the document in question would be deemed incomplete or disapproved.</p> <p>Separately, CalRecycle proposes the following edits to section 18973.1(a) for clarity:</p> <p><u>(a) A program operator submitting a stewardship plan, initial program budget, annual report, or annual budget shall provide to the department, upon request and by the requested deadline, clarifying information that is necessary to assist the department in its consideration of completeness and/or approval.</u></p>
015-005	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.1 (b)	Y	<p>Proposed Regulations § 18973.1(b) Should Clarify When Stewardship Plans, Annual Reports, and Stewardship Program Budgets Are "Complete"</p> <p>Under SB 212, the Department has authority to determine whether, under certain criteria, a Stewardship Plan, annual report, or Stewardship Program budget is "complete." See PRC § 42032(c) (Stewardship Plans); PRC § 42033.2(d) (annual reports and Stewardship Program budgets). SB 212 establishes that Stewardship Plans are "complete" when they "meet[] the requirements of Section 42032.2 for the establishment and implementation of a stewardship program" See PRC § 42032(a)(1); see also PRC § 42032.2(a)(1) ("To be complete, a stewardship plan for covered drugs shall do all of the following"); PRC § 42032.2(d)(1) ("To be complete, a stewardship plan for home-generated sharps waste shall do all of the following"). While SB 212 does not specify when annual reports and Stewardship Program budgets are "complete," the structure of SB 212 makes that clear. See PRC § 42033.2 (addressing both Department reviews to determine whether annual reports and Stewardship Program budgets are "complete" and the requirements for annual reports and Stewardship Program budgets).</p>	<p>015-005. CalRecycle agrees that a change to the proposed regulatory text is necessary to clarify the criteria the department will use to determine whether a stewardship plan, annual report, or program budget is "complete." However, the department prefers the following edit to section 18973.1(b):</p> <p><u>(b) Within 30 days of the department's receipt of a document, the department shall determine if a document is complete or incomplete and notify the submitting program operator within 30 days of receipt. The department shall consider a document to be complete if: 1) it contains provisions intended to meet each requirement in sections 18973, 18973.1, 18973.2, 18973.3, 18973.4, 18973.5, 18973.6, 18974, 18974.1, 18974.2, and 18974.3 of this Article, as applicable to each document; and 2) it contains sufficient detail for the department to determine if the requirements listed in subpart 1) have been met.</u></p> <p>The proposed change above provides a more specific and comprehensive list of criteria than the commenter's proposed edit, and</p>

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					<p>Consistent with SB 212, the Proposed Regulations should clarify when a Stewardship Plan, annual reports, and Stewardship Program budgets are complete. As drafted, the Proposed Regulations give the Department authority to determine whether a Stewardship Plan, annual reports, or Stewardship Program budgets are complete without referencing SB 212, defining the term "complete," or discussing Department completeness reviews in the context of substantive Stewardship Plan, annual report, or Stewardship Program budget requirements. See Proposed Regulations § 18973.1(b). This approach creates ambiguity in the Proposed Regulations regarding the baseline for Department determinations of whether a Stewardship Plan, annual reports, or Stewardship Program budgets are "complete."</p> <p>As SB 212 contains no such ambiguity, the Department should amend the Proposed Regulations to eliminate it with simple change. The Department should revise Proposed Regulations §18973.1 (b) to read: "The department shall determine if a document <u>stewardship plan, annual report, or program budget</u> is complete pursuant to PRC § 42032.2 or 42033.2 and notify the submitting program operator within 30 days of receipt."</p> <p>Clarifying when Stewardship Plans, annual reports, and Stewardship Program budgets are complete will provide Program Operators certainty, increasing the likelihood that submitted Stewardship Plans, annual reports, and Stewardship Program budgets meet SB 212 requirements.</p>	clarifies that the department will not consider a document to be "complete" unless it contains enough detail for the department to be able to make its subsequent determination of approval, conditional approval, or disapproval.
015-006	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.1 (c)	Y	<p>Proposed Regulations § 18973.1(c) Should Clarify that Department Consultations with Other Agencies Toll Completeness Review Timelines</p> <p>Proposed Regulations §18973.1(c) provides that if the Department "consult[s] with or submit[s] a stewardship plan to the State Board of Pharmacy or other agencies for review of completeness or approval, the duration of time this takes the department shall not count toward the 90-day review." Proposed Regulations § 18973.1(c). SB 212 requires the Department to conclude "completeness" reviews on a 30-day timeline, however; not a 90-day timeline. See PRC § 42032(c)(1); see also Proposed Regulations § 18973.1(b). If the Department intends for consultations with the State Board of Pharmacy or other agencies to toll the Department's 30 day completeness review timeline, it should revise Proposed Regulations § 18973.1(c) to read: "the duration of time this takes the department shall not count toward the <u>30-day review or 90-day review, respectively.</u>"</p>	<p>015-006. CalRecycle concurs with the commenter's interpretation of statute, but the department prefers the following edit to the proposed regulatory text for clarity:</p> <p><u>(c) Should it be necessary for the department to consult with or submit a stewardship plan to the State Board of Pharmacy or other agencies for review of completeness or approval, the duration of time this takes the department shall not count toward the 30-day review to determine completeness or 90-day review to determine approval, conditional approval, or disapproval.</u></p>
015-007a	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.2 (d)(1)(A)	N	<p>The Department Should Promote Stewardship Program Safety and Security by Revising Proposed Regulations § 18973.2(d)(1)(A) to Keep Authorized Collector Contact Information Confidential</p> <p>Stewardship Programs prioritize safety and security. Because Covered Drug Stewardship Plans provide for the collection and disposal of a wide range of Covered Drugs including controlled substances, it is an unfortunate reality that certain Stewardship Plan information is valuable to individuals attempting to divert controlled substances. Working together, the Department and Program Operators must avoid public disclosure of information that could compromise Stewardship Program safety and security. One such category of information is</p>	015-007a. A change to the proposed regulatory text is not necessary. Public Resources Code section 42032.2(a)(1)(B) states that a stewardship plan for covered drugs must include "contact information for the authorized collectors for the stewardship program." The proposed regulations clarify that this contact information includes a contact name and title; according to CalRecycle's Initial Statement of Reasons, this information is "necessary to allow efficient correspondence, inspections, and audits as necessary."

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					<p>"Authorized Collector" (as defined in PRC § 42030(b)) contact names and titles. The Proposed Regulations require Covered Drug Stewardship Plans to include "[c]ontact name[s] and title[s]" for Authorized Collectors. Proposed Regulations § 18973.2(d)(1)(A). Publicizing Authorized Collector contact information would make it easy for individuals to contact an Authorized Collector impersonating a Stewardship Program vendor. It would also allow individuals seeking to divert controlled substances to identify Authorized Collector staff most familiar with Stewardship Program operations. There is no reason to create these potential safety and security risks by publicizing Authorized Collector contact names and titles. SB 212 already requires Program Operators to provide the Department Authorized Collector entity contact information. See PRC § 42032.2(a)(1)(B). Accordingly, the Department should strike Proposed Regulations § 18973.2(d)(1)(A)¹. Corresponding revisions should also be made to annual reporting provisions in Proposed Regulations §§ 18973.4(j) and 18973.5(i).</p> <p>¹In addition to safety and security concerns, given the anticipated number of Authorized Collectors and personnel turnover, at least some contacts are likely to be outdated within months of Stewardship Plan submission.</p>	<p>The value this information provides the department for facilitating compliance reviews, especially when one authorized collector oversees many authorized collection sites, outweighs the minimal safety and security concerns and the possibility of the information becoming outdated. Program operators and authorized collectors could mitigate potential safety and security issues by taking simple precautions, such as not disclosing sensitive information to unverified parties.</p>
015-007b	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.4 (j)	N	<p>The Department Should Promote Stewardship Program Safety and Security by Revising Proposed Regulations § 18973.2(d)(1)(A) to Keep Authorized Collector Contact Information Confidential</p> <p>Stewardship Programs prioritize safety and security. Because Covered Drug Stewardship Plans provide for the collection and disposal of a wide range of Covered Drugs including controlled substances, it is an unfortunate reality that certain Stewardship Plan information is valuable to individuals attempting to divert controlled substances. Working together, the Department and Program Operators must avoid public disclosure of information that could compromise Stewardship Program safety and security. One such category of information is "Authorized Collector" (as defined in PRC § 42030(b)) contact names and titles. The Proposed Regulations require Covered Drug Stewardship Plans to include "[c]ontact name[s] and title[s]" for Authorized Collectors. Proposed Regulations § 18973.2(d)(1)(A). Publicizing Authorized Collector contact information would make it easy for individuals to contact an Authorized Collector impersonating a Stewardship Program vendor. It would also allow individuals seeking to divert controlled substances to identify Authorized Collector staff most familiar with Stewardship Program operations. There is no reason to create these potential safety and security risks by publicizing Authorized Collector contact names and titles. SB 212 already requires Program Operators to provide the Department Authorized Collector entity contact information. See PRC § 42032.2(a)(1)(B). Accordingly, the Department should strike Proposed Regulations § 18973.2(d)(1)(A)¹. Corresponding revisions should also be made to annual reporting provisions in Proposed Regulations §§ 18973.4(j) and 18973.5(i).</p>	<p>015-007b. A change to the proposed regulatory text is not necessary. CalRecycle disagrees with the commenter's recommendation. Public Resources Code section 42032.2(a)(1)(B) states that a stewardship plan for covered drugs must include "contact information for the authorized collectors for the stewardship program." The proposed regulations clarify that this contact information includes a contact name and title; according to CalRecycle's Initial Statement of Reasons, this information is "necessary to allow efficient correspondence, inspections, and audits as necessary."</p> <p>The value this information provides the department for facilitating compliance reviews, especially when one authorized collector oversees many authorized collection sites, outweighs the minimal safety and security concerns and the possibility of the information becoming outdated. Program operators and authorized collectors could mitigate potential safety and security issues by taking simple precautions, such as not disclosing sensitive information to unverified parties. Typically, stewardship plans are public documents and are posted on the Department's website so that the public is aware of the programs that the Department is approving. To the extent that a plan may have confidential information, those portions of the plan may be redacted from what is publicly made available, but they are potentially subject to a Public Records Act request. Consistent with Public Resources Code section 40062 and Title 14, Division 7, Chapter 1 of the California Code of Regulations under Article 4, Public Records (Section 17041 et seq.), when a public records act request is made, there is a process for determining if the claimed confidential records are in fact confidential.</p>

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					¹ In addition to safety and security concerns, given the anticipated number of Authorized Collectors and personnel turnover, at least some contacts are likely to be outdated within months of Stewardship Plan submission.	This process involves notifying the entity claiming confidentiality for them to provide an explanation of the basis for that claim. The requirement in these regulations is designed to streamline that process and potentially allow a faster determination. If the initial explanation is sufficient, no further action would be needed from the covered entity to maintain confidentiality. If the initial explanation is not sufficient to verify the claim of confidentiality, CalRecycle would provide a program operator notice of a public records act request pursuant to Title 14, Division 7, Chapter 1 of the California Code of Regulations, Section 17046 in order to provide additional explanation. The information required to be submitted under this law is in no way automatically confidential without justification, just because it is labelled as such.
015-007c	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.5 (j)	N	<p>The Department Should Promote Stewardship Program Safety and Security by Revising Proposed Regulations § 18973.2(d)(1)(A) to Keep Authorized Collector Contact Information Confidential</p> <p>Stewardship Programs prioritize safety and security. Because Covered Drug Stewardship Plans provide for the collection and disposal of a wide range of Covered Drugs including controlled substances, it is an unfortunate reality that certain Stewardship Plan information is valuable to individuals attempting to divert controlled substances. Working together, the Department and Program Operators must avoid public disclosure of information that could compromise Stewardship Program safety and security. One such category of information is "Authorized Collector" (as defined in PRC § 42030(b)) contact names and titles. The Proposed Regulations require Covered Drug Stewardship Plans to include "[c]ontact name[s] and title[s]" for Authorized Collectors. Proposed Regulations § 18973.2(d)(1)(A). Publicizing Authorized Collector contact information would make it easy for individuals to contact an Authorized Collector impersonating a Stewardship Program vendor. It would also allow individuals seeking to divert controlled substances to identify Authorized Collector staff most familiar with Stewardship Program operations. There is no reason to create these potential safety and security risks by publicizing Authorized Collector contact names and titles. SB 212 already requires Program Operators to provide the Department Authorized Collector entity contact information. See PRC § 42032.2(a)(1)(B). Accordingly, the Department should strike Proposed Regulations § 18973.2(d)(1)(A)¹. Corresponding revisions should also be made to annual reporting provisions in Proposed Regulations §§ 18973.4(j) and 18973.5(i).</p> <p>¹In addition to safety and security concerns, given the anticipated number of Authorized Collectors and personnel turnover, at least some contacts are likely to be outdated within months of Stewardship Plan submission.</p>	<p>015-007c. A change to the proposed regulatory text is not necessary. Public Resources Code section 42032.2(a)(1)(B) states that a stewardship plan for covered drugs must include "contact information for the authorized collectors for the stewardship program." The proposed regulations clarify that this contact information includes a contact name and title; according to CalRecycle's Initial Statement of Reasons, this information is "necessary to allow efficient correspondence, inspections, and audits as necessary."</p> <p>The value this information provides the department for facilitating compliance reviews, especially when one authorized collector oversees many authorized collection sites, outweighs the minimal safety and security concerns and the possibility of the information becoming outdated. Program operators and authorized collectors could mitigate potential safety and security issues by taking simple precautions, such as not disclosing sensitive information to unverified parties.</p> <p>To the extent that an annual report may contain proprietary or confidential information, those portions of the report may be redacted from what is publicly made available, but they are potentially subject to a Public Records Act request. Consistent with Public Resources Code section 40062 and Title 14, Division 7, Chapter 1 of the California Code of Regulations under Article 4, Public Records (Section 17041 et seq.), when a public records act request is made, there is a process for determining if the claimed confidential records are in fact confidential. This process involves notifying the entity claiming confidentiality for them to provide an explanation of the basis for that claim. The requirement in these regulations is designed to streamline that process and potentially allow a faster determination. If the initial explanation is sufficient, no further action would be needed from the covered entity to maintain confidentiality. If the initial explanation is not sufficient to verify the claim of confidentiality, CalRecycle would provide a program operator notice of a public records act request pursuant to Title 14, Division 7, Chapter 1 of the California Code of Regulations, Section</p>

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						17046 in order to provide additional explanation. The information required to be submitted under this law is in no way automatically confidential without justification, just because it is labelled as such.
015-008	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.2 (g)(3)	N	<p>Proposed Regulations § 18973.2(g)(3) Should Not Require Stewardship Plans to Describe Confidential Covered Drug Tracking Mechanisms</p> <p>Under DEA regulations, registrants must track Covered Drug inner liners through certain recordkeeping requirements. See, e.g., 21 CFR § 1317.60(a)(5) ("The inner liner shall bear a permanent, unique identification number that enables the inner liner to be tracked."); 21 CFR § 1304 (recordkeeping requirements). The Proposed Regulations require that Stewardship Plans describe these Covered Drug "[t]racking mechanism(s) for collection, transportation, and disposal." Proposed Regulations § 18973.2(g)(3). Because DEA tracking mechanisms are mandated by law and known to the public, Program Operators can describe them in Stewardship Plans without impairing Stewardship Program safety and security.</p> <p>To provide safe and secure Stewardship Programs, some Program Operators may decide to employ Covered Drug tracking mechanisms exceeding DEA requirements. The Proposed Regulations should not require disclosure of these voluntary tracking efforts. Just like DEA required tracking, the primary purpose of these voluntary tracking mechanisms is to prevent diversion. See Disposal of Controlled Substances, 79 Fed. Reg. 53520, 53553 (Sept. 9, 2014). Unlike DEA-required tracking mechanisms, however, voluntary tracking mechanisms can be kept confidential to Program Operators, as individuals attempting diversion are less likely to circumvent tracking mechanisms of which they are unaware. Requiring Program Operators to describe these voluntary tracking mechanisms in Stewardship Plans would give individuals attempting diversion more information about how Stewardship Programs detect diversion. Doing so impairs the effectiveness of those tracking mechanisms and, ultimately, Stewardship Program safety and security.</p> <p>Given these concerns, the Department should amend the Proposed Regulations to require that Stewardship Plans describe only the tracking mechanisms federal, state, and local laws, regulations, and other legal requirements expressly require. The revised Proposed Regulations § 18973.2(g)(3) should state: "Tracking mechanism(s) <u>expressly required by applicable federal, state, and local laws and regulations</u> for collection, transportation, and disposal."² Without this revision, the Proposed Regulations may unintentionally increase diversion risks and discourage Program Operators from adopting voluntary tracking mechanisms.</p> <p>²Corresponding annual reporting provisions should also be revised accordingly. See Proposed Regulations §§ 18973.4(d)(1), 18973.5(d)(1).</p>	<p>015-008. A change to the proposed regulatory text is not necessary. CalRecycle will assume, for the purposes of this response, that the commenter's concern is about potential release of confidential information. Typically, stewardship plans are public documents and are posted on the Department's website so that the public is aware of the programs that the department is approving. If certain tracking mechanisms not required by DEA regulations are considered proprietary information, those portions of the plan may be redacted from what is publicly made available, but they are potentially subject to a Public Records Act request. Consistent with Public Resources Code section 40062 and Title 14, Division 7, Chapter 1 of the California Code of Regulations under Article 4, Public Records (Section 17041 et seq.), when a public records act request is made, there is a process for determining if the claimed confidential records are in fact confidential. This process involves notifying the entity claiming confidentiality for them to provide an explanation of the basis for that claim. The requirement in these regulations is designed to streamline that process and potentially allow a faster determination. If the initial explanation is sufficient, no further action would be needed from the covered entity to maintain confidentiality. If the initial explanation is not sufficient to verify the claim of confidentiality, CalRecycle would provide a program operator notice of a public records act request pursuant to Title 14, Division 7, Chapter 1 of the California Code of Regulations, Section 17046 in order to provide additional explanation. The information required to be submitted under this law is in no way automatically confidential without justification, just because it is labelled as such.</p>
015-009a	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.2 (b)	Y	<p>The Department Must Revise Proposed Regulations §§ 18973.2(b) and 18973.3(b) to Protect Private Individuals' Information</p> <p>MED-Project prioritizes the protection of private individuals' information. Unfortunately, the Proposed Regulations would compel the disclosure of such</p>	<p>015-009a. The department chooses not to delete sections 18973.2(b)(1) and 18973.3(b)(1). Amongst other possible reasons, the contact information required in the proposed regulations is necessary "so the department will know who to contact if a stewardship plan is revoked</p>

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					<p>information. Under the Proposed Regulations, Covered Product Stewardship Plans must identify Covered Entity contact names, titles, and, potentially, email addresses. See Proposed Regulations § § 18973.2(b), 18973. 3(b). Compelling the public disclosure of this individual information could expose these individuals to online attacks and harassment. To avoid these consequences, the Department should strike Proposed Regulations §§ 18973.2(b)(1) (requiring contact names and titles) and 18973.3(b)(1) (same). It should also make clear that Proposed Regulations §§ 18973.2(b)(4) (requiring email addresses) and 18973.3(b)(4) (same) apply to Covered Entity email addresses, not individual contacts' email addresses.³ The revised Proposed Regulations §§ 18973.2(b)(4) and 18973.3(b)(4) should state: "<u>Covered Entity</u> email address."</p> <p>There is no discernable public policy justification to expose Covered Entity contacts' individual information. The Proposed Regulations' requirement that Stewardship Plans include Covered Entity contact information provides the Department sufficient contact information for SB 212 implementation and oversight. See id. The Department should revise the Proposed Regulations to protect these private individuals and their information.</p> <p>³In fact, many pharmacy Authorized Collector contacts do not have email addresses because they regularly handle protected health information.</p>	<p>pursuant to subsection (a) of section 42035.4 of the Public Resources Code or terminated pursuant to subsection (h) of section 42032 of the Public Resources Code or if the department needs to inform a covered entity of pending compliance actions" (from the Initial Statement of Reasons). Listing the contact name and title of a person representing a covered entity does not expose any sensitive information.</p> <p>However, CalRecycle acknowledges the ambiguity and sensitivity of the email address required by sections 18973.2(b)(4) and 18973.3(b)(4), and accepts the proposed edit: "<u>Covered Entity eEmail address.</u>" This edit should alleviate any issues with exposing private individual contact information online. The regulations do not require that a private individual disclose any personal information.</p> <p>Additionally, note that covered entity internet website address and phone number are now required to be provided (as opposed to being available upon request) in the stewardship plan due to the necessity of having multiple forms of contact information if a situation arises. Proposed regulatory text sections 18973.2(b) and 18973.3(b) have been revised as follows:</p> <p style="text-align: center;"><u>(5) Covered entity internet website address</u></p> <p style="text-align: center;"><u>(6) Covered entity phone number</u></p> <p>Upon request by the department, the internet website address and phone number of participating covered entities shall be provided, if available. The requested information shall be submitted within 30 days of the request unless extended as determined by the department.</p>
015-009b	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.3 (b)	Y	<p>The Department Must Revise Proposed Regulations §§ 18973.2(b) and 18973.3(b) to Protect Private Individuals' Information</p> <p>MED-Project prioritizes the protection of private individuals' information. Unfortunately, the Proposed Regulations would compel the disclosure of such information. Under the Proposed Regulations, Covered Product Stewardship Plans must identify Covered Entity contact names, titles, and, potentially, email addresses. See Proposed Regulations § § 18973.2(b), 18973. 3(b). Compelling the public disclosure of this individual information could expose these individuals to online attacks and harassment. To avoid these consequences, the Department should strike Proposed Regulations §§ 18973.2(b)(1) (requiring contact names and titles) and 18973.3(b)(1) (same). It should also make clear that Proposed Regulations §§ 18973.2(b)(4) (requiring email addresses) and 18973.3(b)(4) (same) apply to Covered Entity email addresses, not individual contacts' email addresses.³ The revised Proposed Regulations §§ 18973.2(b)(4) and 18973.3(b)(4) should state: "<u>Covered Entity</u> email address."</p>	<p>015-009b. The department chooses not to delete sections 18973.2(b)(1) and 18973.3(b)(1). As is stated in the Initial Statement of Reasons, the contact information required in the proposed regulations is necessary "so the department will know who to contact if a stewardship plan is revoked pursuant to subsection (a) of section 42035.4 of the Public Resources Code or terminated pursuant to subsection (h) of section 42032 of the Public Resources Code or if the department needs to inform a covered entity of pending compliance actions." Listing the contact name and title of a person representing a covered entity does not expose any sensitive information.</p> <p>However, CalRecycle acknowledges the ambiguity and sensitivity of the email address required by sections 18973.2(b)(4) and 18973.3(b)(4), and accepts the proposed edit: "<u>Covered Entity Eemail address.</u>" This edit should alleviate any issues with exposing private individual contact information online. The regulations do not require that a private individual disclose any personal information.</p>

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					<p>There is no discernable public policy justification to expose Covered Entity contacts' individual information. The Proposed Regulations' requirement that Stewardship Plans include Covered Entity contact information provides the Department sufficient contact information for SB 212 implementation and oversight. See id. The Department should revise the Proposed Regulations to protect these private individuals and their information.</p> <p>³In fact, many pharmacy Authorized Collector contacts do not have email addresses because they regularly handle protected health information.</p>	<p>Additionally, note that covered entity internet website address and phone number are now required (not just available upon request) in the stewardship plan due to the necessity of having multiple forms of contact information if a situation arises. Proposed regulatory text sections 18973.2(b) and 18973.3(b) have been revised as follows:</p> <p><u>(5) Covered entity internet website address</u></p> <p><u>(6) Covered entity phone number</u></p> <p>Upon request by the department, the internet website address and phone number of participating covered entities shall be provided, if available. The requested information shall be submitted within 30 days of the request unless extended as determined by the department.</p>
015-010a	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.2 (g)(1)	Y	<p>Proposed Regulations §§ 18973.2(g)(1) and 18973.3(f)(5) Should Require Program Operators to Support Participating Entity Compliance, Not Ensure It</p> <p>Because Authorized Collectors, "Home-Generated Sharps Consolidation Points" (as defined in Proposed Regulations § 18972.1(e)), and Stewardship Program vendors are independent entities with independent compliance obligations, Program Operators cannot describe how they will "ensure all entities participating in the program will operate under and comply with all applicable local, state, and federal laws and regulations." Proposed Regulations § 18973.2(g)(1); see also Proposed Regulations § 18973.3(f)(5). Covered Product collection and disposal is tightly regulated. Authorized Collectors, Home-Generated Sharps Consolidation Points, and Stewardship Program vendors have obligations under many applicable federal, state, and local laws, regulations, and other legal requirements. See, e.g., PRC § 42032.2(a)(1)(G)(iii)(II) ("An authorized collector shall comply with applicable federal and state laws regarding collection and transportation standards, and the handling of covered drugs, including United States Drug Enforcement Administration regulations."). SB 212 does not require Program Operators to describe how they will ensure Authorized Collectors, Home-Generated Sharps Consolidation Points, and Stewardship Program vendors comply with these obligations. Even if it did, there is no legal mechanism that allows Program Operators to assume these independent entities' obligations or compel their compliance. Because "ensuring" Authorized Collector, Home-Generated Sharps Consolidation Point, and Stewardship Program vendor compliance exceeds Program Operator authority, this requirement does not force Program Operator action; rather, it sets Program Operators up to fail.</p> <p>So what can Program Operators do to provide compliant Stewardship Programs? Program Operators can support Authorized Collector, Home-Generated Sharps Consolidation Point, and Program Operator compliance. They can require Authorized Collector, Home-Generated Sharps Consolidation</p>	<p>015-010a. CalRecycle acknowledges the commenter's concerns, but proposes an alternative edit to section 18973.2(g)(1) of the proposed regulatory text:</p> <p><u>(1) Processes and policies that will be used to safely and securely collect, track, and properly manage covered drugs from collection through final disposal.</u> to ensure all entities participating in the program will operate under and comply with all applicable local, state, and federal laws and regulations.</p> <p>A program operator is responsible for establishing processes and policies to safely and securely collect, track, and manage covered drugs; in this instance, the phrase beginning with "to ensure" serves as a "reason" for the requirement that adds ambiguity and actually limits its scope. The department is interested in all relevant processes and policies, not only the ones applicable to "local, state, and federal laws and regulations." Deleting the phrase in its entirety both addresses the commenter's concern and clarifies the required information to be included in a proposed stewardship plan.</p> <p>Additionally, CalRecycle notes that section 18973.3(f)(5) of the proposed regulatory text has been deleted in order to remove duplicative requirements.</p>

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					<p>Point, and Program vendor compliance with all applicable laws, regulations, and other legal requirements by contract. They can provide Authorized Collectors and Home-Generated Sharps Consolidation Points training materials to assist compliance efforts. They can also respond to Authorized Collector and Home-Generated Sharps Consolidation Point needs through a helpdesk and perform periodic monitoring on Authorized Collector, Home-Generated Sharps Consolidation Point, and Stewardship Program vendor practices. Through measures like these -measures within Program Operator authority- Program Operators can operate compliant Stewardship Programs and describe how they do so in Stewardship Plans.</p> <p>For these reasons, instead of requiring Program Operators to describe how they will "ensure" actions beyond their control, the Department should revise Proposed Regulations §§ 18973.2(g)(1) and 18973.3(f)(5) to require that Program Operators describe how they will support Authorized Collector, Home-Generated Sharps Consolidation Point, and Stewardship Program vendor compliance. The revised Proposed Regulations § 18973.2(g)(1) should require Program Operators to describe:</p> <p style="padding-left: 40px;">Processes and policies that will be used to safety and securely collect, track, and properly manage covered drugs from collection through final disposal to ensure all entities participating in the program will operate under and comply and used to support participating entities' compliance with all applicable local, state, and federal laws and regulations.</p> <p>The revised Proposed Regulations § 18973.3(f)(5) should require Program Operators to describe:</p> <p style="padding-left: 40px;">Processes and policies to be followed by persons handling home-generated sharps waste under the stewardship plan and efforts the program operator will take to ensure that all entities participating will operate under and comply with all applicable local, state, and federal laws and regulations used to support participating entities' compliance with all applicable local, state, and federal laws and regulations.</p> <p>These revisions would recognize the limits of Program Operator authority over Authorized Collectors, Home-Generated Sharps Consolidation Points, and Stewardship Program vendors. At the same time, it would force all Program Operators to take actions to implement compliant Stewardship Programs, increasing the likelihood of successful Stewardship Programs under SB 212.</p>	
015-010b	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.3 (f)(5)	Y	<p>Proposed Regulations §§ 18973.2(g)(1) and 18973.3(f)(5) Should Require Program Operators to Support Participating Entity Compliance, Not Ensure It</p> <p>Because Authorized Collectors, "Home-Generated Sharps Consolidation Points" (as defined in Proposed Regulations § 18972.1(e)), and Stewardship Program vendors are independent entities with independent compliance</p>	015-010b. CalRecycle agrees that a change to the proposed regulatory text is necessary and prefers to delete section 18973.3(f)(5) and section 18973.3(f)(6)(ii) to consolidate process and policy requirements into section 18973.3(f)(1) of the proposed regulatory text as follows:

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					<p>obligations, Program Operators cannot describe how they will "ensure all entities participating in the program will operate under and comply with all applicable local, state, and federal laws and regulations." Proposed Regulations § 18973.2(g)(1); see also Proposed Regulations § 18973.3(f)(5). Covered Product collection and disposal is tightly regulated. Authorized Collectors, Home-Generated Sharps Consolidation Points, and Stewardship Program vendors have obligations under many applicable federal, state, and local laws, regulations, and other legal requirements. See, e.g., PRC § 42032.2(a)(1)(G)(iii)(II) ("An authorized collector shall comply with applicable federal and state laws regarding collection and transportation standards, and the handling of covered drugs, including United States Drug Enforcement Administration regulations."). SB 212 does not require Program Operators to describe how they will ensure Authorized Collectors, Home-Generated Sharps Consolidation Points, and Stewardship Program vendors comply with these obligations. Even if it did, there is no legal mechanism that allows Program Operators to assume these independent entities' obligations or compel their compliance. Because "ensuring" Authorized Collector, Home-Generated Sharps Consolidation Point, and Stewardship Program vendor compliance exceeds Program Operator authority, this requirement does not force Program Operator action; rather, it sets Program Operators up to fail.</p> <p>So what can Program Operators do to provide compliant Stewardship Programs? Program Operators can support Authorized Collector, Home-Generated Sharps Consolidation Point, and Program Operator compliance. They can require Authorized Collector, Home-Generated Sharps Consolidation Point, and Program vendor compliance with all applicable laws, regulations, and other legal requirements by contract. They can provide Authorized Collectors and Home-Generated Sharps Consolidation Points training materials to assist compliance efforts. They can also respond to Authorized Collector and Home-Generated Sharps Consolidation Point needs through a helpdesk and perform periodic monitoring on Authorized Collector, Home-Generated Sharps Consolidation Point, and Stewardship Program vendor practices. Through measures like these -measures within Program Operator authority- Program Operators can operate compliant Stewardship Programs and describe how they do so in Stewardship Plans.</p> <p>For these reasons, instead of requiring Program Operators to describe how they will "ensure" actions beyond their control, the Department should revise Proposed Regulations §§ 18973.2(g)(1) and 18973.3(f)(5) to require that Program Operators describe how they will support Authorized Collector, Home-Generated Sharps Consolidation Point, and Stewardship Program vendor compliance. The revised Proposed Regulations § 18973.2(g)(1) should require Program Operators to describe:</p> <p style="text-align: center;">Processes and policies that will be used to safety and securely collect, track, and properly manage covered drugs from collection</p>	<p><u>18973.3(f)(1) Processes and policies that will be used to safely and securely collect, track, and properly manage home-generated sharps waste from collection through final disposal. Processes, policies, and metrics for the mail back program that will be used to safely and securely collect, track, transport, and dispose of home-generated sharps waste.</u></p> <p>A program operator is responsible for establishing processes and policies to safely and securely collect, track, and manage home-generated sharps waste. The department is interested in all relevant processes and policies, not only the ones applicable to "local, state, and federal laws and regulations." Deleting the phrase in its entirety both addresses the commenter's concern and clarifies the required information to be included in a proposed stewardship plan.</p> <p>Regarding the commenter's concern that "there is no legal mechanism that allows Program Operators to assume these independent entities' obligations or compel their compliance", It is the program operator's responsibility, under the Statute (Public Resources Code sections 42032.2(d)(1)(D) and 42035.8), to maintain compliance with all applicable local, state, and federal laws and regulations.</p>

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					<p>through final disposal to ensure all entities participating in the program will operate under and comply and used to support participating entities' compliance with all applicable local, state, and federal laws and regulations.</p> <p>The revised Proposed Regulations § 18973.3(f)(5) should require Program Operators to describe:</p> <p>Processes and policies to be followed by persons handling home-generated sharps waste under the stewardship plan and efforts the program operator will take to ensure that all entities participating will operate under and comply with all applicable local, state, and federal laws and regulations used to support participating entities' compliance with all applicable local, state, and federal laws and regulations.</p> <p>These revisions would recognize the limits of Program Operator authority over Authorized Collectors, Home-Generated Sharps Consolidation Points, and Stewardship Program vendors. At the same time, it would force all Program Operators to take actions to implement compliant Stewardship Programs, increasing the likelihood of successful Stewardship Programs under SB 212.</p>	
015-011A1	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.2	N	<p>MED-Project Supports the Proposed Regulations Recognizing Program Operator Flexibility to Use Various Collection Methods</p> <p>Given the scope and scale of California Stewardship Programs, the flexibility to use alternative forms of collection and disposal systems, provide supplemental collection methods, and provide or initiate the distribution of sharps waste containers will help Program Operators implement successful Stewardship Programs. "Authorized Collection Site" (as defined in PRC § 42030(a)) or Home-Generated Sharps Consolidation Point availability, public facility availability, and population densities, among other factors, affect how successful collection methods are in a locale. To serve Ultimate Users, several provisions of the Proposed Regulations wisely allow Program Operators to adapt their collection methods to varying circumstances, consistent with SB 212. See Proposed Regulations §§ 18973.2(g)(5)(A) (recognizing Program Operator flexibility to use mail-back distribution locations in certain circumstances), 18973.2(g)(6) (providing for alternative forms of collection and disposal systems), 18973.3(f)(6) (providing for supplemental Home-Generated Sharps Waste collection methods), 18972.1(j) (providing multiple methods to provide or initiate distribution of a sharps waste container).</p> <p>MED-Project supports the Department recognizing that Program Operators can use different collection methods to maximize Stewardship Program effectiveness. Subject to SB 212's requirements, this flexibility allows Program Operators to use the collection method most effective and convenient for Ultimate Users. Additionally, this flexibility promotes development of new</p>	015-011A1. 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 for programmatic flexibility.

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					collection methods that may provide even more effective collection services in the future.	
015-011A2	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.3	N	<p>MED-Project Supports the Proposed Regulations Recognizing Program Operator Flexibility to Use Various Collection Methods</p> <p>Given the scope and scale of California Stewardship Programs, the flexibility to use alternative forms of collection and disposal systems, provide supplemental collection methods, and provide or initiate the distribution of sharps waste containers will help Program Operators implement successful Stewardship Programs. "Authorized Collection Site" (as defined in PRC § 42030(a)) or Home-Generated Sharps Consolidation Point availability, public facility availability, and population densities, among other factors, affect how successful collection methods are in a locale. To serve Ultimate Users, several provisions of the Proposed Regulations wisely allow Program Operators to adapt their collection methods to varying circumstances, consistent with SB 212. See Proposed Regulations §§ 18973.2(g)(5)(A) (recognizing Program Operator flexibility to use mail-back distribution locations in certain circumstances), 18973.2(g)(6) (providing for alternative forms of collection and disposal systems), 18973.3(f)(6) (providing for supplemental Home-Generated Sharps Waste collection methods), 18972.1(j) (providing multiple methods to provide or initiate distribution of a sharps waste container).</p> <p>MED-Project supports the Department recognizing that Program Operators can use different collection methods to maximize Stewardship Program effectiveness. Subject to SB 212's requirements, this flexibility allows Program Operators to use the collection method most effective and convenient for Ultimate Users. Additionally, this flexibility promotes development of new collection methods that may provide even more effective collection services in the future.</p>	015-011A2. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. CalRecycle notes the commenter's statement.
015-011B	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18972.1(j)	N	<p>The flexibility to "[p]rovide or initiate[]" distribution of a sharps waste container" through the multiple methods identified in the Proposed Regulations is especially critical for Stewardship Program operations. See Proposed Regulations § 18972.1(j). SB 212's requirement that Program Operators "distribute a container and mail-back materials sufficient to accommodate the volume of sharps purchased by an ultimate user over a selected time period" could be understood to require that Program Operators or sharps retailers obtain information from ultimate users regarding the number of sharps they purchase. See PRC § 42032.2(d)(1)(F)(i). Collecting such information would raise operational and privacy issues that sharps retailers and Program Operators would be challenged to resolve if the Proposed Regulations did not provide the flexibility to use various collection methods.</p> <p>In sum, Proposed Regulations provisions recognizing Program Operator flexibility to implement different collection methods promote effective Stewardship Programs over the long term.</p>	015-011B. A change to the proposed regulatory text is not necessary. While CalRecycle acknowledges the commenter's support for programmatic flexibility, the department does not interpret Public Resources Code section 42032.2(d)(1)(F)(i) as requiring a program operator or sharps retailer to obtain information from ultimate users regarding the number of sharps they purchase. The requirement relating to the "sufficient volume" and "selected time period" for sharps containers could involve internal calculations or estimations that do not rely on collecting private medical data.
015-012a	MED-Project USA	Michael R. Van Winkle,	18973.2	N	<p>Consistent with SB 212, the Proposed Regulations Properly Give Program Operators Discretion to Choose Collection Models</p>	015-012a. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary.

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		Dr. Victoria Travis			<p>Program Operators can give Authorized Collectors varying degrees of control over "Covered Product" (as defined in PRC § 42030(g)) collection and disposal services through different "collection models." Some collection models permit Authorized Collectors to perform inner liner or container installation, removal, and packaging, giving them control over when collection occurs. Other collection models involve vendors in some of these tasks. The collection model(s) a Program Operator offers are central to that Program Operator's implementation strategy, affecting Authorized Collector responsibilities, contracts, training materials, vendor selection, disposal facilities, implementation timelines, and Program Operator costs. With such broad ranging impacts to Stewardship Program operations, SB 212 properly gives Program Operators the discretion to choose collection models. SB 212 generally requires that Stewardship Plans provide for collection models that safely and securely collect, transport, and dispose of Covered Drugs in compliance with all applicable federal, state, and local laws, regulations, and other legal requirements. See, e.g., PRC §§ 42032.2(a)(1), 42035.8. Additionally, SB 212 provides that Stewardship Plans must require Program Operators to: Provide a service schedule that meets the needs of each authorized collection site to ensure that [1] each secure collection receptacle is serviced as often as necessary to avoid reaching capacity and [2] that collected covered drugs are transported to final disposal in a timely manner. Additionally, a receipt or collection manifest shall be left with the authorized collection site to support verification of the service. PRC § 42032.2(a)(1)(G)(iii)(I). Because many collection models can satisfy these statutory requirements to, generally, comply with law and provide convenient service schedules, SB 212 provides Program Operators broad discretion to choose the collection models they offer Authorized Collectors. The Proposed Regulations maintain the discretion SB 212 gives Program Operators to determine Covered Product collection models. The Proposed Regulations require that Stewardship Plans describe policies and procedures for the safe and secure collection and disposal of Covered Drugs in compliance with all applicable laws, regulations, and other legal requirements. See, e.g., Proposed Regulations §§ 18973.2(g)(1), 18973.2. They also require that Stewardship Plans describe "how service schedules are determined to ensure that collection receptacles do not reach capacity, and procedures to be followed if capacity is reached." Proposed Regulations § 18973.2(g)(8). Requirements for the collection and disposal of Home-Generated Sharps Waste are substantially similar. See Proposed Regulations § 18973.3(f)(6)(A)(ii), (iii). MED-Project supports the Proposed Regulations' approach maintaining this Program Operator discretion, consistent with SB 212. This approach allows Program Operators to use the collection models providing the most effective services for Authorized Collectors and Ultimate Users. Program Operator flexibility to use novel collection models will also promote innovation and vendor competition, whereas mandating specific collection models would, by regulation, pick winners and losers among Stewardship Program vendors. Conversely, prescribing specific collection methods by regulation or, subsequently, through Stewardship Plan approval</p>	CalRecycle acknowledges the commenter's support for programmatic flexibility.

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					would deprive Program Operators of the ability to tailor collection models to provide the most effective services. It would also run afoul of SB 212 and California case law. See <i>PaintCare v. Mortensen</i> , 233 Cal. App. 4th 1292, 1298-99 (2015) ("[T]he regulations do not go beyond the Program because they do not dictate how manufacturers comply with the Program. Rather, they set forth what information manufacturers must provide to CalRecycle to comply with the Program.") (emphasis in original).	
015-012b	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.3	N	<p>Consistent with SB 212, the Proposed Regulations Properly Give Program Operators Discretion to Choose Collection Models</p> <p>Program Operators can give Authorized Collectors varying degrees of control over "Covered Product" (as defined in PRC § 42030(g)) collection and disposal services through different "collection models." Some collection models permit Authorized Collectors to perform inner liner or container installation, removal, and packaging, giving them control over when collection occurs. Other collection models involve vendors in some of these tasks. The collection model(s) a Program Operator offers are central to that Program Operator's implementation strategy, affecting Authorized Collector responsibilities, contracts, training materials, vendor selection, disposal facilities, implementation timelines, and Program Operator costs. With such broad ranging impacts to Stewardship Program operations, SB 212 properly gives Program Operators the discretion to choose collection models. SB 212 generally requires that Stewardship Plans provide for collection models that safely and securely collect, transport, and dispose of Covered Drugs in compliance with all applicable federal, state, and local laws, regulations, and other legal requirements. See, e.g., PRC §§ 42032.2(a)(1), 42035.8. Additionally, SB 212 provides that Stewardship Plans must require Program Operators to: Provide a service schedule that meets the needs of each authorized collection site to ensure that [1] each secure collection receptacle is serviced as often as necessary to avoid reaching capacity and [2] that collected covered drugs are transported to final disposal in a timely manner. Additionally, a receipt or collection manifest shall be left with the authorized collection site to support verification of the service. PRC § 42032.2(a)(1)(G)(iii)(I). Because many collection models can satisfy these statutory requirements to, generally, comply with law and provide convenient service schedules, SB 212 provides Program Operators broad discretion to choose the collection models they offer Authorized Collectors. The Proposed Regulations maintain the discretion SB 212 gives Program Operators to determine Covered Product collection models. The Proposed Regulations require that Stewardship Plans describe policies and procedures for the safe and secure collection and disposal of Covered Drugs in compliance with all applicable laws, regulations, and other legal requirements. See, e.g., Proposed Regulations §§ 18973.2(g)(1), 18973.2. They also require that Stewardship Plans describe "how service schedules are determined to ensure that collection receptacles do not reach capacity, and procedures to be followed if capacity is reached." Proposed Regulations § 18973.2(g)(8). Requirements for the collection and disposal of Home-Generated Sharps Waste are substantially similar. See Proposed Regulations§</p>	015-012b. This comment does not specify a proposed change to the regulations. A change to the proposed regulatory text is not necessary. CalRecycle notes the commenter's statement.

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					18973.3(f)(6)(A)(ii), (iii). MED-Project supports the Proposed Regulations' approach maintaining this Program Operator discretion, consistent with SB 212. This approach allows Program Operators to use the collection models providing the most effective services for Authorized Collectors and Ultimate Users. Program Operator flexibility to use novel collection models will also promote innovation and vendor competition, whereas mandating specific collection models would, by regulation, pick winners and losers among Stewardship Program vendors. Conversely, prescribing specific collection methods by regulation or, subsequently, through Stewardship Plan approval would deprive Program Operators of the ability to tailor collection models to provide the most effective services. It would also run afoul of SB 212 and California case law. See <i>PaintCare v. Mortensen</i> , 233 Cal. App. 4th 1292, 1298-99 (2015) ("[T]he regulations do not go beyond the Program because they do not dictate how manufacturers comply with the Program. Rather, they set forth what information manufacturers must provide to CalRecycle to comply with the Program.") (emphasis in original).	
015-013a	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.2(g)(10)	Y	<p>Proposed Regulations §§ 18973.2(g)(10) and 18973.3(f)(6)(A)(v) Should Require that Stewardship Plans Describe Processes to Address Critical Participant Policy and Procedure Deviations, Not Participant Non-Compliance</p> <p>Under the Proposed Regulations, Program Operators must provide Stewardship Plans that describe "[w]hat corrective actions will be taken if a program operator discovers an authorized collector or service provider is not maintaining compliance with all collection, transportation, and disposal standards related to the handling of covered drugs, including, but not limited to, United States Drug Enforcement Administration regulations." Proposed Regulations § 18973.2(g)(10); see also § 18973.3(f)(6)(A)(v) (analogous requirement for Home-Generated Sharps Waste). When implemented, these provisions effectively require Program Operators to make definitive conclusions regarding other entities' compliance – conclusions that annual reporting would make public in certain cases. See Proposed Regulations § 18973.4(e) (requiring reporting on certain corrective actions); see also 18973.5(e) (analogous requirement for Home-Generated Sharps Waste annual reports). To avoid putting Program Operators in this untenable position, the Department should revise Proposed Regulations § § 18973.2(g)(10) and 18973.3(f)(6)(A)(v) to require that Stewardship Plans identify processes for addressing critical Authorized Collector, Home-Generated Sharps Consolidation Point, or service provider deviations from Stewardship Program policies and procedures.</p> <p>Specifically, SB 212 requires Stewardship Plans to:</p> <p style="padding-left: 40px;">Provide the policies and procedures for the safe and secure collection, transporting, and disposing of the covered drug ... and how, at a minimum, instances of security problems that occur will be addressed, and explain the processes that will be taken to change the</p>	<p>015-013a. CalRecycle agrees with the commenter that proposed regulatory text in sections 18973.2(g)(10), 18973.4(e), and 18973.5(e) should be clarified to specify that only critical deviations from stewardship plan policies and procedures should be described in those sections. Note that section 18973.3(f)(6)(A)(v) has been deleted and section 18973.3(f)(9) has been added so that it applies to all home-generated sharps waste collection, transportation, and disposal activities, not just those that occur under supplemental collection methods. See the following edits to section 18973.2(g)(10):</p> <p><u>(10) What corrective actions will be taken if a program operator discovers critical deviations from stewardship plan policies and procedures, an authorized collector or service provider is not maintaining compliance with all collection, transportation, and disposal standards related to the handling of covered drugs, including, but not limited to, United States Drug Enforcement Administration regulations.</u></p> <p>CalRecycle agrees that policies and procedures surrounding compliance with applicable laws and regulations are not the only ones relevant to stewardship program implementation. However, it is essential for a program operator to conduct "corrective actions" if its service providers deviate from key stewardship program policies and procedures, and the commenter appropriately lists several possible actions.</p> <p>Editing the proposed regulations in this manner both: (1) addresses the commenter's concern of reporting noncompliance with laws and regulations beyond those relevant to implementing stewardship plan policies and procedures, and (2) provides a program operator the flexibility to determine what "corrective actions" are taken depending on the circumstances and the type of deviation.</p>

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					<p>policies, procedures, and tracking mechanisms to alleviate the problems and improve safety and security.</p> <p>PRC § 42032.2(a)(1)(H). This requirement makes plain that Stewardship Plans should describe the processes used to address deviations from policies and procedures, not deviations from compliance with certain applicable laws, regulations, and other legal requirements. SB 212 also requires Stewardship Plans to describe these processes for addressing "security problems," or critical -not minor -deviations from these policies and procedures. For unknown reasons, however, the Proposed Regulations muddle these requirements. Proposed Regulations §§ 18973.2(g)(10) and 18973.3(f)(6)(A)(v) appear to require that Stewardship Plans identify corrective actions for any non-compliance with certain legal standards, not Stewardship Program critical deviations from Program policies and procedures, diminishing what the statute emphasizes. Consistent with SB 212, Proposed Regulations §§ 18973.2(g)(10) and 18973.3(f)(6)(A)(v) should be revised to require that Stewardship Plans explain the processes that will be taken to address critical Authorized Collector, Home-Generated Sharps Consolidation Point, or service provider deviations from Stewardship Program policies and procedures.</p> <p>In addition to tracking SB 212, revising the Proposed Regulations to focus on deviations from Stewardship Program policies and procedures facilitates Stewardship Program implementation. Program Operators can describe how they evaluate, monitor, correct, and report on deviations from Stewardship Program policies and procedures. For example, Program Operators use incident management systems to identify, document, investigate, and analyze the causes for policy and procedure deviations. As appropriate, Program Operators then correct for these deviations through actions that include providing training or compliance aids, performing additional due diligence, changing service offerings, or, as warranted, amending contracts or terminating relationships.</p> <p>Evaluating, monitoring, collecting, and reporting on compliance with applicable laws, regulations, and other legal requirements is far more challenging. As discussed above in Section III.B.2., Authorized Collectors, Home-Generated Sharps Consolidation Points, and service providers are independent entities with independent compliance obligations and independent legal interpretations. Program Operators do not know how government agencies interpret an Authorized Collector, Home-Generated Sharps Consolidation Point, or service provider's compliance status. Such uncertainty presents serious risks for Program Operators obligated to provide annual reporting on corrective actions associated with certain service provider failures to maintain compliance. See Proposed Regulations §§ 18973.4(e), 18973.5(e). Making representations regarding service provider compliance in a publicly available annual report could potentially expose Program Operators to lawsuits, disrupting or interfering with Stewardship Program services and negatively affecting the convenience to the Ultimate User.</p>	<p>Further, regarding the commenter's statement that "these provisions effectively require program operators to make definitive conclusions regarding other entities' compliance," it is the program operator's responsibility, pursuant to Public Resources Code sections 42032.2(a)(1)(E), 42032.2(d)(1)(D) and 42035.8, to maintain compliance with all applicable local, state, and federal laws and regulations. For the same reason, CalRecycle disagrees that the regulations should limit the corrective actions to authorized collectors or service providers.</p>

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					<p>For consistency with SB 212, and to facilitate Program Operator evaluation, monitoring, corrective actions, and reporting, the Department should revise the Proposed Regulations to require that Stewardship Plans identify processes for addressing critical Authorized Collector, Home-Generated Sharps Consolidation Point, or service provider deviations from Stewardship Program policies and procedures. As revised, Proposed Regulations §§ 18973.2(g)(10) and 18973.3(f)(6)(A)(v) should require Plans to describe:</p> <p>Processes that address critical deviations from stewardship plan policies and procedures. What corrective actions will be taken if a program operator discovers an authorized collector or service provider is not maintaining compliance with all collection, transportation, and disposal standards related to the handling of covered drugs, including, but not limited to, United States Drug Enforcement Administration regulations.</p>	
015-013b	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.3(f)(6)(A)(v)	Y	<p>Proposed Regulations §§ 18973.2(g)(10) and 18973.3(f)(6)(A)(v) Should Require that Stewardship Plans Describe Processes to Address Critical Participant Policy and Procedure Deviations, Not Participant Non-Compliance</p> <p>Under the Proposed Regulations, Program Operators must provide Stewardship Plans that describe "[w]hat corrective actions will be taken if a program operator discovers an authorized collector or service provider is not maintaining compliance with all collection, transportation, and disposal standards related to the handling of covered drugs, including, but not limited to, United States Drug Enforcement Administration regulations." Proposed Regulations § 18973.2(g)(10); <i>see also</i> § 18973.3(f)(6)(A)(v) (analogous requirement for Home-Generated Sharps Waste). When implemented, these provisions effectively require Program Operators to make definitive conclusions regarding other entities' compliance – conclusions that annual reporting would make public in certain cases. <i>See</i> Proposed Regulations § 18973.4(e) (requiring reporting on certain corrective actions); <i>see also</i> 18973.5(e) (analogous requirement for Home-Generated Sharps Waste annual reports). To avoid putting Program Operators in this untenable position, the Department should revise Proposed Regulations § § 18973.2(g)(10) and 18973.3(f)(6)(A)(v) to require that Stewardship Plans identify processes for addressing critical Authorized Collector, Home-Generated Sharps Consolidation Point, or service provider deviations from Stewardship Program policies and procedures.</p> <p>Specifically, SB 212 requires Stewardship Plans to:</p> <p style="padding-left: 40px;">Provide the policies and procedures for the safe and secure collection, transporting, and disposing of the covered drug ... and how, at a minimum, instances of security problems that occur will be addressed, and explain the processes that will be taken to change the policies, procedures, and tracking mechanisms to alleviate the problems and improve safety and security.</p>	<p>015-013b. CalRecycle agrees with the commenter that proposed regulatory text in sections 18973.2(g)(10), 18973.4(e), and 18973.5(e) should be clarified to specify that only critical deviations from established policies and procedures should be described in those sections and made corresponding edits to those sections. Note that section 18973.3(f)(6)(A)(v) has been deleted and section 18973.3(f)(9) has been added so that it applies to all home-generated sharps waste collection, transportation, and disposal activities, not just those that occur under supplemental collection methods. The department finds the following edit to be a more effective solution than the commenter's proposed edit:</p> <p>Proposed regulatory text section 18973.3(f): <u>(9) What corrective actions will be taken if a program operator discovers critical deviations from stewardship plan policies and procedures.</u></p> <p>Further, regarding the commenter's statement that "these provisions effectively require program operators to make definitive conclusions regarding other entities' compliance", It is the program operator's responsibility, under the Statute (Public Resources Code sections 42032.2(d)(1)(D) and 42035.8), to maintain compliance with all applicable local, state, and federal laws and regulations. For the same reason, CalRecycle disagrees that the regulations should limit the corrective actions to home-generated sharps consolidation points or service providers.</p>

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					<p>PRC § 42032.2(a)(1)(H). This requirement makes plain that Stewardship Plans should describe the processes used to address deviations from policies and procedures, not deviations from compliance with certain applicable laws, regulations, and other legal requirements. SB 212 also requires Stewardship Plans to describe these processes for addressing "security problems," or critical -not minor -deviations from these policies and procedures. For unknown reasons, however, the Proposed Regulations muddle these requirements. Proposed Regulations §§ 18973.2(g)(10) and 18973.3(f)(6)(A)(v) appear to require that Stewardship Plans identify corrective actions for any non-compliance with certain legal standards, not Stewardship Program critical deviations from Program policies and procedures, diminishing what the statute emphasizes. Consistent with SB 212, Proposed Regulations §§ 18973.2(g)(10) and 18973.3(f)(6)(A)(v) should be revised to require that Stewardship Plans explain the processes that will be taken to address critical Authorized Collector, Home-Generated Sharps Consolidation Point, or service provider deviations from Stewardship Program policies and procedures.</p> <p>In addition to tracking SB 212, revising the Proposed Regulations to focus on deviations from Stewardship Program policies and procedures facilitates Stewardship Program implementation. Program Operators can describe how they evaluate, monitor, correct, and report on deviations from Stewardship Program policies and procedures. For example, Program Operators use incident management systems to identify, document, investigate, and analyze the causes for policy and procedure deviations. As appropriate, Program Operators then correct for these deviations through actions that include providing training or compliance aids, performing additional due diligence, changing service offerings, or, as warranted, amending contracts or terminating relationships.</p> <p>Evaluating, monitoring, collecting, and reporting on compliance with applicable laws, regulations, and other legal requirements is far more challenging. As discussed above in Section III.B.2., Authorized Collectors, Home-Generated Sharps Consolidation Points, and service providers are independent entities with independent compliance obligations and independent legal interpretations. Program Operators do not know how government agencies interpret an Authorized Collector, Home-Generated Sharps Consolidation Point, or service provider's compliance status. Such uncertainty presents serious risks for Program Operators obligated to provide annual reporting on corrective actions associated with certain service provider failures to maintain compliance. See Proposed Regulations §§ 18973.4(e), 18973.5(e). Making representations regarding service provider compliance in a publicly available annual report could potentially expose Program Operators to lawsuits, disrupting or interfering with Stewardship Program services and negatively affecting the convenience to the Ultimate User.</p> <p>For consistency with SB 212, and to facilitate Program Operator evaluation, monitoring, corrective actions, and reporting, the Department should revise</p>	

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					<p>the Proposed Regulations to require that Stewardship Plans identify processes for addressing critical Authorized Collector, Home-Generated Sharps Consolidation Point, or service provider deviations from Stewardship Program policies and procedures. As revised, Proposed Regulations §§ 18973.2(g)(10) and 18973.3(f)(6)(A)(v) should require Plans to describe:</p> <p>Processes that address critical deviations from stewardship plan policies and procedures. What corrective actions will be taken if a program operator discovers an authorized collector or service provider is not maintaining compliance with all collection, transportation, and disposal standards related to the handling of covered drugs, including, but not limited to, United States Drug Enforcement Administration regulations.</p>	
015-013c	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.4 (e)	Y	<p>Proposed Regulations §§ 18973.2(g)(10) and 18973.3(f)(6)(A)(v) Should Require that Stewardship Plans Describe Processes to Address Critical Participant Policy and Procedure Deviations, Not Participant Non-Compliance</p> <p>Under the Proposed Regulations, Program Operators must provide Stewardship Plans that describe "[w]hat corrective actions will be taken if a program operator discovers an authorized collector or service provider is not maintaining compliance with all collection, transportation, and disposal standards related to the handling of covered drugs, including, but not limited to, United States Drug Enforcement Administration regulations." Proposed Regulations § 18973.2(g)(10); <i>see also</i> § 18973.3(f)(6)(A)(v) (analogous requirement for Home-Generated Sharps Waste). When implemented, these provisions effectively require Program Operators to make definitive conclusions regarding other entities' compliance – conclusions that annual reporting would make public in certain cases. <i>See</i> Proposed Regulations § 18973.4(e) (requiring reporting on certain corrective actions); <i>see also</i> 18973.5(e) (analogous requirement for Home-Generated Sharps Waste annual reports). To avoid putting Program Operators in this untenable position, the Department should revise Proposed Regulations § § 18973.2(g)(10) and 18973.3(f)(6)(A)(v) to require that Stewardship Plans identify processes for addressing critical Authorized Collector, Home-Generated Sharps Consolidation Point, or service provider deviations from Stewardship Program policies and procedures.</p> <p>Specifically, SB 212 requires Stewardship Plans to:</p> <p style="padding-left: 40px;">Provide the policies and procedures for the safe and secure collection, transporting, and disposing of the covered drug ... and how, at a minimum, instances of security problems that occur will be addressed, and explain the processes that will be taken to change the policies, procedures, and tracking mechanisms to alleviate the problems and improve safety and security.</p>	<p>015-013c. CalRecycle acknowledges the commenter's concern and agrees that an edit to the proposed regulations is warranted. However, the department finds the following edit to be a more effective solution than the commenter's proposed edit:</p> <p>Proposed regulations section 18973.4(e) is revised as follows:</p> <p><u>(e) Corrective actions taken if the program operator discovered critical deviations from stewardship plan policies and procedures and a description of each critical deviation. that a service provider did not maintain compliance with all collection, transportation, and disposal standards, including, but not limited to, local, state, and federal laws and regulations and United States Drug Enforcement Administration regulations.</u></p> <p>Stewardship plan implementation relies on adherence to key policies and procedures in many areas. These policies and procedures may often take the form of contractual agreements between the program operator and service providers. It is essential for a program operator to conduct "corrective actions" if service providers deviate from stewardship program policies and procedures, and the commenter lists several possible actions. Thus, the department's proposed edit requires reporting corrective actions taken to address any "critical" deviation from the policies and procedures used to safely and securely collect, track, and properly manage covered drugs from collection through final disposal as is outlined in the stewardship plan.</p> <p>Editing the proposed regulations in this manner both: (1) addresses the commenter's concern of reporting noncompliance with laws and regulations versus noncompliance with stewardship plan policies and procedures, and (2) provides a program operator the flexibility to determine what "corrective actions" are taken depending on the circumstances and the type of deviation.</p>

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					<p>PRC § 42032.2(a)(1)(H). This requirement makes plain that Stewardship Plans should describe the processes used to address deviations from policies and procedures, not deviations from compliance with certain applicable laws, regulations, and other legal requirements. SB 212 also requires Stewardship Plans to describe these processes for addressing "security problems," or critical -not minor -deviations from these policies and procedures. For unknown reasons, however, the Proposed Regulations muddle these requirements. Proposed Regulations §§ 18973.2(g)(10) and 18973.3(f)(6)(A)(v) appear to require that Stewardship Plans identify corrective actions for any non-compliance with certain legal standards, not Stewardship Program critical deviations from Program policies and procedures, diminishing what the statute emphasizes. Consistent with SB 212, Proposed Regulations §§ 18973.2(g)(10) and 18973.3(f)(6)(A)(v) should be revised to require that Stewardship Plans explain the processes that will be taken to address critical Authorized Collector, Home-Generated Sharps Consolidation Point, or service provider deviations from Stewardship Program policies and procedures.</p> <p>In addition to tracking SB 212, revising the Proposed Regulations to focus on deviations from Stewardship Program policies and procedures facilitates Stewardship Program implementation. Program Operators can describe how they evaluate, monitor, correct, and report on deviations from Stewardship Program policies and procedures. For example, Program Operators use incident management systems to identify, document, investigate, and analyze the causes for policy and procedure deviations. As appropriate, Program Operators then correct for these deviations through actions that include providing training or compliance aids, performing additional due diligence, changing service offerings, or, as warranted, amending contracts or terminating relationships.</p> <p>Evaluating, monitoring, collecting, and reporting on compliance with applicable laws, regulations, and other legal requirements is far more challenging. As discussed above in Section III.B.2., Authorized Collectors, Home-Generated Sharps Consolidation Points, and service providers are independent entities with independent compliance obligations and independent legal interpretations. Program Operators do not know how government agencies interpret an Authorized Collector, Home-Generated Sharps Consolidation Point, or service provider's compliance status. Such uncertainty presents serious risks for Program Operators obligated to provide annual reporting on corrective actions associated with certain service provider failures to maintain compliance. See Proposed Regulations §§ 18973.4(e), 18973.5(e). Making representations regarding service provider compliance in a publicly available annual report could potentially expose Program Operators to lawsuits, disrupting or interfering with Stewardship Program services and negatively affecting the convenience to the Ultimate User.</p> <p>For consistency with SB 212, and to facilitate Program Operator evaluation, monitoring, corrective actions, and reporting, the Department should revise</p>	<p>Further, regarding the commenter's statement that "these provisions effectively require program operators to make definitive conclusions regarding other entities' compliance", It is the program operator's responsibility, under the Statute (Public Resources Code section 42035.8), to maintain compliance with all applicable local, state, and federal laws and regulations. For the same reason, CalRecycle disagrees that the regulations should limit the corrective actions to authorized collectors or service providers.</p>

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					<p>the Proposed Regulations to require that Stewardship Plans identify processes for addressing critical Authorized Collector, Home-Generated Sharps Consolidation Point, or service provider deviations from Stewardship Program policies and procedures. As revised, Proposed Regulations §§ 18973.2(g)(10) and 18973.3(f)(6)(A)(v) should require Plans to describe:</p> <p>Processes that address critical deviations from stewardship plan policies and procedures. What corrective actions will be taken if a program operator discovers an authorized collector or service provider is not maintaining compliance with all collection, transportation, and disposal standards related to the handling of covered drugs, including, but not limited to, United States Drug Enforcement Administration regulations.</p>	
015-013d	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.5 (e)	Y	<p>Proposed Regulations §§ 18973.2(g)(10) and 18973.3(f)(6)(A)(v) Should Require that Stewardship Plans Describe Processes to Address Critical Participant Policy and Procedure Deviations, Not Participant Non-Compliance</p> <p>Under the Proposed Regulations, Program Operators must provide Stewardship Plans that describe "[w]hat corrective actions will be taken if a program operator discovers an authorized collector or service provider is not maintaining compliance with all collection, transportation, and disposal standards related to the handling of covered drugs, including, but not limited to, United States Drug Enforcement Administration regulations." Proposed Regulations § 18973.2(g)(10); <i>see also</i> § 18973.3(f)(6)(A)(v) (analogous requirement for Home-Generated Sharps Waste). When implemented, these provisions effectively require Program Operators to make definitive conclusions regarding other entities' compliance – conclusions that annual reporting would make public in certain cases. <i>See</i> Proposed Regulations § 18973.4(e) (requiring reporting on certain corrective actions); <i>see also</i> 18973.5(e) (analogous requirement for Home-Generated Sharps Waste annual reports). To avoid putting Program Operators in this untenable position, the Department should revise Proposed Regulations § § 18973.2(g)(10) and 18973.3(f)(6)(A)(v) to require that Stewardship Plans identify processes for addressing critical Authorized Collector, Home-Generated Sharps Consolidation Point, or service provider deviations from Stewardship Program policies and procedures.</p> <p>Specifically, SB 212 requires Stewardship Plans to:</p> <p style="padding-left: 40px;">Provide the policies and procedures for the safe and secure collection, transporting, and disposing of the covered drug ... and how, at a minimum, instances of security problems that occur will be addressed, and explain the processes that will be taken to change the policies, procedures, and tracking mechanisms to alleviate the problems and improve safety and security.</p> <p>PRC § 42032.2(a)(1)(H). This requirement makes plain that Stewardship Plans should describe the processes used to address deviations from policies and</p>	<p>015-013d. CalRecycle acknowledges the commenter's concern and agrees that an edit to the proposed regulations is warranted. However, the department finds the following edit to be a more effective solution than the commenter's proposed edit:</p> <p>Proposed regulations section 18973.5(e): <u>(e) Corrective actions taken if the program operator discovered critical deviations from stewardship plan policies and procedures and a description of each critical deviation. that a service provider did not maintain compliance with all collection, transportation, and disposal standards, including, but not limited to, local, state, and federal laws and regulations and United States Drug Enforcement Administration regulations.</u></p> <p>Stewardship plan implementation relies on adherence to key policies and procedures in many areas. These policies and procedures may often take the form of contractual agreements between the program operator and service providers. It is essential for a program operator to conduct "corrective actions" if service providers deviate from stewardship program policies and procedures, and the commenter lists several possible actions. Thus, the department's proposed edit requires reporting corrective actions taken to address any "critical" deviation from the policies and procedures used to safely and securely collect, track, and properly manage covered drugs from collection through final disposal that is outlined in the stewardship plan.</p> <p>Editing the proposed regulations in this manner both: (1) addresses the commenter's concern of reporting noncompliance with laws and regulations versus noncompliance with stewardship plan policies and procedures, and (2) provides a program operator the flexibility to determine what "corrective actions" are taken depending on the circumstances and the type of deviation.</p>

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					<p>procedures, not deviations from compliance with certain applicable laws, regulations, and other legal requirements. SB 212 also requires Stewardship Plans to describe these processes for addressing "security problems," or critical -not minor -deviations from these policies and procedures. For unknown reasons, however, the Proposed Regulations muddle these requirements. Proposed Regulations §§ 18973.2(g)(10) and 18973.3(f)(6)(A)(v) appear to require that Stewardship Plans identify corrective actions for any non-compliance with certain legal standards, not Stewardship Program critical deviations from Program policies and procedures, diminishing what the statute emphasizes. Consistent with SB 212, Proposed Regulations §§ 18973.2(g)(10) and 18973.3(f)(6)(A)(v) should be revised to require that Stewardship Plans explain the processes that will be taken to address critical Authorized Collector, Home-Generated Sharps Consolidation Point, or service provider deviations from Stewardship Program policies and procedures.</p> <p>In addition to tracking SB 212, revising the Proposed Regulations to focus on deviations from Stewardship Program policies and procedures facilitates Stewardship Program implementation. Program Operators can describe how they evaluate, monitor, correct, and report on deviations from Stewardship Program policies and procedures. For example, Program Operators use incident management systems to identify, document, investigate, and analyze the causes for policy and procedure deviations. As appropriate, Program Operators then correct for these deviations through actions that include providing training or compliance aids, performing additional due diligence, changing service offerings, or, as warranted, amending contracts or terminating relationships.</p> <p>Evaluating, monitoring, collecting, and reporting on compliance with applicable laws, regulations, and other legal requirements is far more challenging. As discussed above in Section III.B.2., Authorized Collectors, Home-Generated Sharps Consolidation Points, and service providers are independent entities with independent compliance obligations and independent legal interpretations. Program Operators do not know how government agencies interpret an Authorized Collector, Home-Generated Sharps Consolidation Point, or service provider's compliance status. Such uncertainty presents serious risks for Program Operators obligated to provide annual reporting on corrective actions associated with certain service provider failures to maintain compliance. See Proposed Regulations §§ 18973.4(e), 18973.5(e). Making representations regarding service provider compliance in a publicly available annual report could potentially expose Program Operators to lawsuits, disrupting or interfering with Stewardship Program services and negatively affecting the convenience to the Ultimate User.</p> <p>For consistency with SB 212, and to facilitate Program Operator evaluation, monitoring, corrective actions, and reporting, the Department should revise the Proposed Regulations to require that Stewardship Plans identify processes for addressing critical Authorized Collector, Home-Generated</p>	<p>Further, regarding the commenter's statement that "these provisions effectively require program operators to make definitive conclusions regarding other entities' compliance", It is the program operator's responsibility, under the Statute (Public Resources Code sections 42032.2(d)(1)(D) and 42035.8), to maintain compliance with all applicable local, state, and federal laws and regulations. For the same reason, CalRecycle disagrees that the regulations should limit the corrective actions to home-generated sharps consolidation points or service providers.</p>

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					Sharps Consolidation Point, or service provider deviations from Stewardship Program policies and procedures. As revised, Proposed Regulations §§ 18973.2(g)(10) and 18973.3(f)(6)(A)(v) should require Plans to describe: Processes that address critical deviations from stewardship plan policies and procedures. What corrective actions will be taken if a program operator discovers an authorized collector or service provider is not maintaining compliance with all collection, transportation, and disposal standards related to the handling of covered drugs, including, but not limited to, United States Drug Enforcement Administration regulations.	
015-014a	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.2 (j)(1)	N	The Department Should Strike the Term "Maximize" from Proposed Regulations §§ 18973.2(j)(1) and 18973.3(i)(1) Regardless of how extensively a Program Operator promotes its Stewardship Program, more could always be done. Another advertisement, another sign, another social media post, and so on. Stewardship Program education and outreach is impossible to "maximize." Unfortunately, the Proposed Regulations require just that, providing that Stewardship Plans must describe how Stewardship Programs include "[a]ctivities to promote awareness and maximize ultimate user participation in the stewardship program." Proposed Regulations § 18973.2(j)(1); see also § 18973.3(i)(1) (same for Home-Generated Sharps Waste). There is no requirement to maximize Ultimate User participation in SB 212. To provide achievable requirements consistent with SB 212, the Department should revise Proposed Regulations § § 18973.2(j)(1) and 18973.3(i)(1) to strike the term "maximize."	015-014a. A change to the proposed regulatory text is not necessary. While CalRecycle acknowledges the practical constraints of an education and outreach program, the proposed stewardship plan should outline how the program operator plans to most effectively employ the limited funds allocated to education and outreach in the proposed budget. The term "maximize" is necessary to convey how funds should be spent and clarifies Public Resources Code section 42031.6(a).
015-014b	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.3 (i)(1)	N	The Department Should Strike the Term "Maximize" from Proposed Regulations §§ 18973.2(j)(1) and 18973.3(i)(1) Regardless of how extensively a Program Operator promotes its Stewardship Program, more could always be done. Another advertisement, another sign, another social media post, and so on. Stewardship Program education and outreach is impossible to "maximize." Unfortunately, the Proposed Regulations require just that, providing that Stewardship Plans must describe how Stewardship Programs include "[a]ctivities to promote awareness and maximize ultimate user participation in the stewardship program." Proposed Regulations § 18973.2(j)(1); see also § 18973.3(i)(1) (same for Home-Generated Sharps Waste). There is no requirement to maximize Ultimate User participation in SB 212. To provide achievable requirements consistent with SB 212, the Department should revise Proposed Regulations § § 18973.2(j)(1) and 18973.3(i)(1) to strike the term "maximize."	015-014b. A change to the proposed regulatory text is not necessary. While CalRecycle acknowledges the practical constraints of an education and outreach program, the proposed stewardship plan should outline how the program operator plans to most effectively employ the limited funds allocated to education and outreach in the proposed budget. The term "maximize" is necessary to convey how funds should be spent and clarifies Public Resources Code section 42031.6(a).
015-015a	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.2 (j)(1)	N	Proposed Regulations §§ 18973.2(j)(1) and 18973.3(i)(1) Should Require Program Operators to Promote Proper Covered Product Disposal The Departments should revise Proposed Regulations §§ 18973.2(j)(1) and 18973.3(i)(1) to focus Program Operator education and outreach activities on proper Covered Product collection and disposal. Currently, the Proposed Regulations require that Stewardship Programs include "[a]ctivities to promote	015-015a. A change to the proposed regulatory text is not necessary. Public Resources Code section 42031.6(a) requires a program operator to conduct a "comprehensive education and outreach program intended to promote participation in the stewardship program." Furthermore, subsection (b) of the same section states that "a program operator shall not, as part of the education and outreach program, promote the

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					awareness and maximize ultimate user participation in the stewardship program." Stewardship Program participation does not necessarily equate to Covered Product disposal, however. It is inevitable that many Ultimate Users will participate in a Stewardship Program by obtaining mail-back materials or sharps containers, but then never actually use those items. Rather than focus on Ultimate User participation in a Stewardship Program, Program Operators should promote proper Covered Product disposal consistent with the Stewardship Program's services. This focus on proper Covered Product disposal is consistent with SB 212. See PRC § 42031.6(a)(4) (requiring education and outreach programs to "[p]repare and provide additional outreach materials not specified in this section, as needed to promote the collection and proper management of covered drugs and home-generated sharps waste." For these reasons, Proposed Regulations §§ 18973.2(j)(1) and 18973.3(i)(1) should require Stewardship Programs to include "[a]ctivities to promote awareness and the collection and proper management of [covered drugs or home-generated sharps waste] maximize ultimate user participation in the stewardship program."	disposal of a covered product in a manner inconsistent with the services offered to ultimate users by the stewardship program." Promoting ultimate user participation in the stewardship program is exactly how a program operator can promote the proper collection and disposal of covered drugs and home-generated sharps waste. Separately, CalRecycle proposes the following edit to section 18973.2(j)(1) of the proposed regulatory text for clarity and consistency with section 42031.6(a)(2) of the Public Resources Code: (1) Any activities to promote awareness and maximize ultimate user participation in the stewardship program, <u>including, but not limited to, provision of educational and outreach materials for persons authorized to prescribe drugs, pharmacies, pharmacists, ultimate users, and others, as necessary.</u>
015-015b	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.3 (i)(1)	N	Proposed Regulations §§ 18973.2(j)(1) and 18973.3(i)(1) Should Require Program Operators to Promote Proper Covered Product Disposal The Departments should revise Proposed Regulations §§ 18973.2(j)(1) and 18973.3(i)(1) to focus Program Operator education and outreach activities on proper Covered Product collection and disposal. Currently, the Proposed Regulations require that Stewardship Programs include "[a]ctivities to promote awareness and maximize ultimate user participation in the stewardship program." Stewardship Program participation does not necessarily equate to Covered Product disposal, however. It is inevitable that many Ultimate Users will participate in a Stewardship Program by obtaining mail-back materials or sharps containers, but then never actually use those items. Rather than focus on Ultimate User participation in a Stewardship Program, Program Operators should promote proper Covered Product disposal consistent with the Stewardship Program's services. This focus on proper Covered Product disposal is consistent with SB 212. See PRC § 42031.6(a)(4) (requiring education and outreach programs to "[p]repare and provide additional outreach materials not specified in this section, as needed to promote the collection and proper management of covered drugs and home-generated sharps waste." For these reasons, Proposed Regulations §§ 18973.2(j)(1) and 18973.3(i)(1) should require Stewardship Programs to include "[a]ctivities to promote awareness and the collection and proper management of [covered drugs or home-generated sharps waste] maximize ultimate user participation in the stewardship program."	015-015b. A change to the proposed regulatory text is not necessary. Public Resources Code section 42031.6(a) requires a program operator to conduct a "comprehensive education and outreach program intended to promote participation in the stewardship program." Furthermore, subsection (b) of the same section states that "a program operator shall not, as part of the education and outreach program, promote the disposal of a covered product in a manner inconsistent with the services offered to ultimate users by the stewardship program." Promoting ultimate user participation in the stewardship program is exactly how a program operator can promote the proper collection and disposal of covered drugs and home-generated sharps waste.
015-016a	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.2 (j)(2)	N	Proposed Regulations §§ 18973.2(j)(2) and 18973.3(i)(2) Should Clarify the Locations at which Program Operators Must Provide Materials SB 212 requires that Program Operators "[p]rovide educational and outreach materials for persons authorized to prescribe drugs, pharmacies, pharmacists, ultimate users, and others, as	015-016a. A change to the proposed regulatory text is not necessary. Specifying which locations qualify as "other locations" or specifying that the locations be "physical" or "not exempt from the stewardship program where covered products are properly dispensed" would limit program operator flexibility in designing a comprehensive education and outreach program. Signage could be provided in a wide variety of locations, both

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					<p>necessary." PRC § 42031.6(a)(2) (emphasis added). The term "others" is ambiguous. The Proposed Regulations clarify that "others" are "locations," but still leave uncertainty regarding the scope of this. requirement. See Proposed Regulations § 18973 .2(j)(2) ("Materials to be utilized that are distributed in languages suited to local demographics. These materials shall include, but are not limited to, signage for hospitals, pharmacies, and other locations, as necessary."); see also § 18973.3(i)(2) (same for Home-Generated Sharps Waste). The Department should further clarify the meaning of these "other locations" through the Proposed Regulations to guide Program Operators and the public.</p> <p>Specifically, the Department should revise Proposed Regulations §§ 18973.2(j)(2) and 18973.3(i)(2) to clarify that "other locations" are physical locations not exempt from the Stewardship Program (e.g., needle exchange programs) where Covered Products are properly dispensed. By directing Program Operator materials to the physical locations where Ultimate Users receive Covered Products in compliance with all applicable laws, regulations, and other legal requirements, this revision would effectively promote Stewardship Program participation while providing Program Operators needed certainty. As revised, Proposed Regulations §§ 18973.2(j)(2) and 18973.3(i)(2) should read: "Materials to be utilized that are distributed in languages suited to local demographics. These materials shall include, but are not limited to, signage for hospitals, pharmacies, and other <u>physical</u> locations <u>not exempt from the stewardship program where covered products are properly dispensed</u>, as necessary."</p>	<p>online and physical, and the most effective location for a sign may be somewhere that does not dispense covered products, such as an assisted-living facility or a law enforcement office.</p> <p>Additionally, the term "others" as used in Public Resources Code section 42031.6(a)(2) is not necessarily equivalent to the term "other locations" used in section 18973.2(j)(2) of the proposed regulations. The "materials to be utilized" could be more than just signage (for example, pamphlets), and the "others" in statute could refer to other persons. The phrase "shall include, but are not limited to" in the proposed regulations adequately captures the breadth of possible materials that could be used in an education and outreach program.</p>
015-016b	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.3 (i)(2)	N	<p>Proposed Regulations §§ 18973.2(j)(2) and 18973.3(i)(2) Should Clarify the Locations at which Program Operators Must Provide Materials</p> <p>SB 212 requires that Program Operators "[p]rovide educational and outreach materials for persons authorized to prescribe drugs, pharmacies, pharmacists, ultimate users, and others, as necessary." PRC § 42031.6(a)(2) (emphasis added). The term "others" is ambiguous. The Proposed Regulations clarify that "others" are "locations," but still leave uncertainty regarding the scope of this. requirement. See Proposed Regulations § 18973 .2(j)(2) ("Materials to be utilized that are distributed in languages suited to local demographics. These materials shall include, but are not limited to, signage for hospitals, pharmacies, and other locations, as necessary."); see also § 18973.3(i)(2) (same for Home-Generated Sharps Waste). The Department should further clarify the meaning of these "other locations" through the Proposed Regulations to guide Program Operators and the public.</p> <p>Specifically, the Department should revise Proposed Regulations §§ 18973.2(j)(2) and 18973.3(i)(2) to clarify that "other locations" are physical locations not exempt from the Stewardship Program (e.g., needle exchange programs) where Covered Products are properly dispensed. By directing</p>	<p>015-016b. A change to the proposed regulatory text is not necessary. Specifying which locations qualify as "other locations" or specifying that the locations be "physical" and "not exempt from the stewardship program where covered products are properly dispensed" would limit program operator flexibility in designing a comprehensive education and outreach program. Signage could be provided in a wide variety of locations, both online and physical, and the most effective location for a sign may be somewhere that does not dispense covered products, such as an assisted-living facility or a law enforcement office.</p> <p>Additionally, the term "others" as used in Public Resources Code section 42031.6(a)(2) is not necessarily equivalent to the term "other locations" used in section 18973.2(j)(2) of the proposed regulations. The "materials to be utilized" could be more than just signage (for example, pamphlets), and the "others" in statute could refer to other persons. The phrase "shall include, but are not limited to" in the proposed regulations adequately captures the breadth of possible materials that could be used in an education and outreach program.</p>

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					Program Operator materials to the physical locations where Ultimate Users receive Covered Products in compliance with all applicable laws, regulations, and other legal requirements, this revision would effectively promote Stewardship Program participation while providing Program Operators needed certainty. As revised, Proposed Regulations §§ 18973.2(j)(2) and 18973.3(i)(2) should read: "Materials to be utilized that are distributed in languages suited to local demographics. These materials shall include, but are not limited to, signage for hospitals, pharmacies, and other <u>physical</u> locations <u>not exempt from the stewardship program where covered products are properly dispensed, as necessary.</u> "	
015-017a	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.2 (j)(3)	N	<p>Proposed Regulations § § 18973.2(j)(3)(E) and 18973.3(i)(3) Should Recognize Practical Constraints When Program Operators Maintain Third Party Information Online</p> <p>SB 212 requires that Program Operators establish websites publicizing Authorized Collector locations and promoting the Stewardship Program. See PRC § 42031.6(a)(3). In turn, the Proposed Regulations require that Program Operators describe how they will maintain these websites "to ensure all information is up to date and accurate." See Proposed Regulations §§ 18973.2(j)(3)(E), 18973.3(i)(3) (same for Home-Generated Sharps Waste). Program Operators can routinely update their websites to include the latest information regarding Authorized Collection Sites or Home-Generated Sharps Consolidation Points locations, telephone numbers, and days and hours of operation, among other required information. See id. These updates cannot be instantaneous, however. Program Operators depend on Authorized Collectors (or their own monitoring) to obtain this information. Even if a Program Operator diligently maintains its website for the public, a single Authorized Collector changing its hours of operation without providing prior notice would cause the Program Operator's website to have outdated information.</p> <p>To reflect the realities of maintaining a large and changing dataset, the Department should revise the Proposed Regulations to require that Program Operators describe how they will diligently maintain their websites, not how they will "ensure" websites are up to date and accurate. The revised Proposed Regulations §§ 18973.2(j)(3)(E) and 18973.3(i)(3) should require that Program Operators describe how they will establish "an internet website designed with functionality for mobile platforms and maintained to ensure all information is provide up to date and accurate information to the extent practicable." This revision would balance the public's need for accurate and current Stewardship Program information with practical information constraints.</p>	015-017a. A change to the proposed regulatory text is not necessary. Based on the commenter's suggested edits to the proposed regulatory text, CalRecycle believes the comment is referring to section 18973.2(j)(3), not 18973.2(j)(3)(E). While CalRecycle recognizes the practical constraints to providing information that is up to date, a program operator is responsible for maintaining its website within the scope of its program budget, and describing its website maintenance efforts in the proposed stewardship plan. Including the phrase "to the extent practicable" would only add unnecessary ambiguity. A website that contains accurate information is essential to effective program implementation, as this platform is likely the primary method for ultimate users to learn about available disposal options.
015-017b	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.3 (i)(3)	N	<p>Proposed Regulations § § 18973.2(j)(3)(E) and 18973.3(i)(3) Should Recognize Practical Constraints When Program Operators Maintain Third Party Information Online</p> <p>SB 212 requires that Program Operators establish websites publicizing Authorized Collector locations and promoting the Stewardship Program. See PRC § 42031.6(a)(3). In turn, the Proposed Regulations require that Program Operators describe how they will maintain these websites "to ensure all</p>	015-017b. A change to the proposed regulatory text is not necessary. While CalRecycle recognizes the practical constraints to providing information that is up to date, a program operator is responsible for maintaining its website within the scope of its program budget, and describing its website maintenance efforts in the proposed stewardship plan. Including the phrase "to the extent practicable" would only add unnecessary ambiguity. A website that contains accurate information is

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					<p>information is up to date and accurate." See Proposed Regulations §§ 18973.2(j)(3)(E), 18973.3(i)(3) (same for Home-Generated Sharps Waste). Program Operators can routinely update their websites to include the latest information regarding Authorized Collection Sites or Home-Generated Sharps Consolidation Points locations, telephone numbers, and days and hours of operation, among other required information. See id. These updates cannot be instantaneous, however. Program Operators depend on Authorized Collectors (or their own monitoring) to obtain this information. Even if a Program Operator diligently maintains its website for the public, a single Authorized Collector changing its hours of operation without providing prior notice would cause the Program Operator's website to have outdated information.</p> <p>To reflect the realities of maintaining a large and changing dataset, the Department should revise the Proposed Regulations to require that Program Operators describe how they will diligently maintain their websites, not how they will "ensure" websites are up to date and accurate. The revised Proposed Regulations §§ 18973.2(j)(3)(E) and 18973.3(i)(3) should require that Program Operators describe how they will establish "an internet website designed with functionality for mobile platforms and maintained to ensure all information is provide up to date and accurate information to the extent practicable." This revision would balance the public's need for accurate and current Stewardship Program information with practical information constraints.</p>	essential to effective program implementation, as this platform is likely the primary method for ultimate users to learn about available disposal options.
015-018a	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.2(j)(3)(E)	N	<p>The Department Should Clarify that Proposed Regulations §§ 18973.2(j)(3)(E) and 18973.3(i)(3)(B) Do Not Regulate Covered Product Directions for Use</p> <p>The Proposed Regulations require that Program Operator internet websites include "instructions for safe handling" of Covered Products. See Proposed Regulations § § 18973.2(j)(3)(E), 18973.3(i)(3)(B). These requirements appear to use the term "safe handling" to mean safe storage within the home. However, to avoid ambiguity, the Department should revise the Proposed Regulations to refer expressly to "safe storage" instead of "safe handling." This clarification will eliminate any suggestion that the Proposed Regulations require Program Operators to instruct the public on directions for the use of Drugs or Sharps – directions subject to federal regulation. See 21 CFR Parts 201, 801.</p>	015-018a. A change to the proposed regulatory text is not necessary. The term "handling" in these instances could refer to more actions than just the storage of covered products (for example, transportation). CalRecycle acknowledges that specific directions for product use are outside the scope of a stewardship program's education and outreach activities.
015-018b	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.3(i)(3)(B)	N	<p>The Department Should Clarify that Proposed Regulations §§ 18973.2(j)(3)(E) and 18973.3(i)(3)(B) Do Not Regulate Covered Product Directions for Use</p> <p>The Proposed Regulations require that Program Operator internet websites include "instructions for safe handling" of Covered Products. See Proposed Regulations § § 18973.2(j)(3)(E), 18973.3(i)(3)(B). These requirements appear to use the term "safe handling" to mean safe storage within the home. However, to avoid ambiguity, the Department should revise the Proposed Regulations to refer expressly to "safe storage" instead of "safe handling." This clarification will eliminate any suggestion that the Proposed Regulations require Program Operators to instruct the public on directions for the use of Drugs or Sharps – directions subject to federal regulation. See 21 CFR Parts 201, 801.</p>	015-018b. A change to the proposed regulatory text is not necessary. The term "handling" in these instances could refer to more actions than just the storage of covered products (for example, transportation). CalRecycle acknowledges that specific directions for product use are outside the scope of a stewardship program's education and outreach activities.

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015-019A1	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.2 (k)	Y	<p>The Department Should Strike the Phrase "Most Effectively" from Proposed Regulations §§ 18973.2(k) and 18973.3(j)</p> <p>The Proposed Regulations set an impossible standard by requiring Program Operators to describe how they will "make a good faith effort to work with the other stewardship program(s) in order to most effectively achieve the requirements of the statute and regulations " See Proposed Regulations §§ 18973.2(k), 18973.3(j). No matter how extensively a Program Operator works with other Stewardship Programs, it could always do more. Like the term "maximize" as discussed above, the phrase "most effectively" is an aspirational standard that Stewardship Programs can never satisfy.</p>	<p>015-019A1. In a similar manner to the term "maximize" in comment 015-014a, the term "most effectively" is simply meant to convey that the department wishes to see the program operator's best proposal for coordination with the other stewardship program(s), within the practical confines of the proposed budget.</p> <p>However, CalRecycle proposes the following edits to section 18973.2(k) of the proposed regulatory text:</p> <p><u>(k) Coordination Efforts. Description of how the program operator will make a good faith effort to work with the other stewardship program(s) in order to most effectively achieve the requirements of statute and regulations, coordinate with other program operators to avoid conflict, duplication, and confusion to the public and all program participants in the event that multiple stewardship programs for covered drugs are in operation concurrently or new stewardship programs begin operating.</u></p> <p>The department has removed the phrase "good faith effort" from section 18973.2(k) of the proposed regulatory text, while leaving the language that requires a description of how a program operator will work with other program operators in the event that multiple stewardship programs are in operation concurrently. Coordination efforts will be evaluated for compliance with the statute and regulations, and thus the department prefers to provide greater specificity for this requirement by listing the types of implementation issues that the description should address, rather than relying on the term "good faith effort," which is ambiguous in this context. Furthermore, these proposed edits clarify that the required description should account for not only existing stewardship programs, but also for the possibility of new stewardship programs arising in the future.</p>
015-019A2	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.3 (j)	Y	<p>The Department Should Strike the Phrase "Most Effectively" from Proposed Regulations §§ 18973.2(k) and 18973.3(j)</p> <p>The Proposed Regulations set an impossible standard by requiring Program Operators to describe how they will "make a good faith effort to work with the other stewardship program(s) in order to most effectively achieve the requirements of the statute and regulations " See Proposed Regulations §§ 18973.2(k), 18973.3(j). No matter how extensively a Program Operator works with other Stewardship Programs, it could always do more. Like the term "maximize" as discussed above, the phrase "most effectively" is an aspirational standard that Stewardship Programs can never satisfy.</p>	<p>015-019A2. In a similar manner to the term "maximize" in comment 015-014b, the term "most effectively" is simply meant to convey that the department wishes to see the program operator's best proposal for coordination with the other stewardship program(s), within the practical confines of the proposed budget.</p> <p>The phrase "good faith effort" has been removed from the proposed regulatory text section 18973.3(j) while leaving the language that requires a description of how a program operator will work with other program operators in the event that multiple stewardship programs are in operation concurrently. Coordination efforts will be evaluated for compliance with the statute and regulations, and thus the department prefers to provide greater specificity for this requirement by listing the types of implementation issues that the description should address, rather than relying on the term "good faith effort," which is ambiguous in this context. Furthermore, these proposed edits clarify that the required description should account for not only existing stewardship programs,</p>

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						<p>but also for the possibility of new stewardship programs arising in the future. The proposed regulatory text section 18973.3 is revised as follows:</p> <p><u>(j) Coordination Efforts. Description of how the program operator will make a good faith effort to work with the other stewardship program(s) in order to most effectively achieve the requirements of the statute and regulations, coordinate with other program operators to avoid conflict, duplication, and confusion to the public and all program participants in the event that multiple stewardship programs for home-generated sharps waste are in operation concurrently or new stewardship programs begin operating.</u></p>
015-019B1	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.2 (k)	Y	<p>Additionally, nothing in SB 212 requires Program Operators to meet this standard. To make these Stewardship Program coordination requirements achievable and consistent with SB 212, the Department should strike the phrase "most effectively" from Proposed Regulations §§ 18973.2(k), 18973.3(j) and the corresponding annual reporting provisions (Proposed Regulations §§ 18973.4(n) and 18973.5(o)).</p>	<p>015-019B1. While SB 212 does not explicitly address the potential issues that may arise from multiple stewardship programs for the same type of covered products operating concurrently, achievement of certain statutory requirements would likely necessitate coordination in many instances, such as, but not limited to, the convenience standards listed in Public Resources Code sections 42032.2(a)(1)(F)(i)-(iii) and the requirement in Public Resources Code section 42031.6(a) that education and outreach programs be "comprehensive." The requirements in the proposed regulations surrounding coordination efforts are essential for the department to understand what steps will be taken (or were taken) to address these issues.</p> <p>However, the department proposes the following edits to section 18973.2(k) of the proposed regulatory text:</p> <p><u>(k) Coordination Efforts. Description of how the program operator will make a good faith effort to work with the other stewardship program(s) in order to most effectively achieve the requirements of statute and regulations, coordinate with other program operators to avoid conflict, duplication, and confusion to the public and all program participants in the event that multiple stewardship programs for covered drugs are in operation concurrently or new stewardship programs begin operating.</u></p> <p>The department has removed the phrase "most effectively achieve" from section 18973.2(k) of the proposed regulatory text, which addresses the commenter's concern, while leaving the language that requires a description of how a program operator will work with other program operators in the event that multiple stewardship programs are in operation concurrently. Removing the phrase "most effectively achieve" also avoids ambiguity. Coordination efforts will be evaluated for compliance with the statute and regulations, and thus the department</p>

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						prefers to provide greater specificity for this requirement by listing the types of implementation issues that the description should address.
015-019B2	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.3 (j)	Y	Additionally, nothing in SB 212 requires Program Operators to meet this standard. To make these Stewardship Program coordination requirements achievable and consistent with SB 212, the Department should strike the phrase "most effectively" from Proposed Regulations §§ 18973.2(k), 18973.3(j) and the corresponding annual reporting provisions (Proposed Regulations §§ 18973.4(n) and 18973.5(o)).	<p>015-019B2. While SB 212 does not explicitly address the potential issues that may arise from multiple stewardship programs for the same type of covered products operating concurrently, achievement of certain statutory requirements would likely necessitate coordination in many instances, such as, but not limited to, the convenience standards listed in Public Resources Code sections 42032.2(a)(1)(F)(i)-(iii) and the requirement in Public Resources Code section 42031.6(a) that education and outreach programs be "comprehensive." The requirements in the proposed regulations surrounding coordination efforts are essential for the department to understand what steps will be taken (or were taken) to address these issues. However, the department proposes the following edits to section 18973.3(j) of the proposed regulatory text:</p> <p><u>(j) Coordination Efforts. Description of how the program operator will make a good faith effort to work with the other stewardship program(s) in order to most effectively achieve the requirements of statute and regulations, coordinate with other program operators to avoid conflict, duplication, and confusion to the public and all program participants in the event that multiple stewardship programs for covered drugs are in operation concurrently or new stewardship programs begin operating.</u></p> <p>The department has removed the phrase "most effectively achieve" from section 18973.3(j) of the proposed regulatory text, which addresses the commenter's concern, while leaving the language that requires a description of how a program operator will work with other program operators in the event that multiple stewardship programs are in operation concurrently. Removing the phrase "most effectively achieve" also avoids ambiguity. Coordination efforts will be evaluated for compliance with the statute and regulations, and thus the department prefers to provide greater specificity for this requirement by listing the types of implementation issues that the description should address, rather than relying on the term "good faith effort," which is ambiguous in this context. Furthermore, these proposed edits clarify that the required description should account for not only existing stewardship programs, but also for the possibility of new stewardship programs arising in the future.</p>
015-019B3	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.4 (n)	Y	Additionally, nothing in SB 212 requires Program Operators to meet this standard. To make these Stewardship Program coordination requirements achievable and consistent with SB 212, the Department should strike the phrase "most effectively" from Proposed Regulations §§ 18973.2(k), 18973.3(j) and the corresponding annual reporting provisions (Proposed Regulations §§ 18973.4(n) and 18973.5(o)).	015-019B3. CalRecycle agrees to remove the phrase "most effectively" from section 18973.4(n) of the proposed regulatory text to avoid unnecessary ambiguity in this context. The department has made revisions to the text to clarify the types of conditions the department seeks to avoid such as conflict, duplication, and confusion to the public and program participants by requiring a description of coordination efforts in the event that multiple stewardship programs are in operation

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						<p>concurrently. Coordination efforts will be evaluated for compliance with the statute and regulations, and thus the department prefers to provide greater specificity for this requirement by listing the types of implementation issues that the description should address.</p> <p>While SB 212 does not explicitly address the potential issues that may arise from multiple stewardship programs for the same type of covered products operating concurrently, achievement of certain statutory requirements would likely necessitate coordination in many instances, such as, but not limited to, the convenience standards listed in Public Resources Code sections 42032.2(a)(1)(F)(i)-(iii) and the requirement in Public Resources Code section 42031.6(a) that education and outreach programs be “comprehensive.” The requirements in the proposed regulations surrounding coordination efforts are essential for the department to understand what steps were taken to address these issues.</p> <p>The following edits are made to section 18973.4(n) of the proposed regulatory text:</p> <p><u>(n) Coordination Efforts. Description of how the program operator coordinated with other program operators to avoid conflict, duplication, and confusion to the public and all program participants in the event that multiple stewardship programs for covered drugs are in operation concurrently or new stewardship programs begin operating. made a good faith effort to work with any other stewardship program(s) in order to most effectively achieve the requirements of the statute and regulations, if applicable.</u></p>
015-019B4	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.5 (o)	Y	<p>Additionally, nothing in SB 212 requires Program Operators to meet this standard. To make these Stewardship Program coordination requirements achievable and consistent with SB 212, the Department should strike the phrase "most effectively" from Proposed Regulations §§ 18973.2(k), 18973.3(j) and the corresponding annual reporting provisions (Proposed Regulations §§ 18973.4(n) and 18973.5(o)).</p>	<p>015-019B4. CalRecycle agrees to remove the phrase “most effectively” from section 18973.5(o) of the proposed regulatory text to avoid unnecessary ambiguity in this context. The department has made revisions to the text to clarify the types of conditions the department seeks to avoid such as conflict, duplication, and confusion to the public and program participants by requiring a description of coordination efforts in the event that multiple stewardship programs are in operation concurrently. Coordination efforts will be evaluated for compliance with the statute and regulations, and thus the department prefers to provide greater specificity for this requirement by listing the types of implementation issues that the description should address.</p> <p>While SB 212 does not explicitly address the potential issues that may arise from multiple stewardship programs for the same type of covered products operating concurrently, achievement of certain statutory requirements would likely necessitate coordination in many instances, such as, but not limited to, the convenience standards listed in Public</p>

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						<p>Resources Code sections 42032.2(a)(1)(F)(i)-(iii) and the requirement in Public Resources Code section 42031.6(a) that education and outreach programs be “comprehensive.” The requirements in the proposed regulations surrounding coordination efforts are essential for the department to understand what steps were taken to address these issues.</p> <p>The following edits are made to section 18973.5(o) of the proposed regulatory text:</p> <p><u>(o) Coordination Efforts. Description of how the program operator coordinated with other program operators to avoid conflict, duplication, and confusion to the public and all program participants in the event that multiple stewardship programs for covered drugs are in operation concurrently or new stewardship programs begin operating. made a good faith effort to work with any other stewardship program(s) in order to most effectively achieve the requirements of the statute and regulations, if applicable.</u></p>
015-020a	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.2 (m)	N	<p>Market Competition Compels Privately Funded Stewardship Programs to Keep Vendor Selection Procedures Confidential (Proposed Regulations §§ 18973.2(m) and 18973.3(l))</p> <p>As described in Section IV.A., Covered-Entity funded Stewardship Programs receive no public funding and must use standard commercial practices to provide effective services. These practices include keeping vendor selection procedures confidential. Consistent with the private nature of Stewardship Program funding, the Department should strike Proposed Regulations §§ 18973.2(m) and 18973.3(l), which require that Stewardship Plans describe the "[p]rocess for selecting service providers, including a description of any competitive procedure[s] used, as applicable."</p> <p>Nothing in SB 212 requires a description of vendor selection procedures in Stewardship Plans.</p> <p>Requirements like these may be appropriate when entities receive public funding, but have adverse effects for privately-funded Stewardship Programs. Disclosing vendor selection procedures would reveal Program Operator priorities and strategies, information that potential Stewardship Program vendors could use to undermine competitive markets for vendor services. Striking Proposed Regulations §§ 18973.2(m) and 18973.3(l) would avoid these anticompetitive effects. Moreover, because Covered Entities fund Stewardship Programs, not the public, striking these requirements would not impair a public interest in understanding Stewardship Organization commercial decisions.</p>	<p>015-020a. A change to the proposed regulatory text is not necessary. Typically, stewardship plans are public documents and are posted on the Department's website so that the public is aware of the programs that the Department is approving. If certain vendor selection procedures contain proprietary or confidential information, those portions of the plan may be redacted from what is publicly made available, but they are potentially subject to a Public Records Act request. Consistent with Public Resources Code section 40062 and Title 14, Division 7, Chapter 1 of the California Code of Regulations under Article 4, Public Records (Section 17041 et seq.), when a public records act request is made, there is a process for determining if the claimed confidential records are in fact confidential. This process involves notifying the entity claiming confidentiality for them to provide an explanation of the basis for that claim. The requirement in these regulations is designed to streamline that process and potentially allow a faster determination. If the initial explanation is sufficient, no further action would be needed from the covered entity to maintain confidentiality. If the initial explanation is not sufficient to verify the claim of confidentiality, CalRecycle would provide a program operator notice of a public records act request pursuant to Title 14, Division 7, Chapter 1 of the California Code of Regulations, Section 17046 in order to provide additional explanation. The information required to be submitted under this law is in no way automatically confidential without justification, just because it is labelled as such.</p> <p>As discussed in the Initial Statement of Reasons, sections 18973.2(m) and 18973.3(l) of the proposed regulations are necessary “to enable the</p>

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						<p>department to determine if a program operator has demonstrated that costs and funding necessary to implement and operate the stewardship program will be managed in a prudent and responsible manner pursuant to subsection (c)(2) of section 42033.2 of the Public Resources Code.”</p> <p>There is a significant public interest in the department being able to evaluate whether stewardship programs are being run prudently and responsibly (which is required by Public Resources Code, Section 42033.2(c)(2)). This public interest far outweighs the minimal burden of complying with this requirement.</p>
015-020b	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.3 (l)	N	<p>Market Competition Compels Privately Funded Stewardship Programs to Keep Vendor Selection Procedures Confidential (Proposed Regulations §§ 18973.2(m) and 18973.3(l))</p> <p>As described in Section IV.A., Covered-Entity funded Stewardship Programs receive no public funding and must use standard commercial practices to provide effective services. These practices include keeping vendor selection procedures confidential. Consistent with the private nature of Stewardship Program funding, the Department should strike Proposed Regulations §§ 18973.2(m) and 18973.3(l), which require that Stewardship Plans describe the "[p]rocess for selecting service providers, including a description of any competitive procedure[s] used, as applicable."</p> <p>Nothing in SB 212 requires a description of vendor selection procedures in Stewardship Plans.</p> <p>Requirements like these may be appropriate when entities receive public funding, but have adverse effects for privately-funded Stewardship Programs. Disclosing vendor selection procedures would reveal Program Operator priorities and strategies, information that potential Stewardship Program vendors could use to undermine competitive markets for vendor services. Striking Proposed Regulations §§ 18973.2(m) and 18973.3(l) would avoid these anticompetitive effects. Moreover, because Covered Entities fund Stewardship Programs, not the public, striking these requirements would not impair a public interest in understanding Stewardship Organization commercial decisions.</p>	<p>015-020b. A change to the proposed regulatory text is not necessary. Typically, stewardship plans are public documents and are posted on the Department’s website so that the public is aware of the programs that the Department is approving. If certain vendor selection procedures contain proprietary or confidential information, those portions of the plan may be redacted from what is publicly made available, but they are potentially subject to a Public Records Act request. Consistent with Public Resources Code section 40062 and Title 14, Division 7, Chapter 1 of the California Code of Regulations under Article 4, Public Records (Section 17041 et seq.), when a public records act request is made, there is a process for determining if the claimed confidential records are in fact confidential. This process involves notifying the entity claiming confidentiality for them to provide an explanation of the basis for that claim. The requirement in these regulations is designed to streamline that process and potentially allow a faster determination. If the initial explanation is sufficient, no further action would be needed from the covered entity to maintain confidentiality. If the initial explanation is not sufficient to verify the claim of confidentiality, CalRecycle would provide a program operator notice of a public records act request pursuant to Title 14, Division 7, Chapter 1 of the California Code of Regulations, Section 17046 in order to provide additional explanation. The information required to be submitted under this law is in no way automatically confidential without justification, just because it is labelled as such.</p> <p>As discussed in the Initial Statement of Reasons, sections 18973.2(m) and 18973.3(l) of the proposed regulations are necessary “to enable the department to determine if a program operator has demonstrated that costs and funding necessary to implement and operate the stewardship program will be managed in a prudent and responsible manner pursuant to subsection (c)(2) of section 42033.2 of the Public Resources Code.”</p> <p>There is a significant public interest in the department being able to evaluate whether stewardship programs are being run prudently and responsibly (which is required by Public Resources Code, Section 42033.2(c)(2)). This public interest far outweighs the minimal burden of complying with this requirement.</p>

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015-021	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.3 (f)(8)	Y	<p>Proposed Regulations § 18973.3(f)(8) Should Allow Program Operators to Estimate Disposal Quantities When Weighing Covered Products is Impractical</p> <p>Under the Proposed Regulations, Stewardship Programs appropriately have the flexibility to implement supplemental collection methods in addition to a mail-back program. Stewardship Plans offering such supplemental collection methods must describe, among other things, "[m]etrics that will be used to measure the weight of home-generated sharps waste collected through supplemental collection method(s), if applicable." Proposed Regulations § 18973.3(f)(8). The Department should revise this standard to provide Program Operators flexibility to implement collection methods that can only provide estimated weights of Home-Generated Sharps Waste disposed of. For example, Program Operators may consider offering rebate programs for Ultimate Users that independently purchase sharps mail-back materials. Although the Stewardship Program would cover disposal costs through the rebate, the Stewardship Program would not have custody over the Ultimate Users' mail-back materials and, thus, could only provide an estimated weight of Home-Generated Sharps Waste disposed of through the rebate program. Maintaining requirements to weigh collected Home-Generated Sharps Waste in all cases could discourage collection methods that may prove convenient for Ultimate Users, like rebate programs. The Department should revise the Proposed Regulations to accommodate collection methods that can only provide estimated weights of Home-Generated Sharps Waste disposed of. A revised Proposed Regulations § 18973.3(f)(8) should read: "[m]etrics that will be used to measure or estimate the weight of home-generated sharps waste collected through supplemental collection method(s), if applicable."</p>	<p>015-021. CalRecycle acknowledges the commenter's concern, and proposes the following edit to section 18973.3(f)(7) of the proposed regulatory text, noting that section 18973.3(f)(8) has been renumbered to section 18973.3(f)(7) due to changes elsewhere in the text:</p> <p>(7) Metrics that will be used to measure the amount-weight of home-generated sharps waste collected through supplemental collection method(s), if applicable.</p> <p>The above change recognizes that actual numbers are preferable to estimations wherever possible, but that the wide variety of potential supplemental collection methods warrants additional flexibility in reporting metrics.</p>
015-022	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.3 (g)(2)(A)	N	<p>Program Operator Timelines to Reimburse Local Agencies Under Proposed Regulations § 18973.3(g)(2)(A) Should Begin Upon Receipt of an Accurate Invoice</p> <p>SB 212 compels Stewardship Programs to reimburse local agencies for certain home-generated sharps waste disposal costs upon request, unless the Program Operator otherwise provides for the removal of such waste. See PRC § 42032.2(d)(1)(F)(ii). Under the Proposed Regulations, "[a] program operator that selects to resolve a request through reimbursement to a local agency shall issue payment within 45 days of the local agency providing an invoice." Proposed Regulations § 18973.3(g)(2)(A). Generally, 45 days is a reasonable timeline for Program Operators to process a local agency's request. However, from time to time local agency invoices are likely to contain errors or inaccuracies. In such cases, Program Operators may need more than 45 days to discuss the errors or inaccuracies with local agencies, receive a revised invoice, and process that revised invoice. Accordingly, the Department should revise the Proposed Regulations to start the 45 day timeline for processing local agency invoices upon the Program Operator's receipt of an accurate invoice. Revised Proposed Regulations § 18973.3(g)(2)(A) should read: "[a] program operator that selects to resolve a request through reimbursement to a local agency shall issue payment within 45</p>	<p>015-022. A change to the proposed regulatory text is not necessary. CalRecycle declines the proposed edit as the department does not seek to mediate disputes over whether an invoice is "accurate," and because such an ambiguous standard could theoretically allow a program operator to indefinitely delay reimbursement on the grounds of invoice "inaccuracy."</p> <p>Any instances where a program operator delays reimbursement or denies a local agency request should be described in the annual report per section 18973.5(p)(4) of the proposed regulatory text.</p>

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					<p>days of the Program Operator's receipt of an accurate local agency local agency providing an invoice. Revising the Proposed Regulations to require start reimbursement timelines on a Program Operator's receipt of an accurate invoice is consistent with SB 212, which requires that local agencies to submit declarations under penalty of perjury attesting to invoice contents. See PRC § 42032.2(d)(1)(F)(ii)(III); see also PRC § 42033.5 (requiring local agencies seeking reimbursement to provide Program Operators information about Home-Generated Sharps Waste upon request).</p>	
015-023A	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.6 (a)-(d)	Y	<p>The Scope of information and Level of Detail Sought in the Budgets (at Proposed Regulations § 18973.6(a)-(d)) Is Exceptionally Extensive and Unreasonably Burdensome</p> <p>As currently written, Proposed Regulations § 18973.6 requires Program Operators to submit initial and annual budgets to the Department with "at a minimum, the following information":</p> <ul style="list-style-type: none"> • "separate line items" for nine (9) subcategories of anticipated costs including: capital costs; collection of covered products; transportation of covered products; processing of covered products; disposal of covered products; administrative costs; education and outreach; costs related to grants, loans, sponsorships, or other incentives as part of program implementation; and reserve level; • "narrative description[s]" of the "types of activities" associated with each of the 9 subcategory of anticipated costs listed above; • A "recommended funding level necessary to implement the stewardship program"; • "actual expenses incurred" in the prior year; and • an independent financial audit of the Stewardship Program, that is conducted by a certified public accountant and complies with all criteria contained in Proposed Regulations § 189736(e)(1)-(5), including conducting the annual audit in accordance with not only generally accepted auditing standards, but also Generally Accepted Government Auditing Standards. <p>MED-Project believes that the above information is unreasonably burdensome and unjustifiably extensive in scope and level of detail sought, and in some cases infeasible, such that it will hinder Stewardship Program effectiveness and impose unnecessary burdens and costs on Program Operators on an annual basis. For instance, as noted in public comments previously submitted during the informal rulemaking process by both MED-Project and Stericycle, experienced parties in this space, costs associated with collection, transportation, processing and disposal services provided by vendors in this highly regulated and competitive industry are bundled for proprietary, confidential and/or trade secret-based reasons. See, Stericycle Letter Re Proposed Regulations -Pharmaceutical and Sharps Waste Stewardship Program, July, 1 2019; MED-Project LLC Comments Regarding CalRecycle's Informal Draft Regulatory Text Implementing California SB 212, July 1, 2019 at</p>	<p>015-023A. CalRecycle has considered the commenter's recommendation and has modified the categories listed in section 18973.6(b).</p> <p>Due to insertion of a new subsection 18973.6(a), the subsection has been changed from 18973.6(a) to 18973.6(b).</p> <p>CalRecycle agrees that consolidation of collection, transportation, processing, and disposal costs into one budget category is appropriate for this program, and has separated the reserve level information requirement, but does not agree to eliminate the requirement for the remaining categories.</p> <p>The level of detail required in section 18973.6 is necessary for the department's compliance review of an initial and annual budget. For example, an important aspect to evaluate implementation of a "comprehensive" education and outreach program is to understand the level of funding allocated to that budget category. If funding is over-allocated to certain cost categories and under-allocated to budget categories where compliance is not being met, this could potentially indicate where resources should be focused or increased to best provide services to ultimate users.</p> <p>Public Resources Code section 42033.2(c)(2) requires program budgets to include "anticipated costs and the recommended funding level necessary to implement the stewardship program, including, but not limited to, costs to cover the stewardship plan's budgeted costs and to operate the stewardship program over a multiyear period in a prudent and responsible manner." The language in statute does not specify that these costs are to be aggregated, and aggregated costs would prevent the department from being able to evaluate whether the budget is sufficient to "operate the stewardship program over a multiyear period in a prudent and responsible manner." The proposed regulations clarify which specific costs and funding mechanisms are necessary for the department to be able to make this determination.</p> <p>To the extent that an annual report may contain proprietary or confidential information, those portions of the report may be redacted</p>

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					p. 25-26. Therefore, Program Operators like MED-Project do not have the level of specificity sought by the regulations and thus, would be unable to pass this information along to the Department as desired under the current draft Proposed Regulations.	from what is publicly made available, but they are potentially subject to a Public Records Act request. Consistent with Public Resources Code section 40062 and Title 14, Division 7, Chapter 1 of the California Code of Regulations under Article 4, Public Records (Section 17041 et seq.), when a public records act request is made, there is a process for determining if the claimed confidential records are in fact confidential. This process involves notifying the entity claiming confidentiality for them to provide an explanation of the basis for that claim. The requirement in these regulations is designed to streamline that process and potentially allow a faster determination. If the initial explanation is sufficient, no further action would be needed from the covered entity to maintain confidentiality. If the initial explanation is not sufficient to verify the claim of confidentiality, CalRecycle would provide a program operator notice of a public records act request pursuant to Title 14, Division 7, Chapter 1 of the California Code of Regulations, Section 17046 in order to provide additional explanation. The information required to be submitted under this law is in no way automatically confidential without justification, just because it is labelled as such.
015-023B	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.6 (a)-(d)	N	MED-Project understands that the level of detail sought by the Department in the proposed regulations may align with what has been adopted in Department regulations for other product stewardship programs overseen by the Department (e.g., mattresses, carpet, etc.); however, there is one critical distinction that is relevant here: unlike the other stewardship programs established in the state, the Pharmaceutical and Sharps Waste Stewardship Program is not publicly funded. The Pharmaceutical and Sharps Waste Stewardship Program is wholly funded by private, industry funds paid by covered entities, and therefore, there are no taxpayer/customer dollars at play such that every dollar and cent spent warrants careful scrutiny by the Department, transparency to the public, etc. This distinction is highlighted throughout SB 212's legislative history, and those materials suggest that the Legislature did not intend for the same level of detail or scrutiny regarding costs to be imposed on Program Operators for this very reason. The legislative history of SB 212 indicated that an itemization of costs was not intended to be required, and that a general description of how the proposed funding would cover the Plan's anticipated costs would suffice. See e.g., Cal. Assembly Committee On Environmental Safety And Toxic Materials SB 212 Committee Report, June 27, 2018, available at: https://leginfo.legislature.ca.gov/faces/billAnalysisClient.xhtml?bill id=201720 80SB2 2# (last visited Jan. 29, 2020). These legislative history materials are consistent with the plain language of SB 212, which generally only requires the following two (2) items for the initial Stewardship Program budget: "total anticipated revenues and costs of implementing the stewardship program" and "total recommended funding level sufficient to cover the plan's budgeted costs and to operate the stewardship program over a multiyear period," and the following two (2) items for annual budgets thereafter: an independent financial audit of the Stewardship Program, and anticipated costs and the recommended funding	<p>015-023B. A change to the proposed regulatory text is not necessary. While the Pharmaceutical and Sharps Waste Stewardship Program is not publicly funded, there still is a significant public interest in its financial integrity.</p> <p>The commenter refers to a Senate Bill Committee Analysis, which summarizes the requirements of the contents of an annual program budget but does not go into specifics. The plain words of Public Resources Code section 42033.2(c), which are operative, are: that an annual program budget shall include, "at a minimum..." the information required in subdivisions (1) and (2). Moreover, under subdivision (2), the costs that are listed are not the only ones the department can require the program operator to provide: they are part of what the department can require. Section 42033.2(c)(2) of the Public Resources Code requires the program operator to submit "[a]nticipated costs and the recommended funding level necessary to implement the stewardship program, including but not limited to...". The commenter asserts that only the specifically listed costs in subdivision (2) are required, which is not the case. The statutory language does not rule out some level of itemization of budget categories.</p> <p>Based on stakeholder feedback, CalRecycle has modified the nine categories in the proposed regulatory text to combine the costs of collection, transportation, processing, and disposal, and separated the reserve level information requirement, but will not eliminate other budget categories.</p>

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					level necessary to implement the Stewardship Program "in a prudent and responsible manner." PRC §§ 42033(a)-(b) & 42033.2(c)(1)-(2). Additionally, and significantly from a statutory interpretation perspective, although the legislature expressly authorized the Department to request additional information from that which is enumerated in SB 212 for the annual reports, provided the additional information is "reasonably require[d]", no such authorization was granted for purposes of budget submissions. Compare PRC § 42033.2(b)(9), with §§ 42033 & 42033.2(c).	CalRecycle finds the proposed budget categories to strike the appropriate balance between private industry discretion and effective program oversight.
015-023C	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.6 (a)	Y	<p>Based on the foregoing, Proposed Regulations § 18973.6 should be revised as follows:</p> <p>Proposed Regulations § 18973.6(a) should be amended to consolidate the 9 "line item" anticipated cost categories into no more than the following three (3), which represent the core aspects of a Stewardship Program: (1) Stewardship Program collection, transportation, processing and disposal costs; (2) administrative costs; and (3) education and outreach costs. All other itemized costs, including a "reserve level" should be stricken, as it is contrary to the plain language and intent of SB 212, unduly burdensome, and unjustified from a policy perspective for the reasons discussed above. Thus, Proposed Regulations § 18973.6(a), as amended, should read "Anticipated costs to implement the stewardship program, including: (1) Collection, Transportation, Processing and Disposal Costs (2) Administrative Costs (3) Education and outreach."</p>	<p>015-023C. CalRecycle has considered the commenter's recommendation and has modified the categories listed in section 18973.6(b).</p> <p>Due to insertion of a new subsection 18973.6(a), the subsection has been changed from 18973.6(a) to 18973.6(b).</p> <p>CalRecycle agrees that consolidation of collection, transportation, and disposal into one budget category is appropriate for a budget for this program. This category will also capture processing costs. CalRecycle has consolidated the budget categories in section 18973.6(b) of the proposed regulatory text.</p> <p>CalRecycle disagrees that inclusion of the other categories is contrary to the language in SB 212 and reiterates that they are necessary for CalRecycle to determine adequate funding for the proposed activities of a stewardship program.</p>
015-023D	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.6 (d)	N	Proposed Regulations § 18973.6(d) -which requires "all actual expenses incurred during the previous program year" to be included in all annual budgets -should be stricken in its entirety, as it is contrary to the plain language and intent of SB 212, unduly burdensome, and unjustified from a policy perspective for the reasons discussed above.	015-023D. A change to the proposed regulatory text is not necessary. Evaluating compliance with the requirement in Public Resources Code section 42033.2(c)(2) that the annual program budget contain "anticipated costs and the recommended funding level necessary to implement the stewardship program" depends heavily on understanding what actual costs were incurred during the previous reporting period, and if the budget should be adjusted accordingly. Reporting actual program expenses is also not overly burdensome as programs will need to track expenses anyway in order to maintain the program, generate budgets, and in the case of a non-profit stewardship organization, to bill its members. Additionally, several local stewardship programs already require the program operator (currently Med-Project in all local jurisdictions) to report actual expenditures, indicating that processes for tracking and reporting program costs are already well-established. Public Resources Code section 42033.2(c) does not limit the required information to that specifically listed in subdivisions (1) and (2). This is the "minimum" information that the annual budget must contain.
015-023E	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.6 (e)	Y	Proposed Regulations § 18973.6(e) should be amended to be consistent with SB 212; in other words, the annual financial audit of the Stewardship Program conducted by Program Operators should be an audit of "the minutes, books, and records of a program operator ... at the program operator's expense by an independent certified public accountant retained by the program operator at least once each calendar year." PRC §§ 42033.2(c)(1) & 42033.4(b). No more	015-023E. CalRecycle has considered the commenter's recommendation and agrees that removal of the requirement that audits be conducted in accordance with Generally Accepted Government Auditing Standards is appropriate for this program. Section 18973.6(g) has been amended as follows:

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					language, specifications or obligations should be included in the Proposed Regulations in excess of what is explicitly required or intended by the SB 212, including the obligation to conduct an annual audit in accordance with Generally Accepted Government Auditing Standards, which are rigorous accounting standards that do not apply to non-governmental entities like Program Operators. In order to effectuate these changes most effectively, Proposed Regulations§ 18973.6(e), as amended, should read in full: "An independent financial audit of the stewardship program, as required by Sections 42033.2(c)(1) and 42033.4(b) of the Public Resources Code."	<p><u>An independent financial audit of the stewardship program funded by the member covered entities participating in the stewardship program or by a covered entity, if it operates its own stewardship program. The audit shall be performed at least once each calendar year. The audit shall be conducted in accordance with generally accepted auditing standards in the United States of America, and Generally Accepted Government Auditing Standards by a Certified Public Accountant. The Certified Public Accountant shall not perform the non-audit services for the program operator or engage in any activities that would impair independence. The independent financial audit shall include, but not be limited to:</u></p> <p>Due to insertion of a new subsection 18973.6(c), the subsection has been changed from 18973.6(e) to 18973.6(g).</p> <p>The remaining language in section 18973.6(g) of the proposed regulations is necessary as it clarifies key components of the auditing requirements. Without the clarity provided by this subsection regarding crucial elements of an audit, the department will have no assurance that the audit has any validity.</p>
015-024A	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.4 (c)(4)	N	<p>The Granular Level of Detail Sought in the Annual Reports for Each Collection Site (at Proposed Regulations §§ 18973.4(c)(4)) is Unreasonable and Impracticable</p> <p>Proposed Regulations § 18973.4(c)(4) states that the annual reports submitted by a Program Operator for a Covered Drug Stewardship Plan must include the following information for each participating authorized collection site located in the State of California: (1) name and physical address; (2) weight of material collected; (3) number of collections and number of liners collected; and (4) "total number of instances and corresponding number of businesses hours the authorized collection site was not available to the public" during the previous reporting year. (emphasis added). The first two pieces of information listed above -name and physical address of each collection site and weight of material collected at each collection site -is required in SB 212. See PRC § 42033.2(b)(3) & (4). The latter two are not. Pursuant to the enabling statute at PRC § 42033.2(b)(9), the Department may require additional information in the annual reports, provided that the information is "reasonably require[d]." The additional information sought by the Department here, including the total number of business hours in a calendar year that each and every collection site is "not available to the pubic" for any reason, is not only unreasonable, but in many instances likely infeasible to obtain and report out. There are approximately 2,100 business hours in a year, and there will likely be over 1000 collection sites throughout the state of California under a MED-Project Stewardship Plan. Obtaining complete and accurate information on the total number of business hours over a 365 day period that each collection site in the state of California was closed or otherwise inaccessible to the public during business hours for any given reason (renovations, employee errors, etc.) is</p>	<p>015-024A. CalRecycle disagrees with the commenter. A program operator is already required by statute to collect pharmacy-level data and coordinating service schedules with pharmacies already involves a significant level of recordkeeping and interaction with the pharmacists and/or technicians who oversee the collection receptacles. Including a provision in agreements with collection sites to simply record and communicate any instances where the collection receptacle was unavailable during business hours, whether due to store renovations or the program operator not providing adequate service, is not overly burdensome. Additionally, reporting an aggregate annual number of collections/liners collected for each site does not reveal any information about particular service schedules, and thus safety and security risks are minimal.</p> <p>Finally, this information is essential for the department to evaluate compliance with the convenience standards listed in Public Resources Code sections 42032.2(a)(1)(F)(i)-(iii). For example, if a stewardship program has five authorized collection sites in a county, but one of the sites was only available to the public for half of the year due to store renovations, CalRecycle will be prompted to review for a potential program compliance issue.</p>

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					practically impossible. Additionally, requesting that the annual reports for Covered Drugs publicly document the number of collections made at each collection site may create unintended safety and security issues (e.g., the disclosure of this type of information may reveal patterns pertaining to pick up schedules, which is of interest to potential thieves). For these reasons, Proposed Regulations §§ 18973.4(c)(4)(C) and (D) should be stricken, so that the collection site-specific information required in the annual reports for Covered Drug Stewardship Plans is consistent with SB 212.	
015-024B	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.4 (c)(4)	N	MED-Project is also concerned that safety and security issues may arise from the public disclosure of information detailing the amount of weight collected at a particular collection site. Thus, the Proposed Regulations should allow blinded (or "masked") weight reporting without a key identifying the collection site associated with the reported weight amounts. Program Operators could provide a key identifying individual collection sites to the Department under separate cover as a confidential submission.	015-024B. A change to the proposed regulatory text is not necessary. CalRecycle disagrees with the commenter. Public Resources Code section 42033.2(b)(3) requires reporting of the weight of covered drugs collected at each authorized collection site. This information is aggregated for each site and does not reveal any information about service schedules. Many local stewardship programs have reported similar data every year, and CalRecycle is not aware of any resulting safety or security concerns. Additionally, to the extent that an annual report may contain proprietary or confidential information, those portions of the report may be redacted from what is publicly made available, but they are potentially subject to a Public Records Act request. Consistent with Public Resources Code section 40062 and Title 14, Division 7, Chapter 1 of the California Code of Regulations under Article 4, Public Records (Section 17041 et seq.), when a public records act request is made, there is a process for determining if the claimed confidential records are in fact confidential. This process involves notifying the entity claiming confidentiality for them to provide an explanation of the basis for that claim. The requirement in these regulations is designed to streamline that process and potentially allow a faster determination. If the initial explanation is sufficient, no further action would be needed from the covered entity to maintain confidentiality. If the initial explanation is not sufficient to verify the claim of confidentiality, CalRecycle would provide a program operator notice of a public records act request pursuant to Title 14, Division 7, Chapter 1 of the California Code of Regulations, Section 17046 in order to provide additional explanation. The information required to be submitted under this law is in no way automatically confidential without justification, just because it is labelled as such.
015-025a	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.4 (e)	Y	Imposing Mandatory Third Party Reporting Obligations and Corrective Action Duties on Program Operators for Legal Noncompliance Allegedly Committed By Other Private Parties Is Unprecedented, Untenable and Wholly Unreasonable Proposed Regulations §§ 18973.4(e) and 18973.5(e), if adopted in their current form, would impose a mandatory obligation on Program Operators to not only disclose violations of federal, state and local laws and regulations (laws and regulations over which the Department has no jurisdiction or enforcement authority) committed by service providers but also take affirmative steps to initiate undefined "corrective action" to remedy a third party's alleged	015-025a. CalRecycle agrees that a change to the proposed regulatory text is necessary. For consistency with the edits made in section 18973.2(g)(10) of the proposed regulatory text, CalRecycle proposes the following edits to the annual report, section 18973.4(e): <u>(e) Corrective actions taken if the program operator discovered critical deviations from stewardship plan policies and procedures and a description of each critical deviation.</u> that a service provider did not maintain compliance with all collection, transportation, and disposal standards, including, but not limited to, local, state, and federal laws and

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					<p>noncompliance. Proposed Regulations §§ 18973.4(e) and 18973.5(e) also would require Program Operators to report all such information in publicly available annual reports. This type of mandatory third party disclosure and corrective action obligation is legally unprecedented, and absent from the enabling statute.</p> <p>This type of reporting obligation is also wholly unreasonable and unworkable for numerous reasons. As mentioned above, in Section IV.B., the enabling statute at PRC § 42033.2(b)(9) limits the Department's authority to require additional information in annual report submissions, above and beyond that which is enumerated in SB 212, to information is "reasonably require[d]." Program Operators like MED-Project are private entities, as are their vendors. MED-Project is not a government inspector or enforcement agency. Therefore, is not in a role where it is qualified to assess the legal compliance status of another private party or "order" corrective action to be taken regarding the same. Such a mandatory third party reporting system would also discourage vendors from working with a Program Operator to implement a Stewardship Plan (vendors in an industry that is also already highly regulated and therefore small), thereby putting at risk the effectiveness of the entire Stewardship Program. It is industry standard for vendor contracts to include provisions requiring the vendor to comply with all applicable federal, state and local laws and regulations. This plus the checks and balances intended by the Legislature, as stated in SB 212 is sufficient to ensure that all parties involved in the Stewardship Program make their best efforts to comply with all applicable laws and regulations, as well as any additional policies and procedures established under a Stewardship Plan. For the foregoing reasons, Proposed Regulations §§ 18973.4(e) and 18973.5(e) should be revised to strike the language imposing a mandatory third party disclosure and corrective action obligation on Program Operators and to be consistent with the SB 212 at Proposed Regulations § 42033.2(b)(6). Proposed language that would effectuate this change is set forth below:</p> <p>"The annual report shall contain the following corrective actions taken if the program operator discovered that a service provider did not maintain compliance with the collection, transportation, and disposal standards, including, but not limited, to local, state and federal laws and regulations and United State Drug Enforcement Administration regulations a statement as to whether the policies and procedures for collecting, transporting, and disposing of covered drugs [or sharps waste], as established in the stewardship plan, were followed during the reporting period and a brief summary of any known critical incidents of noncompliance that occurred."</p>	<p>regulations and United States Drug Enforcement Administration regulations.</p> <p>Regarding the commenter's concern of third party monitoring of service providers for compliance beyond what is outlined in contractual agreements, it is the program operator's responsibility, under the Statute (Public Resources Code section 42035.8), to maintain compliance with all applicable local, state, and federal laws and regulations.</p> <p>Stewardship plan implementation relies on adherence to key policies and procedures in many areas. Thus, it is essential for a program operator to conduct "corrective actions" if service providers deviate from these agreements. It is not unreasonable for a program operator to report on what corrective actions were taken in the annual report. The proposed regulatory text provides a program operator the flexibility to determine what "corrective actions" are taken depending on the circumstances and the type of deviation.</p>
015-025b	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.5 (e)	Y	<p>Imposing Mandatory Third Party Reporting Obligations and Corrective Action Duties on Program Operators for Legal Noncompliance Allegedly Committed By Other Private Parties Is Unprecedented, Untenable and Wholly Unreasonable</p>	<p>015-025b. CalRecycle agrees that a change to the proposed regulatory text is necessary. For consistency with the edits made in section 18973.3(f)(9) of the Second Draft proposed regulatory text (formerly numbered as section 18973.3(f)(6)(A)(v)), CalRecycle proposes the following edits to the annual report requirements, section 18973.5(e):</p>

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					<p>Proposed Regulations §§ 18973.4(e) and 18973.5(e), if adopted in their current form, would impose a mandatory obligation on Program Operators to not only disclose violations of federal, state and local laws and regulations (laws and regulations over which the Department has no jurisdiction or enforcement authority) committed by service providers but also take affirmative steps to initiate undefined "corrective action" to remedy a third party's alleged noncompliance. Proposed Regulations §§ 18973.4(e) and 18973.5(e) also would require Program Operators to report all such information in publicly available annual reports. This type of mandatory third party disclosure and corrective action obligation is legally unprecedented, and absent from the enabling statute.</p> <p>This type of reporting obligation is also wholly unreasonable and unworkable for numerous reasons. As mentioned above, in Section IV.B., the enabling statute at PRC § 42033.2(b)(9) limits the Department's authority to require additional information in annual report submissions, above and beyond that which is enumerated in SB 212, to information is "reasonably require[d]." Program Operators like MED-Project are private entities, as are their vendors. MED-Project is not a government inspector or enforcement agency. Therefore, is not in a role where it is qualified to assess the legal compliance status of another private party or "order" corrective action to be taken regarding the same. Such a mandatory third party reporting system would also discourage vendors from working with a Program Operator to implement a Stewardship Plan (vendors in an industry that is also already highly regulated and therefore small), thereby putting at risk the effectiveness of the entire Stewardship Program. It is industry standard for vendor contracts to include provisions requiring the vendor to comply with all applicable federal, state and local laws and regulations. This plus the checks and balances intended by the Legislature, as stated in SB 212 is sufficient to ensure that all parties involved in the Stewardship Program make their best efforts to comply with all applicable laws and regulations, as well as any additional policies and procedures established under a Stewardship Plan. For the foregoing reasons, Proposed Regulations §§ 18973.4(e) and 18973.5(e) should be revised to strike the language imposing a mandatory third party disclosure and corrective action obligation on Program Operators and to be consistent with the SB 212 at Proposed Regulations § 42033.2(b)(6). Proposed language that would effectuate this change is set forth below:</p> <p>"The annual report shall contain the following corrective actions taken if the program operator discovered that a service provider did not maintain compliance with the collection, transportation, and disposal standards, including, but not limited, to local, state and federal laws and regulations and United State Drug Enforcement Administration regulations a statement as to whether the policies and procedures for collecting, transporting, and disposing of covered drugs [or sharps waste], as established in the stewardship plan,</p>	<p>(e) Corrective actions taken if the program operator discovered critical deviations from stewardship plan policies and procedures and a description of each critical deviation, that a service provider did not maintain compliance with all collection, transportation, and disposal standards, including, but not limited to, local, state, and federal laws and regulations and United States Drug Enforcement Administration regulations.</p> <p>Regarding the commenter's concern of third party monitoring of service providers for compliance beyond what is outlined in contractual agreements, it is the program operator's responsibility, under the Statute (Public Resources Code sections 42032.2(d)(1)(D) and 42035.8), to maintain compliance with all applicable local, state, and federal laws and regulations.</p> <p>Stewardship plan implementation relies on adherence to key policies and procedures in many areas. It is essential for a program operator to conduct "corrective actions" if service providers deviate from these agreements. It is not unreasonable for a program operator to report on what corrective actions were taken in the annual report. The proposed regulatory text provides a program operator the flexibility to determine what "corrective actions" are taken depending on the circumstances and the type of deviation.</p>

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					were followed during the reporting period and a brief summary of any known critical incidents of noncompliance that occurred."	
015-026a	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.4 (o)	Y	<p>Imposing Imprecise Obligations on Stewardship Program Operators to Furnish "Agency Determinations of Compliance and Noncompliance" in Annual Report Submissions Is Unreasonable and Unnecessary</p> <p>For the same reasons as those stated immediately above in Section IV.C. and in addition to those described below, Proposed Regulations §§ 18973.4(o) and 18973.5(q) should be stricken in their entirety. As mentioned above, in Section IV.B., the enabling statute at PRC § 42033.2(b)(9) limits the Department's authority in supplementing the information required in annual report submissions to information that is "reasonably require[d]."</p> <p>Proposed Regulations §§ 18973.4(o) and 18973.5(q) currently state that annual report submissions to the Department must include "all agency determination(s) of compliance, noncompliance and superseding determinations of compliance, if any, for the reporting period." It is unclear which "agency" the Proposed Regulations are intended to refer to and/or the scope of documentation sought. For instance, Program Operators are unlikely to have documents in their possession regarding inspection reports issued to third party vendors, and it is unreasonable to expect a private party Program Operator to successfully collect copies of this type of documentation from all of its vendors.</p> <p>The rationale behind this requirement -which is not included in SB 212- is also unclear. In today's internet age, most federal, state and local agencies with jurisdiction over California activities have publicly searchable databases regarding the compliance status of private parties (see e.g., the CalEPA Regulated Site Portal, available at: https://siteportal.calepa.ca.gov/nsite/map/help and U.S. EPA Envirofacts, available at https://enviro.epa.gov/). Thus, Proposed Regulations §§ 18973.4(o) and 18973.5(q) should be stricken in their entirety.</p>	<p>015-026a. CalRecycle disagrees with the commenter. The "agency determinations" referred to in the annual report requirements are related to the determinations issued in the stewardship plan approval process (Public Resources Code sections 42032(b)(1)-(4)). However, if an agency issues a determination of noncompliance outside of its initial 90-day window for stewardship plan review, then the proposed regulations require the program operator to include this determination (including any superseding determination of compliance) in its annual report. Sections 18973.4(o) and 18973.5(q) of the proposed regulations do not require a program operator to collect compliance documentation from third-party vendors.</p> <p>CalRecycle does not believe that providing issuances of state agency determinations of compliance is unreasonable and unnecessary for the reasons stated above, however, the department recognizes that additional clarity is warranted. Section 18973.4(o) of the proposed regulatory text is revised as follows:</p> <p><u>(o) State Agency Determinations pursuant to section 42032.2(d)(1)(B) of the Public Resources Code. Submit all agency determination(s) of compliance, noncompliance and superseding determinations of compliance, if any, for the reporting period.</u></p>
015-026b	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.5 (q)	Y	<p>Imposing Imprecise Obligations on Stewardship Program Operators to Furnish "Agency Determinations of Compliance and Noncompliance" in Annual Report Submissions Is Unreasonable and Unnecessary</p> <p>For the same reasons as those stated immediately above in Section IV.C. and in addition to those described below, Proposed Regulations §§ 18973.4(o) and 18973.5(q) should be stricken in their entirety. As mentioned above, in Section IV.B., the enabling statute at PRC § 42033.2(b)(9) limits the Department's authority in supplementing the information required in annual report submissions to information that is "reasonably require[d]."</p> <p>Proposed Regulations §§ 18973.4(o) and 18973.5(q) currently state that annual report submissions to the Department must include "all agency determination(s) of compliance, noncompliance and superseding determinations of compliance, if any, for the reporting period." It is unclear</p>	<p>015-026b. A change to the proposed regulatory text is not necessary. CalRecycle disagrees with the commenter. The "agency determinations" referred to in the annual report requirements are related to the determinations issued in the stewardship plan approval process (Public Resources Code sections 42032(b)(1)-(4)). However, if an agency issues a determination of noncompliance outside of its initial 90-day window for stewardship plan review, then the proposed regulations require the program operator to include this determination (including any superseding determination of compliance) in its annual report. Sections 18973.4(o) and 18973.5(q) of the proposed regulations do not require a program operator to collect compliance documentation from third-party vendors.</p>

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					<p>which "agency" the Proposed Regulations are intended to refer to and/or the scope of documentation sought. For instance, Program Operators are unlikely to have documents in their possession regarding inspection reports issued to third party vendors, and it is unreasonable to expect a private party Program Operator to successfully collect copies of this type of documentation from all of its vendors.</p> <p>The rationale behind this requirement -which is not included in SB 212- is also unclear. In today's internet age, most federal, state and local agencies with jurisdiction over California activities have publicly searchable databases regarding the compliance status of private parties (see e.g., the CalEPA Regulated Site Portal, available at: https://siteportal.calepa.ca.gov/nsite/map/help and U.S. EPA Envirofacts, available at https://enviro.epa.gov/). Thus, Proposed Regulations §§ 18973.4(o) and 18973.5(q) should be stricken in their entirety.</p>	<p>CalRecycle does not believe that providing issuances of state agency determinations of compliance is unreasonable and unnecessary for the reasons stated above. However, the department recognizes that additional clarity is warranted. Section 18973.5(q) of the proposed regulatory text is revised as follows:</p> <p><u>(q) State Agency Determinations pursuant to section 42032.2(d)(1)(B) of the Public Resources Code. Submit all agency determination(s) of compliance, noncompliance and superseding determinations of compliance, if any, for the reporting period.</u></p>
015-027a	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.4 (h)	Y	<p>The Safety and Security-Related Recordkeeping and Potential Disclosure Obligations Imposed in Proposed Regulations §§ 18973.4(h) and 18973.5(h) Are Unreasonable and Impracticable</p> <p>In addition to requiring certain safety and security information in the annual reports (such as a description of any incidents and any corrective action taken), Proposed Regulations §§ 18973.4(h) and 18973.5(h) appear to also include a recordkeeping and potential production requirement for safety and security-related information, requiring that "[t]he following shall be made available to the department upon request, including, but not limited to: (1) Location and date; (2) Description of incident; (3) Cause(s) of incident; (4) Parties involved; (5) Regulatory or law enforcement agencies involved and any litigation, arbitration, or other legal proceedings that result from each incident."</p> <p>The language in Proposed Regulations §§ 18973.4(h) and 18973.5(h), as currently, written is ambiguous insomuch as it is not clear whether the provision is imposing an affirmative obligation on Program Operators to prepare and/or collect all of the above-listed information for any "safety and security incident" that is reported in the annual reports. It is unreasonable and infeasible to expect a Program Operator to have all of the above-listed information in its possession or to be able to gain access to it (including, namely, details of legal proceedings or enforcement actions in which the Program Operators may not be a party to).</p> <p>The corresponding provisions in SB 212 only require Program Operators to annually report on whether "any safety or security problems occurred ... during the reporting period and if so, what change have been or will be made ... to alleviate the problem and to improve safety and security." PRC § 42033.2(b)(7). Proposed Regulations §§ 18973.4(h) and 18973.5(h) should be</p>	<p>015-027a. A change to the proposed regulatory text is not necessary, based on the comment. CalRecycle disagrees with the commenter. Other changes to the proposed text were made, but not based on this comment. Public Resources Code section 42033.2(b)(7) requires a program operator to report "whether any safety or security problems occurred during collection, transportation, or disposal of collected covered products during the reporting period and, if so, what changes have been or will be made to policies, procedures, or tracking mechanisms to alleviate the problem and to improve safety and security." If a safety or security problem occurs, conveying certain information about the problem is essential to understanding whether proposed changes to policies, procedures, or tracking mechanisms will be sufficient to alleviate the problem in the future.</p> <p>The information required upon request in sections (1)-(5) of 18973.4(h) of the proposed regulations are perfectly reasonable for a program operator to collect for safety or security issues directly related to its operations. It is up to the program operator to ensure that its authorized collectors will provide it with sufficient information to comply with the statutory requirement.</p> <p>However, the department proposes the following edit to further clarify which information is required to be included in the annual report and which is made available to the department upon request:</p> <p>Proposed regulations sections 18973.4(h): <u>(h) Safety and Security. Describe the general nature of any incidents with safety or security related to collection, transportation, or disposal of collected covered drugs. Explain what corrective actions were taken to address the issue and improve safety and security. The</u></p>

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					<p>revised to be consistent with SB 212. Proposed language that would effectuate this change is set forth below:</p> <p>Safety and Security. Describe the nature of any incidents with safety or security related to collection, transportation, or disposal of collected covered drugs [or sharps waste]. Explain what corrective actions were taken to address the issue and improve safety and security. The following shall be made available to the department upon request, including, but not limited to [sic]: (1) Location and date; (2) Description of incident; (3) Cause(s) of incident; (4) Parties involved; (5) Regulatory or law enforcement agencies involved and any litigation, arbitration, or other legal proceedings that result from each incident."</p>	<p>following information about any incident(s) shall be made available to the department upon request, and shall include including, but not be limited to, the following:</p> <ul style="list-style-type: none"> <u>(1) Location and date</u> <u>(2) Description of specific incident</u> <u>(3) Cause(s) of specific incident</u> <u>(4) Parties involved</u> <u>(5) Regulatory or law enforcement agencies involved and any litigation, arbitration, or other legal proceedings that result from each incident</u>
015-027b	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.5 (h)	Y	<p>The Safety and Security-Related Recordkeeping and Potential Disclosure Obligations Imposed in Proposed Regulations §§ 18973.4(h) and 18973.5(h) Are Unreasonable and Impracticable</p> <p>In addition to requiring certain safety and security information in the annual reports (such as a description of any incidents and any corrective action taken), Proposed Regulations §§ 18973.4(h) and 18973.5(h) appear to also include a recordkeeping and potential production requirement for safety and security-related information, requiring that "[t]he following shall be made available to the department upon request, including, but not limited to: (1) Location and date; (2) Description of incident; (3) Cause(s) of incident; (4) Parties involved; (5) Regulatory or law enforcement agencies involved and any litigation, arbitration, or other legal proceedings that result from each incident."</p> <p>The language in Proposed Regulations §§ 18973.4(h) and 18973.5(h), as currently, written is ambiguous inasmuch as it is not clear whether the provision is imposing an affirmative obligation on Program Operators to prepare and/or collect all of the above-listed information for any "safety and security incident" that is reported in the annual reports. It is unreasonable and infeasible to expect a Program Operator to have all of the above-listed information in its possession or to be able to gain access to it (including, namely, details of legal proceedings or enforcement actions in which the Program Operators may not be a party to).</p> <p>The corresponding provisions in SB 212 only require Program Operators to annually report on whether "any safety or security problems occurred ... during the reporting period and if so, what change have been or will be made ... to alleviate the problem and to improve safety and security." PRC § 42033.2(b)(7). Proposed Regulations §§ 18973.4(h) and 18973.5(h) should be revised to be consistent with SB 212. Proposed language that would effectuate this change is set forth below:</p>	<p>015-027b. A change to the proposed regulatory text is not necessary, based on the comment. CalRecycle disagrees with the commenter. Other changes to the proposed text were made, but not based on this comment. Public Resources Code section 42033.2(b)(7) requires a program operator to report "whether any safety or security problems occurred during collection, transportation, or disposal of collected covered products during the reporting period and, if so, what changes have been or will be made to policies, procedures, or tracking mechanisms to alleviate the problem and to improve safety and security." If a safety or security problem occurs, conveying certain information about the problem is essential to understanding whether proposed changes to policies, procedures, or tracking mechanisms will be sufficient to alleviate the problem in the future.</p> <p>The information required upon request in sections (1)-(5) of 18973.5(h) of the proposed regulatory text are perfectly reasonable for a program operator to collect for safety or security issues directly related to its operations. It is up to the program operator to ensure that its authorized collectors will provide it with sufficient information to comply with the statutory requirement.</p> <p>However, the department proposes the following edit to further clarify which information is required to be included in the annual report and which is made available to the department upon request:</p> <p>Proposed regulations section 18973.5(h) is revised as follows: <u>(h) Safety and Security. Describe the general nature of any incidents with safety or security related to collection, transportation, or disposal of collected covered drugs. Explain what corrective actions were taken to address the issue and improve safety and security. The following information about any incident(s) shall be made available to the</u></p>

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					Safety and Security. Describe the nature of any incidents with safety or security related to collection, transportation, or disposal of collected covered drugs [or sharps waste]. Explain what corrective actions were taken to address the issue and improve safety and security. The following shall be made available to the department upon request, including, but not limited to [sic]: (1) Location and date; (2) Description of incident; (3) Cause(s) of incident; (4) Parties involved; (5) Regulatory or law enforcement agencies involved and any litigation, arbitration, or other legal proceedings that result from each incident."	department upon request, and shall include <u>including, but not be limited to, the following:</u> <u>(1) Location and date</u> <u>(2) Description of specific incident</u> <u>(3) Cause(s) of specific incident</u> <u>(4) Parties involved</u> <u>(5) Regulatory or law enforcement agencies involved and any litigation, arbitration, or other legal proceedings that result from each incident</u>
015-028a	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.4 (k)-(m)	N	Requiring Program Operators to Annually Report on Miscellaneous Non-Substantive Obligations (in Proposed Regulations §§ 18973.4(k)-(m) and 18973.5(l)-(n)) Is Unnecessarily and Unreasonably Burdensome Proposed Regulations §§ 18973.4(k)-(m) and 18973.5(l)-(n) would require Program Operators to annually report a variety of miscellaneous, non-substantive information regarding programmatic changes to their Covered Drug Stewardship Plans and Home-Generated Sharps Waste Stewardship Plans made during the reporting period (including staffing changes and process based changes for selecting service providers and providing grants, loans, and other incentives). This information is not required by SB 212 and it exceeds the Department's authority to supplement the information required in the annual report as it unreasonable in nature. As mentioned above, the enabling statute at PRC § 42033.2(b)(9) limits the Department's authority in supplementing the information required in annual report submissions to information that is "reasonably require[d]." Imposing these types of additional, non-substantive reporting obligations on Program Operators annually is unnecessary and unreasonable, as it will only divert resources and costs away from standing up an effective Stewardship Program. Therefore, the above referenced sections of the Proposed Regulations should be deleted from the final regulations.	015-028a. CalRecycle disagrees with the commenter. The requirements listed in sections 18973.4(k)-(m) and 18973.5(l)-(n) of the proposed regulations are not "miscellaneous" nor "non-substantive". They are reasonable and essential for the department to understand both if the stewardship program adhered to its approved plan during the reporting period, and whether the program was operated in a "prudent and responsible manner," pursuant to Public Resources Code section 42033.2(c)(2). Public Resources Code section 42033.2(b)(9) grants CalRecycle the authority to require "any other information the department reasonably requires" in the annual report. The risk of unnecessarily undermining collection services or education and outreach activities due to non-competitive business practices or staffing cuts far outweighs the possibility of "diverting resources and costs" due to compliance with these requirements.
015-028b	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.5 (l)-(n)	N	Requiring Program Operators to Annually Report on Miscellaneous Non-Substantive Obligations (in Proposed Regulations §§ 18973.4(k)-(m) and 18973.5(l)-(n)) Is Unnecessarily and Unreasonably Burdensome Proposed Regulations §§ 18973.4(k)-(m) and 18973.5(l)-(n) would require Program Operators to annually report a variety of miscellaneous, non-substantive information regarding programmatic changes to their Covered Drug Stewardship Plans and Home-Generated Sharps Waste Stewardship Plans made during the reporting period (including staffing changes and process based changes for selecting service providers and providing grants, loans, and other incentives). This information is not required by SB 212 and it exceeds the	015-028b. CalRecycle disagrees with the commenter. The requirements listed in sections 18973.4(k)-(m) and 18973.5(l)-(n) of the proposed regulations are not "miscellaneous" nor "non-substantive." They are reasonable and essential for the department to understand both if the stewardship program adhered to its approved plan during the reporting period, and whether the program was operated in a "prudent and responsible manner," pursuant to Public Resources Code section 42033.2(c)(2). Public Resources Code section 42033.2(b)(9) grants CalRecycle the authority to require "any other information the department reasonably requires" in the annual report. The risk of

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					<p>Department's authority to supplement the information required in the annual report as it unreasonable in nature. As mentioned above, the enabling statute at PRC § 42033.2(b)(9) limits the Department's authority in supplementing the information required in annual report submissions to information that is "reasonably require[d]."</p> <p>Imposing these types of additional, non-substantive reporting obligations on Program Operators annually is unnecessary and unreasonable, as it will only divert resources and costs away from standing up an effective Stewardship Program. Therefore, the above referenced sections of the Proposed Regulations should be deleted from the final regulations.</p>	<p>unnecessarily undermining collection services or education and outreach activities due to non-competitive business practices or staffing cuts far outweighs the possibility of "diverting resources and costs" due to compliance with these requirements.</p>
015-029	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.5 (p)	N	<p>The Proposed Regulations Request an Unreasonable Level of Detail on Local Household Hazardous Waste Facilities in the Annual Reports (Proposed Regulations §§ 18973.5(p))</p> <p>Proposed Regulations § 18973.5(p) would require Program Operators of Home-Generated Sharps Waste Stewardship Programs to annually report on "each local agency that has requested removal or reimbursement" including, specifically, details regarding, among other things, "[f]or each household hazardous waste facility: (A) Facility location[;] (B) Reimbursement payment amount, as applicable [; and] (C) Weight of collected material." Proposed Regulations § 18973.5(p)(2) (emphasis added).</p> <p>The above information is not required by the legislature, as specified in the annual reporting section contained in SB 212, see Cal. Pub. Resources Code § 42033.2(b), and therefore, it is an additional requirement subject to the statutory limitation of "reasonableness" previously mentioned. See Cal. Pub. Resources Code § 42033.2(b)(9). The additional information sought by the Department in Proposed Regulations § 18973.5(p) is unreasonable in its nature and in the level of granular detail sought (including, namely requiring the collection, calculation and reporting out of data regarding material weights and reimbursement amounts broken down at the local facility level). Furthermore, as discussed above in Section IV.A. in regards to the level of detail sought in the proposed budgets, requiring annual reporting on a granular level for reimbursement costs related to disposal services would disclose proprietary, confidential and/or trade secret information in a public document.</p> <p>Based on the foregoing, Proposed Regulations § 18973.5(p) should be revised to be reasonable in scope and nature, and should read follows: "Local Agency Requests. For each A list of local agencies that requested removal or reimbursement <u>during the reporting period</u> details, including, but not limited to, the following: (1) Name of local agency, or agency acting on behalf of local agency. (2) For each household hazardous waste facility: (A) Facility location (B) Reimbursement payment amount, as applicable (C) Weight of collected material."</p>	<p>015-029. A change to the proposed regulatory text is not necessary. CalRecycle disagrees with the commenter. The reporting requirements relating to household hazardous waste facilities are reasonable and essential for the department to understand whether the program operator was actually adhering to its approved stewardship plan and complying with its statutory obligations to fulfill local agency requests relating to home-generated sharps waste.</p> <p>Furthermore, these requirements are not overly burdensome. The requested information is expected to be collected anyway during negotiations between the program operator and local agencies; for example, any invoice submitted to a program operator for reimbursement would certainly include the weight of collected material and the payment amount. The importance of this information for effective program oversight far outweighs the minimal costs of maintaining it and consolidating it for an annual report.</p> <p>Additionally, to the extent that an annual report may contain proprietary or confidential information, those portions of the report may be redacted from what is publicly made available, but they are potentially subject to a Public Records Act request. Consistent with Public Resources Code section 40062 and Title 14, Division 7, Chapter 1 of the California Code of Regulations under Article 4, Public Records (Section 17041 et seq.), when a public records act request is made, there is a process for determining if the claimed confidential records are in fact confidential. This process involves notifying the entity claiming confidentiality for them to provide an explanation of the basis for that claim. The requirement in these regulations is designed to streamline that process and potentially allow a faster determination. If the initial explanation is sufficient, no further action would be needed from the covered entity to maintain confidentiality. If the initial explanation is not sufficient to verify the claim of confidentiality, CalRecycle would provide a program operator notice of a public records act request pursuant to Title 14, Division 7, Chapter 1 of the California Code of Regulations, Section 17046 in order to provide additional explanation. The information</p>

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						required to be submitted under this law is in no way automatically confidential without justification, just because it is labelled as such.
015-030A	MED-Project US	Michael R. Van Winkle, Dr. Victoria Travis	General	N	<p>The Department Should Revise the Proposed Regulations to Eliminate Paraphrasing of SB 212</p> <p>SB 212 is a prescriptive statute. Over twenty pages long, it comprehensively regulates the collection and disposal of Covered Products and the associated Stewardship Programs. Despite these detailed statutory requirements, however, the Proposed Regulations paraphrase certain sections of SB 212 in an apparent attempt to consolidate Stewardship Program requirements into a single document. Unfortunately, discrepancies between SB 212 and paraphrased provisions of SB 212 in the Proposed Regulations raise questions about what the requirements actually are, making compliance harder. To make the requirements more understandable, the Department should revise the Proposed Regulations to eliminate these discrepancies.</p> <p>These discrepancies create uncertainty. There is no need for the Proposed Regulations to paraphrase what SB 212 makes plain. The regulatory framework would be most clear if the Department removes sections of the Proposed Regulations that paraphrase SB 212 and simply cross-references the statute as needed. Short of that, the Department should eliminate discrepancies by revising the Proposed Regulations for consistency with SB 212. If Proposed Regulation provisions are intended to require the same thing as SB 212 provisions, they should use the same language. Such revisions would clarify the Proposed Regulations, making Stewardship Program implementation and Department oversight more successful.</p>	015-030A. A change to the proposed regulatory text is not necessary. One goal of the proposed regulations is to provide convenience to the regulated community; for example, listing all necessary components of a stewardship plan in the regulations minimizes confusion for a program operator that would otherwise have to constantly compare the statute with the regulations when developing its plan. Incorporating statutory requirements into the regulations involves adjusting phrasing in certain instances; however, the department strives to provide regulatory language that is clear and consistent with statute, and has welcomed public comments on any instances of perceived ambiguity. See responses to comments 015-030B1 through G regarding specific instances of paraphrasing.
015-030B1	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973	Y	<p>In some cases, paraphrasing SB 212 requirements in the Proposed Regulations results in discrepancies that could carry compliance consequences. For example, the following discrepancies could affect Stewardship Plan approval or Stewardship Program implementation:</p> <p>The Proposed Regulations refer to the Department determining whether undefined "document[s]" are complete, whereas SB 212 applies these completeness reviews to only Stewardship Plans, annual reports, and Stewardship Program budgets. Compare Proposed Regulations § 18973.1(b) with PRC §§ 42032(d)(1), 42033.2(d).⁴</p> <p>⁴Proposed Regulations § 18973 also refers to the undefined term "document." Although likely referring to only Stewardship Plans, annual reports, and Stewardship Program budgets, as written the term could refer to any document a Program Operator provides the Department. The Department should define the term document as "Stewardship Plans, annual reports, or Stewardship Program budgets" or eliminate it from the Proposed Regulations.</p>	<p>015-030B1. CalRecycle agrees that the term "document" as used in sections 18973 and 18973.1 of the proposed regulatory text is ambiguous. The department proposes the following additions to clarify this term:</p> <p>18973. DOCUMENT SUBMITTALS: STEWARDSHIP PLAN, INITIAL PROGRAM BUDGET, ANNUAL REPORT, AND ANNUAL BUDGET.</p> <p><u>A stewardship plan, initial program budget, annual report, annual budget, or any document associated with the foregoing that is submitted to the department shall meet the following requirements:</u></p> <p>18973.1. DOCUMENT APPROVALS: STEWARDSHIP PLAN, INITIAL PROGRAM BUDGET, ANNUAL REPORT, AND ANNUAL BUDGET.</p> <p><u>A program operator that submits a stewardship plan, initial program budget, annual report, or annual budget to the department shall meet the following requirements:</u></p> <p>While CalRecycle concurs with the commenter that the requirements in section 18973.1 (document approvals) only apply to stewardship plans,</p>

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						annual reports, and program budgets, the department wishes to highlight that the requirements in section 18973 (document submittals) also apply to any documents associated with stewardship plans, annual reports, or program budgets. These requirements are necessary to streamline the document submittal process, minimize confusion, and to clarify details of this process that were not articulated in statute.
015-030B2	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.1 (b)	Y	<p>In some cases, paraphrasing SB 212 requirements in the Proposed Regulations results in discrepancies that could carry compliance consequences. For example, the following discrepancies could affect Stewardship Plan approval or Stewardship Program implementation:</p> <p>The Proposed Regulations refer to the Department determining whether undefined "document[s]" are complete, whereas SB 212 applies these completeness reviews to only Stewardship Plans, annual reports, and Stewardship Program budgets. Compare Proposed Regulations § 18973.1(b) with PRC §§ 42032(d)(1), 42033.2(d).⁴</p> <p>⁴Proposed Regulations § 18973 also refers to the undefined term "document." Although likely referring to only Stewardship Plans, annual reports, and Stewardship Program budgets, as written the term could refer to any document a Program Operator provides the Department. The Department should define the term document as "Stewardship Plans, annual reports, or Stewardship Program budgets" or eliminate it from the Proposed Regulations.</p>	<p>015-030B2. CalRecycle agrees that the term "document" as used in sections 18973 and 18973.1 of the proposed regulatory text is ambiguous. The department proposes the following additions to clarify this term:</p> <p>18973. DOCUMENT SUBMITTALS: STEWARDSHIP PLAN, INITIAL PROGRAM BUDGET, ANNUAL REPORT, AND ANNUAL BUDGET.</p> <p><u>A stewardship plan, initial program budget, annual report, annual budget, or any document associated with the foregoing that is submitted to the department shall meet the following requirements:</u></p> <p>18973.1. DOCUMENT APPROVALS: STEWARDSHIP PLAN, INITIAL PROGRAM BUDGET, ANNUAL REPORT, AND ANNUAL BUDGET.</p> <p><u>A program operator that submits a stewardship plan, initial program budget, annual report, or annual budget to the department shall meet the following requirements:</u></p> <p>While CalRecycle concurs with the commenter that the requirements in section 18973.1 (document approvals) only apply to stewardship plans, annual reports, and program budgets, the department wishes to highlight that the requirements in section 18973 (document submittals) also apply to any documents associated with stewardship plans, annual reports, or program budgets. These requirements are necessary to streamline the document submittal process, minimize confusion, and to clarify details of this process that were not articulated in statute.</p>
015-030C	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.3 (f)(2)(C)	Y	<p>The Proposed Regulations provide that "[c]ontainer labels and mail-back materials shall include the stewardship program internet website and toll-free telephone number." SB 212, by contrast, alternatively allows Program Operators to include this information on "a separate insert included in the container or packaging." Compare Proposed Regulations § 18973.3(f)(2)(C) with PRC § 42032.2(d)(1)(F)(i)(II); see also Proposed Regulations § 18973.3(f)(2)(B); PRC § 42032.2(d)(1)(F)(i)(I).</p>	<p>015-030C. CalRecycle acknowledges these instances of mismatched language between statute and the proposed regulations and proposes the following edits to section 18973.3(f)(2) of the proposed regulations:</p> <p><u>(B) For any sharps, the packaging, an insert or instructions, or separate information provided to the ultimate user shall include all necessary information on proper sharps waste disposal. Mail-back materials shall include information for proper home-generated sharps disposal.</u></p> <p><u>(C) All sharps waste containers shall include on a label affixed to the container or packaging, or on a separate insert included in the container or packaging, the program operator's internet website and toll-free telephone number. Container labels and mail-back materials shall</u></p>

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						include the stewardship program internet website and toll-free telephone number.
015-030D	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.2 (g)(7)	Y	The Proposed Regulations require that Stewardship Plans describe alternative collection methods for Covered Drugs, other than controlled substances, that cannot be accepted or commingled with other Covered Drugs in collection receptacles or through a mail-back program. Proposed Regulations § 18973.2(g)(7). The Proposed Regulations omit a limitation on this requirement that SB 212 made clear: Stewardship Plans must only describe these alternative collection methods if they are "technically feasible and permissible under applicable state and federal law, including, but not limited to, United States Drug Enforcement Administration regulations." Compare Proposed Regulations § 18973.2(g)(7) with PRC § 42032.2(a)(1)(G)(ii).	015-030D. CalRecycle acknowledges this instance of mismatched language between statute and the proposed regulations and accepts the commenter's proposal, noting that the reference in question changed to 18973.2(g)(8) in the proposed regulatory text due to a separate proposed change. 18973.2(g)(8): <u>(7) Method(s) of collection for covered drugs, other than controlled substances, that cannot be accepted or commingled with other covered drugs in secure collection receptacles or through a mail-back program., to the extent technically feasible and permissible under applicable state and federal law, including, but not limited to, United States Drug Enforcement Administration regulations.</u>
015-030E	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.3 (f)(2)(A)	Y	The Proposed Regulations require that Stewardship Plans describe how "[c]ontainers and mail-back materials shall be distributed in amounts sufficient to accommodate the volume of sharps purchased by the ultimate user." Proposed Regulations § 18973.3(f)(2)(A). Conversely, SB 212 requires such distribution "sufficient to accommodate the volume of sharps purchased by an ultimate user over a selected time period." PRC § 42032.2(d)(1)(F)(i) (emphasis added).	015-030E. CalRecycle acknowledges this instance of mismatched language between statute and the proposed regulations and accepts the commenter's proposal. The proposed regulatory text section 18973.3(f)(2)(A) is revised as follows: <u>(A) 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.</u>
015-030F	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.2 (d)(4)	Y	In other cases, paraphrasing resulted in SB 212 and the Proposed Regulations appearing to require the same thing, but using slightly different language. Whether these discrepancies are intentional or meaningful is unclear. For example, among other discrepancies, the Proposed Regulations require Stewardship Plans to identify the "conditions for excluding" Authorized Collectors, whereas SB 212 requires Stewardship Plans to identify the "reasons for excluding" Authorized Collectors. Compare Proposed Regulations § 18973.2(d)(4) with PRC § 42032.2(a)(1)(B).	015-030F. Regarding this specific instance of mismatched language between statute and the proposed regulations, CalRecycle accepts the proposed edit. Proposed regulations section 18973.2(d)(4): <u>(4) Description of the conditions reasons for excluding any potential authorized collectors, including those who requested joining the program, as applicable.</u> Regarding the general comment on paraphrasing, see response to comment 015-030A.
015-030G	MED-Project USA	Michael R. Van Winkle, Dr. Victoria Travis	18973.5 (k)	Y	In another example, the Proposed Regulations require that Home-Generated Sharps Waste annual reports include an "[u]pdated list of covered products," whereas SB 212 refers to "[t]he updated and reverified list provided pursuant to paragraph (2) of subdivision (a) of Section 42031." Compare Proposed Regulations § 18973.5(k) with PRC § 42033.2(b)(2).	015-030G. CalRecycle agrees that additional clarity is needed regarding the submittal of covered product lists in the annual report and concurs with the commenter's interpretation of corresponding statutory requirements. Section 18973.5(k) of the proposed regulatory text is revised as follows: <u>(k) A copy of the list of covered products submitted to the Board of Pharmacy pursuant to subsection (2) of subdivision (a) of section 42031 of the Public Resources Code. Updated list of covered products</u>

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016-001	Lil' Drug Store Products, Inc. & Convenience Valet	Neil Dow, Barry Margolin	18972.2	N	<p>1. A clear statement that the responsibility for participation in the Program shall be limited exclusively to the “covered entities” pursuant to PRC 42030 and CCR 18972.2 (as proposed).</p> <p>SB 212 establishes a tiered definition for the term “covered entity,” making manufacturers responsible for the program and establishing other entities that may be held liable should no entity meet the initial definition. While both SB 212 and the Proposed Regulations clearly articulate manufacturer responsibility for “covered products” under the Program, the inclusion of other entities (such as distributors, repackages, trademark owners, and importers) as potential “covered entities” may be selectively interpreted to hold parties other than the manufacturer financially responsible for “covered products” under the Program. Such interpretation creates the possibility of a multi-layer fee, in which multiple entities—from manufacturers to wholesalers to importers—all share a portion of the financial responsibility for the same product through a stewardship organization, for example. The possible inclusion of parties other than a manufacturer sharing this responsibility creates a tremendous amount of uncertainty and business risk for those parties, especially when trying to understand and budget for potential cost liabilities related to potential participation in California’s takeback program. Furthermore, due to the fact that so many entities could qualify as “covered entities” under this scenario, it would make it more far more difficult to identify and hold violators and non-participants accountable.</p> <p>For this reason, we respectfully ask that CalRecycle clearly state in the Proposed Regulations that any entity other than the identified “covered entity” for a “covered product” does not have any responsibility to participate in the Program either as a program operator or through a stewardship organization.</p>	016-001. A change to the proposed regulatory text is not necessary. A stewardship organization has the ability to determine its own fee structure, and imposing requirements on those fees would be outside the scope of the proposed regulations. The covered entity for each covered product is responsible for participating in a stewardship program, and stating that other entities are not responsible would be unnecessary.
016-002	Lil' Drug Store Products, Inc. & Convenience Valet	Neil Dow, Barry Margolin	18972.2	N	<p>2. A clear statement of the steps CalRecycle must take undertake to establish a “covered entity” and exact circumstances that would allow CalRecycle to make a finding that no entity meets the definition of “manufacturer” for purposes of BPC 42030(f)(1)(A).</p> <p>As referenced above, while both SB 212 and the Proposed Regulations clearly articulate manufacturer responsibility for “covered products” under the Program, the inclusion of other entities (such as distributors, repackages, trademark owners, and importers) as potential “covered entities” creates a tremendous amount of uncertainty and business risk for those parties, especially when trying to understand and budget for potential cost liabilities related to potential participation in California’s takeback program.</p> <p>Given the clear legislative intent of SB 212 to hold product manufacturers responsible for the requirements of the Program, the Proposed Regulations</p>	016-002. A change to the proposed regulatory text is not necessary. CalRecycle declines to further clarify the terms “manufacturer” and “covered entity” because the statutory definition of “covered entity” is sufficient to determine the priority in which a covered entity is identified. Compliance determinations are made on a case-by-case basis. As part of the effort to make a determination of the covered entity, consistent with the statute, the Department will look to determine who sold a covered product in or into California. Entities that could be considered covered entities based on the statutory definition should endeavor to coordinate amongst appropriate entities within their respective supply chains to determine how the statutory requirements will be met.

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					should clearly specify the steps that CalRecycle must undertake to identify a manufacturer for every “covered product” and the exact circumstances that would allow CalRecycle to make a finding that no entity meets the definition of manufacturer for purposes of BPC 42030(f)(1)(A). If and when that entity is not identifiable, the regulations should clearly state the steps that CalRecycle must undertake to identify a wholesaler for every “covered product” where a manufacturer does not exist and clearly specify the exact circumstances that would allow CalRecycle to make a finding that no entity meets the definition of “wholesaler” for purposes of BPC 42030(f)(1)(B). Additionally, the regulations should clearly state that a repackager does NOT meet the definition of a covered entity if either the manufacturer or wholesaler have been identified.	
016-003	Lil' Drug Store Products, Inc. & Convenience Valet	Neil Dow, Barry Margolin	18972.1	N	<p>3. An exemption for immediate or single-use products.</p> <p>Single-use products, which contain a single dose of over-the-counter medication offer value to both retailers and consumers, as they are packaged in a very small quantity designed for immediate use. Many convenience stores have limited space and prefer to offer these smaller product packages. Products with larger quantities of medication are more expensive than products with convenience-sized packaging and can thus serve as a barrier to treating health concerns; products with convenience-sized packaging thus create low-cost options designed to provide immediate relief. Because the product is packaged to be used within a very short period of time, with the first dose to be taken within the hour following its purchase, it essentially eliminates the possibility of the product being unused, expired, or leftover and entering the waste stream.</p> <p>For these reasons, we request that CalRecycle include language that exempts immediate-use nonprescription packaged drugs from all return requirements, including exempting companies which only provide drug products in these formats from the requirement of participating in stewardship plans. We believe that this request is consistent with the legislative intent and statements associated with SB 212, and we do not read SB 212 to prohibit a de minimus exemption of packages of such small size that their contents will have a negligible (if any) chance of reaching the waste stream.</p>	016-003. A change to the proposed regulatory text is not necessary. It is outside the scope and authority of these regulations to impose an exemption for single dose medications. Single dose medications meet the conditions for a “covered drug”, per Public Resources Code section 42030(e)(1). Covered drugs in quantities described in the comment meet the statutory definition of covered products.
017-001	Sanitation Districts of Los Angeles County	Martha Tremblay	General	N	In addition to broader goals related to reducing drug abuse and diversion of unused drugs, reducing the disposal of unwanted pharmaceuticals is important because, when disposed by flushing down the drain or put out with household trash, wastewater treatment facilities and municipal solid waste facilities can serve as pathways for pharmaceutical waste residuals to enter the aquatic environment. Trace amounts of pharmaceuticals can also affect the quality of recycled water or drinking water. Furthermore, sharps that are disposed in trash or flushed down the drain pose health and safety concerns for sanitation workers, as improperly disposed sharps may cause injuries to workers at materials recovery facilities where household solid waste is sorted and to wastewater system workers when flushed. Household trash disposal also presents additional opportunities for diversion, such as by scavengers that may	017-001. 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 regulations to implement SB 212.

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					<p>discover drugs in trash left at the curbside, or at materials recovery facilities, where increasingly trash is sent for sorting prior to recycling or disposal.</p> <p>For all these reasons, we support the adoption of regulations to implement SB 212 in order to provide a consistent statewide approach for residents in the many local jurisdictions that have not yet established EPR programs for pharmaceuticals and sharps waste.</p>	
PH001	Nat'l Stewardship Action Council, CalPSC	Jason Schmelzer	18972.1 (j)(3)	Y	<p>Provides or initiates distribution of sharps waste container. Under 3 it says: Other methods of providing sharps waste container and mail- back materials as approved by the Department, if 1 or 2 are not reasonably feasible.</p> <p>So, this is kind of pertaining to the requirement that a sharps container and mail-back materials be provided at the point of sale. And I just want to clarify that in the authorizing statute there is not a feasibility off ramp. There is a legality off ramp. The PRC specifically says that you have to provide the sharps container and mail-back materials at the point of sale to the extent that it's allowable by law.</p> <p>The issue and the reason that that's in the bill is that when the bill was being negotiated sharps manufacturers were concerned that providing the container and the mail-back materials would be considered an illegal inducement under federal law. So, we created an off ramp specifically for that. But there is no feasibility off ramp. It is really just a legality off ramp. If they cannot as a matter of law do that, then there's an alternative to that.</p> <p>So, we just wanted to make sure. It's pretty important and that point of sale requirement is really critical to the convenience of the sharps mail-back program.</p>	PH001. See responses to corresponding written comments 005-002A and 005-002B.
PH002	Lil' Drugstore Products and Convenience Valet	James Jack	18972.2	N	<p>This is also pursuant to the written comments that we had submitted. Both of our clients I think share concerns around what types of scenarios would potentially trigger the covered entity responsibility shifting from the manufacturer to one of the other entities that are referenced, and this is on page 3, starting on line 15 through 18. We know that, obviously, Senate Bill 212 created kind of a cascading list of other potential responsible parties if a manufacturer is not identified. And we would just encourage the staff to articulate clearly, potentially in the next set of revisions to the proposed regulation what efforts CalRecycle would have to take to identify a manufacturer for purposes of the program before that responsibility could be assigned elsewhere.</p>	PH002. A change to the proposed regulatory text is not necessary. See response to corresponding written comment 009-001A.
PH003	Nat'l Stewardship Action Council, CalPSC	Jason Schmelzer	18972.2	N	<p>There's really no indication in the regulations about when you move up or down the list. If there's an approved plan and suddenly it's disapproved, what's the notice to the distributors, you know, retailers, et cetera down the list? Is there going to be any sort of notification process? What are the timelines for them coming into compliance? It's really just unclear at this point how you move up or down that list.</p>	PH003. A change to the proposed regulatory text is not necessary. See response to corresponding written comment 005-003.
PH004	PPSWG	John Gay	18973.4 (j)(2)	Y	<p>The item I want to focus on here is we're concerned that in 18973.4 of the proposed regulations -- the page number is 17, the line is 13 -- the proposed</p>	PH004. CalRecycle accepts the proposed edit included in the commenter's corresponding comment letter 010-001a, and agrees that

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					<p>regulations' proposal could require the submission of updated, verified, or reverified lists of covered products in annual reports, which is contrary to what is required by SB 212.</p> <p>Section 42031(a)(2) of SB 212 requires that covered entities or a stewardship organization update and submit a list of covered products to the Board of Pharmacy on or before January 15th, each calendar year. The bill does not impose any new obligations on program operators during the annual reporting process. I.e., there's no obligation to prepare new, updated or reverified lists of covered products during that roughly two and a half month period between January 15th for the pharmacy submission, and the March 31st annual reporting deadline.</p> <p>Rather, the legislative intent was simply to and only to require that the same covered products list be resubmitted to the Board of Pharmacy on January 15th -- that was submitted on January 15th be included in the annual report submitted to CalRecycle on March 31st.</p> <p>However, the section I noted of the proposed regulation states, without further elaboration, that the annual report submitted to CalRecycle for a covered drug stewardship plan must include, quote "A list of covered products", unquote. As drafted, this language in the proposed regulations could be construed as imposing additional obligations on program operators to undertake another exercise in preparing a different update or reverified list of covered products included in the March 31st annual report submissions.</p> <p>Accordingly, we suggest that this provision of the proposed regulation should be revised to be consistent with SB 212.</p>	<p>clarity is needed regarding the submittal of covered product lists in the annual report.</p> <p>Proposed regulations section 18973.4(j)(2) is revised as follows: <u>(2) A copy of the list of covered products submitted to the Board of Pharmacy pursuant to subsection (2) of subdivision (a) of section 42031 of the Public Resources Code.</u> List of covered products</p>
PH005	Lil' Drug Store Products, Inc. & Convenience Valet	James Jack	18972.2	N	<p>And one suggestion that we would like to make to the department regarding this section is inherently there is a natural desire within stewardship organizations to spread the cost of the program across as many entities as possible to reduce the overall burden to any particular entity with regard to the cost of administering the program.</p> <p>However, a situation will likely exist where members of the pharmaceutical supply chain, who are not the covered entities could potentially be looked to as -- for financial or program support through a stewardship organization, even if they are not defined under the regulation as the covered entity for that covered drug.</p> <p>And so, the clarification that we would request that I think would create a lot of uncertainty for smaller companies, like the two that we represent, is that participation in the stewardship group shall not be required unless you are a covered entity for a covered drug under the program.</p>	PH005. A change to the proposed regulatory text is not necessary. Only covered entities must implement stewardship programs, either individually or as part of a stewardship organization. Public Resources Code section 42031.4(b) states that "in order to comply with the requirements of this chapter, a covered entity may establish and implement a stewardship program independently, or as part of a group of covered entities through membership in a stewardship organization exempt from taxation under Section 501(c)(3) of the federal Internal Revenue Code of 1986 (21 U.S.C. 501(c)(3))." Participating in a stewardship organization is not mandatory under SB 212. However, a covered entity that chooses not to join a stewardship organization must establish and implement its own stewardship program in order to be compliant.
PH006	Nat'l Stewardship Action	Jen Jackson	18973.2 (d)(3)	Y	Page 6, line 21 and 22, where it's talking about creating a description for the process in which good faith negotiations with potential authorized collectors is conducted.	PH006. See responses to corresponding written comments 005-008 and 005-020.

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	Council, CalPSC				<p>We would ask that there would be a separate process described for authorized collectors who request to join the program specifically under 42032.2(b)(3) of the PRC. That's the provision that says, you know, once a plan has been approved and once the minimum convenience standard has been met that any authorized collector, any valid authorized collector can request to join the Med Program and needs to be basically brought in within 90 days.</p> <p>This is an extremely important provision in the bill. This was kind of the balancer on meeting the convenience standard. There's a kind of a numerical convenience standard and this was the stop gap to make sure that any holes were filled. So, we think that's a very important process and we want to see that measured very specifically. Because to us, that's part of the convenience standards is, you know, those requesters joining and how they're dealt with and processed.</p> <p>And we would kind of extend that further to say if they're rejected for any reason, once they've requested to join, we think the stewardship organization should have to provide an explanation as to why they were rejected.</p>	
PH007	MED-Project USA	Michael Van Winkle	General	N	<p>And I do have one issue on this section I'd like to bring forward. And that while we've provided substantial written comments, one of the things that we'd point out in this section is that CalRecycle should revise the regulations to recognize the appropriate program operator roles as contemplated in the SB 212.</p> <p>To basically operate successful and compliant stewardship programs, program operators can support collection site and program vendor compliance, but they cannot ensure these independent entities comply with their independent legal obligations.</p> <p>You know, while program operators can describe processes to address certain critical collection site, or certain provider policy or procedure deviations, only government agencies can conclusively determine that collection services or service providers are in noncompliance.</p>	PH007. This is a general comment and a change to the proposed regulatory text is not necessary. The following comments from the commenter's written letter correspond with the specific instances of the proposed regulatory text where this concern is addressed: 015-010a and b, 015-013a through d, and 015-025a and b.
PH008	Nat'l Stewardship Action Council, CalPSC	Jason Schmelzer	18973.2 (i)	N	<p>Page 8, line 23 to 26, on ordinance repeals.</p> <p>So, the coverage for the entire program, whether it's meds or sharps, obviously the program does not apply and program operators, and stewardship organizations don't have to cover a county where there's an existing ordinance. But part of what we've set up in the bill is a process whereby a stewardship organization or a program operator can negotiate with a county with an ordinance to get them to repeal their ordinance and come into the statewide program, which I think is important.</p> <p>But to the extent that that happens I think, and to the extent that you can, the regulations need to help control that process. Let me give you an example. Say there's a county with an existing local ordinance that has requirements that are</p>	PH008. A change to the proposed regulatory text is not necessary. See response to corresponding written comment 005-013.

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					<p>higher than what's in the legislation, so they negotiate to repeal their ordinance and come into the statewide program, but there's conditions for that county. Yes, we will join the statewide program, but you have to provide us with this level of service for us to repeal the ordinance.</p> <p>Well, the ordinance repeal is going to be permanent. So, to the extent that CalRecycle can, we'd like to examine ways were that kind of deal, that negotiation, the conditions for leaving the local program and joining the statewide program are preserved. Program operators will change. Stewardship organizations may change. If a county negotiates with one program operator, but then they go away and a new operator comes in to run the program, are those negotiations going to carry forward? How does that process work? Because it won't happen if counties don't have certainty. And there obviously is some value to bringing everybody into one program as far as efficiency, et cetera.</p> <p>So, to the extent that the department can kind of help control that situation, we think it would be helpful.</p>	
PH009	CRA, NACDS, & CPhA	Jennifer Snyder	18973.2 (g)(8)	N	<p>This is relative to Section 18973.2, paragraph G8.</p> <p>So, this has to do with collection site maintenance. And organizations I represent have turned in some written comments, but I just wanted to note this one in particular. For them, I think also in our discussions with the Pharmacist Association and the Independent Pharmacies, there's a lot of concern about collection site maintenance and making sure that program operators that work with pharmacies effectively help them with collection site maintenance. And many of them have a lot of concerns about that their collection sites are not properly maintained. And they don't really have accessibility or know who to report that to, who to call.</p> <p>So, we would look for stronger language in paragraph 8 with respect to keeping program operators accountable for, if we're going to have collection receptacles that they're properly maintained.</p>	PH009. A change to the proposed regulatory text is not necessary. See response to corresponding written comment 008-003.
PH010	Nat'l Stewardship Action Council, CalPSC	Jason Schmelzer	18973.3 (f)(2)(A)	Y	<p>Again, we just want to kind of double down on the comment that we made earlier about how important the issue of providing at the point of sale, providing or initiating distribution of the sharps mail-back container at the point of sale is -- the law is drafted very tight, drafted very tightly to make sure that this occurs. So, it's just paramount importance.</p> <p>Frankly, I think from a negotiating perspective, the folks that were for the program in the first place, we weren't really comfortable with the mail-back program, and that convenience factor again is really central.</p> <p>One thing that's not anticipated by the regulations, but that we think would be helpful, when we were talking about the bill with the sharps manufacturers they said, hey, we may want to do, you know, a container for three months' worth of</p>	<p>PH010. Regarding the "point of sale" requirement, see responses to corresponding written comments 005-002A and 005-002B. Additional language added to section 18973.3(f)(2)(A) as indicated in response to comment 005-017 allows for a large container to be distributed in lieu of a small container at each point of sale. The proposed regulatory text section 18973.3(f)(2)(A) is revised as follows:</p> <p><u>(A) 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.</u></p>

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					<p>sharps, you know, and not at every point of sale. Maybe we know somebody gets 30 a month and we want to give them a container for a hundred sharps. We should be able to do that. How can you do that if you're supposed to give them something at the point of sale every time?</p> <p>So, maybe the regulations should anticipate the program providing larger containers for multiple months or multiple purchases, and how they would kind of work that out.</p>	
PH011	PPSWG	John Gay	18973.5 (k)	Y	<p>The issue I'd like to raise this time is on page 20, line 5, Section 18973.5(k).</p> <p>Similar to what I mentioned earlier, this provision states that: The annual reports for a home-generated sharps waste stewardship plan must include, quote, "Updated", unquote -- "Updated list of covered products", unquote. So, as drafted, this language in the proposed regulations could be construed as imposing additional obligations on program operators to undertake another exercise in preparing a different, updated, and/or reverified list of covered products to include the March -- products to include in the March 31st annual report submission.</p> <p>Accordingly, we suggest that Section 18973.5(k) of the proposed regulations should be revised to be consistent with SB 212.</p>	<p>PH011. CalRecycle agrees that additional clarity is needed regarding the submittal of covered product lists in the annual report and concurs with the commenter's interpretation of corresponding statutory requirements. Section 18973.5(k) of the proposed regulatory text is revised as follows:</p> <p><u>(k) A copy of the list of covered products submitted to the Board of Pharmacy pursuant to subsection (2) of subdivision (a) of section 42031 of the Public Resources Code. Updated list of covered products</u></p>
PH012	Nat'l Stewardship Action Council, CalPSC	Jason Schmelzer	18973.3 (g)(2)	Y	<p>It seems like 42033.2(b) says that an annual report submitted shall include at a minimum all of the following. It seems like you guys have pretty broad authority to include other things that you think are important under that piece of language. So, I would point that out.</p> <p>And then, second, page 20, line 13 on the local agency requests, again this was another really important piece with respect to the sharps program. There was some discomfort with the mail-back structure as opposed to a kiosk-based system. So, the point of this is to catch any sharps that fall through the cracks so to speak and end up at local government facilities.</p> <p>So, in the annual report what we'd like to see is the language expanded, which we think you can do, to say that the annual report should include a specific list of the local jurisdictions that have requested either pickup or reimbursement under the law, the date of the request, the date of the response, and the ultimate disposition, what happened.</p> <p>And if, for whatever reason, the request was rejected there should be an explanation about why the request was rejected. So, we would ask that to be included.</p>	<p>PH012. CalRecycle agrees to expand reporting requirements regarding local agency requests. The proposed regulatory text has been revised as follows:</p> <p><u>18973.3(g)(2) Requests by local agencies, or an agent on behalf of a local agency, shall include an invoice and shall be submitted to the program operator as necessary. Program operators will respond to requests by local agencies within 14 days of receipt in a timely manner and identify the method to resolve the request by selecting either reimbursement or removal from household hazardous waste facility(ies).</u></p> <p><u>18973.5(p)(3) Any requests that were rejected and the reason(s) each request was rejected.</u></p> <p><u>18973.5(p)(4) Any requests where response, removal, or reimbursement was performed outside of the required timelines.</u></p> <p>However, regarding "the date of the request," "the date of the response" and "the ultimate disposition," CalRecycle declines to incorporate these requirements into the proposed regulations. Local agencies will likely make many requests for pickup or reimbursement for home-generated sharps waste during a reporting period, and most of these requests would be fulfilled without issue under a well-functioning stewardship program. The proposed regulations require only aggregated data for each facility, and the department is editing the proposed text to require</p>

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						reporting on any specific requests that were not fulfilled within 45 days. The department finds this level of detail to be sufficient for effective program oversight without being overly burdensome on program operators.
PH013	MED-Project USA	Michael Van Winkle	General	N	<p>So, in this section, 18973, it's a broad comment for this and it probably does apply also back to the 18973.4. That the pharmaceutical and sharps waste program was established by SB 212 is not publicly funded, like other extended producer responsibility programs established by the Legislature in California.</p> <p>And under SB 212, this stewardship program is wholly funded by the covered entities. This distinction was relevant to the Legislature and should be honored in the proposed regulations. The amount of supplemental information and level of detailed oversight sought by CalRecycle in the annual reporting, and then also, then, in the following budget section does not account for this private funding scheme and this appears inconsistent with SB 212.</p> <p>So, we've got a number of comments on this, so I'd refer you to our written comments that we think should be revised for this distinction, in line with the level of detail intended by the Legislature.</p>	PH013. A change to the proposed regulatory text is not necessary to respond to this general comment. See responses to corresponding written comments 015-023A through 015-024B.
PH014	Nat'l Stewardship Action Council, CalPSC	Jason Schmelzer	18973.6	N	<p>I guess I can ask this question in the context of this section, but it actually kind of applies across the board to the regulations. On page 21, line 2 there's this reference to, you know, the first five calendar years of operation. You know, provide the budget for the first five years of operation.</p> <p>It seems like throughout the regulations we're leaning towards a five- year plan, but it never says that. So, I guess I would just suggest if what CalRecycle is anticipating is kind of a long-term plan that's implemented over time, and there's a long-term budget, and things like that that maybe that just be called out very specifically in the regulations. Hey, here's going to be the duration of the plan. It would just give everybody more certainty as to what they're looking at. Because looking at the regulations I can't really tell if they could propose a three- year plan that has like a five-year funding structure, it's just a little bit unclear. So, I'd just make a general comment about that.</p>	PH014. A change to the proposed regulatory text is not necessary. Public Resources Code section 42033 states that "with the submission of a stewardship plan, a program operator shall submit to the department an initial stewardship program budget for the first five calendar years of operation of its stewardship program."
PH015	Nat'l Stewardship Action Council, CalPSC	Jason Schmelzer	18975(a)	N	<p>Page 24, line 7.</p> <p>So, I guess this is more of a general comment than what's in the regulations. The statute's pretty limited as far as the application of civil penalties. It's really only as you've described it in that paragraph.</p> <p>So, I think we would make a comment about your general enforcement posture, which is there's a lot of other very important aspects of this program that can't be penalized through civil penalties. Rejecting local government requests for pickup would not be punishable under a civil penalty. That's not -- that doesn't meet the test under the statute or the regulations.</p>	PH015. This comment does not specify a proposed change to the regulations. A change to the regulatory text is not necessary. General statements about the regulations have been provided. CalRecycle is unable to review and analyze specific information to reach a conclusion.

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					<p>Failing to provide the sharps container at the point of sale does not count for civil penalties.</p> <p>Which means, really, your only recourse if there are problems, which I actually don't expect there will be, respectfully I don't think there are going to be problems. But if there is, really your only recourse is an aggressive policy related to repeal, suspension, revocation, whatever you want to call it of the plan then you can impose civil penalties.</p> <p>So, we would just suggest that if for whatever reason there are problems such as that on key provisions of the requirements under the law, that CalRecycle take a very aggressive enforcement posture. Because there have been other programs in the past that have floundered because of difficulty with enforcement and this one, obviously, that we really want to work very well.</p> <p>So, being as that you have limited tools, we would say use them aggressively to the extent that you have to.</p>	
PH016	Nat'l Stewardship Action Council, CalPSC	Jason Schmelzer	18975	N	<p>Following up on my prior comment, this is where it might be a good idea to telegraph both to the program operators and, you know, people who are going to be using the program if there are certain things that will automatically trigger a revocation process. Again, doing some of those big ticket, or failing to do some of those big ticket items in the bill, maybe if -- maybe it doesn't belong here. I'm not sure, I'm not a regulator. But maybe the regulations could anticipate certain offenses we're going to move straight to revocation, we're not messing around. Very strict enforcement posture.</p>	PH016. A change to the proposed regulatory text is not necessary. CalRecycle will take into consideration all facts on a case-by-case basis when considering possible revocation. Narrowing how CalRecycle implements revocation by indicating in regulation which violations justify an automatic triggering of revocation of a stewardship plan could result in unintended consequences.
PH017	MED-Project USA	Michael Van Winkle	General	N	<p>So, as I think we brought up before, and certainly in our written comments, and many detailed discussions, SB 212 is a very detailed and prescriptive statute. And the proposed regulations build on this already detailed framework and in many ways adding new requirements and in other ways creating some inconsistent obligations or ambiguities where conflicting readings are potentially possible. And a full list of these additions, and inconsistencies, ambiguities are included in our written comments. And our request is that these should be eliminated to preserve the language and intent of SB 212 to maintain its flexibility which in turn will promote a successful program operation.</p>	PH017. A change to the proposed regulatory text is not necessary to respond to this general comment. See responses to corresponding written comments 015-030A through 015-030G.

**Comments Received in Response to CalRecycle's
SB 212 45-Day Formal Rulemaking Comment Period**

Comment Letter Number:	Comments Submitted By:	Representative Organization: (If Applicable)
001	Wanda Lingner	Sharps Compliance, Incorporated
002	Staci Heaton	Rural County Representatives of California
003	Don McEnhill	Russian Riverkeeper
004	Kirk Galarneau	City of San Diego
005	Doug Kobold, Heidi Sanborn, William Grimes, & Leslie Lukacs	Nat'l Stewardship Action Council, CalPSC, County of Santa Clara, & Zero Waste Sonoma
006	Jen Jackson	San Francisco Dept. of the Environment
007	Melanie To	Coalition for Prevention and Awareness in Los Angeles Metro
008	Rachel Michelin, Steve C. Anderson, & Rajan Vaidya	California Retailers Association, National Association of Chain Drug Stores, & California Pharmacists Association
009	Leah Lindahl	Healthcare Distribution Alliance
010	Anne Vogel-Marr	Pharmaceutical Product Stewardship Work Group
011	Fielding Graves	AdvaMed
012	Larry Kenemore	Stat-Medicament-Disposal Corporation
013	Domingo Isasi	Inmar Intelligence
014	Wade Scheel	Stericycle
015	Michael R. Van Winkle & Dr. Victoria Travis	MED-Project USA
016	Neil Dow & Barry Margolin	Lil' Drug Store Products, Incorporated & Convenience Valet
017	Martha Tremblay	Sanitation Districts of Los Angeles County

From: [Wanda Lingner, RN, BSN](#)
To: [PharmaSharps](#)
Subject: Comments to
Date: Monday, February 10, 2020 1:01:08 PM
Attachments: [Sharps Compliance Inc Comments to SB 212 Proposed Rules_02_10_2020.pdf](#)

[[EXTERNAL]]

Dear Mr. Smyth:

Attached please find Sharps Compliance, Inc.'s comments on the adoption of California Code of Regulations, Title 14, Division 7, Chapter 11, Article 4 commencing with Section 18972.

Please let me know if you have any questions regarding our comments.

Thank you again for the opportunity to comment.

Sincerely

Wanda Lingner

Wanda Lingner, RN, BSN | Director, Regulatory Compliance

Sharps Compliance, Inc. | www.sharpsinc.com
d- 713-353-1152 | o- 800-772-5657 | f- 713-353-1161

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

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February 10, 2020

Jason Smyth
Materials Management and Local Assistance Division
California Department of Resources Recycling and Recovery
P.O. Box 4025
Sacramento, CA 95812-4025
Fax: (916) 319 – 7147
e-mail: pharmasharps@calrecycle.ca.gov

RE: Sharps Compliance, Inc. Comments on the adoption of California Code of Regulations, Title 14, Division 7, Chapter 11, Article 4 commencing with Section 18972

Dear Mr. Smyth:

Please accept the attached comments and recommended modifications to the proposed adoption of California Code of Regulations, Title 14, Division 7, Chapter 11, Article 4 commencing with Section 18972 intended to clarify the processes for implementing the Pharmaceutical and Sharps Waste Stewardship Act.

Sharps Compliance, Inc. (Sharps) has been the leader in ultimate user medication disposal as well as the disposal of sharps waste via mailback disposal solutions since 1994. 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 and pharmaceutical waste.

We appreciate the opportunity to provide feedback on the proposed new rules related to the implementation process for Pharmaceutical and Sharps Waste Stewardship Act.

Thank you,

Wanda Lingner, RN, BSN
Director of Regulatory Compliance
Sharps Compliance, Inc.
wlingner@sharpsinc.com
www.sharpsinc.com
713-353-1152

Below are **Sharps Compliance, Inc.**'s comments and questions related to the adoption of California Code of Regulations, Title 14, Division 7, Chapter 11, Article 4 commencing with Section 18972:

Pg. 2 Ln 16 Proposed regulation: "To provide a sharps waste container and mail-back materials to the ultimate user at the point of sale at no cost to the ultimate user;"

001-001

Issue: Tangible provision of sharps waste containers at "point of sale" places all the burden on pharmacies who do not have the space nor personnel to handle distribution.

Proposed Resolution: Though Pg. 2 Ln 23 allows for "other methods" such as, for example, a patient support program, we still suggest to change Ln 16 to: "To initiate provision of a sharps mail-back system to the ultimate user either upon the point of prescribing the drug or at point of sale."

Pg. 2 Ln 19 Proposed regulation: "...mail-back materials to be sent to the ultimate user and arrive within 3 business days at no cost or inconvenience to the ultimate user."

001-002

Issue: No way to guarantee delivery of mail-back solution within 3 days without significant cost increase to the mail-back solution in order to have guaranteed 3-day delivery.

Proposed Resolution: Change statement to either: "...mail-back materials to be shipped to the ultimate user within 3 business days at no cost or inconvenience to the ultimate user". Or, "...mail-back materials to be sent to the ultimate user and arrive within 3-5 business days..."

Pg. 2 Ln 20 Proposed regulation: "...no cost or inconvenience to the ultimate user..."

001-003

Issue: Inconvenience is a very subjective word and has no definition. What is an inconvenience for an 80-year-old housebound person is not going to be an inconvenience to an 18-year-old diabetic.

Proposed Resolution: Either define "inconvenience" or have it read "...no cost to the ultimate user..."

Pg. 2 Ln 23 Proposed regulation: "...if (1) or (2) are not reasonably feasible, and which results in substantially the same level of convenience to the ultimate user"

001-004

Issue: Again, this sentence has very subjective measurements of "reasonably feasible" and "substantially the same level of convenience". These can have very different meanings to different people.

Proposed Resolution: "...as approved by the department in a stewardship plan if (1) or (2) are not available."

Pg. 7 Ln 29 Proposed regulation: "Metrics that will be used to measure the amount of materials distributed and weight of material returned".

001-005

Issue: There is no clear definition of exactly what metrics you will be wanting program operator to provide.

Proposed Resolution: Define the metrics that will be required. This way the program operator will know, when developing their plan, what data they will be required to provide and how they will be able to provide that information.

Pg. 8 Ln 31 Proposed regulation: "...materials to be utilized that are distributed in languages suited to local demographics" ...

001-006

Issue: Given the number of different languages spoken in California, how will the program operator know what language translations will be required in each county? Is there a minimum population

threshold that must be met before materials must be produced in that language? Additionally, who will be responsible for making such determinations and notifying program operators or stewardship organizations of languages, by county, required for materials?

Proposed Resolution: There should be a minimum population number that would then trigger production of materials in the specified location. Additionally, CalRecycle should be responsible for providing the list of required languages by county to program operators and stewardship organizations.

Pg. 9 Ln 15 Proposed regulation: “Metrics to evaluate performance of the comprehensive education and outreach program...”

001-007 **Issue:** There is no definition of what exact metrics required to evaluate the performance of the education and outreach program.

Proposed Resolution: Define the metrics that will be required. This way the program operator will know, when developing their plan, what data they will be required to provide and how they will be able to provide that information.

Pg. 10 Ln 26 Proposed regulation: “...initiates distribution of sharps waste containers and mail-back materials...”

001-008 **Issue:** the mailback sharps disposal system should be a single system, all inclusive. It should not entail a consumer being handed a sharps container and then separately obtaining shipping materials later, for several reasons:

1. If transporting via USPS – the entire mailback system must be independently tested to meet the mailability requirements set by USPS, and, once approved, only those system components can be used. You cannot just place a full sharps container into any box that is laying around a home.
2. If transporting via common carrier then DOT requirements for packaging, marking, and labeling must be met before UPS or FedEx could transport a full sharps container.
3. Inconvenience of consumer is mentioned earlier in the proposed rules, and, wouldn't it be an inconvenience to have to obtain shipping materials at a separate time and location than the sharps container?

Proposed Resolution: change language to the following: “...initiates distribution of the mailback disposal *system*, at no cost...”

Pg. 11 Ln 21 Proposed regulation: “Secure Receptacle Collection”

001-009 **Issue:** Having sharps collection receptacles raises several issues as follows:

1. Safety issue of individuals transporting home sharps to a collection receptacle.
2. Loose sharps being placed into collection receptacles places unnecessary risks on transporter collecting from receptacles once full
3. Regulation calls for “not inconveniencing” ultimate user; however, requiring them to transport their full sharps container to a secondary location could be considered by many as an inconvenience.
4. No way to limit that only covered drugs would be placed into receptacle and not things like illicit drug syringes.

Proposed Resolution: Given 100% of California counties can be more efficiently and safely serviced by mail-back solutions, remove secure receptacle collection as a means of disposing covered sharps products.

Pg. 12 Ln 13 Proposed regulation: “Take-back collection events”

001-010

Issue: Take-back collection events are for medications but do not include syringes or sharps. Community take-back events would have a difficult time safely collecting and immediately disposing of collected sharps. Additionally, how do you mitigate the public bringing loose sharps or sharps that are inappropriately contained into FDA-cleared and DOT-approved sharps containers for transport?

Proposed resolution: Given 100% of California counties can be more efficiently and safely serviced by mail-back solutions, remove take-back events as a means of disposing covered sharps products.

Pg. 12 Ln 15 Proposed regulation: “... metrics that will be used to measure the amount of sharps waste containers...”

001-011

Issue: There is no definition of what metrics will have to be provided by the program operator.

Proposed Resolution: Define the metrics that will be required. This way the program operator will know, when developing their plan, what data they will be required to provide and how they will be able to provide that information.

Pg. 12 Ln 17 Proposed regulation: “...metrics that will be used to measure the amount of sharps waste containers and mail-back materials collected through supplemental collection methods...”

001-012

Issue: We proposed that both alternative methods be removed as 100% of counties in California can be serviced more efficiently and safely by mail-back solutions. Additionally, there is the issue of how to collect meaningful metrics on these supplemental methods of collection – take-back events and collection receptacles. For example, use of receptacles does not allow for quantifying how many persons have placed their sharps into the receptacle, nor if they were even a covered product. The same holds true for take-back events.

Proposed Resolution: Remove alternative sharps collection methods. If you do not remove these alternative methods, then you will need to define the required metrics that will produce meaningful data.

Pg. 13 Ln 29 Proposed regulations: Metrics to evaluate performance of the comprehensive education and outreach program...”

001-013

Issue: There is no definition of what exact metrics are required to evaluate the performance of the education and outreach program.

Proposed Resolution: Define the metrics that will be required. This way the program operator will know, when developing their plan, what data they will be required to provide and how they will be able to provide that information.

From: [Maggie Chui](#)
To: [PharmaSharps](#)
Subject: RCRC Letter re Pharmaceutical and Sharps Waste Stewardship Program
Date: Friday, February 14, 2020 12:15:30 PM
Attachments: [Pharmaceutical and Sharps Waste Stewardship Program Ltr to CalRecycle 02142020.pdf](#)

[[EXTERNAL]]

Good Afternoon:

Attached please find RCRC's letter regarding the Pharmaceutical and Sharps Waste Stewardship Program, 45-Day Public Comments.

Please contact us at (916) 447-4806 if you have any questions.

Thank you,

Maggie Chui
Senior Governmental Affairs Coordinator
Rural County Representatives of California (RCRC)
1215 K Street, Suite 1650
Sacramento, CA 95814
Phone: (916) 447-4806
mchui@rcrcnet.org



February 14, 2020

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

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

RE: Pharmaceutical and Sharps Waste Stewardship Program, 45-Day Public Comments

Dear Mr. Smyth:

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

RCRC supported SB 212 to create a stewardship program for these products and ensure all members in the product chain share the responsibility to manage these products. Manufacturers of pharmaceuticals and sharps should design a system that works for their business model while alleviating significant financial burdens to local governments, not to mention the compromised safety of local municipal workers, when these wastes are irresponsibly, and illegally, disposed in residential trash and recycling bins.

In general, ESJPA supports the regulatory model as proposed. We appreciate the assurances by the California Department of Resources Recycling and Recovery (CalRecycle) throughout the proposed regulations to ensure these stewardship programs are complying with all applicable local, state, and federal laws and regulations. It is our

1215 K Street, Suite 1650, Sacramento, CA 95814 | www.rcrcnet.org | 916.447.4806 | Fax: 916.448.3154

overarching desire that these stewardship programs do not result in a reduction of currently available services in counties.

We offer more detailed comments in the respective sections of the proposed regulatory text, discussed below.

Section 18972.1, Definitions

002-001 CalRecycle should consider supplementing the definition of “ultimate user,” defined in Public Resources Code Section 42032 subdivision (z), in order to allow for Household Hazardous Waste program sponsors to also receive home-generated sharps containers. SB 212 allows Household Hazardous Waste programs to accept filled sharps containers, however, providing empty approved sharps containers would be a valuable part of the Stewardship Plan for Home-Generated Sharps Program and provide convenient service for residents.

002-002 Further, CalRecycle should describe criteria to determine “good faith negotiations” and “reasonable effort” by the program operator and potentially authorized collectors of drug and sharps waste.

Section 18973.2, Stewardship Plan for Covered Drugs

002-003 We recommend clarifying the Stewardship Plan is solely funded by participating covered entities. As currently written, Section 18973.2 subdivision (f) could be interpreted to mean that future program budgets and funding could be borne by consumers or others. Specifically, we request the following amendment, which is noted **as follows**:

(f) Initial Program Budget and Program Funding. Demonstration of adequate funding for all administrative and operational costs of the stewardship program, to be borne by participating entities, for the first five calendar years of operation pursuant to section 18973.6.

002-004 As with the Stewardship Plan for Home-Generated Sharps Program, there needs to be provisions in the Stewardship Plan for Covered Drugs regarding Local Agency Requests. Pharmaceuticals can wind up in solid waste, wastewater or sanitation facilities, not to mention parks or other public places, and there should be a mechanism to ensure they are recovered by covered entities. The regulatory language should contemplate requests by local jurisdictions and applicable reimbursement requests. Further, local agencies that conduct testing of inert drugs, such as an aquatic toxicity test, should be reimbursed for this activity in the course of ensuring that pharmaceuticals are properly disposed and managed.

002-005a CalRecycle should also encourage program operators or the Stewardship
& Organization(s) to financially contribute to a local agency's advertisements rather than
002-005b create separate campaigns for education and outreach. Local entities, for example,
provide public education through its Household Hazardous Waste (HHW) programs.
Residents and consumers should receive consistent and comprehensive messaging.

Section 18973.3, Stewardship Plan for Home-Generated Sharps Program

As stated above, we recommend clarifying the Stewardship Plan is funded by participating covered entities only. As currently written, Section 18973.3 subdivision (e) could be interpreted to mean that future program budgets and funding could be borne by consumers or others. Specifically, we request the following amendment, which is noted *as follows*:

002-006 (e) Initial Program Budget and Program Funding. Demonstration of adequate funding for all administrative and operational costs of the stewardship program, to be borne by participating entities, for the first five calendar years of operation pursuant to section 18973.6.

002-007 Rural local agencies often have limited budgets and staffing and rely on timely reimbursements. We appreciate requiring program operators to issue payment within 45 days but encourage CalRecycle to expand the types of reimbursements that could be made to local jurisdictions beyond transportation and disposal costs. For example, HHW facilities should be eligible to receive funding for empty approved sharps containers as part of their program, as well as the use of specialized tools and other worker safety equipment to properly handle these containers.

002-008 CalRecycle should also clarify how program operators will remove home-generated sharps from HHW facilities. Many of these HHW programs have large (e.g. 30-gallon) containers to hold collected sharps, which should be eligible for free disposal rather than having to stockpile mail-away containers. Similarly, load-checking programs and illegal dumping cleanup efforts encounter improperly disposed sharps, posing a hazard to solid waste and municipal workers. These programs should have an opportunity to dispose collected sharps under the stewardship program.

002-009 CalRecycle should also encourage program operators or the Stewardship Organization(s) to financially contribute to a local agency's advertisements rather than create separate campaigns for education and outreach. Residents and consumers should receive consistent and comprehensive messaging.

Mr. Jason Smyth
Pharmaceutical and Sharps Waste
Stewardship Program
February 14, 2020
Page 4

002-010 Given that these Stewardship Organizations do not have Advisory Committees and open meetings like other Extended Producer Responsibility laws, it is vital that CalRecycle provide clear and consistent expectations as well as results for local agencies and ultimate users.

Thank you for your consideration of our comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Staci Heaton", written in a cursive style.

STACI HEATON
Senior Regulatory Affairs Advocate

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

From: [Don McEnhill](#)
To: [PharmaSharps](#)
Subject: Comment letter on SB 212 California Pharmaceutical and Sharps Waste Stewardship Program
Date: Friday, February 14, 2020 1:28:21 PM
Attachments: [SB212 PSWSP Comment letter 14Feb20.pdf](#)
[icons8-facebook-50.png](#)
[icons8-twitter-50.png](#)
[icons8-instagram-50.png](#)

[[EXTERNAL]]

Dear Mr. Symth,

Please see our comments for today's deadline and let us know if you have any questions?

Thank you,
Don

Don McEnhill
Executive Director
Russian Riverkeeper
PO Box 1335
Healdsburg, CA 95448
707-433-1958 Ext. 2

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Ariel Majorana
Development Coordinator

Lola Dvorak
Communications Director

February 14, 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

Dear Mr. Smyth,

Thank you for the opportunity to comments on the proposed regulations to implement California's Pharmaceutical and Sharps Waste Stewardship Program. We are concerned about our ability to dispose of pharmaceutical and sharps waste we collect from homeless camps.

Our Clean River Alliance program works with homeless individuals in our Clean Camp and Education Program to maintain a clean camp and we conduct weekly trash pickups at over 75 camps along the Russian River. We also are called out to clean up abandoned camps or camps after residents are evicted. We often find discarded needles and pharmaceuticals that we didn't purchase or generate.

At this time we can't figure out from the bill language – reading it hastily as this just came across our desk today – allows our staff to legally dispose of this medical waste through the program this bill is creating. Currently we work with a local hospital who disposes of medical waste for us but it is tenuous and sometimes they do not accept it so we have to store it so it doesn't go into landfills.

Please make sure we have some avenue of participating in this program with our homeless cleanup work!

Thank you for your consideration.

Sincerely,

Don McEnhill
Executive Director



From: [Galarneau, Kirk](#)
To: [PharmaSharps](#)
Subject: Pharmaceutical and Sharps Waste Stewardship Program - comments to proposed regulations
Date: Friday, February 14, 2020 2:57:40 PM

[[EXTERNAL]]

The City of San Diego's Environmental Services Department is submitting the following written comments on the proposed regulations with additions indicated in underlined text.

Page 1, Section 18972.1. Definitions

...

(b) "Administrative and operational costs" means costs to implement and operate a stewardship program, including, but not limited to, collection, consolidation, transportation, processing, disposal, and education and outreach costs, as well as administrative costs of operating the stewardship organization and administrative fees charged by the department.

Page 8, Section 18973.2. Stewardship Plan for Covered Drugs

Local Agency Requests.

(1) Description of the process for coordinating with local agencies, or an agent on behalf of a local agency, for the removal of covered drugs from local household hazardous waste facilities other local agency collection locations, either by reimbursement for consolidation, transportation, and disposal costs or removal of covered drugs.

(2) Requests by local agencies, or an agent on behalf of a local agency, shall be submitted to the program operator as necessary. Program operators will respond to requests by local agencies in a timely manner and identify the method to resolve the request by selecting either reimbursement or removal from household hazardous waste facility(ies) or other local agency collection locations.

(A) A program operator that selects to resolve a request through reimbursement to a local agency shall issue payment within 45 days of the local agency providing an invoice.

(B) A program operator that provides for the removal of covered drugs from the local household hazardous waste facilities or other local agency collection locations shall do so as often as required according to section 118280 of the Health and Safety Code or by the local enforcement authority.

Page 12, Section 18973.3 (g) Local Agency Requests

(g) Local Agency Requests.

(1) Description of the process for coordinating with local agencies, or an agent on behalf of a local agency, for the removal of home-generated sharps waste from local household hazardous waste facilities, either by reimbursement for consolidation, transportation, and disposal costs or removal of the home-generated sharps waste.

(2) Requests by local agencies, or an agent on behalf of a local agency, shall be submitted to the program operator as necessary. Program operators will respond to requests by local agencies in a timely manner and identify the method to resolve the request by selecting either reimbursement or

removal from household hazardous waste facility(ies).

(A) A program operator that selects to resolve a request through reimbursement to a local agency shall issue payment within 45 days of the local agency providing an invoice.

(B) A program operator that provides for the removal of the home-generated sharps waste from the local household hazardous waste facilities shall do so as often as required according to section 117904 of the Health and Safety Code or by the local enforcement authority.

The following explanations for the written comments are included as some of the comments may not be applicable given the restrictions of relevant statutes. By providing this background information, if appropriate, potential options may be considered that recover the full costs incurred by local agencies and are within the scope of statute.

Explanation of proposed revisions to Section 18973.2: The City of San Diego (City) has Safe Prescription Drug Drop-Off collection kiosks located as San Diego Police Department (SDPD) facilities and accepts prescription drugs at the City's household hazardous waste facility. Reimbursement for the costs for the collection, consolidation, and disposal of covered drugs by local agencies could be specifically added to the proposed regulations similar to Section 18973.3.

Explanation of proposed revisions to Section 17983.3 (g): The City of San Diego (City) has sharps collection kiosks located as San Diego Police Department (SDPD) facilities for the collection of home-generated sharps waste. The kiosks are serviced weekly by our hazardous waste contractor. The sharps collection kiosk waste from the SDPD locations is transported back to the City's permanent household hazardous waste facility for consolidation and accumulation prior to disposal. The City is charged a separate fee for the pickup and consolidation of sharps kiosk waste from the SDPD locations and is proposing the revisions above to recover those additional costs associated with the proper disposal of home-generated sharps.

There may be other local agencies that collect sharps at other local agency supported locations in addition to or as an alternate to a permanent household hazardous waste facility. This section could be further expanded to include other agency locations in addition to household hazardous waste facilities.

Thank you for the opportunity to provide comments on the proposed regulations.

Kirk Galarneau
Hazardous Substances Enforcement Supervisor
Environmental Services Department
9601 Ridgehaven Court, Suite 310
T (858) 573-1338
KGalarneau@sandiego.gov



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From: KGalarneau@sandiego.gov

To: Pharmasharps@calrecycle.ca.gov

The City of San Diego's Environmental Services Department is submitting the following written comments on the proposed regulations with additions indicated in underlined text.

Page 1, Section 18972.1. Definitions

...

004-001 (b) "Administrative and operational costs" means costs to implement and operate a stewardship program, including, but not limited to, collection, consolidation, transportation, processing, disposal, and education and outreach costs, as well as administrative costs of operating the stewardship organization and administrative fees charged by the department.

Page 8, Section 18973.2. Stewardship Plan for Covered Drugs

Local Agency Requests.

004-002 (1) Description of the process for coordinating with local agencies, or an agent on behalf of a local agency, for the removal of covered drugs from local household hazardous waste facilities other local agency collection locations, either by reimbursement for consolidation, transportation, and disposal costs or removal of covered drugs.

004-002 (2) Requests by local agencies, or an agent on behalf of a local agency, shall be submitted to the program operator as necessary. Program operators will respond to requests by local agencies in a timely manner and identify the method to resolve the request by selecting either reimbursement or removal from household hazardous waste facility(ies) or other local agency collection locations.

(A) A program operator that selects to resolve a request through reimbursement to a local agency shall issue payment within 45 days of the local agency providing an invoice.

(B) A program operator that provides for the removal of covered drugs from the local household hazardous waste facilities or other local agency collection locations shall do so as often as required according to section 118280 of the Health and Safety Code or by the local enforcement authority.

Page 12, Section 18973.3 (g) Local Agency Requests

(g) Local Agency Requests.

004-003 (1) Description of the process for coordinating with local agencies, or an agent on behalf of a local agency, for the removal of home-generated sharps waste from local household hazardous waste facilities, either by reimbursement for consolidation, transportation, and disposal costs or removal of the home-generated sharps waste.

(2) Requests by local agencies, or an agent on behalf of a local agency, shall be submitted to the program operator as necessary. Program operators will respond to requests by local agencies in a timely manner and identify the method to resolve the request by selecting either reimbursement or removal from household hazardous waste facility(ies).

(A) A program operator that selects to resolve a request through reimbursement to a local agency shall issue payment within 45 days of the local agency providing an invoice.

(B) A program operator that provides for the removal of the home-generated sharps waste from the local household hazardous waste facilities shall do so as often as required according to section 117904 of the Health and Safety Code or by the local enforcement authority.

The following explanations for the written comments are included as some of the comments may not be applicable given the restrictions of relevant statutes. By providing this background information, if appropriate, potential options may be considered that recover the full costs incurred by local agencies and are within the scope of statute.

Explanation of proposed revisions to Section 18973.2: The City of San Diego (City) has Safe Prescription Drug Drop-Off collection kiosks located as San Diego Police Department (SDPD) facilities and accepts prescription drugs at the City's household hazardous waste facility. Reimbursement for the costs for the collection, consolidation, and disposal of covered drugs by local agencies could be specifically added to the proposed regulations similar to Section 18973.3.

Explanation of proposed revisions to Section 17983.3 (g): The City of San Diego (City) has sharps collection kiosks located as San Diego Police Department (SDPD) facilities for the collection of home-generated sharps waste. The kiosks are serviced weekly by our hazardous waste contractor. The sharps collection kiosk waste from the SDPD locations is transported back to the City's permanent household hazardous waste facility for consolidation and accumulation prior to disposal. The City is charged a separate fee for the pickup and consolidation of sharps kiosk waste from the SDPD locations and is proposing the revisions above to recover those additional costs associated with the proper disposal of home-generated sharps.

There may be other local agencies that collect sharps at other local agency supported locations in addition to or as an alternate to a permanent household hazardous waste facility. This section could be further expanded to include other agency locations in addition to household hazardous waste facilities.

Thank you for the opportunity to provide comments on the proposed regulations.

Kirk Galarneau
Hazardous Substances Enforcement Supervisor
Environmental Services Department
9601 Ridgehaven Court, Suite 310
T (858) 573-1338
KGalarneau@sandiego.gov



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From: [Jordan](#)
To: [PharmaSharps](#)
Cc: [Heidi Sanborn](#); [Doug Kobold \(doug@calpsc.org\)](mailto:doug@calpsc.org)
Subject: California's Pharmaceutical and Sharps Waste Stewardship Program Regulations Comments
Date: Thursday, February 20, 2020 9:51:57 AM
Attachments: [NSAC_CPSC_Santa Clara_ZW_Sonoma_SB_212_Regulation_Comments_2-20-2020.pdf](#)

[[EXTERNAL]]

Good Day Mr. Smyth,

Please see attached for the National Stewardship Action Council, California Product Stewardship Council, County and Santa Clara, and Zero Waste Sonoma's joint comments on the proposed regulations to implement California's Pharmaceutical and Sharps Waste Stewardship Program.

Please let us know if you have any questions.

Thank you,

Jordan Wells

Ms. Jordan Wells | Special Projects Manager II



O: (916) 431-7804

jordan@nsaction.us





February 20, 2020* *ORIGINALLY SUBMITTED FEBRUARY 14, 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

Dear Mr. Smyth,

Thank you for the opportunity to submit comments on the proposed regulations to implement California's Pharmaceutical and Sharps Waste Stewardship Program. We very much appreciate the pre-rulemaking efforts by the department and found that process to be quite useful. Please accept the enclosed comments on behalf of the California Product Stewardship Council (CPSC), the National Stewardship Action Council, (NSAC), and the County of Santa Clara.

We would like to call special attention to the following comments that are also included in the enclosed comments matrix. These are:

- Performance standards – In order for this program to be successful, certain minimum performance standards will need to be required. We have included comments on the attached addressing our concerns about certain performance standards.
- Sharps containers at Point-of-Sale (POS) – In order for the Sharps program to be successful, the POS requirements are extremely important. We have made specific comments regarding POS distribution of sharps containers.
- Education & Outreach – The quality of the Public education provided could be the difference between the success and failure of this program. Existing programs with extensive public education have demonstrated what is needed for a program to be successful. We are recommending that the Director be given authority to require certain performance requirements relating to Education and Outreach.

Thank you again for providing the opportunity to submit comments on the proposed regulations. Should you have any questions about our comments, please do not hesitate to contact us for clarification.

Sincerely,

A blue ink signature of Doug Kobold.

Doug Kobold, Executive Director

A purple ink signature of Heidi Sanborn.

Heidi Sanborn, Executive Director

Letter 5 - Nat'l SC, CalPSC, County of Santa Clara, & Zero Waste Sonoma

California Product Stewardship Council



William Grimes, Hazardous Materials Program
Manager
County of Santa Clara

National Stewardship Action Council



Leslie Lukacs, Executive Director
Zero Waste Sonoma

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

SECTION	PAGE	SUBJECT	PROPOSED ALTERNATIVE LANGUAGE	COMMENT / EXPLANATION
18972.1(i) 005-001	2	Definition: "Point of Sale"	N/A	<p>Our coalition is supportive of the definition contained in the proposed regulations. Defining "point of sale" effectively is vitally important to the implementation of the Sharps Stewardship Program.</p> <p>Section 42032.2 of the Public Resources Code (PRC) contains the requirements for stewardship plans. The requirements for drug stewardship plans are different from sharps stewardship plans for one reason – the sharps manufacturers requested a mail-back only program instead of the collection site approach used for drugs.</p> <p>One of the key requirements (42032.2(d)(1)(F)(i) is that the mail-back containers and materials are provided at the point of sale. The point of sale requirement <u>is the convenience standard</u> for the Sharps Stewardship Plan. Under this requirement, the purchase of sharps, whether in-store or online, automatically triggers provision of the mail-back container and materials to the consumer. Without this type of consumer convenience, the program will not be effective.</p>
18972(j) 005-002A	2	Definition: "provides or initiates distribution of a sharps waste container"	<p>(j) "Provides or initiates distribution of a sharps waste container" means:</p> <p>(1) To provide a sharps waste container and mail-back materials to the ultimate user at the point of sale at no cost to the ultimate user;</p> <p>(2) To arrange, at the point of sale, for a sharps waste container and mail-back materials to be sent to the ultimate user and arrive within three business days at no cost or inconvenience to the ultimate user;</p> <p>or,</p>	<p>Our coalition is strongly supportive of (1) and (2) because the proposed language clearly meets the requirements of the requirements of PRC 42032.2 and will result in maximum consumer convenience, which is a key aspect of ensuring the efficacy of any Sharps Stewardship Plan.</p> <p>The ability to arrange for delivery of the mail-back container and materials at the point of sale instead of physically handing them to the consumer is contained in (2). We support the precise requirements in (2) that the mail-back container and materials be delivered to the consumer within "three business days at no cost or inconvenience to the ultimate user". If the mail-back container and materials are not physically handed to the consumer at the point of sale, then it needs to be delivered to the consumer within a specific time period and with no further action required of the consumer.</p> <p><u>CONCERNS WITH (3) AND ALTERNATIVE LANGUAGE</u></p>

		005-002B	<p>(3) Other methods of providing a sharps waste container and mail-back materials, as approved by the department in a stewardship plan, if (1) or (2) are not reasonably feasible <i>if (1) and (2) are found to be illegal</i>, and which result in substantially the same level of convenience to the ultimate user.</p>	<p>Our coalition has concerns with the wording of (3) and have recommended alternative language. This provision moves away from point of sale provision of the mail-back container in a manner that is not supported by PRC 42032.2(d)(1)(F)(i), which only allows “other methods” like those anticipated by (3) if providing containers is prohibited by law.</p> <p>There is some history to this legal offramp in PRC 42032.2(d)(1)(F)(i). During the negotiations on SB 212 the sharps manufacturers contended that providing anything of value to the consumer at the point of sale was considered an illegal inducement to purchase their product. No evidence was provided to support this contention, so the exception was added to PRC 42032.2(d)(1)(F)(i) to provide for an offramp that could be utilized only if there was a conflict in law.</p> <p>The proposed regulations expand this offramp in a manner that is inconsistent with PRC 42032.2(d)(1)(F)(i) because it allows “other methods” for reasons of feasibility when the statute is clear that the only offramp is for illegality of the requirement that mail-back containers and materials be provided at the point of sale.</p>
18972.2 005-003	3	Criteria for Determining a Covered Entity	N/A	<p>Our coalition is supportive of the general notion that the department will start by looking to the manufacturers, and then will move down the list contained in PRC 42030(1)(B)-(E). We do, however, recommend that the proposed regulations give those on the list some indication of the process for moving down the list. Specifically, at what point and via what process will an entity identified in PRC 42030(1)(B)-(E) be notified that the department is moving down the list and what timeframes will apply for compliance? We would recommend that the department more clearly address the process by which a Covered Entity in PRC 42030(1)(B)-(E) will be required to weave in and out of an ongoing program based largely on actions outside of their control.</p>
18973.1(b)	4	Document Approvals: Stewardship Plan, Initial Program Budget, annual report, and Annual Budget	<p>(b) The department shall determine if a document is complete and notify the submitting program operator within 30 days of receipt. If the department determines that the document is complete, the department’s 90-day review period for</p>	<p>Subsection (b) describes the process by which plans, budgets, and annual reports will be deemed “complete” by the department. The proposed regulations provide for a reasonable process of submission by the covered entity, review by the department, and potential re-submission if a document is determined to be incomplete.</p>

005-004			<p>consideration of approval, conditional approval, or disapproval of the document will commence upon the original date of receipt. If the department determines that the document is incomplete, the department shall identify for the program operator the required additional information and the program operator shall resubmit the document within 30 days of the department's notification that the document is incomplete. If the department determines upon resubmittal that the document is complete, the department's 90-day review period for consideration of approval, conditional approval, or disapproval of the document will commence upon the original date of receipt of the resubmittal. <u><i>If the department determines upon resubmittal that the document is incomplete, the department shall disapprove the document and the covered entities operating under the stewardship plan are not in compliance until the program operator submits a document the department approves.</i></u></p>	<p>Subsection (b) does not provide a clear end to the process of determining whether a document is complete. Our coalition believes that this process should be limited to one resubmission for completeness. If a program operator resubmits a document as outlined in subsection (b) and the department determines that the resubmitted document is still incomplete, then the document should be deemed disapproved by the department and the program operator should be out of compliance. We believe that the regulations should limit the back-and-forth required to simply get a complete document.</p>
18973.1(e) 005-005	5	Document Approvals: Stewardship Plan, Initial Program Budget, annual report, and Annual Budget	N/A	<p>Similar to the comment we made above with respect to Section 18972.2 on "Criteria for Determining a Covered Entity", we believe that it would be positive for the regulations to more clearly identify which events will trigger the department to look to the entities listed in PRC 42030(1)(B)-(E). If the department disapproved a Stewardship Plan under this provision will they then look to the listed entities?</p>
18973.1(f)	5		(f) If the department conditionally approves an annual report or program budget, the	<p>Subsection (f) is not clear in terms of whether a disapproved annual report or program budget results in the program operator and covered entities being out</p>

005-006		Document Approvals: Stewardship Plan, Initial Program Budget, annual report, and Annual Budget	department shall identify the deficiencies and the program operator shall comply with the conditions within 60 days of the notice date unless the director determines that additional time is needed. If the program operator does not comply and the conditions are not met within 60 days of the notice date for a conditional approval, the department shall disapprove the annual report or program budget. <u><i>If the department disapproves the annual report or program budget, then the covered entities operating under the stewardship plan are not in compliance until the program operator submits a document the department approves.</i></u>	of compliance. Our coalition has proposed language to make it clear that disapproval of the annual report or program budget will result in a determination that the covered entities and program operators are not in compliance.
18973.2(d)(2) 005-007	6	Stewardship Plan for Covered Drugs	N/A	Our coalition supports the requirement to report on efforts to bring authorized collectors into the program because it will be relevant to enforcement decisions if a plan does not meet the minimum convenience standard in PRC 43032.2(a)(1)(F).
18973.2(d)(3) 005-008	6	Stewardship Plan for Covered Drugs	(3) Description of the process in which good faith negotiations with potential authorized collectors is conducted, <u><i>including a process designed specifically for requests from authorized collectors under Section 42032.2(b)(3) of the PRC.</i></u>	We support the inclusion of this provision but think it should be modified just slightly. It is vitally important to the effective operation of this program that program operators conduct business in good faith. PRC 43032(b)(1)(3) allows authorized collectors to request entrance to the program and requires a program operator to include them within 90 days. Our coalition is concerned that stewardship organizations may erect unnecessary roadblocks to onboarding authorized collectors once the minimum convenience standard has been met. The regulations should include a requirement that the plan include a process specifically for onboarding authorized collectors under PRC 43032.2(b)(3).
18973.2(d)(4)	6	Stewardship Plan for Covered Drugs	N/A	We believe strongly that this portion of the regulations needs to intersect with the department's enforcement efforts and application of civil penalties. The

Letter 5 - Nat'l SC, CalPSC, County of Santa Clara, & Zero Waste Sonoma

005-009				requirement contained in PRC 43032.2(b)(1)(3) is, in our opinion, a vital component of any stewardship plan for covered drugs. The department needs to consider how it will enforce against a program operator that does not meet the requirements of the statute. Because the civil penalties are limited to specific circumstances the department should consider plan revocation in circumstances where the program operator violates key requirements of the program. We would also recommend an appeals process for any authorized collectors whose request under PRC 43032.3(b)(3) is rejected.
18973.2(g)(2)(A) 005-010	7	Stewardship Plan for Covered Drugs	N/A	Our coalition is supportive of the requirement that the Stewardship Plan include an explanation of how the collection network provides for a reasonable geographic spread. It is important that these county-based networks serve the population broadly and are not concentrated in a few specific areas.
18973.2(g)(8) 005-011	8	Stewardship Plan for Covered Drugs	N/A	Our coalition is supportive of the requirement that the Stewardship Plan provide a process by which bins will be maintained and do not reach capacity. The program cannot operate if the bins are full and consumers cannot access them for disposal.
18973.2(g)(10) 005-012	8	Stewardship Plan for Covered Drugs	N/A	The draft regulations circulated by the department during the informal rulemaking workshops included a requirement for the stewardship organization to provide, where needed, training to authorized collectors to ensure compliance. We would support the inclusion of that provision in the proposed regulations.
18973.2(i) 005-013	8	Stewardship Plan for Covered Drugs – Local Ordinance Repeals	N/A	While we do not have recommended language, we would encourage the department to consider expansion of the regulations to more closely oversee the process by which local ordinances are repealed and counties migrate into the statewide program. Counties that currently have a drug or sharps take-back program in place through the establishment of a local ordinance will not simply repeal their ordinance and move into this statewide program. Any movement away from a local ordinance and into the statewide program established under SB 212 will likely come as the result of negotiations with an individual county.

			<p><u>Further, the director may require specific any performance measures, performance requirements or targets when approving the plan.</u></p>	<p>005-014C1 Multiple Communication Platforms and Mediums: The plan should span internet, television, radio, and print media platforms because of the need to reach such a diverse audience of ultimate users.</p> <p>005-014C2</p> <p>005-014E1 - Action: The plan should be about action. The plan should describe what efforts will be undertaken to broadly distribute the printed materials to the parties outlined in Section 42031.6(a)(2). The plan should also describe how the program operator plans to drive traffic to their internet website. We would recommend that the department consider these types of requirements throughout this portion of the regulations.</p> <p>005-014E2</p> <p>005-014F1 - Market Research: The education and outreach plan should be market tested for effectiveness before it is implemented, and then again periodically to ensure that it is performing as designed.</p> <p>005-014F2</p> <p>005-014H1 Finally, we think that the regulations should restate the prohibition in Section 42031.6(b). This subsection states unequivocally that the education and outreach program under this program shall not promote disposal options that are inconsistent with the services offered under the program. This section was included in SB 212 because there have been instances where programs under local ordinances promoted flushing and trashing meds. The education and outreach component of any stewardship plan for drugs or sharps should only promote disposal options offered by the program. The statute is clear – the education and outreach program should “promote participation in the stewardship program”.</p> <p>005-014H2</p>
<p>18973.2(k) and 18973.3(j)</p>	<p>9 and 13</p>	<p>Stewardship Plan for Covered Drugs</p>	<p>N/A</p> <p>005-015a 005-015b</p>	<p>We are somewhat confused by these portions of the regulations. It would be helpful to understand how department believes that the statute allows for different stewardship organizations to combine their efforts to meet the requirements of SB 212. The Initial Statement of Reasons cites an obvious potential for conflict in the education, outreach, and instructions to ultimate users. However, we’d want to know from the department if they envision coordination in other areas. If this is specific just to the education and outreach portion of the regulations, maybe this requirement should be imbedded in those sections of the regulations.</p>

<p>18973.3 (f)(2) 005-016</p>	<p>10</p>	<p>Stewardship Plan for Home-Generated Sharps Waste</p>	<p>N/A</p>	<p>Our coalition is a strong supporter of the language in this portion of the regulations. The language, as drafted, correctly implements the requirement that sharps stewardship program “provide or initiate distribution” of the sharps container and mail-back materials at the point-of-sale. This is one of the defining provisions of the sharps mail-back program contained in SB 212 because it provides maximum convenience to the ultimate user.</p>
<p>18973.3(f)(2)(A) 005-017</p>	<p>10</p>	<p>Stewardship Plan for Home-Generated Sharps Waste</p>	<p>N/A</p>	<p>The department may want to consider a scenario where a sharps stewardship organization may want to provide containers and mail-back materials sufficient for several purchases. For example, if an ultimate user is receiving their sharps via mail delivery a program operator may want to send them a container suitable for several months of sharps deliveries. This should be allowed so long as the containers, when full, are not too heavy or large for an ultimate user to lift and carry safely.</p>
<p>18973.3(f)(6)(A) 005-018</p>	<p>11</p>	<p>Stewardship Plan for Home-Generated Sharps Waste</p>	<p>N/A</p>	<p>We are supportive of this option for a sharps stewardship plan to supplement their mail-back collection efforts with secure receptacles. While this is not required by the statute, we believe that it would be beneficial to ultimate users to have receptacles as part of the program.</p>
<p>18973.3(g) 005-019</p>	<p>12</p>	<p>Stewardship Plan for Home-Generated Sharps Waste – Local Agency Requests</p>	<p>N/A</p>	<p>Section 42032.2(d)(1)(F)(ii) of the PRC was included to ensure that the mail-back program was designed for success. This provision requires a stewardship plan to address sharps waste that slips through their mail-back program by either picking up sharps from local agencies or reimbursing local agencies for their costs. This is an extremely important provision because it serves as a sort of insurance on the quality of the mail-back program and protects local agencies from dangerous waste that can harm their employees.</p> <p>We are supportive of the regulations as drafted, but would encourage a few minor changes:</p> <ul style="list-style-type: none"> - 18973.3(g)(2): Instead of requiring that a program operator “respond to requests in a timely manner” we would suggest a specific response time requirement of 14 days.

				-
18973.4(c) and 18973.4(d)	14 and 16	Annual Report for Covered Drugs	N/A 005-020	Subsection (c) requires stewardship organizations to report on their “efforts to include authorized collectors beyond the minimum convenience standards” pursuant to the requirements of the PRC. Subsection (d) requires stewardship organizations to identify the reasons that “potential authorized collectors” were excluded from program participation. Our coalition would recommend that there be a specific requirement that the annual report contain a list of the authorized collectors that have requested to join the program under Section 42032.2(a)(1)(F), including how their request was ultimately addressed in the required timeframe, the date of full inclusion if the request is approved, and the specific justification for each rejection.
18973.4(c)(4)(D) 005-021	15	Annual Report for Covered Drugs	N/A	We support the inclusion of this data point but would suggest that the department also require the reason for each instance where the collection site was not available to the public.
18973.4(i) and 18973.5(i)	17 and 19	Annual Report for Covered Drugs and Annual Report for Home-Generated Sharps Waste	N/A 005-022a 005-022b	We support thorough reporting on the educational and outreach portion of the plan because of its importance in implementing an effective program. We think the regulations require broad reporting, but we’d recommend that the department add a component requiring the stewardship organizations to report any internal metrics used to measure the efficacy of their education and outreach program. This includes market research that is conducted on this program, and any measurements of performance such as website traffic, email open rates, and similar metrics.
18973.5(p) 005-023	20	Annual Report for Home-Generated Sharps Waste	N/A	We support this reporting requirement but suggest that it be expanded to include a list of any local agency requests where responses, pick-up, or payment was performed outside of the required timelines. Additionally, the annual report should include the details of any specific local agency request for pick-up or reimbursement was rejected.
18975(a)	24	Criteria to Impose a Civil Penalty	N/A	

005-024				<p>The scope of this section seems limited to a “covered entity” when the statute allows the department to assess a civil penalty on a covered entity, program operator, stewardship organization, or authorized collector.</p> <p>We would underscore the general comment made in our cover letter. The application of civil penalties is relatively limited by the statute and applies only to the sale of a covered product in violation of the chapter. This seems to limit the department’s recourse in addressing material programmatic deficiencies to revocation of the plan.</p>

From: [Lester, Christopher \(ENV\)](#)
To: [PharmaSharps](#)
Cc: [Jackson, Jen \(ENV\)](#); [Johnson, Margaret \(ENV\)](#)
Subject: SF Environment comment letter regarding SB 212 1.3.2020 Proposed Regulations
Date: Friday, February 14, 2020 4:36:59 PM
Attachments: [SF Environment SB 212 Jan 2020 Proposed Regulations Comment Letter 2.14.2020.pdf](#)

[[EXTERNAL]]

Hello CalRecycle Staff,

Please find attached the San Francisco Department of the Environment's comment letter regarding the 1/3/2020 Proposed Regulations for implementing the Pharmaceutical and Sharps Waste Stewardship Act (SB 212).

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

Please don't hesitate to contact me if there's a problem with the attached file or any other related matter.

Best,

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

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

Please consider the environment before printing this email.

From: CalRecycle: Pharmaceutical and Sharps Waste Stewardship Listserv
<pharmasharps@calrecycle.ca.gov>
Sent: Friday, January 03, 2020 9:13 AM
To: Lester, Christopher (ENV) <christopher.lester@sfgov.org>
Subject: Formal Rulemaking Begins for SB 212 – California's Pharmaceutical and Sharps Waste Stewardship Program

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

CalRecycle is required to adopt regulations to implement the Pharmaceutical and Sharps Waste Stewardship Act ([Jackson, Senate Bill 212](#)). The [Proposed Regulations for the Pharmaceutical and Sharps Waste Stewardship Program](#) clarify statutory

requirements including definitions, procedures for the submittal and approval of stewardship plans, annual reports, program budgets, and enforcement provisions for program participants.

[Notice of Proposed Rulemaking](#) to implement SB 212 will be published in the [California Regulatory Notice Register by the Office of Administrative Law \(OAL\)](#) (https://oal.ca.gov/publications/notice_register/) on January 3, 2020. This notice begins the formal 45-day comment period of the rulemaking process. The notice, proposed regulatory language, and other relevant rulemaking materials can be found on the Pharmaceutical and Sharps Rulemaking page at: <https://www.calrecycle.ca.gov/laws/rulemaking/pharmasharps>.

Any interested person, or his or her authorized representative, may submit to CalRecycle written comments relevant to the proposed regulations. The written comment period for this rulemaking closes on February 17, 2020.

Please submit written comments to:

Jason Smyth

Materials Management and Local Assistance Division

California Department of Resources Recycling and Recovery

P.O. Box 4025

Sacramento, CA 95812-4025

Fax: (916) 319-7147

e-mail: pharmasharps@calrecycle.ca.gov

A public hearing to receive public comments is scheduled for February 19, 2020 at 1:00 pm. The hearing will be held at the:

Joe Serna Jr., Cal EPA Building

Sierra Hearing Room

1001 I Street, 2nd Floor

Sacramento, CA 95814

Information on the hearing agenda and other related materials, including webcast link for remote participants, can be found on the [CalRecycle Public Notice page](#).

Thank you,

The CalRecycle Pharmaceutical & Sharps Stewardship Team

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

~

Serial Number: J0ZV8IOZ

Sent On: 01/03/2020 9:12 AM

~

Letter 6: San Francisco Department of the Environment

February 14, 2020

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

BY ELECTRONIC MAIL to PharmaSharps@CalRecycle.ca.gov

Re: Comments on January 3, 2020 Proposed Regulations for implementing the Pharmaceutical and Sharps Waste Stewardship Act (SB 212)

Dear Mr. Smythe:

The San Francisco Department of the Environment appreciates the opportunity to provide comments on CalRecycle's January 3, 2020 Proposed Regulations for implementing the Pharmaceutical and Sharps Waste Stewardship Act (California Code of Regulations, Title 14, Division 7, Chapter 11, Article 4 commencing with Section 18972).

The City and County of San Francisco is one of fourteen jurisdictions in California which passed a local ordinance prior to the passage of SB 212 to require a product stewardship program for management of home-generated medicines, home-generated sharps, or both. The San Francisco Department of the Environment was given responsibility for implementing the local ordinance – the San Francisco Safe Drug Disposal Stewardship Ordinance. The Department of Environment has also sponsored a pharmacy-based home-generated sharps collection program since 1991 which is funded through our local refuse collection and disposal rate structure.

As part of those efforts, we have worked on safe disposal of household medicines and sharps for many years, overcoming regulatory and operational challenges to create convenient and responsive programs for our residents. We offer the following comments organized around five elements of the Proposed Regulations which we believe are key to the successful implementation of statewide product stewardship programs for home-generated medicine and sharps.

Collector Participation and Convenience Standard

- 006- 1. Description of Authorized Collector Recruitment Efforts. We request that CalRecycle add a new
001 subparagraph to Section 18973.2(d) that requires the program operator to describe what efforts will be made to recruit potential authorized collectors to participate in the stewardship program, as follows:

(5) Description of the recruitment efforts that will be made for each potential authorized collector, including but not limited to mail, email, phone calls, and in-person site visits.

2. Discussion of Chain Retail Pharmacy Participation. We request a new subparagraph be added to Section 18973.2(d) that requires the program operator to include an evaluation of the program operator's and retail pharmacy chain's efforts to meet the participation requirements of Section 42032.2(b)(2) of the statute. We suggest the following language:

(6) Description of the program operator's and retail pharmacy chains' respective efforts to meet the requirements of Section 42032.2(b)(2) of the statute, including the "reasonable effort" and "minimum threshold" participation requirements, if applicable.

3. Description of Authorized Collector "Opt-In" Process. We ask CalRecycle to add a new subparagraph to Section 18973.2(d) that requires the program operator to establish a process by which potential authorized collectors will be included in the stewardship program – even if the convenience standard has been met – within 90 days as required in Section 42032.2(b)(3) of the statute:

(7) Processes that will be used to include all potential authorized collectors that offer to participate within 90 days of plan approval, as required by Section 42032.2(b)(3) of the statute. At minimum, this shall include a description of how potential authorized collectors shall submit written offers to participate and any conditions for excluding interested potential collectors.

4. Supplemental Services to Maintain Convenience Standard. In our experience, it is likely that the number of authorized collector locations will vary frequently due to retail pharmacies opening and closing. Program operators should account for this by describing the supplemental services that will be provided in the interim until additional authorized collector locations are added to meet the convenience standard. We request that CalRecycle add the following as a new subparagraph under Section 18973.2(g)(2):

(C) Describe what supplemental collection services, such as mail-back services or an alternative form of collection and disposal system, will be provided to ultimate users if the minimum convenience standard is no longer met in a county due to one or more authorized collectors discontinuing participation for any reason.

5. Collection Records Training. We recommend revising the language in Section 18973.2(g)(9) and Section 18973.3(f)(6)(A)(iv) to reflect that program operators are responsible for training authorized collectors or home-generated sharps consolidation points, respectively, so they remain aware of their responsibility to maintain collection records and make them available to the department. Mere notification may not be sufficient because retail pharmacy staff often rotate or change locations. We suggest the following language:

(9) How each authorized collection site [or "home-generated sharps consolidation point" in Section 18973.3] will be trained so that it remains aware of its responsibilities to maintain and make available collection records to the department and all other applicable authorities upon request.

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6. Collector Compliance Monitoring. We urge CalRecycle to modify the language in Section 18973.2(g)(10) and Section 18973.3(f)(6)(A)(v) to require the program operator to monitor compliance of authorized collectors or home-generated sharps consolidation points, respectively, on an ongoing basis. As currently drafted, the Proposed Regulations establish a reactive approach by referencing corrective actions that will be taken after non-compliance is discovered. We suggest the following change:

(10) What ongoing steps will be conducted by the program operator to ensure authorized collectors [or "home-generated sharps consolidation points" in Section 18973.3] maintain compliance with all collection, transportation, and disposal standards related to the handling of covered drugs [or "home-generated sharps waste" in Section 18973.3].

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7. Unplanned Incident Notification. In the event of an unplanned incident involving safety and security, various local, state and federal agencies would need to be notified, as determined by the nature of the incident. Accordingly, we urge CalRecycle to require program operators to include a process for notifying all required regulatory and/or law enforcement agencies in their standard operating procedures for an unplanned incident. We propose the following revisions to Section 18973.2(g)(12):

(12) Standard operating procedures that address safety and security issues for an unplanned incident, including processes to ensure CalRecycle and any local, state and/or federal agencies required by law, rule or regulation are notified of the incident.

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8. Annual Report: Supplemental Services to Maintain Convenience Standard. We ask that a new subparagraph be added to Section 18973.4(c)(3) that requires a program operator to describe any supplemental services that were provided to ultimate users in a county where the minimum convenience standard was not met due to one of more authorized collectors discontinuing participation. We suggest:

(3)(B) What supplemental collection services were provided to ultimate users if the minimum convenience standard was not met in a county at any time during the reporting period.

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9. Annual Report: Evaluation of Retail Pharmacy Chain Participation. Similar to comment #2 above, we recommend requiring an evaluation of the program operator's and retail pharmacy chain's efforts to meet the participation requirements of Section 42032.2(b)(2) of the statute in an Annual Report for Covered Drugs. We urge CalRecycle to add the following as two new subparagraphs under Section 18973.4(c):

(7) An evaluation of the program operator's and retail pharmacy chain's respective efforts to meet the "reasonable effort to serve as an authorized collector" requirement in Section 42032.2(b)(2) of the statute.
(8) An evaluation of retail pharmacy chain's efforts to serve as authorized collectors in any county required because the convenience standard minimum threshold is not being met.

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10. Annual Report: Reporting Mail-Back Packaging by Type. Due to Board of Pharmacy regulations and federal DOT/USPS transportation rules, there are currently two types of dosage forms – inhalers and pre-filled injector products (e.g. EpiPens®) – that require separate mail-back packaging from other covered drugs. Therefore, any stewardship program approved for covered drugs will have to provide at least three types of mail-back packaging. We request that Section 18973.4(c)(5) be revised to add mail-back

packaging type to the information required in the Annual Report:

(5) For each type of mail-back services utilized, provide, as applicable:

11. Annual Report: Collection Records Training. In accordance with our previous comment #5, program operators should be required to describe how authorized collection locations and home-generated sharps consolidation points were kept aware of their responsibility to maintain collection records and make them available to the department. We request a new subparagraph be added to Section 18973.4 and Section 18973.5, as follows:

(p) Training and other activities undertaken by the program operator to ensure each authorized collection site [or "home-generated sharps consolidation point" in Section 18973.5] remained aware of its responsibility to maintain collection records and make them available to the department.

12. Annual Report: Collector Compliance Monitoring. In accordance with our previous comment #6, we request modifications to Section 18973.4(e) and Section 18973.5(e) to require a program operator to describe the ongoing steps they took to ensure collectors complied with all applicable laws and regulations. We propose the following changes:

(e) Description of the ongoing steps the program operator took to ensure authorized collectors [or "home-generated sharps consolidation points" in Section 18973.5(e)] maintained compliance with all collection, transportation, and disposal standards related to the handling of covered drugs [or "home-generated sharps waste" in Section 18973.5(e)].

13. Annual Report: Unplanned Incident Reporting. As noted in comment #7 above, unplanned incidents involving safety and security will typically require notification of at least one regulatory and/or law enforcement agency. To confirm the appropriate authorities were notified, we urge CalRecycle to require identification of all entities that were notified of an unplanned incident in the program operator's Annual Report. We recommend adding the following as a new subsection under Section 18973.4(h) and Section 18973.5(h):

(6) Any regulatory and/or law enforcement agencies that were notified of the incident, as required by all applicable laws and regulations

Outreach and Education

14. Kiosk Signage Accessibility. Signage for the secure collection receptacles for covered drugs should be designed with explanatory graphics and other readily understood imagery to minimize participation barriers for the diverse audience of ultimate users throughout the state. Consistent with this goal, we request the following language be added to Section 18973.2(g):

(13) Signage for the secure collection receptacles shall be designed with explanatory graphics, imagery and other features so that they shall be readily understandable by all residents, including individuals with limited literacy.

15. Expanded Outreach Activities. Section 42031.6(a) of the statute requires program operators to conduct “a comprehensive education and outreach program intended to promote participation in the stewardship program.” To better align the language in Section 18973.2(j)(1) and Section 18973.3(i)(1) with this requirement, we propose the following changes:

006-015a & 006-015b *(1) Activities and materials to promote awareness and maximize user participation in the stewardship program, which shall include: print and out of home media; television and radio; social media and online advertisements; and brochures or flyers.*

16. Website Multi-Language Support. A stewardship plan’s internet website should be required to provide support in multiple languages that are commonly used in California to ensure the diverse audience of ultimate users throughout the state can access program information and services. We request that CalRecycle modify the internet website requirements described in Section 18973.2(j)(3) and Section 18973.3(i)(3) to specify the following:

006-016a & 006-016b *(F) The required internet website shall provide a functionally-equivalent user experience – including content, access and navigability – in languages other than English that are commonly used in California. At minimum, these shall include the languages used by the Board of Pharmacy to satisfy the requirements of Title 16 California Code of Regulations Section 1707.5(b).*

17. Website Accessibility. A stewardship plan’s internet website should be held to at least the same accessibility standards required for a stewardship plan document and for CalRecycle’s own website. We request that CalRecycle add the following as a new subparagraph under Section 18973.2(j)(3) and Section 18973.3(i)(3):

006-017a & 006-017b *(G) The required internet website shall comply with section 7405 of the Government Code and the Web Content Accessibility Guidelines 2.0, or a subsequent version.*

18. Toll-Free Telephone Number Specifications. The toll-free telephone number provided by a program operator should be required to provide support in “real-time” (i.e. on-demand and with a live customer service representative) and in languages other than English that are commonly used in California. To accomplish this, we ask CalRecycle to modify Section 18973.2(j)(4) and Section 18973.3(i)(4) to require the toll-free telephone number described to meet the following specifications:

006-018a & 006-018b *(A) Accept calls via human customer service representatives
(B) Provide translation support in the languages used by the Board of Pharmacy to satisfy the requirements of Title 16 California Code of Regulations Section 1707.5(b)
(C) Comply with any requirements of the Americans With Disabilities Act, including but not limited to provisions for hearing-impaired individuals.*

19. Mail-Back Package Information. We ask CalRecycle to revise the language in Section 18973.3(f)(2)(B) to specify that “all necessary information” for proper home-generated sharps disposal shall be included in the mail-back materials:

006-019 *(B) Mail-back materials shall include all necessary information for proper home-generated sharps disposal.*

20. Training for Point-of-Sale Staff. Given the statute's requirement to provide or initiate distribution of sharps mail-back containers and materials at the point of sale, sharps retailers play a critical role in the program's success. To ensure that the necessary staff are aware of the program and able to provide ultimate users guidance on how to access mail-back services, we request the following subsection be added to Section 18973.3(i):

(6) Activities and materials to ensure that retail staff involved with distributing or initiating distribution of sharps waste containers and mail-back materials are aware of the program and can assist ultimate users with accessing program services.

21. Outreach Metric Reporting. Section 18973.2(j)(5) and Section 18973.3(i)(5) of the Proposed Regulations require program operators to establish metrics for evaluating the outreach and education program. However, there is no corresponding requirement to provide or discuss the metrics in the Annual Report. We ask CalRecycle to revise Section 18973.4(i) and Section 18973.5(i) to add the following requirements:

(i) Education and Outreach. Description and evaluation of the comprehensive education and outreach activities pursuant to Section 18973.2(j) [or "Section 18973.3(i)" for Section 18973.5], including:

- (1) Electronic examples of promotional marketing materials*
- (2) Numerical results of the outreach and education metrics established in the approved stewardship plan*
- (3) A discussion of what the metrics and other results reveal about ultimate user awareness, program usage, and accessibility*

22. Annual Report: Training for Point of Sale Staff. In accordance with comment #20 above, we recommend adding an additional subparagraph to Section 18973.5(i) that requires the program operator to discuss the training and other activities conducted to ensure point-of-sale staff can assist ultimate users with accessing program services. We propose the following language:

(4) A discussion of the program operator's efforts to train retail staff involved with distributing or initiating distribution of sharps waste containers and mail-back materials to ensure staff can assist ultimate users with accessing program services.

Coordination Among Multiple Plans

23. Minimum Requirements for Plan Coordination. We appreciate language in Section 18973.2(k) and Section 18973.3(j) requiring program operators to describe the "good faith" efforts that will be made to work with other program operators. However, we are concerned that the proposed language does not provide adequate safeguards to prevent ultimate users from being negatively impacted by conflicting messaging or instructions from multiple stewardship organizations. We strongly recommend revising the language in these sections to be more detailed and to establish certain minimum requirements for plan coordination. We suggest modifying the language in Section 18973.2(k) and Section 18973.3(j) as follows:

(k) In the event that there is more than one stewardship plan approved for covered drugs [or “home-generated sharps waste” for Section 18973.3(j)], a program operator shall coordinate with all other program operators to most effectively achieve the requirements of the statute and regulations. At minimum, each program operator shall:

(A) Accept all covered products in the secure receptacles and mail-back packages provided by their stewardship plan to the extent allowed by law or regulation.

(B) Coordinate with other program operators to develop and implement a single system of promotion, including a single toll-free telephone number and single internet website to promote to ultimate users the opportunity to dispose of covered products.

(C) If program operators cannot come to agreement on a single system of promotion, CalRecycle shall develop a single system of promotion on behalf of program operators, which program operators shall be required to fund and implement.

24. Process for Handling Local Agency Requests Among Multiple Program Operators. The Proposed Regulations are silent on how local agency reimbursement requests will be handled if there is more than one approved stewardship plan for home-generated sharps waste. It is important that CalRecycle establish prescriptive coordination requirements for program operators to ensure local agency requests are fulfilled in a timely manner. We request that CalRecycle add the following subparagraph as an additional requirement of Section 18973.3(g):

(3) Description of the processes that will be used to receive, process, and fulfill local agency requests in the event that there is more than one approved program operator. At minimum, the processes shall address:

(A) Submittal of local agency requests

(B) Operator to operator coordination of removal service

(C) Local agency reimbursement

(D) Apportioning costs

(E) If program operators cannot come to agreement on the coordination processes for handling local agency requests, CalRecycle shall develop processes on behalf of program operators, which program operators shall be required to implement

25. Annual Report: Rejected Local Agency Requests. We urge CalRecycle to revise Section 18973.5(p) so that a program operator is required to list any Local Agency Requests that were rejected in the Annual Report – if applicable – and indicate the reason(s) why each Request was rejected. We suggest adding the following subsection:

(3) Any local agency requests that were rejected and the reason(s) each request was rejected

Stewardship Plan Submission

26. Plan Submission After Initial 6 Month Window. Section 42032(a)(1) of the statute requires program operators to submit stewardship plans for approval within 6 months of CalRecycle adopting regulations. There is no other language in the statute or Proposed Regulations that addresses plan submission after this initial 6-month window has elapsed. This is a significant omission that could effectively prohibit submission of new stewardship plans after 6 months and/or limit revision of existing stewardship plans to the

"Significant Change" process outlined in the statute. We urge CalRecycle to modify the Proposed Regulations to clarify that new stewardship plans can be accepted after the initial 6-month window and establish processes, deadlines, and other guidance for plan submission, review, and approval.

27. Plan Submission by a New Covered Entity. Similar to comment #26 above, the statute and Proposed Regulations are silent on what happens when a new covered entity begins selling one or more covered products in California more than 6 months after regulations are adopted. The current language seems to provide a covered entity no option other than joining an existing approved plan. We encourage CalRecycle to add language that establishes processes, deadlines, and other guidance to provide new covered entities clarity and flexibility in meeting the requirements of the statute.

Additional Definitions Needed

28. Add New Definition for "Inert." The term "Inert" is used in the statute in Section 42032.2(a)(1)(G)(i) as the treatment goal for CalRecycle approval of an Alternative Collection and Disposal System for covered drugs. The Proposed Regulations must include a definition for the term to provide explicit requirements that an Alternative Collection and Disposal System shall meet for approval. We propose the following definition to ensure that any approved Alternative Collection and Disposal System meets Drug Enforcement Administration regulations and California's requirements for landfill:

"Inert" means the covered drug or mixture of covered drugs is rendered chemically inactive prior to disposal and complies with all applicable local, state and federal laws and regulations, including those of the United State Drug Enforcement Administration and California statutes and regulations governing disposal in a municipal solid waste landfill.

29. Add New Definition for "Local Stewardship Program." "Local stewardship program" is used in Section 42036.2 of the statute and in the Proposed Regulations in reference to local programs for collection and disposal of covered drugs or covered home-generated sharps waste that are mandated by an ordinance that took effect before April 18, 2018. A definition for this term is needed to (1) clarify that local jurisdictions with an ordinance for a single type of covered product (e.g. covered drugs but not home-generated sharps waste) can participate in a statewide stewardship program for the other type of covered product without dissolving their existing local stewardship program; and (2) to provide that specific types of local programs, not mandated by a local ordinance, are not included. We request that CalRecycle add the following definition:

A "local stewardship program" means a program for the collection and disposal of either covered drugs or home-generated sharps waste, or both, which is mandated by a local ordinance or by any other state or federal statute. A local stewardship program, for the purposes of this chapter, does not include any voluntary program or activity related to collection and disposal of covered drugs or home-generated sharps waste. Nothing in this chapter shall require a local jurisdiction to dissolve a local stewardship program for covered drugs in order to participate in a statewide program for home-generated sharps waste, or vice versa.

29. Add New Definition for "Repeal." "Repeal" is used in the statute in Section 42036.2(a) and in the Proposed Regulations in reference to the requirements and procedures for California counties which passed a local stewardship ordinance prior to April 2018 to participate in a CalRecycle-approved stewardship program for covered drugs or home-generated sharps waste. In order to clarify that a repeal must be complete such that the local program is "dissolved" as described in Section 42032.2(c) of the statute, we suggest the following new definition:

006
-030

"Repeal" means to revoke or annul a law or ordinance in its entirety such that any program mandated by the law or ordinance is permanently dissolved. For the purposes of this chapter, an amendment or modification of an existing law or ordinance and/or its implementing regulations does not constitute a Repeal unless the changes fundamentally alter the program to the extent that it no longer meets the definition of "local stewardship program" in this chapter.

Thank you for the opportunity to comment on the January 3, 2020 Proposed Regulations for implementing the Statewide Pharmaceutical and Sharps Waste Stewardship Act. As the Governor indicated in his signing message for SB 212, the regulations for this legislation are of importance due to the complex nature and innovative goals of the bill. We are encouraged by the thoughtful and thorough process which CalRecycle is undertaking and look forward to participating in their continued development.

Please do not hesitate to contact Christopher Lester of my staff at 415-355-3750 or by email at Christopher.Lester@sfgov.org if you have questions or need additional information on these comments or on our experience implementing the San Francisco Safe Drug Disposal Stewardship Ordinance.

Sincerely,



Jen Jackson
Toxics Reduction and Healthy Ecosystems Program Manager

From: [CoPALM](#)
To: [PharmaSharps](#)
Cc: rblanks@kycccla.org
Subject: Letter of Support for Public Comment - SB 212
Date: Friday, February 14, 2020 5:08:34 PM
Attachments: [SB 212-Public Comment CoPALM FINAL.pdf](#)

[[EXTERNAL]]

Hello,

Please see attached for a letter of support with recommendations for the proposed Senate Bill 212. Our coalition would like to submit this letter as public comment.

Thank you,

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



February 17, 2020

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

Re: Comments on Proposed Regulatory Action

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 comment and provide recommendations on the released SB 212 informal regulatory text. CoPALM is a coalition of prevention service providers and community organizations that represent neighborhoods such as Boyle Heights, Koreatown, and Hollywood. These neighborhoods do not have reasonable access to collection sites to safely dispose of expired, unused, or unwanted prescription medicine and are desperately looking for solutions to address its negative impacts on safety and public health. As a coalition, we seek to bolster resilience in communities. Increasing local oversight with regards to safe prescription medicine and disposal would be an effective strategy to build healthy, productive, and collaborative communities.

Prescription medicine misuse has a tremendous public health impact. As stated in the policy statement overview, “*four million Californians do not have reasonable access to disposal sites ...as a result these products are inappropriately disposed of in household garbage, toilets, or sinks.*” For this reason, we support your suggestion to implement an extensive educational and outreach campaign to the Act.

We propose that the following recommendations be incorporated:

- 007-001a • Development of a safe disposal hotline in addition to the disposal locator
- 007-001b • websites for individuals without access to the internet. Hotline services

should be provided in multiple languages.

- 007-002a • Providing necessary resources and funding for nonprofit organizations to assist with information dissemination, outreach, and to educate the community on proper safe disposal and disposal locations.
- 007-002b
- 007-003 • Locating drop-off boxes in secured, public spaces that are easily accessible for everyone, including the homeless.
- 007-004a • Thorough evaluation and assessment to measure the effectiveness of education and outreach efforts.
- 007-004b
- 007-005 • Pharmacies be required to include safe disposal instructions and information on their instructions page for all medications prescribed.
- 007-006 • 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.

CoPALM would like to express gratitude for the opportunity to provide recommendations in this process.

Sincerely,

Melanie To
CoPALM Chair

From: [Lindsay Gullahorn](#)
To: [PharmaSharps; Smyth, Jason@CalRecycle](#)
Cc: [Jennifer Hendrick-Snyder](#)
Subject: CRA/NACDS/CPhA Comments re: SB 212 Implementation
Date: Saturday, February 15, 2020 4:58:22 PM
Attachments: [CRA_NACDS_CPhA Letter re SB 212 021420.pdf](#)
[PastedGraphic-1.tiff](#)

[[EXTERNAL]]

Please see attached for joint comments from the California Retailers Association, the National Association of Chain Drug Stores, and the California Pharmacists Association regarding the implementation of SB 212 (pharmaceutical and sharps waste stewardship program). Let us know if you have any questions.

Thank you.

Lindsay Gullahorn
Capitol Advocacy
1301 I Street
Sacramento, CA 95814
916-273-1208 direct
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Lgullahorn@capitoladvocacy.com



February 14, 2020

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

Re: California Retailers Association/National Association of Chain Drug Stores/California Pharmacists Association - Comments Regarding Proposed Regulations. Article 4. Pharmaceutical and Sharps Waste Stewardship Program

Dear Mr. Smyth:

We are writing on behalf of the California Retailers Association (CRA), the National Association of Chain Drug Stores (NACDS) and the California Pharmacists Association (CPhA) to provide comments regarding the Department of Resources, Recycling and Recovery's (CalRecycle) proposed regulations related to Article 4 - Pharmaceutical and Sharps Waste Stewardship Program.

CRA, NACDS and CPhA are supportive of the intent of SB 212 (Chapter No. 1004, 2018) which establishes a statewide framework that provides the maximum flexibility for manufacturers to fund and implement a drug or sharps take back program in California and that supports pharmacies' efforts to be active participants in these programs. Hundreds of pharmacies throughout the state already provide a number of different take back options for consumers. We continue to welcome the opportunity to work with CalRecycle and key stakeholders to develop an effective pharmaceutical and sharps waste stewardship program in the state. In an effort to further the success of a pharmaceutical and sharps waste stewardship program in California, we would like to make the following suggestions for modifications to CalRecycle's proposed regulations. They are as follows:

Definition of "provides or initiates distribution of a sharps waste container"

Section 18972.1 (j)

The definition of providing a sharps waste container seems to require that a sharps waste container must be provided to a consumer at the point of sale. Our members have strong concerns about the ability of pharmacies to have on-hand and in-stock the number of containers necessary to achieve this goal. In addition, pharmacies are concerned that too many containers will be distributed. Manufacturers or program operators and pharmacies should have the flexibility to work together on a solution that works best for their partnerships while ensuring compliance with the program requirements.

008-001A

008-001B

- 008-002A **Outreach to pharmacies to encourage participation**
Section 18973.2 (d)
 Our members are concerned as to how each manufacturer or program operator on their behalf will be reaching out to potential pharmacies to participate in the drug and sharps waste stewardship program. We would like to see more explicit requirements for outreach and specific detail required as to how the manufacturer or program operator handles this outreach.
- 008-002B
 In addition, we believe it is important for the new stewardship program to support and incorporate those collection efforts already being administered by pharmacies either under county specific requirements or through their own company efforts. Collaboration and inclusion of all types of collection sites and efforts will be key to the success of the program.
- 008-003 **Collection site maintenance**
Section 18973.2 (g)
 Many pharmacies have expressed frustration with their collection receptacles reaching capacity and the lack of a timely response or consistent maintenance of the collection bins. Each program operator should be required to have a contact number for authorized collectors to utilize to notify the operator of the full receptacle. It is important for CalRecycle to develop general standards for timeliness related to responses by operators to pharmacy requests.
- 008-004 **Recordkeeping requirements for pharmacies**
Section 18974
 Current language included in Section 18974 that requires pharmacies to maintain and provide access for CalRecycle to records should be clarified so that a pharmacy chain corporate representative can maintain records for all pharmacies under their jurisdiction. The records that CalRecycle is requiring are not kept at the individual pharmacy level for chain pharmacies. These records are generally held at the regional or corporate level. For small independent pharmacies, this requirement may be too cumbersome to comply and might require some time or flexibility to gather and generate the information required by the Department. Pharmacies would like to retain any records electronically and would appreciate a template or some additional direction from the Department to assure compliance.
- 008-005 **Retailer product verification**
Section 18974.3
 While we appreciate the modifications that CalRecycle has made to the retailer product verification requirements, we are still concerned that each individual pharmacy will not have the capability to check a specified website every time they stock or sell a new drug or new drug dosage form. We do understand the importance of participation by pharmacies and pharmacy chains in assisting CalRecycle ensure that manufacturers that are selling in the California market are participating in the required stewardship program. We ask that CalRecycle specify that the requirement to consult the website will be at least

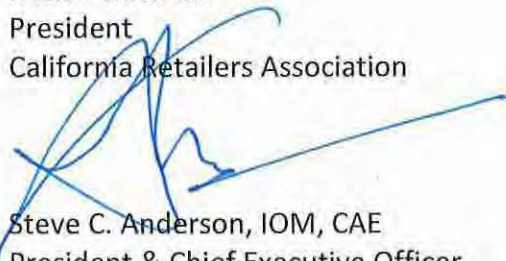
on an annual basis and also specify how the pharmacy will inform the Department if they learn of a non-compliant product.

CRA, NACDS and CPhA thank you for the opportunity to comment on the Pharmaceutical and Sharps Waste Stewardship Program Proposed Regulations. We look forward to continuing to work with CalRecycle to ensure appropriate and effective oversight of the Stewardship Program.

Sincerely,



Rachel Michelin
President
California Retailers Association



Steve C. Anderson, IOM, CAE
President & Chief Executive Officer
National Association of Chain Drug Stores



Rajan Vaidya, PharmD
Director, Pharmacy Practice & Policy
California Pharmacists Association

From: [Lindahl, Leah](#)
To: [PharmaSharps; Smyth, Jason@CalRecycle](#)
Subject: HDA Comments on CalRecycle Proposed Regulations Implementing SB 212
Date: Sunday, February 16, 2020 7:48:18 PM
Attachments: [HDA Redlined Comments Pharmaceutical and Sharps Waste Stewardship Program Proposed Rules.pdf](#)
[HDA Comments Pharmaceutical and Sharps Waste Stewardship Program Proposed Rules.pdf](#)

[[EXTERNAL]]

Good Evening Jason,

Thank you for allowing us to provide comments on CalRecycle's proposed regulations seeking to implement the pharmaceutical and sharps waste stewardship program. Please find the attached comment letter and redlined edits to the proposed regulations on behalf of the Healthcare Distribution Alliance (HDA) and our member companies. Please let me know if you have any questions.

Thank you,

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

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O – (703) 885-0243
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LLindahl@hda.org
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PATIENTS MOVE US.

February 17, 2020

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

Re: HDA Comments on the proposed regulation to implement the Pharmaceutical and Sharps Waste Stewardship Act [Chapter 1004, Statutes of 2018 (Jackson, Senate Bill 212)]

Mr. Smyth:

On behalf of the Healthcare Distribution Alliance (HDA) please find the below comments and attached revisions in response to the Notice of Proposed Rulemaking to implement the Pharmaceutical and Sharps Waste Stewardship Act [Chapter 1004, Statutes of 2018 (Jackson, Senate Bill 212)]. HDA and our members appreciate the opportunity to provide these comments to CalRecycle, which provide an overview of our concerns and offer suggestions to help address these issues in order to establish a more effective and viable stewardship program within the state of California.

Background:

HDA represents primary pharmaceutical wholesale distributors, the vital link between the nation's pharmaceutical manufacturers and more than 200,000 pharmacies, hospitals, long-term care facilities, clinics and others nationwide, with over 17,000 located in California. Since 1876, HDA has helped members navigate regulations and innovations to get the right medicines to the right patients at the right time, safely and efficiently. HDA distributor members do not research, develop, manufacture pharmaceuticals or market them to physicians or patients. Wholesalers do not prescribe or dispense medications to patients or have any impact on a patient's pharmacy benefit design. Wholesale distributors' role is to purchase pharmaceutical products from state and federally licensed manufacturers, securely store, and finally safely deliver them to state and federally licensed healthcare providers. HDA members operate 24 hours a day, 365 days a year, shipping approximately 15 million products across the nation every day. Simply put, wholesale distributors are logistics experts that ensure pharmacies and hospitals keep their shelves stocked with medications their patients need.

HDA and our primary pharmaceutical wholesale distributor members recognize the importance of efforts to ensure the safe, secure, and convenient disposal of unused, unwanted, or expired

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

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

Comments and Recommendations:

1. 18972.2 Criteria for Determining a Covered Entity:

009-001A

The proposed regulatory text fails to provide any additional clarity around the term “Covered Entity,” instead placing much of the guidance on the legislative text which was specifically noted during the legislative process as needing additional clarity. As provided within comments during the informal rulemaking process, the current language creates uncertainty as to which entity is ultimately responsible and could result in a multi-layer fee where the manufacturer, wholesaler, repackager, licensee, importer, etc. fund the disposal of a single product. Additionally, the language also fails to offer a definition as to what constitutes a “manufacturer.”

009-001B

HDA request the proposed regulations provide further clarity that any manufacturer who avails itself of the California market should be the responsible entity required to participate in the stewardship program. In other words, if a manufacturer’s product is for sale within the state of California, they are therefore “in” the state and responsible for participating in the Pharmaceutical and Sharps Waste Stewardship Program. It is clear that the legislative intent was that all manufacturers must participate in the stewardship program. Therefore, it is imperative that a manufacturer not be permitted to avoid participation simply by claiming that they do not have a facility in the state and are therefore not “in” the state. Based on current case law, the state of California clearly has jurisdiction over pharmaceutical manufacturers whose products are dispensed in California to comply with the proposed statewide take back program. Additionally, HDA requests that regulations stipulate a clear process by which CalRecycle will identify the manufacturer and how the department would utilize the tiered definition should the manufacturer not be identifiable.

009-001C

009-001D HDA also requests that a clear definition is developed as to what constitutes a “Manufacturer” and offers the below definition for consideration:

“Manufacturer” means a person, company, corporation or other entity engaged in the manufacture of (a) a covered drug as defined in subsection (e)(1) of section 42030 of the Public Resources Code sold, offered for sale, or dispensed in the state pursuant to a United States Food and Drug Administration (FDA) approved New Drug Application (NDA), an approved Abbreviated New Drug Application (ANDA), or an over-the-counter drug monograph, or (b) hypodermic needles sold, offered for sale, or dispensed in the state pursuant to an FDA pre-market approval (PMA), or 510k. Manufacturer does not include the activities of a repackager, relabeler, private label distributor or wholesale distributor.

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

009-002A We appreciate CalRecycle’s efforts to provide more clarity on how wholesalers and others will verify products being sold in or into California. HDA recommends the regulations stipulate that reporting entities should review the website at least annually and provide a listing of apparent non-compliant manufacturers or covered entities to the department in a format that has been agreed upon by the industry and the department. HDA also requests the department, in coordination with the board, notify licensees and reporting entities when a non-compliant entity has been identified. HDA further recommends the regulations provide clarity that these reporting entities shall be held harmless for any assessment of penalties placed on the actual manufacturer for lack of participation in the stewardship program.

009-002B

009-002C

009-003A 3. 18975. Criteria to Impose An Administrative Civil Penalty

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

009-003B

009-004 4. Submittal of Product Lists

The proposed regulatory text does not provide any additional guidance on the reporting of product lists to the Board of Pharmacy. HDA and our member companies believe the

current structure outlined in the legislative text establishes an inefficient and ineffective way to collect information to identify which entities should be participating in the stewardship program, resulting in the board receiving incredibly voluminous and duplicative information to analyze and interpret.

Due to the vague definition of “Covered Entity” there is no mechanism for which an entity identified under the tiered definition can determine if the prior entity has provided a report to the state board, therefore each entity identified will be responsible to submit information on the products they sell or offer for sale within the state. Due to the structure of the pharmaceutical supply chain, these reports will be largely duplicative since a single product will flow through each of the listed entities prior to the point of dispensing.

HDA and our member companies request the Board of Pharmacy establish regulations on this issue which specifically require reporting from the actual manufacturer of the product, these manufacturers can be identified through the above suggested definition. HDA and our members further request a uniform format for reporting to the state board include the following data sets: Name of Supplier, Description of Drug, and National Drug Code (NDC). Every drug product approved for marketing by the FDA, including prescription and over-the-counter, is assigned a unique 10-digit, 3-segment NDC number. This number identifies the labeler, product, and trade package size and is utilized throughout the product’s lifecycle. The regulations should also stipulate that entities shall be held harmless for any assessment of penalties on the manufacturer or preceding covered entity for lack of reporting.

009-005

Similar to the concerns expressed above, the requirement to provide a list and description of any drugs or sharps that are “not covered” would be incredibly difficult to ascertain, specifically due to the vague definitions provided in the law. Many of the “not covered” products listed do not include a specific or standard definition for such products, leaving open the interpretation as to what constitutes “not covered” products and what should and should not be reported. Utilizing a clear definition of “Manufacturer” and the NDC for reporting requirements should alleviate the need to report a full list of “not covered” products, unless the state board is seeking to clarify a specific question or product being submitted. We request the reporting of “not covered” products only be required upon request from the board under specific situations or to help identify specific product classes and not required on an annual basis.

Conclusion:

HDA and our member companies appreciate the ongoing work of CalRecycle and the proposed regulations to implement Senate Bill 212. While we believe the proposed regulatory text provides additional guidance and support for industry to effectively implement and comply with the newly enacted law, there remain outstanding issues that need further clarity and consideration. We believe the above comments and suggestions provided within this document and the attached revisions to the proposed regulations would help better address the wholesale industry's concerns.

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

Sincerely,

A handwritten signature in black ink that reads "Leah D. Lindahl". The signature is written in a cursive, flowing style.

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

HDA Redlined Comments Pharmaceutical and Sharps Waste Stewardship Program Proposed Rules

Please find the attached comment letter and redlined edits to the proposed regulations on behalf of the Healthcare Distribution Alliance (HDA) and our member companies.

Thank you,

Leah Lindahl

Senior Director, State Government Affairs, Western Region Healthcare
Distribution Alliance (HDA)

1 (5) Any changes in the facility(ies) to be used to process or dispose of a covered
2 drug or home-generated sharps waste collected through the stewardship
3 program not identified in the approved plan.

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

11 **18972.2. CRITERIA FOR DETERMINING A COVERED ENTITY.**

12 (a) The department shall consider all manufacturers of covered products that are sold,
13 offered for sale, or dispensed in California, whether they are program operators or are
14 represented by a stewardship organization, as the covered entities.

15
16 (b) The department will consider any manufacturer with products offered for sale in the
state of California as being "in" the state.

17 (c) "Manufacturer" means a person, company, corporation or other entity engaged in the
manufacture of (a) a covered drug as defined in subsection (e)(1) of section 42030 of
the Public Resources Code sold, offered for sale, or dispensed in the state pursuant to
a United States Food and Drug Administration (FDA) approved New Drug Application
(NDA), an approved Abbreviated New Drug Application (ANDA), or an over-the-counter
drug monograph or (b) hypodermic needles sold, offered for sale, or dispensed in the
state pursuant to an FDA pre-market approval (PMA) or 510k. Manufacturer does not
include the activities of a repackager, relabeler, private label distributor or wholesale
distributor.

18 (bd) The department will use the priority set forth in subsections(1)(B)-(E) of subdivision
19 (f) of section 42030 of the Public Resources Code to identify the covered entity for any
20 covered products, which do not meet the definition of subsection (1)(A) of subdivision (f)
21 of section 42030 of the Public Resources Code.

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

23 Note: Authority cited: Sections 40401, 42031.2 and 40502, Public Resources Code.
24 Reference: Section 42030, Public Resources Code.

25 **18973. DOCUMENT SUBMITTALS: STEWARDSHIP PLAN, INITIAL PROGRAM
26 BUDGET, ANNUAL REPORT, AND ANNUAL BUDGET.**

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

009-Supp.-001A

Commented [HDA1]: HDA appreciates the inclusion of this provision, stipulating that any manufacturer who avails itself of the California market should be the responsible entity required to participate in the stewardship program. Due to the vague nature of the legislative text, we request the rules further stipulate that a manufacturer is "in" the states if any of their products are offered for sale within California.

009-Supp.-001B

Commented [HDA2]: HDA further requests CalRecycle include a clear definition as to what constitutes a "Manufacturer" as this term can have varying meanings depending on the context. HDA recommends the incorporated definition for consideration. Lack of a clear definition within the law and rules allows for open interpretation of the law and could potentially include other entities outside of the actual manufacturer.

009-Supp.-001C

Commented [HDA3]: HDA continues to request the CalRecycle establish a clear process by which the department will identify the manufacturer and how the department would utilize the tiered definition should the manufacturer not be identifiable.

1 (3) The date(s) the retailer offered the covered product(s) for sale.

2 (4) Certification letter(s) from the department, if provided by a manufacturer, to
3 demonstrate that a particular covered product from the manufacturer is or was
4 subject to a department-approved covered product stewardship plan. A retail
5 pharmacy/retail pharmacy chain must provide access to a certification letter only
6 if it is being used as proof of compliance, pursuant to subdivision (b) of section
7 42035 of the Public Resources Code, or that a covered entity or stewardship
8 organization not listed on the department's internet website is in compliance and
9 may sell or offer for sale pharmaceuticals and/or sharps in California.

10 Note: Authority cited: Sections 40401, 42031.2 and 40502, Public Resources Code.
11 Reference: Sections 42030, 42033.4, 42035, 42035.6 and 42036.4, Public Resources
12 Code; and Section 17041, California Code of Regulations.

13 **18974.1. ADMINISTRATIVE FEE TO DEPARTMENT OF RESOURCES RECYCLING**
14 **AND RECOVERY.**

15 The department will set the administrative fee pursuant to sections 42034 and 42034.2
16 of the Public Resources Code.

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

19 **18974.2. STEWARDSHIP ORGANIZATION AUDITS OF COVERED ENTITIES OR**
20 **AUTHORIZED COLLECTORS.**

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

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

27 **18974.3. RETAILER, WHOLESALER, DISTRIBUTOR PRODUCT VERIFICATION.**

28 Each distributor, wholesaler, pharmacy, and retailer that sells, offers for sale, or
29 dispenses a covered product shall:

30 (a) Successfully log onto the department's Internet Web site at least annually to verify
that a covered entity of covered products ~~to be~~ sold, offered for sale, or dispensed are in
compliance with the law.

31 (b) Should a distributor, wholesaler, pharmacy, other retailer, or a designated
32 responsible party identify a noncompliant covered product, the distributor, wholesaler,

009-Supp.-002A

Commented [HDA4]: To ensure conformity and clarity, HDA recommends the department require reporting to be conducted at least annually. Further, under Article 6. Section 42305, the list provided by the department will contain "stewardship organizations, including entities with an approved stewardship plan, and covered entities, authorized collection sites, retail pharmacies, and retail pharmacy chains provided in the stewardship plans that are in compliance with this chapter" not a listing of covered products.

1 pharmacy, other retailer, or designated responsible party shall report, in an agreed upon format, the discovery to
2 the department's Enforcement Unit.

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

23 Note: Authority cited: Sections 40401, 42031.2 and 40502, Public Resources Code.
34 Reference: Sections 42030, 42035, 42035.2, 42035.4, 42035.6 and 42035.8, Public
45 Resources Code.

56 **18975. CRITERIA TO IMPOSE AN ADMINISTRATIVE CIVIL PENALTY.**

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

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

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

4013 (bd) In assessing or reviewing the amount of an administrative penalty imposed for a
4414 violation of this Article, the department shall consider the totality of the circumstances,
4215 which may include, but is not limited to, the following:

4316 (1) The nature, circumstances, extent, and gravity of the violation(s)

4417 (2) The number and severity of the violation(s)

4518 (3) Evidence that the violation was intentional, knowing, or negligent

4619 (4) The size of the violator

4720 (5) History of violation(s) of the same or similar nature

4821 (6) The willfulness of the violator's misconduct

4922 (7) Whether the violator took good faith measures to comply with this chapter and
2023 the period of time over which these measures were taken

2124 (8) Evidence of any financial gain resulting from the violation(s)

009-Supp.-002A cont.

Commented [HDA5]: HDA requests the department work with industry to determine how these reports should be conducted and to establish a standardized format for these reports.

Commented [HDA6]: HDA requests the Department notify licensed or reporting entities when they identify a non-compliant stewardship organization or covered entity.

009-Supp.-002B

009-Supp.-003A

Commented [HDA7]: HDA requests the department establish a process to alert covered entities when there has been a compliance issue. These entities should have the ability to understand their requirements before any potential assessment can be levied.

Commented [HDA8]: HDA would like to ensure that should the Department utilize the tiered definition of covered entity, the penalties assessed on the previously reported non-compliant entity will not be applicable to subsequent entities.

009-Supp.-003B

From: [Anne Vogel Marr](#)
To: [PharmaSharps](#)
Subject: Comments on California Department of Resources Recycling and Recovery's Proposed Pharmaceutical and Sharps Waste Stewardship Program Regulations issued on January 3, 2020.
Date: Monday, February 17, 2020 7:18:59 AM
Attachments: [image001.png](#)
[image004.png](#)
[PPSWG Comments on CalRecycle 2-17-20 FINAL.pdf](#)

[[EXTERNAL]]

February 17, 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 95812-4025

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 Proposed Pharmaceutical and Sharps Waste Stewardship Program Regulations that were issued on January 3, 2020.

PPSWG is a membership association with over 400 members and affiliated companies across the broad spectrum of pharmaceutical products and sharps producers. PPSWG has established MED-Project USA to develop, implement and operate stewardship programs for unwanted drugs and sharps from households on behalf of PPSWG's membership.

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

-



February 17, 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 95812-4025

Re: PPSWG Comments on CalRecycle’s January 3, 2020 Proposed Regulatory Action – 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” or “CalRecycle”) Proposed Pharmaceutical and Sharps Waste Stewardship Program Regulations (the “Proposed Regulations”) that were issued on January 3, 2020.

PPSWG is a membership association with over 400 members and affiliated companies across the broad spectrum of pharmaceutical products and sharps producers. PPSWG has established MED-Project USA to develop, implement and operate stewardship programs for unwanted drugs and sharps from households on behalf of PPSWG’s membership.

Lists of Covered Products

PPSWG’s primary concern with the Proposed Regulations relates to the provisions requiring the submission of “updated”, “verified” or “reverified” lists of covered products. As described below, clarity is sought to ensure that the provisions are consistent with SB 212 and do not impose additional and unnecessary burdens on producers and program operators.

010-001a Section 18973.4(j)(2) of the Proposed Regulations states, without further elaboration, that the
& annual reports submitted to CalRecycle for a covered drug stewardship plan must include a
010-001b “[l]ist of covered products.” Section 18973.5(k) states, somewhat similarly, that the annual reports for a home-generated sharps waste stewardship plan must include an “[u]pdated list of covered products.” These provisions should be revised for clarity and to ensure they are consistent with the corresponding statutory language in SB 212.

The corresponding provision in SB 212 states that annual report submissions must include, among other things, “*the updated and reverified list provided pursuant to paragraph (2) of*

subdivision (a) of Section 42031 of covered products that each covered entity subject to the stewardship plan sells or offers for sale.” Cal. Pub. Res. Code § 42033.2(b)(2) (emphasis added). Section 42031(a)(2), in turn, requires that covered entities (or a stewardship organization on behalf of a group of covered entities) update and submit a list of covered products to the Board of Pharmacy on or before January 15 of each calendar year. This statutory language does not impose any new obligations on regulated entities during the annual reporting process; i.e., there is no obligation to prepare a new, updated or re-verified list of covered products during the roughly two month period between the January 15th Board of Pharmacy submission deadline and the March 31st annual reporting deadline. Rather, the intent was to simply – and only – require that a copy of the covered products list submitted to the Board of Pharmacy on January 15th be included in the annual report submitted to CalRecycle on March 31st.

The corresponding language in the Proposed Regulations, as currently drafted, could be construed as imposing additional obligations on regulated entities to undertake another exercise in preparing an updated and/or reverified list of covered products to include in the March 31st annual report submissions. This is inconsistent with SB 212. As such, Sections 18973.4(j)(2) and 18973.5(k) of the Proposed Regulations should be revised for clarity and consistency with the legislature’s intent. Specifically, Sections 18973.4(j)(2) and 18973.5(k) should be amended to read:

“The annual report shall contain the following ... a copy of the list of covered products submitted to the Board of Pharmacy pursuant to subsection (a)(2) of section 42031 of the Public Resources Code.”

Support for MED-Project USA Comments

MED-Project USA is separately submitting comments today on the Proposed Regulations. PPSWG supports the MED-Project USA comments.

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 these Proposed Regulations and the implementation of SB 212.

Respectfully submitted,



Anne Vogel-Marr
Executive Director

010-002

From: [Greaves, Fielding](#)
To: [PharmaSharps](#)
Cc: [Greaves, Fielding](#)
Subject: AdvaMed Comments to SB 212 Regulations
Date: Monday, February 17, 2020 9:11:20 AM
Attachments: [image001.png](#)
[AdvaMed Comment to CalRecycle PDR for SB 212 \(2018\).pdf](#)

[[EXTERNAL]]

Hello,

Please accept our written comments to SB 212 (2018).

Thank you.

Fielding

FIELDING GREAVES

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



Letter 11: 45-Day - AdvaMed



February 17, 2020

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

Subject: AdvaMed Comments on CalRecycle’s Proposed Pharmaceutical and Sharps Waste Stewardship Program Regulations for SB 212 (2018)

Dear Mr. Smyth,

The Advanced Medical Technology Association (AdvaMed), the national association of medical technology providers, appreciates the opportunity to comment on the proposed draft regulations to implement SB 212 (Jackson, 2018).

AdvaMed advocates on a global basis for the highest ethical standards, timely patient access to safe and effective products and economic policies that reward value creation. AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. Medical technology plays a critical role in health care, improving quality of life, extending life and saving life for millions of patients every day. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

011-001

The definition of “provides or initiates distribution of sharps waste container” should be amended to change the number of business days from three to fifteen to promote cost-effectiveness. Long term sustainability of the program will require efforts to contain costs to avoid significant market responses that could impact access. Requiring express mail on every sharps container shipment could cause costs for the mail-back component of the program to rapidly escalate. Under a 15-day requirement, most containers will probably arrive far earlier than the 15th day but this will contain the costs of the program that will ultimately benefit patients and help to ensure the program’s long-term success.

011-002a
&
011-002b

Agency determinations should take into account late responses or non-responses from agencies. SB 212 was drafted with the understanding that state agencies may not respond in a timely manner that would allow the operator to meet other deadlines. In such a situation, the plan operator should be able to self-certify that they believe the plan is in compliance with all



AdvaMed

Advanced Medical Technology Association

applicable laws. The regulation should be amended to include the following: “If any state agency failed to respond in a timely manner, the plan shall include a statement that the plan is self-certifying and list any agency that was solicited but failed to respond by the submission date.”

011-003 **Manufacturers should determine the appropriate volume of containment appropriate.** The statutory language currently provides an undefined metric for containers over a specified period of time. Manufacturers are in the best position to understand the volume of containment needed to accommodate a product used over a period of time, understanding that the volume must be sufficient to fully contain all product used appropriately over the period of time. The regulation should be amended to include the following after 18973.3(f)(2)(a) “...over a selected period of time as determined by the manufacturer or plan operator.” This amendment will prevent inappropriate requests for containment that could lead to waste. The amendment also will prevent over containerization that would prevent excess containers from being deposited in recycling bins or filled with non-program materials. Excess containers increase the use of plastic and make it likely that municipal recycling facility workers will need to shut down lines and clear empty containers that a consumer attempts to recycle from lines as workers would be aware that these containers and their expected contents should not continue down the line with common recyclable materials. In the event of lost, damaged or otherwise non-usable containers, patients could make requests for additional containers.

011-004 **Include “online sales” in definition of “point of sale” as “to the extent feasible” to recognize the reality of existing business models.** In SB 212, the requirements to provide sharps containers to ultimate users was contemplated in lieu of an actual point of sale acquisition of a container at a brick and mortar point of sale. Sharps manufactures and program operators could not possibly have perfect information about every transaction over the Internet. Additionally, it may be difficult to cooperate with every online website that provides sharps and makes the inclusion of the online sales in the scope of “point of sale” practically impossible in all respects. The inclusion of online sales should be eliminated or limited “to the extent feasible.” Alternatively, CalRecycle would need to identify the authority to compel a retailer to notify the purchaser of covered products about the program and how to contact a program operator.

011-005 **Eliminate paraphrasing of the plain text of the statute in SB 212 where the substantive meaning is clear and unambiguous.** In several instances throughout the draft regulation, the language diverges from the language of SB 212 via paraphrasing, either intentionally or unintentionally. The differences may seem subtle or more than subtle but in many cases the language or precise phrase was negotiated or drafted to effectuate a specific outcome. The resulting divergence can produce confusion and uncertainty.

Thank you for considering our concerns. Please contact me at (202) 783-8700 if you have any questions.

Sincerely,

Fielding Greaves

Director, State Government & Regional Affairs

From: [Larry Kenemore Jr.](#)
To: [PharmaSharps](#)
Subject: Attached Comments on Proposed Regulations to Implement California Pharmaceuticals and Sharps Waste Stewardship Program
Date: Monday, February 17, 2020 11:50:42 AM
Attachments: [Letter to Calif on Proposed Regulations.docx](#)

[[EXTERNAL]]

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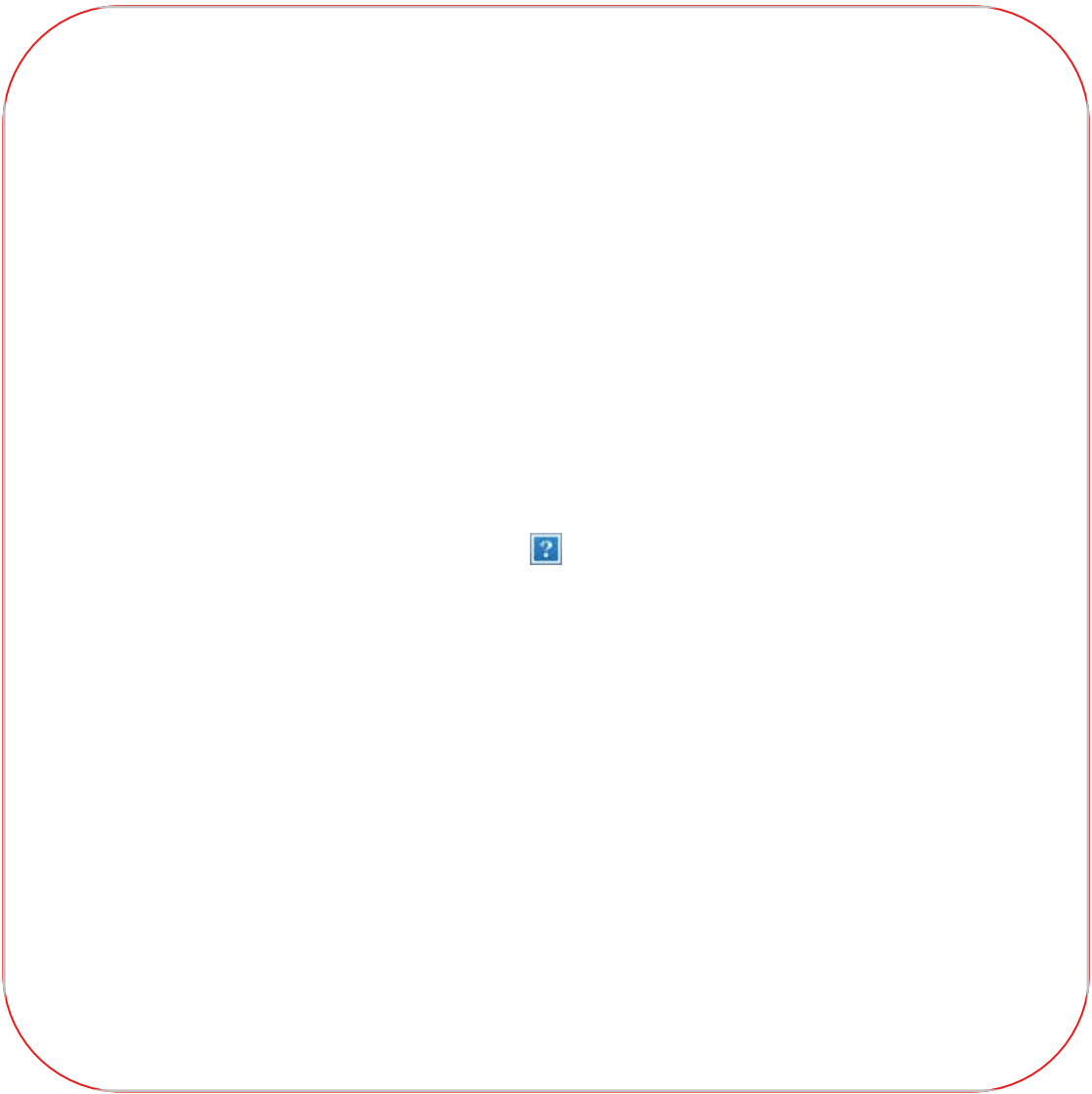
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- **Siloam Springs Arkansas Chamber of Commerce**
- **APNet Arkansas Prevention Network**
- **NAAEE North American Association Environmental Education**
- **Board Member AEEA Arkansas Environmental Education Assn.**
- **NSAC National Stewardship Action Council**
- **Project WET Trainer**





PROVIDING OPPORTUNITY FOR SPECIAL NEEDS COMMUNITY

Mr. Smyth;
Find below our attached comments on the California Pharmaceuticals and Sharps Waste Stewardship Program.
We very much would like to meet with you to discuss the inclusion of Safe-Drug-Disposal in these regulations.
Larry Kenemore CEO





CLICK HERE TO WATCH SAFE IMMEDIATE DRUG DEACTIVATION

CLICK HERE TO WATCH OUR AWARDS VIDEO

CLICK HERE TO SEE BOTTLE USED



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A WOMAN-OWNED MINORITY-OWNED BUSINESS

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



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February 17, 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

Mr. Smyth;

Thank you for the opportunity to submit comments on the proposed regulations to implement California's Pharmaceutical and Sharps Waste Stewardship Program. Please accept the enclosed comments on behalf of Stat-Medicament-Disposal Corporation.

We would like to make these specific comments that are:

- There appears to be lacking any regulations as far as a Safe-Drug-Disposal program inclusion. This program was outlined and recommended in the ODNDPC 2015 Report under Pillar #3. 012-001
- 18973.2(d)(2) Under current DEA Regulations it does not appear that a Stewardship Plan that operates ONLY a Safe-Drug-Disposal program would be classified as an authorized collector as that type of program does not collect Pharmaceuticals. 012-002
- 18973.2(g)(2)(A) Wording needs to included for Safe-Drug-Disposal and removes the words collection. And should include wording for a Safe-Drug-Disposal program to include all mailing addresses with a municipality and any public space that requests a Safe Drug Disposal Kiosk. 012-003
- 18973.2(g)(8) Wording needs to include that a Safe-Drug-Disposal program provide a minimum of two (2) Safe-Drug-Disposal bottles per mailing address and that Kiosks include delivers of two (2) Safe-Drug-Disposal bottles. 012-004
- 18972.2(g)(10) should include language that Safe-Drug-Disposal programs provide in-school training within each District within a Municipality either by in-person or webinar for Students. 012-005a & 012-005b
- 18973.2(j) and 18703.3(i) We think that market research is not necessary under a Safe-Drug-Disposal program. A Safe-Drug-Disposal program reaches every mailing address within a municipality and a properly defined Safe-Drug-Disposal program will provide "actual" stats as to the effectiveness of such a program that is inherent in this type of program. 012-006a & 012-006b

- 012-007a
&
012-007b
- **18973.2(k) and 18973.3(j) It would be possible to combine a Safe-Drug-Disposal program with the standard Take-Back-Program and provide stats on both along with the education and outreach. Such as a municipality could use a Safe-Drug-Disposal for homes and Take-Back-Drop boxes for businesses or vice-versa and should be allowed through these regulations.**
- 012-008a
&
012-008b
- **18973.4 c and 18973.4(d) We recommend that reports from Drug-Take-Back programs provide the “actual weight” of the Pharmaceuticals “NOT” the containers-bottles-blister packages as has been the past practice. This has mis-lead the public in the past by 60-70%.**

Thank you again for providing the opportunity to submit comments on the proposed regulations.

Larry Kenemore CEO

CC: NSAC

Senator Hanna Beth Jackson

Assemblymember Phil Ting

Assemblymember Adam Gray

Melissa Immel, Deputy Legislative Secretary & Chief of Legislative Operations/Gov. Newsom

From: [Ashley Schmidt](#)
To: [PharmaSharps](#)
Cc: [Jennifer Hendrick-Snyder](#)
Subject: Inmar Comments to Pharmaceutical and Sharps Stewardship Act (SB212) Proposed Regulations
Date: Monday, February 17, 2020 2:20:12 PM
Attachments: [Inmar Comments to CalRecycle.pdf](#)

[[EXTERNAL]]

Jason,

Please find attached Inmar's comments regarding SB 212. We appreciate this opportunity to respond and look forward to working with CalRecycle.

Thank you,
Ashley

Ashley Schmidt

Director, Regulatory and Compliance



Ashley.Schmidt@inmar.com

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Letter 13 - 45- Day - INMAR intelligence
Marile

Inmar Intelligence, Comments Regarding Pharmaceutical and Sharps Stewardship Act (SB212)

February 17, 2020

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

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

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

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

Proposed Regulations, Pharmaceutical and Sharps Waste Stewardship Program,
available at <https://www2.calrecycle.ca.gov/Docs/Web/116250>

Dear Mr. Smyth:

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

Over the past 25 years, Inmar has become the national leader in pharmaceutical returns, servicing over 27,000 pharmacies and 80 percent of hospitals and health systems. Inmar processes over 95 percent of the industry's wholesale returns. Additionally, Inmar has three years of experience managing drug take-back programs with over 1,400 receptacles in 42 states, primarily driven through retail and hospital collectors.

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

I. GENERAL COMMENTS

The proposed regulations implement the requirements for the new statewide drug take back program for the safe disposal of drugs and sharps. Inmar is pleased to offer the following suggestions for this important program based on Inmar's nationwide experience with reverse pharmaceutical distribution. These rules provide the basis for Californians to safely dispose of drugs and sharps, protecting their communities and the environment from the misuse or improper disposal of medications. The California program can provide for convenient return channels that Inmar is uniquely positioned to support.

013-001 An overall consideration is that program operations should key on well-established commercial channels and practice. An attempt to develop a reverse distribution process outside commercial norms could be unduly burdensome to stewardship programs and program operators, and introduces unnecessary complexity and costs. Similarly, to ensure the full engagement of all stakeholders, CalRecycle should affirm, through appropriate regulatory coverage, that confidential business information will be protected from disclosure outside the state government.

013-002 The program includes a reasonable "good faith" efforts concept that should apply to negotiations with collectors, as well as among all parties engaged to make the program function effectively. This would include "all covered entities,

013-003

stewardship organizations, program operators, ..." as stated in Proposed Regulation ("PR") 18972. The proposed regulations also require that in the event of "multiple stewardship programs," program operators must work together to most effectively achieve the requirements of the statute and regulations. PR 18973.2(k). Through good faith efforts, many duplicative and potentially inefficient aspects of the program can be eliminated.

II. COMMENTS

18972.1. DEFINITIONS.

(a) Except as otherwise noted, the definitions of this Article supplement and are governed by the definitions set forth in Chapter 2, (commencing with section 42030) Part 3, Division 30 of the Public Resources Code.

013-004

(b) "Administrative and operational costs"¹ means costs to implement and operate a stewardship program, including, but not limited to, collection, transportation, processing, disposal, and education and outreach costs, as well as administrative costs of operating the stewardship organization and administrative fees charged by the department.

Comment: In PR 18972.1, the terms "administrative and operational costs" (§§ 42032.2; 42034),² and "administrative fees" (§ 42034.2) should be defined and referred to separately. They are treated separately in SB 212.

(g) "Minutes, books, and records" means accurate and up-to-date information regarding a program operator's activities.

013-005

Comment: See General Comments, above. Audit and recordkeeping requirements should be consistent with commercial norms to allow program operators to comply with largely uniform standards nationwide.

(k) "Significant change" to an approved stewardship plan includes, but is not limited to:

(1) An addition or discontinuation of a collection method, whether a mail-back program, collection receptacle program, or an alternative method of collection.

(2) Any changes to a stewardship program that are required by local, state, or federal laws and regulations.

(3) Any changes to a stewardship program necessitated by the repeal of a local ordinance for either covered drugs or home-generated sharps waste.

(4) Any changes regarding achievement of convenience standards.

013-006

(5) Any changes in the facility(ies) to be used to process or dispose of a covered drug or home-generated sharps waste collected through the stewardship program not identified in the approved plan.

¹ Unless otherwise noted, emphasis is added.

¹ Statutory citations are Cal. Pub. Resources Code Div. 30, Pt. 3, Ch. 2 (the "Act").

013-006 Comment: The “significant change” definition should include a limiting provision to avoid requiring reporting administrative or operational changes that do not have a material impact on program services. This would avoid creating an undue administrative burden on both the Department and program operators.

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

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

* * *

(e) Any submittals to the department that the program operator believes are confidential in nature shall include a cover letter explaining the justification of confidentiality. Records supplied to the department pursuant to this Article that are, at the time of submission, claimed to be proprietary, confidential, or a trade secret shall be subject to the provisions in Title 14, California Code of Regulations, Division 7, Chapter 1, Article 4 (commencing with section 17041).

013-007(A-C)

Comment: The language of Paragraph (a), above should be revised to provide that “[a] corporate officer, **or a designee**, acting on behalf of the program operator, shall submit” Program operators should have the flexibility to arrange for the submission of stewardship plans, budgets, or reports in an efficient manner consistent with their business practices. 013-007A

Paragraph (a) refers to the “document.” Will there be a template, matrix, or format available, including the format(s) consistent with local ordinances? 013-007B

Paragraph (e) would require that any confidential submittals “shall include a cover letter explaining the justification of confidentiality.” The Act (§ 42036.4) does not contain an “explaining” and “justification” requirement, but rather emphasizes the importance of protecting proprietary information. This prohibition on release is more stringent than other statutory exemptions under the California Public Record Act. PR 18973(e), as proposed, would require a program operator to go beyond the requirements of the Act, and does not emphasize that confidential information should be protected. The legislature emphasized the critical importance of protecting this information in the stewardship bill itself, noting that the protection is necessary “to ensure that the competitive market in the state for the manufacture and sale of drugs and sharps is not compromised.” Stats 2018 ch 1004 Sec. 2. Consistent with practice under the federal Freedom of Information Act, submitters of confidential information should simply be required to mark the pages that contain proprietary information with a restrictive legend. At the time that the Department receives a public records act request seeking such information, the submitter should have advance notice of any potential disclosure, and at that time provide the additional detailed factual and legal justification for withholding information as appropriate under the Act. As currently drafted, PR 18973(e) is inconsistent with the statutory requirement. 013-007C

18973.1. DOCUMENT APPROVALS: STEWARDSHIP PLAN, INITIAL PROGRAM BUDGET, ANNUAL REPORT, AND ANNUAL BUDGET.

(a) **A program operator submitting a stewardship plan, initial program budget, annual report, or annual budget shall provide to the department, upon request and by the requested deadline, clarifying information that is necessary to assist the department in its consideration of approval.**

013-008 (A-B)

¹ Unless otherwise noted, emphasis is added.
¹ Statutory citations are Cal. Pub. Resources Code Div. 30, Pt. 3, Ch. 2 (the “Act”).

013-008A

Comments: PR 18973.1 does not address § 42032(b)(4), which provides that “If, 90 days after submitting a plan to an applicable agency, a program operator has not received a response from the applicable agency, the program operator may submit a certification to the department that the stewardship plan is consistent with all other applicable laws and regulations.” The PR should recognize this and indicate that the certification allows for a reasonable belief a plan is consistent with the statutory and regulatory provisions.

To the extent that other agencies are involved, the PR should confirm that CalRecycle will coordinate all such internal state or federal review and provide the final approval.

013-008B

18973.2. STEWARDSHIP PLAN FOR COVERED DRUGS.

A stewardship plan for covered drugs shall comply with all applicable local, state, and federal laws and regulations, including, but not limited to, regulations adopted by the United States Drug Enforcement Administration. The stewardship plan shall include the following:

013-009 (A-B)

(k) Description of how the program operator will make a good faith effort to work with the other stewardship program(s) in order to most effectively achieve the requirements of the statute and regulations, in the event that multiple stewardship programs for covered drugs are in operation concurrently.

Comment: Pursuant to 18973.2(k) any program operator(s) should be allowed to exercise good faith efforts to collaborate on the above requirements to present the most cost-effective approach on a statewide basis. Accordingly, convenience standards could be met by any program operator(s) individually or collaboratively, or any stewardship organization(s).

013-009A

013-009B

The overall program includes a reasonable “good faith” efforts concept (see, e.g.; PR 18973.2(k); PR 18973.3(j); PR 18973.4(c)(2), and (n); PR 18973.5(o)) that can apply to negotiations with collectors, as well as among all parties engaged to make the program function effectively. This would include “all covered entities, stewardship organizations, program operators, ...” PR 18972. These good faith efforts could easily eliminate, for example, duplicative collection sites. The proposed rule also requires that in the event of “multiple stewardship programs,” program operators must work together to most effectively achieve the requirements of the statute and regulations. PR 18973.2(k). Conversely, in ensuring cooperation in meeting convenience standards, the Department should not permit new entrants to rely entirely on the network(s) established by other program operators without a commensurate financial contribution and otherwise demonstrating their ability to meet the CalRecycle program responsibility requirements (see discussion under PR 18973.6, *infra*).

013-009A

013-009B

Through good faith efforts, many duplicative and potentially inefficient aspects of the program can be eliminated. In fact, the more good faith cooperation to implement the program statewide, the more credibility and effectiveness it can achieve, both with covered entities, as well and the citizens it is designed serve. Thus, the current statute and PR correctly allow for manufacturers to utilize a cooperative approach to complying with convenience standards.

013-009A

Experience with other programs (e.g., federal small business contracting), indicates that “good faith” efforts is not readily definable, but the following are indicative of good faith attempts to maximize program goals: (1) whether a program operator has developed alternative utilization plan consistent with opportunities; (2) whether relevant plans, specifications, or terms and conditions for cooperation are available sufficiently in advance to enable potential cooperation among program operators and an informed response to requests for participation; (3) whether the terms and conditions of any cooperation agreements reasonably compare to the ordinary course of the commercial business standards; and (4) any other information that is relevant or appropriate to determining whether a program operator or stewardship organization has demonstrated a good faith effort to cooperate.

¹ Unless otherwise noted, emphasis is added.

¹ Statutory citations are Cal. Pub. Resources Code Div. 30, Pt. 3, Ch. 2 (the “Act”).

013-010 (A-B) **18973.6. PROGRAM BUDGETS**

The initial stewardship program budget that covers the first five calendar years of operation and annual program budgets shall contain at a minimum, the following information:

(a) Anticipated costs to implement the stewardship program ... * * *

Comment: There is an important and meaningful difference between the performance-based nature of the services provided by program operators, which is funded by the covered entities, and a cost-reimbursement program under which the Department would fund the cost of the drug take back functions. This difference should be clearly distinguished and bears on how PR 18973.6 and related audit requirements should be developed.

Here, the covered entity bears the full risk of unexpected performance cost increases, and thereby exercises its best business judgment in meeting the performance standards (including, but not limited to, PR 18973.2(a) – (m)). By contrast, if the Department were reimbursing the cost of the program, the risk of cost growth would have an impact on state funds, and thus the level of auditing could justifiably be increased. Under the statutory structure of the California drug take back program, however, the risk is allocated to covered entities. The Department’s concern thus is not with the cost of the program, but rather in determining whether a covered entity/program operator is meeting the performance goals. A program operator’s technical and management proposal should address collection, transportation, processing, disposal, education, and other performance metrics, but the underlying cost of the program is the risk and responsibility of the program operator. Total program aggregated costs can be projected and provided, such as: administrative costs, collection and disposal costs, and communication costs. These costs could be subject to audit verification at an aggregated level for purposes of independent financial audit pursuant to PR 18973.6(e), which would also be consistent with the aggregate approach of § 42036.4.

Approving an initial plan and subsequent annual reporting is a function of assessing the responsibility of the program operator evidenced by its technical and management plan. This is best determined based on such factors as a capabilities statement, including a discussion of corporate experience, size, locations, and a current financial statement.

For evaluation purposes, a program operator’s proposal could include the aggregated totals for the following categories, for example, to capture program cost consistent with the Act (§§ 42033.2 , 42033.4 , and 42034.4):

- Administrative costs: contracted and employed personnel; direct and overhead costs; fees (legal, local and state business licensing); taxes; property and rental costs; general equipment and supplies.
- Collection and disposal costs: collection, transportation, and disposal of drugs; purchase, maintenance, and replacement of collection receptacles; compensation of authorized collectors, if separate from personnel costs; and production, distribution, and postage of mailers.
- Communication costs: advertising; marketing; web site creation and maintenance; and operation of a toll-free phone number.

18974. RECORD KEEPING REQUIREMENTS

Each party required to comply with Chapter 2 (commencing with section 42030, Part 3,

013-011 (A-B) Division 30 of the Public Resources Code) shall:

(a) Maintain records to support the requirements in this Article. Covered entities, stewardship organizations, program operators, retail pharmacies and retail pharmacy chains must maintain records to support compliance with the regulations. Retail pharmacies or

¹ Unless otherwise noted, emphasis is added.

¹ Statutory citations are Cal. Pub. Resources Code Div. 30, Pt. 3, Ch. 2 (the “Act”).

**retail pharmacy chains will maintain and provide access to records
required by this Article for three years.**

013-011A Comment: PR 18974 should be defined in terms of a program operator maintaining “reasonable commercial records” to support its meeting the performance standards of the program. PR 18974 should also include a new subsection providing that “records, invoices, and other information made available under this provision shall be maintained as confidential and proprietary or otherwise exempt from disclosure outside the state government.” 013-011B

Thank you for your consideration of our comments. We welcome the opportunity to further discuss this program. I can be reached at (336) 770-3588 or domingo.isasi@inmar.com, or contact Jennifer Snyder, Capitol Advocacy at (916) 444-0400. Please do not hesitate to contact us. We look forward to participating in the implementation of SB 212 with CalRecycle.

Best Regards,

Domingo Isasi

Domingo Isasi

Vice President, Consumer Drug Take-Back

Inmar Intelligence

¹ Unless otherwise noted, emphasis is added.

¹ Statutory citations are Cal. Pub. Resources Code Div. 30, Pt. 3, Ch. 2 (the “Act”).

From: [Scheel, Wade](#)
To: [PharmaSharps](#)
Cc: [Hoboy, Selin](#); [Scheel, Wade](#)
Subject: Comments on Proposed Regulations - Pharmaceutical and Sharps Stewardship Program
Date: Monday, February 17, 2020 2:55:31 PM
Attachments: [image003.png](#)
[Stericycle Comment Cover Letter - FINAL - 02-17-2020.pdf](#)
[CA Rx-Sharps Stewardship - Stericycle Comments - FINAL - 02-17-2020.xlsx](#)

[[EXTERNAL]]

Hello,

Attached are Stericycle's comments on the proposed regulations for the Pharmaceutical and Sharps Waste Stewardship Program - California Code of Regulations, Title 14, Division 7, Chapter 11, Article 4 commencing with Section 18972.

Please contact me with questions regarding this information.

Wade Scheel

Director of Governmental Affairs

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February 17, 2020

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

Submitted electronically via: PharmSharps@calrecycle.ca.gov

**Re: Notice of Proposed Rulemaking – Pharmaceutical and Sharps Waste Stewardship Program
California Code of Regulations, Title 14, Division 7, Chapter 11, Article 4 commencing with
Section 18972**

Stericycle, Inc. (Stericycle) is a publicly traded corporation (NASDAQ: SRCL) based in Lake Forest, Illinois. In 2018, we had estimated revenues of approximately \$3.5B and treated over 1.7 billion pounds of medical waste at our facilities. We operate over 250 medical and hazardous waste facilities, providing services for customers throughout the U.S. primarily in the healthcare field. Our services include compliant collection, transportation and treatment of medical waste, pharmaceutical waste and hazardous waste, as well as secure document destruction. In the State of California, Stericycle operates Regulated Medical Waste (RMW) facilities in Fontana, Fresno, Hayward, Hollister, Lakeport, Rancho Cordova, Redding, San Diego, Vernon, and Yuba City. We operate pharmaceutical and hazardous waste facilities in Bakersfield, Fresno, Inglewood, Los Angeles, Pomona, Rancho Cordova, Rancho Dominguez, Riverside, and San Jose. We operate secure document destruction facilities in Carson, Concord, Eastvale, Foster City, Fremont, Fresno, Moorpark, Sacramento, Santa Ana and Stockton. In all there are over 1,200 employees in the state throughout our different divisions servicing California businesses. Our corporate vision is “Protecting What Matters.”

We would like to take this opportunity to provide comments on the proposed regulations for the Pharmaceutical and Sharps Waste Stewardship Program - California Code of Regulations, Title 14, Division 7, Chapter 11, Article 4 commencing with Section 18972. We want to commend the Agency for the overall stakeholder process in soliciting comments from industry and specifically incorporating the recommendations from Stericycle’s previous comments during the informal rulemaking process.

Specifically, the Agency made necessary changes to clearly defining and delineating responsibilities by entity type for those specific elements related to Program Operators / Stewardship Organizations, Participating Authorized Collectors and the Transportation / Disposal Vendors. Each have very critical tasks and depend on each other, but they each have responsibilities for their own activities, and the current proposed language better defines these requirements.

In general, Stericycle agrees of the overall proposed regulations regarding the stewardship programs for sharps and pharmaceuticals for the State of California. However, Stericycle is submitting additional comments to the proposed regulations in the attached spreadsheet, which we believe should be addressed or be further defined to improve and strengthen the final regulations.



We appreciate the opportunity to submit comments on this important regulation and look forward to continued involvement in the development of this program. If you have any further questions or comments, please feel free to contact me at 612-590-5039 or via email at WScheel@Stericycle.com.

Sincerely,

A handwritten signature in black ink, appearing to read "WScheel", is written over a light gray rectangular background.

Wade Scheel, Director of Governmental Affairs
Stericycle, Inc.

Enclosure

CC: Selin Hoboy, Vice President of Government Affairs and Compliance, Stericycle, Inc.

Proposed Reg Section	PDF Doc Page#	Current / Proposed Language	Stericycle Comment or Suggested Changes
GENERAL OBSERVATIONS DEFINITIONS			
014-001 18972.1	2	(k) "Significant change" to an approved stewardship plan includes, but is not limited to: (1) An addition or discontinuation of a collection method, whether a mail-back program, collection receptacle program, or an alternative method of collection.(2) Any changes to a stewardship program that are required by local, state, or federal laws and regulations.(3) Any changes to a stewardship program necessitated by the repeal of a local ordinance for either covered drugs or home-generated sharps waste. (4) Any changes regarding achievement of convenience standards.(5) Any changes in the facility(ies) to be used to process or dispose of a covered drug or home-generated sharps waste collected through the stewardship program not identified in the approved plan.	Stericycle agrees with this definition
014-002 18972.1	Not included in proposed language	Definition of Home-generated Sharps Waste	Recommend including the definition and limiting definition of home-generated sharps waste, as defined by section 117671 of the Health and Safety Code.
STEWARDSHIP PLAN FOR COVERED DRUGS			
014-003 18973.2	6	Handling, Transportation, and Disposal System. (1) Describe the processes and policies that will be used to safely and securely collect, track, and properly manage unwanted covered drugs from collection to disposal, and how all entities participating will operate under and comply with all applicable state and federal laws and regulations.	We would recommend that this be generic in nature but that there not be a requirement to fully detail out the plan for security. Allow this information on general policies and procedures to be marked confidential to prevent release to the general public with potentially nefarious intent. Full details of this type should not be publicly available.

014-004

014-005

014-006

Proposed Reg	PDF Doc Page#	Current / Proposed Language	Stericycle Comment or Suggested Changes
18973.2	7	(6) Any alternative form of collection and disposal system that complies with applicable local, state, and federal laws and regulations including, but not limited to, United States Drug Enforcement Administration regulations that is used as a supplemental service for any county that does not meet the minimum authorized collection site threshold due to circumstances out of the program operator's control, if applicable.	Recommend clarifying this section to refer to pharmaceutical Take Back Events.
18973.2	8	(8) Process in which collection receptacles will be monitored, how service schedules are determined to ensure that collection receptacles do not reach capacity, and procedures to be followed if capacity is reached.	The restrictions found under 21 CFR 1317.75(c) "Once a substance has been deposited into a collection receptacle, the substance shall not be counted, sorted, inventoried, or otherwise individually handled", make it very difficult to monitor the fill level of kiosks. Stericycle agrees with the proposed language, which allows for an overall explanation of the procedures used to schedule frequent services and manage kiosks that have reached capacity.
STEWARDSHIP PLAN FOR HOME-GENERATED SHARPS WASTE			
General Comment for this section	NA	Mail back programs defined in this section have been left open (meaning doesn't stipulate the use of United States Postal Service -USPS). Stericycle agrees with leaving the options open. However, if a system chooses to use the USPS it is recommended that there is language in the regulation that is clear that it must meet all criteria for USPS.	Recommend that the Department add language that if the mail back system is developed to be used and shipped under USPS that all requirements under USPS for mail back of sharps and medical waste must be met. The sharps system being used through the USPS must meet minimum criteria as outlined in the domestic mail manual and must have approved authorization for the package for shipment through USPS. If an alternative shipping vendor/method is selected, the stewardship program operator should be required to provide documentation that their shipping vendor approves the program and packaging.

Proposed Reg	Section	PDF Doc Page#	Current / Proposed Language	Stericycle Comment or Suggested Changes
18973.3	11	<p>(6) Supplemental collection method(s) for home-generated sharps waste that may be provided, in addition to, but not in lieu of, the mail-back program. These methods may include, but are not limited to: (A) Secure receptacle collection. If a program operator proposes to implement a receptacle-based program to supplement its mail-back program and home-generated sharps consolidation points are authorized and approved by the city, county, or state enforcement authority that provides oversight of the Medical Waste Management Act, then the following information, as applicable, shall be included, but not limited to:</p>	<p>Stericycle approves of the revised language regarding the requirements for secure collection receptacles to be authorized and approved by relevant regulatory agencies. However, the collection of sharps via receptacles presents substantial safety risks for the host collection sites, general public, kiosk service, vendors, disposal vendors, and host collection staff. Stericycle would recommend that language be added to specify the specific locations / settings where receptacles would be allowed and how the sharps receptacles will be located/marked/labeled to prevent cross-contamination with unwanted medication kiosks.</p>	
ANNUAL REPORT FOR COVERED DRUGS				
18973.4	16	<p>(h) Safety and Security. Describe the nature of any incidents with safety or security related to collection, transportation, or disposal of collected covered drugs. Explain what corrective actions were taken to address the issue and improve safety and security. The following shall be made available to the department upon request, including, but not limited to, the following:</p>	<p>Describing the process and incidents that occurred related to safety or security failures could be a potential risk. This would require this information (corrective actions and updates to safety and security plans) to have to go through the confidential documentation process to prevent information on security practices from being available to the public to minimize risk of diversion, which is a more lengthy process. Recommendation would be to minimize the information that is required to be submitted with the annual report. This information should only be made available to the Agency upon request and in this way the program is in place, but does not have to be submitted to the agency directly and have to be maintained under confidentiality constraints.</p>	
18973.4	17	<p>5) Regulatory or law enforcement agencies involved and any litigation, 1 arbitration, or other legal proceedings that result from each incident.</p>	<p>the language of this section should be clarified to require the stewardship program operator identify and track the number of incidents and legal issues under their scope. The Authorized Collectors may be involved in incidents of which the stewardship program operator are unaware of, or are outside the scope of responsibility of the program operator. There may also be circumstances where the authorized collector will not provide information to the program operator due to legal issues, liability or other corporate reasons. The program operator may not have any control or visibility to a host collector issue. Recommendation would be to have the authorized collection sites track and maintain information on only the issues they are having with regulatory or other law enforcement.</p>	

014-007

014-008

014-009

Proposed Reg	Section	PDF Doc Page#	Current / Proposed Language	Stericycle Comment or Suggested Changes
ANNUAL REPORT FOR HOME-GENERATED SHARPS WASTE.				
18973.5	19	(h) Safety and Security. Describe the nature of any incidents with safety or security 18 related to collection, transportation, or disposal of sharps waste. Explain the corrective actions taken to address the issue and improve safety and security. The following shall be made available to the department upon request, including, but not limited to:	Describing the process and incidents that occurred related to safety or security failures could be a potential risk. This would require this information (corrective actions and updates to safety and security plans) to have to go through the confidential documentation process to prevent information on security practices from being available to the public to minimize risk of diversion, which is a more lengthy process. Recommendation would be to minimize the information that is required to be submitted with the annual report. This information should only be made available to the Agency upon request and in this way the program is in place, but does not have to be submitted to the agency directly and have to be maintained under confidentiality constraints.	
PROGRAM BUDGETS				
18973.6	21	(a) Anticipated costs to implement the stewardship program, including, but not limited 5 to, separate line items for the following:	Recommend three groupings/categories for budgetary reporting purposes: 1) Collection/Transportation/Disposal 2) Administration 3) Outreach and Education; Program budgets for covered drugs and sharps can be separate, although consolidating collection/transportation/disposal costs is necessary because these are often combined or intermixed from service vendors and may be difficult to extract separately.	

014-010

014-011

From: [MED-Project \(California\)](#)
To: [PharmaSharps](#); [Smyth, Jason@CalRecycle](mailto:Smyth_Jason@CalRecycle)
Cc: [Michael Van Winkle](#); [Anne Vogel-Marr](#); [Jim Wilson](#); [John Gay](#)
Subject: MED-Project USA Comments on Proposed Pharmaceutical and Sharps Waste Stewardship Program Regulations issued on January 3, 2020
Date: Monday, February 17, 2020 3:18:19 PM
Attachments: [image001.png](#)
[MED-Project California SB 212 Formal Rulemaking Comments 02.17.2020.pdf](#)

[[EXTERNAL]]

Dear Mr. Smyth,

MED-Project USA appreciates the opportunity to submit the attached comments to the California Department of Resources Recycling and Recovery (the "Department " or "CalRecycle") on CalRecycle 's Proposed Pharmaceutical and Sharps Waste Stewardship Program Regulations ("Proposed Regulations") that were issued on January 3, 2020.

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

Sincerely,

Dr. Victoria Travis

Dr. Victoria Travis, PharmD, MS, MBA

National Program Director

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February 17, 2020

[VIA EMAIL AT pharmasharps@calrecycle.ca.gov](mailto:pharmasharps@calrecycle.ca.gov)

Jason Smyth
Materials Management and Local Assistance Division
California Department of Resources Recycling and Recovery
P.O. Box 4025
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Re: MED-Project USA Comments on CalRecycle’s January 3, 2020 Proposed Regulatory Action – 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:

MED-Project USA (“MED-Project”) appreciates the opportunity to submit comments on the California Department of Resources Recycling and Recovery’s (“Department’s” or “CalRecycle’s”) Proposed Pharmaceutical and Sharps Waste Stewardship Program Regulations (the “Proposed Regulations”) issued on January 3, 2020.

MED-Project USA has been established by the Pharmaceutical Product Stewardship Work Group (“PPSWG”) to develop, implement, and operate stewardship programs for unwanted pharmaceutical products and sharps from households on behalf of the producers that are members of PPSWG. MED-Project has substantial, practical, on-the-ground experience implementing pharmaceutical and sharps take-back programs in 21 jurisdictions, including in California. MED-Project appreciates CalRecycle’s willingness to accept comments on the Proposed Regulations, and MED-Project looks forward to continuing to work with CalRecycle during the implementation of the Pharmaceutical and Sharps Waste Stewardship Act (SB 212, Chapter 1004, Statutes of 2018) (“SB 212”).

The comments listed below are organized in chronological order (*i.e.*, in the same order as they appear in the Proposed Regulations). Additionally, the final section of these comments, Section V., contains a general comment that applies more broadly to the Proposed Regulations as a whole. Thank you for considering these comments and MED-Project LLC’s February 15, 2019, March 22, 2019, July 1, 2019, and August 15, 2019 comments in revising the Proposed Regulations.

I. DEFINITIONS

This section suggests practical revisions to definitions in the Proposed Regulations.

A. **Proposed Regulations § 18972.1(i)'s Definition of "Point of Sale" Should Only Include Online Sales As Practicable**

SB 212 provides that a "Home-Generated Sharps Waste" (as defined in California Public Resources Code ("PRC") § 42030(l)) "Stewardship Program" (as defined in PRC § 42030(y)) shall "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 § 4032.2(d)(1)(F)(i); *see also* Proposed Regulations § 18973.3(f)(2) (Home-Generated Sharps Waste "Stewardship Plans" (as defined in PRC § 42030(x)) must, among other things, describe "[h]ow stewardship plan implementation provides or initiates distribution of sharps waste containers and mail-back materials... at no cost to ultimate users at the point of sale..."). The Department's Proposed Regulations broadly define "point of sale," as used in the above referenced provisions, to mean "the ultimate user checkout system utilized by pharmacies, stores, or other retail outlets where a covered product is sold, including online sales." Proposed Regulations § 18972.1(i).

It is critical to note that "Program Operators" (as defined in PRC § 42030(q)) are not a party to the sharps transactions that are the subject of the above provisions. Additionally, MED-Project is not aware of any type of list (public or private) that identifies all retailers (including online retailers) that sell sharps to "Ultimate Users" (as defined in PRC § 42030(z)). Therefore, it is impossible for a Program Operator to be aware of every sharps transaction involving an Ultimate User that is occurring over the internet, regardless of the online retailer's physical location (China, India, etc.) and it is therefore also impossible for a Program Operator to initiate the distribution of a sharps waste container and mail-back materials at the point of sale for any and all online transactions.

Reasonable limitations must be set in the Proposed Regulations to make implementation of a Home-Generated Sharps Waste Stewardship Program practicable. To this end, the definition of "Point of Sale" in the Proposed Regulations at § 18972.1(i) should be revised as follows: "Point of sale" means the ultimate user checkout system utilized by pharmacies, stores, or other retail outlets where a covered product is sold, and shall also include online sales to the extent practicable."

Alternatively, to ensure that the implementation of a Home-Generated Sharps Waste Stewardship Program is practicable as applied to online sales, the definition of "Point of Sale" should only include online sales that retailers or Ultimate Users identify to Program Operators. This revision would give Program Operators a means to identify and service online sales subject to the Stewardship Program. Accordingly, Proposed Regulations § 18972.1(i) should be revised to read: "Point of sale" means the ultimate user checkout system utilized by pharmacies, stores, or other retail outlets where a covered product is sold, including online sales that pharmacies, stores, and other retail outlets and/or ultimate users identify to program operators."

B. Proposed Regulations § 18972.1(j)(2) Should Recognize Fluctuations in Mail Delivery Timelines in Defining “Provides or Initiates Distribution of a Sharps Waste Container”

By defining “provides or initiates distribution of a sharps waste container” to include arranging to send Ultimate Users sharps containers and mail-back materials, Proposed Regulations § 18972.1(j)(2) provides Program Operators needed flexibility to implement Home-Generated Sharps Waste Stewardship Programs in compliance with all applicable laws, regulations, and other legal requirements on the scale that SB 212 requires. The requirement that such sharps waste containers and mail-back materials “arrive within three business days,” however, undermines this well-intentioned approach and should be revised.

Common carriers do not always meet estimated delivery dates. The United States Postal Service estimates that Priority Mail will arrive within 1-3 days, but provides no guarantee. *See* United States Postal Service, <https://faq.usps.com/s/article/What-are-the-Guidelines-for-Mailing-Priority-Mail> (last visited Feb. 13, 2020). With the United States Postal Service unable to confirm arrival dates, Program Operators cannot do so.

Even if arrival dates were guaranteed, requiring delivery within three business days is unreasonable. The Proposed Regulations could be understood as counting the three business day arrival requirement from the sharps sale date. By contrast, USPS calculates Priority Mail delivery timelines from the day after an item is mailed – at a minimum, one day later than the sale date. *See id.* Because these timelines are offset, even if USPS meets its estimated 1-3 day delivery timeline, delivery may arrive four days after a sharps sale.

For these reasons, Program Operators arranging to send Ultimate Users sharps containers and mail-back packages risk exceeding the Proposed Regulations’ three business day arrival requirement through no fault of their own. This risk will discourage Program Operators from using the most effective measures to serve Ultimate Users, contrary to the Department’s intent in adopting Proposed Regulations § 18972.1(j)(2). *See* CalRecycle Initial Statement of Reasons for Pharmaceutical and Sharps Waste Stewardship Program at 9 (Dec. 2019) (“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.”).

To preserve Program Operator flexibility to serve Ultimate Users effectively, the Department should require that Program Operators ship sharps waste containers and mail-back materials to arrive within five business days. This revision would mandate that Program Operators design processes to provide sharps waste containers and mail-back materials promptly, but avoid attaching compliance consequences to common carrier reliability. The revised Proposed Regulations § 18972.1(j)(2) should require Program Operators: “[t]o arrange, at the point of sale, for a sharps waste container and mail-back materials to be sent to the ultimate user and shipped to arrive within threefive business days at no cost or inconvenience to the ultimate user.”



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II. STEWARDSHIP PLAN APPROVAL AND MODIFICATION

This section suggests revisions to the Proposed Regulations that clarify standards for Stewardship Plan approval and modification.

A. **Proposed Regulations § 18973(b) Should Require that a Stewardship Plan, Annual Reports, and Stewardship Program Budget Submissions Comply with All Applicable Legal Requirements for Private Entities Related to Accessibility**

015-003 To ensure that a Stewardship Plan, annual reports, and Stewardship Program budgets are accessible, the Proposed Regulations provide that “[d]ocuments are required to be in compliance with sections 7405 of the Government Code, and the Web Content Accessibility Guidelines 2.0, or a subsequent version, published by the Web Accessibility Initiative of the World Wide Web Consortium at a minimum Level AA success criteria to allow for posting on the department’s website.” Proposed Regulations § 18973(b). Although more definitive than prior iterations of the Proposed Regulations, this language raises due process concerns by tying compliance to third party standards. To ensure public notice of accessibility requirements, the Proposed Regulations should require that Stewardship Program Operators comply with all applicable legal requirements for private entities related to accessibility, such as the Americans with Disabilities Act.

Fundamentally, the public must have notice of regulatory requirements. Dynamically incorporating the Web Content Accessibility Guidelines 2.0 (“WCAG 2.0”) and subsequent versions into the Proposed Regulations could deprive the public, and specifically Program Operators, of this notice. Under the Proposed Regulations, it is possible that Program Operators may not have public notice of proposed or adopted changes to WCAG 2.0 – changes the Proposed Regulations would make binding legal requirements. This outcome would raise due process and other legal concerns. The Department should strike references to WCAG 2.0 and subsequent versions in the Proposed Regulations to avoid these issues. As previously noted in MED-Project comments, the Proposed Regulations should instead require that Program Operators comply with all applicable legal requirements for private entities related to accessibility, such as the Americans with Disabilities Act. *See* MED-Project LLC Comments Regarding CalRecycle’s Informal Draft Regulatory Text Implementing California SB 212, July 1, 2019 at p. 9.

B. **Requests for Clarifying Information Under Proposed Regulations § 18973.1(a) Should Be Reasonable In Scope and Timeline**

015-004 The Proposed Regulations would give the Department authority to require, “upon request and by the requested deadline, clarifying information that is necessary to assist the department in its consideration of approval.” Proposed Regulations § 18973.1(a). MED-Project previously commented that the Department should add a reasonableness element to this provision. *See* MED-Project LLC Comments Regarding CalRecycle’s Informal Draft Regulatory Text

Implementing California SB 212, July 1, 2019 at p. 17. The Department should revise the Proposed Regulations to apply a reasonableness element to both the scope of clarifying information requests and the required response timeline. As revised, Proposed Regulations § 18973.1(a) should read: “A program operator submitting a stewardship plan, initial program budget, annual report, or annual budget shall provide to the department, upon reasonable request and by ~~the requested~~ a reasonable deadline, clarifying information that is necessary to assist the department in its consideration of approval.”

C. Proposed Regulations § 18973.1(b) Should Clarify When Stewardship Plans, Annual Reports, and Stewardship Program Budgets Are “Complete”

Under SB 212, the Department has authority to determine whether, under certain criteria, a Stewardship Plan, annual report, or Stewardship Program budget is “complete.” *See* PRC § 42032(c) (Stewardship Plans); PRC § 42033.2(d) (annual reports and Stewardship Program budgets). SB 212 establishes that Stewardship Plans are “complete” when they “meet[] the requirements of Section 42032.2 for the establishment and implementation of a stewardship program” *See* PRC § 42032(a)(1); *see also* PRC § 42032.2(a)(1) (“To be complete, a stewardship plan for covered drugs shall do all of the following”); PRC § 42032.2(d)(1) (“To be complete, a stewardship plan for home-generated sharps waste shall do all of the following”). While SB 212 does not specify when annual reports and Stewardship Program budgets are “complete,” the structure of SB 212 makes that clear. *See* PRC § 42033.2 (addressing both Department reviews to determine whether annual reports and Stewardship Program budgets are “complete” and the requirements for annual reports and Stewardship Program budgets).

Consistent with SB 212, the Proposed Regulations should clarify when a Stewardship Plan, annual reports, and Stewardship Program budgets are complete. As drafted, the Proposed Regulations give the Department authority to determine whether a Stewardship Plan, annual reports, or Stewardship Program budgets are complete without referencing SB 212, defining the term “complete,” or discussing Department completeness reviews in the context of substantive Stewardship Plan, annual report, or Stewardship Program budget requirements. *See* Proposed Regulations § 18973.1(b). This approach creates ambiguity in the Proposed Regulations regarding the baseline for Department determinations of whether a Stewardship Plan, annual reports, or Stewardship Program budgets are “complete.”

As SB 212 contains no such ambiguity, the Department should amend the Proposed Regulations to eliminate it with simple change. The Department should revise Proposed Regulations § 18973.1(b) to read: “The department shall determine if a ~~document~~ stewardship plan, annual report, or program budget is complete pursuant to PRC § 42032.2 or 42033.2 and notify the submitting program operator within 30 days of receipt.”

Clarifying when Stewardship Plans, annual reports, and Stewardship Program budgets are complete will provide Program Operators certainty, increasing the likelihood that submitted Stewardship Plans, annual reports, and Stewardship Program budgets meet SB 212 requirements.



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D. Proposed Regulations § 18973.1(c) Should Clarify that Department Consultations with Other Agencies Toll Completeness Review Timelines

015-006

Proposed Regulations § 18973.1(c) provides that if the Department “consult[s] with or submit[s] a stewardship plan to the State Board of Pharmacy or other agencies for review of completeness or approval, the duration of time this takes the department shall not count toward the 90-day review.” Proposed Regulations § 18973.1(c). SB 212 requires the Department to conclude “completeness” reviews on a 30-day timeline, however, not a 90-day timeline. *See* PRC § 42032(c)(1); *see also* Proposed Regulations § 18973.1(b). If the Department intends for consultations with the State Board of Pharmacy or other agencies to toll the Department’s 30 day completeness review timeline, it should revise Proposed Regulations § 18973.1(c) to read: “the duration of time this takes the department shall not count toward the 30-day review or 90-day review, respectively.”

III. STEWARDSHIP PLANS

This section suggests revisions to, or supports provisions of, the Proposed Regulations regarding Stewardship Plans. These comments are organized into three subsections: Subsection A – “Covered Drug” (as defined in PRC § 42030(e)) Stewardship Plans; Subsection B – issues common to both Covered Drug and Home-Generated Sharps Waste Stewardship Plans, and; Subsection C – Home-Generated Sharps Waste Stewardship Plans.

A. Covered Drug Stewardship Plans

1. The Department Should Promote Stewardship Program Safety and Security by Revising Proposed Regulations § 18973.2(d)(1)(A) to Keep Authorized Collector Contact Information Confidential

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 &
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Stewardship Programs prioritize safety and security. Because Covered Drug Stewardship Plans provide for the collection and disposal of a wide range of Covered Drugs including controlled substances, it is an unfortunate reality that certain Stewardship Plan information is valuable to individuals attempting to divert controlled substances. Working together, the Department and Program Operators must avoid public disclosure of information that could compromise Stewardship Program safety and security.

One such category of information is “Authorized Collector” (as defined in PRC § 42030(b)) contact names and titles. The Proposed Regulations require Covered Drug Stewardship Plans to include “[c]ontact name[s] and title[s]” for Authorized Collectors. Proposed Regulations § 18973.2(d)(1)(A). Publicizing Authorized Collector contact information would make it easy for individuals to contact an Authorized Collector impersonating a Stewardship Program vendor. It would also allow individuals seeking to divert controlled substances to identify Authorized Collector staff most familiar with Stewardship Program operations. There is no reason to create these potential safety and security risks by publicizing Authorized Collector contact names and titles. SB 212 already requires Program Operators to provide the Department Authorized

Collector entity contact information. *See* PRC § 42032.2(a)(1)(B). Accordingly, the Department should strike Proposed Regulations § 18973.2(d)(1)(A).¹ Corresponding revisions should also be made to annual reporting provisions in Proposed Regulations §§ 18973.4(j) and 18973.5(j).

2. Proposed Regulations § 18973.2(g)(3) Should Not Require Stewardship Plans to Describe Confidential Covered Drug Tracking Mechanisms

Under DEA regulations, registrants must track Covered Drug inner liners through certain recordkeeping requirements. *See, e.g.*, 21 CFR § 1317.60(a)(5) (“The inner liner shall bear a permanent, unique identification number that enables the inner liner to be tracked.”); 21 CFR § 1304 (recordkeeping requirements). The Proposed Regulations require that Stewardship Plans describe these Covered Drug “[t]racking mechanism(s) for collection, transportation, and disposal.” Proposed Regulations § 18973.2(g)(3). Because DEA tracking mechanisms are mandated by law and known to the public, Program Operators can describe them in Stewardship Plans without impairing Stewardship Program safety and security.

015-008

To provide safe and secure Stewardship Programs, some Program Operators may decide to employ Covered Drug tracking mechanisms exceeding DEA requirements. The Proposed Regulations should not require disclosure of these voluntary tracking efforts. Just like DEA-required tracking, the primary purpose of these voluntary tracking mechanisms is to prevent diversion. *See* Disposal of Controlled Substances, 79 Fed. Reg. 53520, 53553 (Sept. 9, 2014). Unlike DEA-required tracking mechanisms, however, voluntary tracking mechanisms can be kept confidential to Program Operators, as individuals attempting diversion are less likely to circumvent tracking mechanisms of which they are unaware. Requiring Program Operators to describe these voluntary tracking mechanisms in Stewardship Plans would give individuals attempting diversion more information about how Stewardship Programs detect diversion. Doing so impairs the effectiveness of those tracking mechanisms and, ultimately, Stewardship Program safety and security.

Given these concerns, the Department should amend the Proposed Regulations to require that Stewardship Plans describe only the tracking mechanisms federal, state, and local laws, regulations, and other legal requirements expressly require. The revised Proposed Regulations § 18973.2(g)(3) should state: “Tracking mechanism(s) expressly required by applicable federal, state, and local laws and regulations for collection, transportation, and disposal.”² Without this revision, the Proposed Regulations may unintentionally increase diversion risks and discourage Program Operators from adopting voluntary tracking mechanisms.

¹ In addition to safety and security concerns, given the anticipated number of Authorized Collectors and personnel turnover, at least some contacts are likely to be outdated within months of Stewardship Plan submission.

² Corresponding annual reporting provisions should also be revised accordingly. *See* Proposed Regulations §§ 18973.4(d)(1), 18973.5(d)(1).



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B. Covered Drug and Home Generated Sharps Waste Stewardship Plans

1. The Department Must Revise Proposed Regulations §§ 18973.2(b) and 18973.3(b) to Protect Private Individuals’ Information

MED-Project prioritizes the protection of private individuals’ information. Unfortunately, the Proposed Regulations would compel the disclosure of such information. Under the Proposed Regulations, Covered Product Stewardship Plans must identify Covered Entity contact names, titles, and, potentially, email addresses. *See* Proposed Regulations §§ 18973.2(b), 18973.3(b). Compelling the public disclosure of this individual information could expose these individuals to online attacks and harassment. To avoid these consequences, the Department should strike Proposed Regulations §§ 18973.2(b)(1) (requiring contact names and titles) and 18973.3(b)(1) (same). It should also make clear that Proposed Regulations §§ 18973.2(b)(4) (requiring email addresses) and 18973.3(b)(4) (same) apply to Covered Entity email addresses, not individual contacts’ email addresses.³ The revised Proposed Regulations §§ 18973.2(b)(4) and 18973.3(b)(4) should state: “Covered Entity Email address.”

There is no discernable public policy justification to expose Covered Entity contacts’ individual information. The Proposed Regulations’ requirement that Stewardship Plans include Covered Entity contact information provides the Department sufficient contact information for SB 212 implementation and oversight. *See id.* The Department should revise the Proposed Regulations to protect these private individuals and their information.

2. Proposed Regulations §§ 18973.2(g)(1) and 18973.3(f)(5) Should Require Program Operators to Support Participating Entity Compliance, Not Ensure It

Because Authorized Collectors, “Home-Generated Sharps Consolidation Points” (as defined in Proposed Regulations § 18972.1(e)), and Stewardship Program vendors are independent entities with independent compliance obligations, Program Operators cannot describe how they will “ensure all entities participating in the program will operate under and comply with all applicable local, state, and federal laws and regulations.” Proposed Regulations § 18973.2(g)(1); *see also* Proposed Regulations § 18973.3(f)(5). Covered Product collection and disposal is tightly regulated. Authorized Collectors, Home-Generated Sharps Consolidation Points, and Stewardship Program vendors have obligations under many applicable federal, state, and local laws, regulations, and other legal requirements. *See, e.g.*, PRC § 42032.2(a)(1)(G)(iii)(II) (“An authorized collector shall comply with applicable federal and state laws regarding collection and transportation standards, and the handling of covered drugs, including United States Drug Enforcement Administration regulations.”). SB 212 does not require Program Operators to describe how they will ensure Authorized Collectors, Home-Generated Sharps Consolidation

³ In fact, many pharmacy Authorized Collector contacts do not have email addresses because they regularly handle protected health information.

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Points, and Stewardship Program vendors comply with these obligations. Even if it did, there is no legal mechanism that allows Program Operators to assume these independent entities' obligations or compel their compliance. Because "ensuring" Authorized Collector, Home-Generated Sharps Consolidation Point, and Stewardship Program vendor compliance exceeds Program Operator authority, this requirement does not force Program Operator action; rather, it sets Program Operators up to fail.

So what can Program Operators do to provide compliant Stewardship Programs? Program Operators can support Authorized Collector, Home-Generated Sharps Consolidation Point, and Program Operator compliance. They can require Authorized Collector, Home-Generated Sharps Consolidation Point, and Program vendor compliance with all applicable laws, regulations, and other legal requirements by contract. They can provide Authorized Collectors and Home-Generated Sharps Consolidation Points training materials to assist compliance efforts. They can also respond to Authorized Collector and Home-Generated Sharps Consolidation Point needs through a helpdesk and perform periodic monitoring on Authorized Collector, Home-Generated Sharps Consolidation Point, and Stewardship Program vendor practices. Through measures like these – measures within Program Operator authority – Program Operators can operate compliant Stewardship Programs and describe how they do so in Stewardship Plans.

For these reasons, instead of requiring Program Operators to describe how they will "ensure" actions beyond their control, the Department should revise Proposed Regulations §§ 18973.2(g)(1) and 18973.3(f)(5) to require that Program Operators describe how they will support Authorized Collector, Home-Generated Sharps Consolidation Point, and Stewardship Program vendor compliance. The revised Proposed Regulations § 18973.2(g)(1) should require Program Operators to describe:

Processes and policies that will be used to safely and securely collect, track, and properly manage covered drugs from collection through final disposal to ensure all entities participating in the program will operate under and comply and used to support participating entities' compliance with all applicable local, state, and federal laws and regulations.

The revised Proposed Regulations § 18973.3(f)(5) should require Program Operators to describe:

Processes and policies to be followed by persons handling home-generated sharps waste under the stewardship plan and efforts the program operator will take to ensure that all entities participating will operate under and comply with all applicable local, state, and federal laws and regulations used to support participating entities' compliance with all applicable local, state, and federal laws and regulations.

These revisions would recognize the limits of Program Operator authority over Authorized Collectors, Home-Generated Sharps Consolidation Points, and Stewardship Program vendors. At the same time, it would force all Program Operators to take actions to implement compliant Stewardship Programs, increasing the likelihood of successful Stewardship Programs under SB 212.

3. MED-Project Supports the Proposed Regulations Recognizing Program Operator Flexibility to Use Various Collection Methods

Given the scope and scale of California Stewardship Programs, the flexibility to use alternative forms of collection and disposal systems, provide supplemental collection methods, and provide or initiate the distribution of sharps waste containers will help Program Operators implement successful Stewardship Programs. “Authorized Collection Site” (as defined in PRC § 42030(a)) or Home-Generated Sharps Consolidation Point availability, public facility availability, and population densities, among other factors, affect how successful collection methods are in a locale. To serve Ultimate Users, several provisions of the Proposed Regulations wisely allow Program Operators to adapt their collection methods to varying circumstances, consistent with SB 212. *See* Proposed Regulations §§ 18973.2(g)(5)(A) (recognizing Program Operator flexibility to use mail-back distribution locations in certain circumstances), 18973.2(g)(6) (providing for alternative forms of collection and disposal systems), 18973.3(f)(6) (providing for supplemental Home-Generated Sharps Waste collection methods), 18972.1(j) (providing multiple methods to provide or initiate distribution of a sharps waste container).

MED-Project supports the Department recognizing that Program Operators can use different collection methods to maximize Stewardship Program effectiveness. Subject to SB 212’s requirements, this flexibility allows Program Operators to use the collection method most effective and convenient for Ultimate Users. Additionally, this flexibility promotes development of new collection methods that may provide even more effective collection services in the future.

The flexibility to “[p]rovide or initiate[] distribution of a sharps waste container” through the multiple methods identified in the Proposed Regulations is especially critical for Stewardship Program operations. *See* Proposed Regulations § 18972.1(j). SB 212’s requirement that Program Operators “distribute a container and mail-back materials sufficient to accommodate the volume of sharps purchased by an ultimate user over a selected time period” could be understood to require that Program Operators or sharps retailers obtain information from ultimate users regarding the number of sharps they purchase. *See* PRC § 42032.2(d)(1)(F)(i). Collecting such information would raise operational and privacy issues that sharps retailers and Program Operators would be challenged to resolve if the Proposed Regulations did not provide the flexibility to use various collection methods.

In sum, Proposed Regulations provisions recognizing Program Operator flexibility to implement different collection methods promote effective Stewardship Programs over the long term.

4. Consistent with SB 212, the Proposed Regulations Properly Give Program Operators Discretion to Choose Collection Models

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015-012b

Program Operators can give Authorized Collectors varying degrees of control over “Covered Product” (as defined in PRC § 42030(g)) collection and disposal services through different “collection models.” Some collection models permit Authorized Collectors to perform inner liner or container installation, removal, and packaging, giving them control over when collection occurs. Other collection models involve vendors in some of these tasks. The collection model(s) a Program Operator offers are central to that Program Operator’s implementation strategy, affecting Authorized Collector responsibilities, contracts, training materials, vendor selection, disposal facilities, implementation timelines, and Program Operator costs.

With such broad ranging impacts to Stewardship Program operations, SB 212 properly gives Program Operators the discretion to choose collection models. SB 212 generally requires that Stewardship Plans provide for collection models that safely and securely collect, transport, and dispose of Covered Drugs in compliance with all applicable federal, state, and local laws, regulations, and other legal requirements. *See, e.g.*, PRC §§ 42032.2(a)(1), 42035.8. Additionally, SB 212 provides that Stewardship Plans must require Program Operators to:

Provide a service schedule that meets the needs of each authorized collection site to ensure that [1] each secure collection receptacle is serviced as often as necessary to avoid reaching capacity and [2] that collected covered drugs are transported to final disposal in a timely manner. Additionally, a receipt or collection manifest shall be left with the authorized collection site to support verification of the service.

PRC § 42032.2(a)(1)(G)(iii)(I). Because many collection models can satisfy these statutory requirements to, generally, comply with law and provide convenient service schedules, SB 212 provides Program Operators broad discretion to choose the collection models they offer Authorized Collectors.

The Proposed Regulations maintain the discretion SB 212 gives Program Operators to determine Covered Product collection models. The Proposed Regulations require that Stewardship Plans describe policies and procedures for the safe and secure collection and disposal of Covered Drugs in compliance with all applicable laws, regulations, and other legal requirements. *See, e.g.*, Proposed Regulations §§ 18973.2(g)(1), 18973.2. They also require that Stewardship Plans describe “how service schedules are determined to ensure that collection receptacles do not reach capacity, and procedures to be followed if capacity is reached.” Proposed Regulations § 18973.2(g)(8). Requirements for the collection and disposal of Home-Generated Sharps Waste are substantially similar. *See* Proposed Regulations § 18973.3(f)(6)(A)(ii), (iii).

MED-Project supports the Proposed Regulations’ approach maintaining this Program Operator discretion, consistent with SB 212. This approach allows Program Operators to use the collection models providing the most effective services for Authorized Collectors and Ultimate Users. Program Operator flexibility to use novel collection models will also promote innovation

and vendor competition, whereas mandating specific collection models would, by regulation, pick winners and losers among Stewardship Program vendors. Conversely, prescribing specific collection methods by regulation or, subsequently, through Stewardship Plan approval would deprive Program Operators of the ability to tailor collection models to provide the most effective services. It would also run afoul of SB 212 and California case law. *See PaintCare v. Mortensen*, 233 Cal. App. 4th 1292, 1298-99 (2015) (“[T]he regulations do not go beyond the Program because they do not dictate *how* manufacturers comply with the Program. Rather, they set forth *what* information manufacturers must provide to CalRecycle to comply with the Program.”) (emphasis in original).

5. Proposed Regulations §§ 18973.2(g)(10) and 18973.3(f)(6)(A)(v) Should Require that Stewardship Plans Describe Processes to Address Critical Participant Policy and Procedure Deviations, Not Participant Non-Compliance

Under the Proposed Regulations, Program Operators must provide Stewardship Plans that describe “[w]hat corrective actions will be taken if a program operator discovers an authorized collector or service provider is not maintaining compliance with all collection, transportation, and disposal standards related to the handling of covered drugs, including, but not limited to, United States Drug Enforcement Administration regulations.” Proposed Regulations § 18973.2(g)(10); *see also* § 18973.3(f)(6)(A)(v) (analogous requirement for Home-Generated Sharps Waste). When implemented, these provisions effectively require Program Operators to make definitive conclusions regarding other entities’ compliance – conclusions that annual reporting would make public in certain cases. *See* Proposed Regulations § 18973.4(e) (requiring reporting on certain corrective actions); *see also* 18973.5(e) (analogous requirement for Home-Generated Sharps Waste annual reports). To avoid putting Program Operators in this untenable position, the Department should revise Proposed Regulations §§ 18973.2(g)(10) and 18973.3(f)(6)(A)(v) to require that Stewardship Plans identify processes for addressing critical Authorized Collector, Home-Generated Sharps Consolidation Point, or service provider deviations from Stewardship Program policies and procedures.

Specifically, SB 212 requires Stewardship Plans to:

Provide the policies and procedures for the safe and secure collection, transporting, and disposing of the covered drug . . . and how, at a minimum, instances of security problems that occur will be addressed, and explain the processes that will be taken to change the policies, procedures, and tracking mechanisms to alleviate the problems and improve safety and security.

PRC § 42032.2(a)(1)(H). This requirement makes plain that Stewardship Plans should describe the processes used to address deviations from policies and procedures, not deviations from compliance with certain applicable laws, regulations, and other legal requirements. SB 212 also requires Stewardship Plans to describe these processes for addressing “security problems,” or critical – not minor – deviations from these policies and procedures. For unknown reasons,

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however, the Proposed Regulations muddle these requirements. Proposed Regulations §§ 18973.2(g)(10) and 18973.3(f)(6)(A)(v) appear to require that Stewardship Plans identify corrective actions for any non-compliance with certain legal standards, not Stewardship Program critical deviations from Program policies and procedures, diminishing what the statute emphasizes. Consistent with SB 212, Proposed Regulations §§ 18973.2(g)(10) and 18973.3(f)(6)(A)(v) should be revised to require that Stewardship Plans explain the processes that will be taken to address critical Authorized Collector, Home-Generated Sharps Consolidation Point, or service provider deviations from Stewardship Program policies and procedures.

In addition to tracking SB 212, revising the Proposed Regulations to focus on deviations from Stewardship Program policies and procedures facilitates Stewardship Program implementation. Program Operators can describe how they evaluate, monitor, correct, and report on deviations from Stewardship Program policies and procedures. For example, Program Operators use incident management systems to identify, document, investigate, and analyze the causes for policy and procedure deviations. As appropriate, Program Operators then correct for these deviations through actions that include providing training or compliance aids, performing additional due diligence, changing service offerings, or, as warranted, amending contracts or terminating relationships.

Evaluating, monitoring, correcting, and reporting on compliance with applicable laws, regulations, and other legal requirements is far more challenging. As discussed above in Section III.B.2., Authorized Collectors, Home-Generated Sharps Consolidation Points, and service providers are independent entities with independent compliance obligations and independent legal interpretations. Program Operators do not know how government agencies interpret an Authorized Collector, Home-Generated Sharps Consolidation Point, or service provider's compliance status. Such uncertainty presents serious risks for Program Operators obligated to provide annual reporting on corrective actions associated with certain service provider failures to maintain compliance. *See* Proposed Regulations §§ 18973.4(e), 18973.5(e). Making representations regarding service provider compliance in a publicly available annual report could potentially expose Program Operators to lawsuits, disrupting or interfering with Stewardship Program services and negatively affecting the convenience to the Ultimate User.

For consistency with SB 212, and to facilitate Program Operator evaluation, monitoring, corrective actions, and reporting, the Department should revise the Proposed Regulations to require that Stewardship Plans identify processes for addressing critical Authorized Collector, Home-Generated Sharps Consolidation Point, or service provider deviations from Stewardship Program policies and procedures. As revised, Proposed Regulations §§ 18973.2(g)(10) and 18973.3(f)(6)(A)(v) should require Plans to describe:

Processes that address critical deviations from stewardship plan policies and procedures. ~~What corrective actions will be taken if a program operator discovers an authorized collector or service provider is not maintaining compliance with all collection, transportation, and disposal standards related to the handling of~~

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

6. The Department Should Strike the Term “Maximize” from Proposed Regulations §§ 18973.2(j)(1) and 18973.3(i)(1)

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Regardless of how extensively a Program Operator promotes its Stewardship Program, more could always be done. Another advertisement, another sign, another social media post, and so on. Stewardship Program education and outreach is impossible to “maximize.” Unfortunately, the Proposed Regulations require just that, providing that Stewardship Plans must describe how Stewardship Programs include “[a]ctivities to promote awareness and maximize ultimate user participation in the stewardship program.” Proposed Regulations § 18973.2(j)(1); *see also* § 18973.3(i)(1) (same for Home-Generated Sharps Waste). There is no requirement to maximize Ultimate User participation in SB 212. To provide achievable requirements consistent with SB 212, the Department should revise Proposed Regulations §§ 18973.2(j)(1) and 18973.3(i)(1) to strike the term “maximize.”

7. Proposed Regulations §§ 18973.2(j)(1) and 18973.3(i)(1) Should Require Program Operators to Promote Proper Covered Product Disposal

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The Departments should revise Proposed Regulations §§ 18973.2(j)(1) and 18973.3(i)(1) to focus Program Operator education and outreach activities on proper Covered Product collection and disposal. Currently, the Proposed Regulations require that Stewardship Programs include “[a]ctivities to promote awareness and maximize ultimate user participation in the stewardship program.” Stewardship Program participation does not necessarily equate to Covered Product disposal, however. It is inevitable that many Ultimate Users will participate in a Stewardship Program by obtaining mail-back materials or sharps containers, but then never actually use those items. Rather than focus on Ultimate User participation in a Stewardship Program, Program Operators should promote proper Covered Product disposal consistent with the Stewardship Program’s services. This focus on proper Covered Product disposal is consistent with SB 212. *See* PRC § 42031.6(a)(4) (requiring education and outreach programs to “[p]repare and provide additional outreach materials not specified in this section, as needed to promote the collection and proper management of covered drugs and home-generated sharps waste.” For these reasons, Proposed Regulations §§ 18973.2(j)(1) and 18973.3(i)(1) should require Stewardship Programs to include “[a]ctivities to promote awareness and the collection and proper management of [covered drugs or home-generated sharps waste] ~~maximize ultimate user participation in the stewardship program.~~”

8. Proposed Regulations §§ 18973.2(j)(2) and 18973.3(i)(2) Should Clarify the Locations at which Program Operators Must Provide Materials

SB 212 requires that Program Operators “[p]rovide educational and outreach materials for persons authorized to prescribe drugs, pharmacies, pharmacists, ultimate users, *and others*, as necessary.” PRC § 42031.6(a)(2) (emphasis added). The term “others” is ambiguous. The

Proposed Regulations clarify that “others” are “locations,” but still leave uncertainty regarding the scope of this requirement. *See* Proposed Regulations § 18973.2(j)(2) (“Materials to be utilized that are distributed in languages suited to local demographics. These materials shall include, but are not limited to, signage for hospitals, pharmacies, and other locations, as necessary.”); *see also* § 18973.3(i)(2) (same for Home-Generated Sharps Waste). The Department should further clarify the meaning of these “other locations” through the Proposed Regulations to guide Program Operators and the public.

Specifically, the Department should revise Proposed Regulations §§ 18973.2(j)(2) and 18973.3(i)(2) to clarify that “other locations” are physical locations not exempt from the Stewardship Program (*e.g.*, needle exchange programs) where Covered Products are properly dispensed. By directing Program Operator materials to the physical locations where Ultimate Users receive Covered Products in compliance with all applicable laws, regulations, and other legal requirements, this revision would effectively promote Stewardship Program participation while providing Program Operators needed certainty. As revised, Proposed Regulations §§ 18973.2(j)(2) and 18973.3(i)(2) should read: “Materials to be utilized that are distributed in languages suited to local demographics. These materials shall include, but are not limited to, signage for hospitals, pharmacies, and other physical locations not exempt from the stewardship program where covered products are properly dispensed, as necessary.”

9. Proposed Regulations §§ 18973.2(j)(3)(E) and 18973.3(i)(3) Should Recognize Practical Constraints When Program Operators Maintain Third Party Information Online

SB 212 requires that Program Operators establish websites publicizing Authorized Collector locations and promoting the Stewardship Program. *See* PRC § 42031.6(a)(3). In turn, the Proposed Regulations require that Program Operators describe how they will maintain these websites “to ensure all information is up to date and accurate.” *See* Proposed Regulations §§ 18973.2(j)(3)(E), 18973.3(i)(3) (same for Home-Generated Sharps Waste). Program Operators can routinely update their websites to include the latest information regarding Authorized Collection Sites or Home-Generated Sharps Consolidation Points locations, telephone numbers, and days and hours of operation, among other required information. *See id.* These updates cannot be instantaneous, however. Program Operators depend on Authorized Collectors (or their own monitoring) to obtain this information. Even if a Program Operator diligently maintains its website for the public, a single Authorized Collector changing its hours of operation without providing prior notice would cause the Program Operator’s website to have outdated information.

To reflect the realities of maintaining a large and changing dataset, the Department should revise the Proposed Regulations to require that Program Operators describe how they will diligently maintain their websites, not how they will “ensure” websites are up to date and accurate. The revised Proposed Regulations §§ 18973.2(j)(3)(E) and 18973.3(i)(3) should require that Program Operators describe how they will establish “an internet website designed with functionality for mobile platforms and maintained to ~~ensure all information is~~ provide up to date and accurate

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information to the extent practicable.” This revision would balance the public’s need for accurate and current Stewardship Program information with practical information constraints.

10. The Department Should Clarify that Proposed Regulations §§ 18973.2(j)(3)(E) and 18973.3(i)(3)(B) Do Not Regulate Covered Product Directions for Use

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The Proposed Regulations require that Program Operator internet websites include “instructions for safe handling” of Covered Products. *See* Proposed Regulations §§ 18973.2(j)(3)(E), 18973.3(i)(3)(B). These requirements appear to use the term “safe handling” to mean safe storage within the home. However, to avoid ambiguity, the Department should revise the Proposed Regulations to refer expressly to “safe storage” instead of “safe handling.” This clarification will eliminate any suggestion that the Proposed Regulations require Program Operators to instruct the public on directions for the use of Drugs or Sharps – directions subject to federal regulation. *See* 21 CFR Parts 201, 801.

11. The Department Should Strike the Phrase “Most Effectively” from Proposed Regulations §§ 18973.2(k) and 18973.3(j)

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The Proposed Regulations set an impossible standard by requiring Program Operators to describe how they will “make a good faith effort to work with the other stewardship program(s) in order to most effectively achieve the requirements of the statute and regulations” *See* Proposed Regulations §§ 18973.2(k), 18973.3(j). No matter how extensively a Program Operator works with other Stewardship Programs, it could always do more. Like the term “maximize” as discussed above, the phrase “most effectively” is an aspirational standard that Stewardship Programs can never satisfy. Additionally, nothing in SB 212 requires Program Operators to meet this standard. To make these Stewardship Program coordination requirements achievable and consistent with SB 212, the Department should strike the phrase “most effectively” from Proposed Regulations §§ 18973.2(k), 18973.3(j) and the corresponding annual reporting provisions (Proposed Regulations §§ 18973.4(n) and 18973.5(o)).

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12. Market Competition Compels Privately Funded Stewardship Programs to Keep Vendor Selection Procedures Confidential (Proposed Regulations §§ 18973.2(m) and 18973.3(l))

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As described in Section IV.A., Covered-Entity funded Stewardship Programs receive no public funding and must use standard commercial practices to provide effective services. These practices include keeping vendor selection procedures confidential. Consistent with the private nature of Stewardship Program funding, the Department should strike Proposed Regulations §§ 18973.2(m) and 18973.3(l), which require that Stewardship Plans describe the “[p]rocess for selecting service providers, including a description of any competitive procedure[s] used, as applicable.” Nothing in SB 212 requires a description of vendor selection procedures in Stewardship Plans.

Requirements like these may be appropriate when entities receive public funding, but have adverse effects for privately-funded Stewardship Programs. Disclosing vendor selection procedures would reveal Program Operator priorities and strategies, information that potential Stewardship Program vendors could use to undermine competitive markets for vendor services. Striking Proposed Regulations §§ 18973.2(m) and 18973.3(1) would avoid these anticompetitive effects. Moreover, because Covered Entities fund Stewardship Programs, not the public, striking these requirements would not impair a public interest in understanding Stewardship Organization commercial decisions.

C. Sharps Stewardship Plans

1. Proposed Regulations § 18973.3(f)(8) Should Allow Program Operators to Estimate Disposal Quantities When Weighing Covered Products is Impractical

Under the Proposed Regulations, Stewardship Programs appropriately have the flexibility to implement supplemental collection methods in addition to a mail-back program. Stewardship Plans offering such supplemental collection methods must describe, among other things, “[m]etrics that will be used to measure the weight of home-generated sharps waste collected through supplemental collection method(s), if applicable.” Proposed Regulations § 18973.3(f)(8). The Department should revise this standard to provide Program Operators flexibility to implement collection methods that can only provide estimated weights of Home-Generated Sharps Waste disposed of. For example, Program Operators may consider offering rebate programs for Ultimate Users that independently purchase sharps mail-back materials. Although the Stewardship Program would cover disposal costs through the rebate, the Stewardship Program would not have custody over the Ultimate Users’ mail-back materials and, thus, could only provide an estimated weight of Home-Generated Sharps Waste disposed of through the rebate program.

Maintaining requirements to weigh collected Home-Generated Sharps Waste in all cases could discourage collection methods that may prove convenient for Ultimate Users, like rebate programs. The Department should revise the Proposed Regulations to accommodate collection methods that can only provide estimated weights of Home-Generated Sharps Waste disposed of. A revised Proposed Regulations § 18973.3(f)(8) should read: “[m]etrics that will be used to measure or estimate the weight of home-generated sharps waste collected through supplemental collection method(s), if applicable.”

2. Program Operator Timelines to Reimburse Local Agencies Under Proposed Regulations § 18973.3(g)(2)(A) Should Begin Upon Receipt of an Accurate Invoice

SB 212 compels Stewardship Programs to reimburse local agencies for certain home-generated sharps waste disposal costs upon request, unless the Program Operator otherwise provides for the removal of such waste. *See* PRC § 42032.2(d)(1)(F)(ii). Under the Proposed Regulations, “[a]

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program operator that selects to resolve a request through reimbursement to a local agency shall issue payment within 45 days of the local agency providing an invoice.” Proposed Regulations § 18973.3(g)(2)(A). Generally, 45 days is a reasonable timeline for Program Operators to process a local agency’s request. However, from time to time local agency invoices are likely to contain errors or inaccuracies. In such cases, Program Operators may need more than 45 days to discuss the errors or inaccuracies with local agencies, receive a revised invoice, and process that revised invoice.

Accordingly, the Department should revise the Proposed Regulations to start the 45 day timeline for processing local agency invoices upon the Program Operator’s receipt of an accurate invoice. Revised Proposed Regulations § 18973.3(g)(2)(A) should read: “[a] program operator that selects to resolve a request through reimbursement to a local agency shall issue payment within 45 days of the Program Operator’s receipt of an accurate local agency ~~local agency providing an invoice.~~” Revising the Proposed Regulations to require start reimbursement timelines on a Program Operator’s receipt of an accurate invoice is consistent with SB 212, which requires that local agencies to submit declarations under penalty of perjury attesting to invoice contents. *See* PRC § 42032.2(d)(1)(F)(ii)(III); *see also* PRC § 42033.5 (requiring local agencies seeking reimbursement to provide Program Operators information about Home-Generated Sharps Waste upon request).

IV. REPORTS AND BUDGETS

The following comments address the language in Proposed Regulations §§ 18973.4 (Annual Report for Covered Drugs), 18973.5 (Annual Report for Home-Generated Sharps Waste), and 18973.6 (Stewardship Program Budgets).

A. **The Scope of Information and Level of Detail Sought in the Budgets (at Proposed Regulations § 18973.6(a)-(d)) Is Exceptionally Extensive and Unreasonably Burdensome**

As currently written, Proposed Regulations § 18973.6 requires Program Operators to submit initial and annual budgets to the Department with “at a minimum, the following information”:

- “separate line items” for nine (9) subcategories of anticipated costs including: capital costs; collection of covered products; transportation of covered products; processing of covered products; disposal of covered products; administrative costs; education and outreach; costs related to grants, loans, sponsorships, or other incentives as part of program implementation; and reserve level;
- “narrative description[s]” of the “types of activities” associated with each of the 9 subcategory of anticipated costs listed above;
- A “recommended funding level necessary to implement the stewardship program”;
- “actual expenses incurred” in the prior year; and

- an independent financial audit of the Stewardship Program, that is conducted by a certified public accountant and complies with all criteria contained in Proposed Regulations § 189736(e)(1)-(5), including conducting the annual audit in accordance with not only generally accepted auditing standards, but also Generally Accepted Government Auditing Standards.

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MED-Project believes that the above information is unreasonably burdensome and unjustifiably extensive in scope and level of detail sought, and in some cases infeasible, such that it will hinder Stewardship Program effectiveness and impose unnecessary burdens and costs on Program Operators on an annual basis. For instance, as noted in public comments previously submitted during the informal rulemaking process by both MED-Project and Stericycle, experienced parties in this space, costs associated with collection, transportation, processing and disposal services provided by vendors in this highly regulated and competitive industry are bundled for proprietary, confidential and/or trade secret-based reasons. See, Stericycle Letter Re Proposed Regulations – Pharmaceutical and Sharps Waste Stewardship Program, July, 1 2019; MED-Project LLC Comments Regarding CalRecycle’s Informal Draft Regulatory Text Implementing California SB 212, July 1, 2019 at p. 25-26. Therefore, Program Operators like MED-Project do not have the level of specificity sought by the regulations and thus, would be unable to pass this information along to the Department as desired under the current draft Proposed Regulations.

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MED-Project understands that the level of detail sought by the Department in the proposed regulations may align with what has been adopted in Department regulations for other product stewardship programs overseen by the Department (e.g., mattresses, carpet, etc.); however, there is one critical distinction that is relevant here: unlike the other stewardship programs established in the state, the Pharmaceutical and Sharps Waste Stewardship Program is not publicly funded. The Pharmaceutical and Sharps Waste Stewardship Program is wholly funded by private, industry funds paid by covered entities, and therefore, there are no taxpayer/customer dollars at play such that every dollar and cent spent warrants careful scrutiny by the Department, transparency to the public, etc.

This distinction is highlighted throughout SB 212’s legislative history, and those materials suggest that the Legislature did not intend for the same level of detail or scrutiny regarding costs to be imposed on Program Operators for this very reason. The legislative history of SB212 indicated that an itemization of costs was not intended to be required, and that a general description of how the proposed funding would cover the Plan’s anticipated costs would suffice. See e.g., Cal. Assembly Committee On Environmental Safety And Toxic Materials SB 212 Committee Report, June 27, 2018, available at: https://leginfo.legislature.ca.gov/faces/billAnalysisClient.xhtml?bill_id=201720180SB212# (last visited Jan. 29, 2020). These legislative history materials are consistent with the plain language of SB 212, which generally only requires the following two (2) items for the initial Stewardship Program budget: “total anticipated revenues and costs of implementing the stewardship program” and “total recommended funding level sufficient to cover the plan’s budgeted costs

and to operate the stewardship program over a multiyear period,” and the following two (2) items for annual budgets thereafter: an independent financial audit of the Stewardship Program, and anticipated costs and the recommended funding level necessary to implement the Stewardship Program “in a prudent and responsible manner.” PRC §§ 42033(a)-(b) & 42033.2(c)(1)-(2). Additionally, and significantly from a statutory interpretation perspective, although the legislature expressly authorized the Department to request additional information from that which is enumerated in SB 212 for the annual reports, provided the additional information is “reasonably require[d]”, no such authorization was granted for purposes of budget submissions. *Compare* PRC § 42033.2(b)(9), *with* §§ 42033 & 42033.2(c).

Based on the foregoing, Proposed Regulations § 18973.6 should be revised as follows:

- 015-023C • Proposed Regulations § 18973.6(a) should be amended to consolidate the 9 “line item” anticipated cost categories into no more than the following three (3), which represent the core aspects of a Stewardship Program: (1) Stewardship Program collection, transportation, processing and disposal costs; (2) administrative costs; and (3) education and outreach costs. All other itemized costs, including a “reserve level” should be stricken, as it is contrary to the plain language and intent of SB 212, unduly burdensome, and unjustified from a policy perspective for the reasons discussed above. Thus, Proposed Regulations § 18973.6(a), as amended, should read “Anticipated costs to implement the stewardship program, including: (1) Collection, Transportation, Processing and Disposal Costs (2) Administrative Costs (3) Education and outreach.”
- 015-023D • Proposed Regulations § 18973.6(d) – which requires “all actual expenses incurred during the previous program year” to be included in all annual budgets – should be stricken in its entirety, as it is contrary to the plain language and intent of SB 212, unduly burdensome, and unjustified from a policy perspective for the reasons discussed above.
- 015-023E • Proposed Regulations § 18973.6(e) should be amended to be consistent with SB 212; in other words, the annual financial audit of the Stewardship Program conducted by Program Operators should be an audit of “the minutes, books, and records of a program operator ... at the program operator’s expense by an independent certified public accountant retained by the program operator at least once each calendar year.” PRC §§ 42033.2(c)(1) & 42033.4(b). No more language, specifications or obligations should be included in the Proposed Regulations in excess of what is explicitly required or intended by the SB 212, including the obligation to conduct an annual audit in accordance with Generally Accepted Government Auditing Standards, which are rigorous accounting standards that do not apply to non-governmental entities like Program Operators. In order to effectuate these changes most effectively, Proposed Regulations § 18973.6(e), as amended, should read in full: “An independent financial audit of the stewardship program, as required by Sections 42033.2(c)(1) and 42033.4(b) of the Public Resources Code.”

B. The Granular Level of Detail Sought in the Annual Reports for Each Collection Site (at Proposed Regulations §§ 18973.4(c)(4)) is Unreasonable and Impracticable

Proposed Regulations § 18973.4(c)(4) states that the annual reports submitted by a Program Operator for a Covered Drug Stewardship Plan must include the following information for each participating authorized collection site located in the State of California: (1) name and physical address; (2) weight of material collected; (3) number of collections and number of liners collected; and (4) “total number of instances and corresponding number of businesses hours the authorized collection site was not available to the public” during the previous reporting year. (emphasis added).

The first two pieces of information listed above - name and physical address of each collection site and weight of material collected at each collection site – is required in SB 212. See PRC § 42033.2(b)(3) & (4). The latter two are not. Pursuant to the enabling statute at PRC § 42033.2(b)(9), the Department may require additional information in the annual reports, provided that the information is “reasonably require[d].” The additional information sought by the Department here, including the total number of business hours in a calendar year that each and every collection site is “not available to the public” for any reason, is not only unreasonable, but in many instances likely infeasible to obtain and report out. There are approximately 2,100 business hours in a year, and there will likely be over 1000 collection sites throughout the state of California under a MED-Project Stewardship Plan. Obtaining complete and accurate information on the total number of business hours over a 365 day period that each collection site in the state of California was closed or otherwise inaccessible to the public during business hours for any given reason (renovations, employee errors, etc.) is practically impossible. Additionally, requesting that the annual reports for Covered Drugs publicly document the number of collections made at each collection site may create unintended safety and security issues (e.g., the disclosure of this type of information may reveal patterns pertaining to pick up schedules, which is of interest to potential thieves).

For these reasons, Proposed Regulations §§ 18973.4(c)(4)(C) and (D) should be stricken, so that the collection site-specific information required in the annual reports for Covered Drug Stewardship Plans is consistent with SB 212.

MED-Project is also concerned that safety and security issues may arise from the public disclosure of information detailing the amount of weight collected at a particular collection site. Thus, the Proposed Regulations should allow blinded (or “masked”) weight reporting without a key identifying the collection site associated with the reported weight amounts. Program Operators could provide a key identifying individual collection sites to the Department under separate cover as a confidential submission.

C. Imposing Mandatory Third Party Reporting Obligations and Corrective Action Duties on Program Operators for Legal Noncompliance Allegedly Committed By Other Private Parties Is Unprecedented, Untenable and Wholly Unreasonable

Proposed Regulations §§ 18973.4(e) and 18973.5(e), if adopted in their current form, would impose a mandatory obligation on Program Operators to not only disclose violations of federal, state and local laws and regulations (laws and regulations over which the Department has no jurisdiction or enforcement authority) committed by service providers but also take affirmative steps to initiate undefined “corrective action” to remedy a third party’s alleged noncompliance. Proposed Regulations §§ 18973.4(e) and 18973.5(e) also would require Program Operators to report all such information in publicly available annual reports. This type of mandatory third party disclosure and corrective action obligation is legally unprecedented, and absent from the enabling statute.

This type of reporting obligation is also wholly unreasonable and unworkable for numerous reasons. As mentioned above, in Section IV.B., the enabling statute at PRC § 42033.2(b)(9) limits the Department’s authority to require additional information in annual report submissions, above and beyond that which is enumerated in SB 212, to information is “reasonably require[d].” Program Operators like MED-Project are private entities, as are their vendors. MED-Project is not a government inspector or enforcement agency. Therefore, is not in a role where it is qualified to assess the legal compliance status of another private party or “order” corrective action to be taken regarding the same. Such a mandatory third party reporting system would also discourage vendors from working with a Program Operator to implement a Stewardship Plan (vendors in an industry that is also already highly regulated and therefore small), thereby putting at risk the effectiveness of the entire Stewardship Program. It is industry standard for vendor contracts to include provisions requiring the vendor to comply with all applicable federal, state and local laws and regulations. This plus the checks and balances intended by the Legislature, as stated in SB 212 is sufficient to ensure that all parties involved in the Stewardship Program make their best efforts to comply with all applicable laws and regulations, as well as any additional policies and procedures established under a Stewardship Plan.

For the foregoing reasons, Proposed Regulations §§ 18973.4(e) and 18973.5(e) should be revised to strike the language imposing a mandatory third party disclosure and corrective action obligation on Program Operators and to be consistent with the SB 212 at Proposed Regulations § 42033.2(b)(6). Proposed language that would effectuate this change is set forth below:

- ~~“The annual report shall contain the following corrective actions taken if the program operator discovered that a service provider did not maintain compliance with the collection, transportation, and disposal standards, including, but not limited, to local, state and federal laws and regulations and United State Drug Enforcement Administration regulations a statement as to whether the policies and procedures for collecting, transporting, and disposing of covered drugs [or sharps waste], as established in the~~

stewardship plan, were followed during the reporting period and a brief summary of any known critical incidents of noncompliance that occurred.”

D. Imposing Imprecise Obligations on Stewardship Program Operators to Furnish “Agency Determinations of Compliance and Noncompliance” in Annual Report Submissions Is Unreasonable and Unnecessary

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For the same reasons as those stated immediately above in Section IV.C. and in addition to those described below, Proposed Regulations §§ 18973.4(o) and 18973.5(q) should be stricken in their entirety. As mentioned above, in Section IV.B., the enabling statute at PRC § 42033.2(b)(9) limits the Department’s authority in supplementing the information required in annual report submissions to information that is “reasonably require[d].”

Proposed Regulations §§ 18973.4(o) and 18973.5(q) currently state that annual report submissions to the Department must include “all agency determination(s) of compliance, noncompliance and superseding determinations of compliance, if any, for the reporting period.” It is unclear which “agency” the Proposed Regulations are intended to refer to and/or the scope of documentation sought. For instance, Program Operators are unlikely to have documents in their possession regarding inspection reports issued to third party vendors, and it is unreasonable to expect a private party Program Operator to successfully collect copies of this type of documentation from all of its vendors.

The rationale behind this requirement – which is not included in SB 212 – is also unclear. In today’s internet age, most federal, state and local agencies with jurisdiction over California activities have publicly searchable databases regarding the compliance status of private parties (*see e.g.*, the CalEPA Regulated Site Portal, available at: <https://siteportal.calepa.ca.gov/nsite/map/help> and U.S. EPA Envirofacts, available at: <https://enviro.epa.gov/>). Thus, Proposed Regulations §§ 18973.4(o) and 18973.5(q) should be stricken in their entirety.

E. The Safety and Security-Related Recordkeeping and Potential Disclosure Obligations Imposed in Proposed Regulations §§ 18973.4(h) and 18973.5(h) Are Unreasonable and Impracticable

In addition to requiring certain safety and security information in the annual reports (such as a description of any incidents and any corrective action taken), Proposed Regulations §§ 18973.4(h) and 18973.5(h) appear to also include a recordkeeping and potential production requirement for safety and security-related information, requiring that “[t]he following shall be made available to the department upon request, including, but not limited to: (1) Location and date; (2) Description of incident; (3) Cause(s) of incident; (4) Parties involved; (5) Regulatory or

law enforcement agencies involved and any litigation, arbitration, or other legal proceedings that result from each incident.”

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015-027b

The language in Proposed Regulations §§ 18973.4(h) and 18973.5(h), as currently, written is ambiguous inasmuch as it is not clear whether the provision is imposing an affirmative obligation on Program Operators to prepare and/or collect all of the above-listed information for any “safety and security incident” that is reported in the annual reports. It is unreasonable and infeasible to expect a Program Operator to have all of the above-listed information in its possession or to be able to gain access to it (including, namely, details of legal proceedings or enforcement actions in which the Program Operators may not be a party to).

The corresponding provisions in SB 212 only require Program Operators to annually report on whether “any safety or security problems occurred ... during the reporting period and if so, what change have been or will be made ... to alleviate the problem and to improve safety and security.” PRC § 42033.2(b)(7). Proposed Regulations §§ 18973.4(h) and 18973.5(h) should be revised to be consistent with SB 212. Proposed language that would effectuate this change is set forth below:

- **Safety and Security.** Describe the nature of any incidents with safety or security related to collection, transportation, or disposal of collected covered drugs [or sharps waste]. Explain what corrective actions were taken to address the issue and improve safety and security. ~~The following shall be made available to the department upon request, including, but not limited to [sic]: (1) Location and date; (2) Description of incident; (3) Cause(s) of incident; (4) Parties involved; (5) Regulatory or law enforcement agencies involved and any litigation, arbitration, or other legal proceedings that result from each incident.~~”

F. Requiring Program Operators to Annually Report on Miscellaneous Non-Substantive Obligations (in Proposed Regulations §§ 18973.4(k)-(m) and 18973.5(l)-(n)) Is Unnecessarily and Unreasonably Burdensome

015-028a
015-028b

Proposed Regulations §§ 18973.4(k)-(m) and 18973.5(l)-(n) would require Program Operators to annually report a variety of miscellaneous, non-substantive information regarding programmatic changes to their Covered Drug Stewardship Plans and Home-Generated Sharps Waste Stewardship Plans made during the reporting period (including staffing changes and process-based changes for selecting service providers and providing grants, loans, and other incentives). This information is not required by SB 212 and it exceeds the Department’s authority to supplement the information required in the annual report as it unreasonable in nature. As mentioned above, the enabling statute at PRC § 42033.2(b)(9) limits the Department’s authority in supplementing the information required in annual report submissions to information that is “reasonably require[d].”

Imposing these types of additional, non-substantive reporting obligations on Program Operators annually is unnecessary and unreasonable, as it will only divert resources and costs away from

standing up an effective Stewardship Program. Therefore, the above referenced sections of the Proposed Regulations should be deleted from the final regulations.

G. The Proposed Regulations Request an Unreasonable Level of Detail on Local Household Hazardous Waste Facilities in the Annual Reports (Proposed Regulations §§ 18973.5(p))

Proposed Regulations § 18973.5(p) would require Program Operators of Home-Generated Sharps Waste Stewardship Programs to annually report on “*each* local agency that has requested removal or reimbursement” including, specifically, details regarding, among other things, “[f]or *each* household hazardous waste facility: (A) Facility location[;] (B) Reimbursement payment amount, as applicable [; and] (C) Weight of collected material.” Proposed Regulations § 18973.5(p)(2) (emphasis added).

015-029 The above information is not required by the legislature, as specified in the annual reporting section contained in SB 212, *see* Cal. Pub. Resources Code § 42033.2(b), and therefore, it is an additional requirement subject to the statutory limitation of “reasonableness” previously mentioned. See Cal. Pub. Resources Code § 42033.2(b)(9). The additional information sought by the Department in Proposed Regulations § 18973.5(p) is unreasonable in its nature and in the level of granular detail sought (including, namely requiring the collection, calculation and reporting out of data regarding material weights and reimbursement amounts broken down at the local facility level). Furthermore, as discussed above in Section IV.A. in regards to the level of detail sought in the proposed budgets, requiring annual reporting on a granular level for reimbursement costs related to disposal services would disclose proprietary, confidential and/or trade secret information in a public document.

Based on the foregoing, Proposed Regulations § 18973.5(p) should be revised to be reasonable in scope and nature, and should read follows: “Local Agency Requests. ~~For each~~ A list of local agencies that requested removal or reimbursement during the reporting period details, including, but not limited to, the following: (1) Name of local agency, or agency acting on behalf of local agency. (2) ~~For each household hazardous waste facility:~~ (A) Facility location (B) Reimbursement payment amount, as applicable (C) ~~Weight of collected material.~~”

V. GENERAL COMMENT

A. The Department Should Revise the Proposed Regulations to Eliminate Paraphrasing of SB 212

015-030A SB 212 is a prescriptive statute. Over twenty pages long, it comprehensively regulates the collection and disposal of Covered Products and the associated Stewardship Programs. Despite these detailed statutory requirements, however, the Proposed Regulations paraphrase certain sections of SB 212 in an apparent attempt to consolidate Stewardship Program requirements into a single document. Unfortunately, discrepancies between SB 212 and paraphrased provisions of SB 212 in the Proposed Regulations raise questions about what the requirements actually are,

making compliance harder. To make the requirements more understandable, the Department should revise the Proposed Regulations to eliminate these discrepancies.

In some cases, paraphrasing SB 212 requirements in the Proposed Regulations results in discrepancies that could carry compliance consequences. For example, the following discrepancies could affect Stewardship Plan approval or Stewardship Program implementation:

- 015-030B1 • The Proposed Regulations refer to the Department determining whether undefined
015-030B2 “document[s]” are complete, whereas SB 212 applies these completeness reviews to only Stewardship Plans, annual reports, and Stewardship Program budgets. *Compare* Proposed Regulations § 18973.1(b) *with* PRC §§ 42032(d)(1), 42033.2(d).⁴
- 015-030C • The Proposed Regulations provide that “[c]ontainer labels and mail-back materials shall include the stewardship program internet website and toll-free telephone number.” SB 212, by contrast, alternatively allows Program Operators to include this information on “a separate insert included in the container or packaging.” *Compare* Proposed Regulations § 18973.3(f)(2)(C) *with* PRC § 42032.2(d)(1)(F)(i)(II); *see also* Proposed Regulations § 18973.3(f)(2)(B); PRC § 42032.2(d)(1)(F)(i)(I).
- 015-030D • The Proposed Regulations require that Stewardship Plans describe alternative collection methods for Covered Drugs, other than controlled substances, that cannot be accepted or commingled with other Covered Drugs in collection receptacles or through a mail-back program. Proposed Regulations § 18973.2(g)(7). The Proposed Regulations omit a limitation on this requirement that SB 212 made clear: Stewardship Plans must only describe these alternative collection methods if they are “technically feasible and permissible under applicable state and federal law, including, but not limited to, United States Drug Enforcement Administration regulations.” *Compare* Proposed Regulations § 18973.2(g)(7) *with* PRC § 42032.2(a)(1)(G)(ii).
- 015-030E • The Proposed Regulations require that Stewardship Plans describe how “[c]ontainers and mail-back materials shall be distributed in amounts sufficient to accommodate the volume of sharps purchased by the ultimate user.” Proposed Regulations § 18973.3(f)(2)(A). Conversely, SB 212 requires such distribution “sufficient to accommodate the volume of sharps purchased by an ultimate user *over a selected time period.*” PRC § 42032.2(d)(1)(F)(i) (emphasis added).

In other cases, paraphrasing resulted in SB 212 and the Proposed Regulations appearing to require the same thing, but using slightly different language. Whether these discrepancies are intentional or meaningful is unclear. For example, among other discrepancies, the Proposed

⁴ Proposed Regulations § 18973 also refers to the undefined term “document.” Although likely referring to only Stewardship Plans, annual reports, and Stewardship Program budgets, as written the term could refer to any document a Program Operator provides the Department. The Department should define the term document as “Stewardship Plans, annual reports, or Stewardship Program budgets” or eliminate it from the Proposed Regulations.



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

015-030F Regulations require Stewardship Plans to identify the “*conditions* for excluding” Authorized Collectors, whereas SB 212 requires Stewardship Plans to identify the “*reasons* for excluding” Authorized Collectors. *Compare* Proposed Regulations § 18973.2(d)(4) with PRC § 42032.2(a)(1)(B). In another example, the Proposed Regulations require that Home-Generated Sharps Waste annual reports include an “[u]pdated list of covered products,” whereas SB 212 refers to “[t]he updated and reverified list provided pursuant to paragraph (2) of subdivision (a) of Section 42031.” *Compare* Proposed Regulations § 18973.5(k) with PRC § 42033.2(b)(2).

015-030G

These discrepancies create uncertainty. There is no need for the Proposed Regulations to paraphrase what SB 212 makes plain. The regulatory framework would be most clear if the Department removes sections of the Proposed Regulations that paraphrase SB 212 and simply cross-references the statute as needed. Short of that, the Department should eliminate discrepancies by revising the Proposed Regulations for consistency with SB 212. If Proposed Regulation provisions are intended to require the same thing as SB 212 provisions, they should use the same language. Such revisions would clarify the Proposed Regulations, making Stewardship Program implementation and Department oversight more successful.

* * * * *

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

Dr. Victoria Travis
National Program Director

From: [James Jack](#)
To: [PharmaSharps](#)
Cc: [Smyth, Jason@CalRecycle](mailto:Smyth_Jason@CalRecycle)
Subject: COMMENT LETTER: SB 212 Rulemaking
Date: Monday, February 17, 2020 4:26:18 PM
Attachments: [image001.png](#)
[CalRecycle Coment Letter 2.16.20.pdf](#)
Importance: High

[[EXTERNAL]]

Jason, attached please find the joint comment letter from Little Drug Store Products and Convenience Valet on the proposed SB 212 regulations.

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

Best,
James



JAMES JACK
Capitol Strategic Advisors, LLC
1215 K Street, Suite 1760
Sacramento, CA 95814
(916) 325-8591



February 16, 2020

Jason Smyth
Materials Management and Local Assistance Division
California Department of Resources Recycling and Recovery
P.O. Box 4025
Sacramento, CA 95812-4025
Submitted Via E-Mail to: PharmaSharps@CalRecycle.ca.gov

RE: Proposed Pharmaceutical and Sharps Waste Stewardship Program Regulations

Lil' Drug Store Products and Convenience Valet, appreciate the opportunity to submit comments to the California Department of Resources Recycling and Recovery (CalRecycle). Both Lil' Drug Store and Convenience Valet are members of the Pharmaceutical Product Stewardship Work Group (PPSWG) and are stakeholders in the forthcoming Pharmaceutical and Sharps Waste Stewardship Program (Program).

First and foremost, we applaud CalRecycle for clearly capturing the legislative intent of Senate Bill 212 (Chapter 1004, Statutes of 2018), which mandates that manufacturers are responsible for the product stewardship of any "covered product" they manufacture that is sold, offered for sale, or dispensed in California. This clear assignment of manufacturer responsibility is definitively articulated in the Proposed Regulations under Section 18972.2 (a), which reads:

"The department shall consider all manufacturers of covered products sold, offered for sale, or dispensed in California whether they are program operators or are represented by a stewardship organization, as the covered entities."

The successful implementation of SB 212 will be predicated upon CalRecycle's ability to clearly identify the appropriate covered entity for each product covered under the Program consistent with PRC 42030. For this reason, we encourage all stakeholders to collaborate with CalRecycle to provide the information needed to support the Department's efforts to establish a fully comprehensive register of covered entities. Lil' Drug Store Products and Convenience Valet look forward to our close collaboration with CalRecycle to support this effort.

Suggested Amendments to Proposed Regulations

As written, the Proposed Regulations provide a sound footing for a statewide pharmaceutical waste and sharps stewardship program. However, our companies believe that the Proposed

Regulations would benefit from three additional clarifications to ensure that the Final Regulations maintain a perspective that supports successful implementation, considers equity in the marketplace, and keeps an eye towards minimizing the burden on small business that were not the focus of SB 212.

As such, our companies respectfully request that the following three suggestions are also included in the next (or Final) revision of the Proposed Regulations:

- 1. A clear statement that the responsibility for participation in the Program shall be limited exclusively to the “covered entities” pursuant to PRC 42030 and CCR 18972.2 (as proposed).**

SB 212 establishes a tiered definition for the term “covered entity,” making manufacturers responsible for the program and establishing other entities that may be held liable should no entity meet the initial definition. While both SB 212 and the Proposed Regulations clearly articulate manufacturer responsibility for “covered products” under the Program, the inclusion of other entities (such as distributors, repackages, trademark owners, and importers) as potential “covered entities” may be selectively interpreted to hold parties other than the manufacturer financially responsible for “covered products” under the Program. Such interpretation creates the possibility of a multi-layer fee, in which multiple entities—from manufacturers to wholesalers to importers—all share a portion of the financial responsibility for the same product through a stewardship organization, for example. The possible inclusion of parties other than a manufacturer sharing this responsibility creates a tremendous amount of uncertainty and business risk for those parties, especially when trying to understand and budget for potential cost liabilities related to potential participation in California’s takeback program. Furthermore, due to the fact that so many entities could qualify as “covered entities” under this scenario, it would make it more far more difficult to identify and hold violators and non-participants accountable.

016-001 For this reason, we respectfully ask that CalRecycle clearly state in the Proposed Regulations that any entity other than the identified “covered entity” for a “covered product” does not have any responsibility to participate in the Program either as a program operator or through a stewardship organization.

- 2. A clear statement of the steps CalRecycle must take undertake to establish a “covered entity” and exact circumstances that would allow CalRecycle to make a finding that no entity meets the definition of “manufacturer” for purposes of BPC 42030(f)(1)(A).**

As referenced above, while both SB 212 and the Proposed Regulations clearly articulate manufacturer responsibility for “covered products” under the Program, the inclusion of other entities (such as distributors, repackages, trademark owners, and importers) as potential “covered entities” creates a tremendous amount of uncertainty and business risk for those parties, especially when trying to understand and budget for potential cost liabilities related to potential participation in California’s takeback program.

016-002

Given the clear legislative intent of SB 212 to hold product manufacturers responsible for the requirements of the Program, the Proposed Regulations should clearly specify the steps that CalRecycle must undertake to identify a manufacturer for every “covered product” and the exact circumstances that would allow CalRecycle to make a finding that no entity meets the definition of manufacturer for purposes of BPC 42030(f)(1)(A). If and when that entity is not identifiable, the regulations should clearly state the steps that CalRecycle must undertake to identify a wholesaler for every “covered product” where a manufacturer does not exist and clearly specify the exact circumstances that would allow CalRecycle to make a finding that no entity meets the definition of “wholesaler” for purposes of BPC 42030(f)(1)(B). Additionally, the regulations should clearly state that a repackager does NOT meet the definition of a covered entity if either the manufacturer or wholesaler have been identified.

3. An exemption for immediate or single-use products.

Single-use products, which contain a single dose of over-the-counter medication offer value to both retailers and consumers, as they are packaged in a very small quantity designed for immediate use. Many convenience stores have limited space and prefer to offer these smaller product packages. Products with larger quantities of medication are more expensive than products with convenience-sized packaging and can thus serve as a barrier to treating health concerns; products with convenience-sized packaging thus create low-cost options designed to provide immediate relief. Because the product is packaged to be used within a very short period of time, with the first dose to be taken within the hour following its purchase, it essentially eliminates the possibility of the product being unused, expired, or leftover and entering the waste stream.

016-003

For these reasons, we request that CalRecycle include language that exempts immediate-use nonprescription packaged drugs from all return requirements, including exempting companies which only provide drug products in these formats from the requirement of participating in stewardship plans. We believe that this request is consistent with the legislative intent and statements associated with SB 212, and we do not read SB 212 to prohibit a de minimus exemption of packages of such small size that their contents will have a negligible (if any) chance of reaching the waste stream.

Thank you for your consideration of these concerns and we look forward to partnering with you on the successful implementation of SB 212.

Sincerely,

Neil Dow
Director of Quality Assurance & Regulatory Affairs
Lil' Drug Store Products, Inc.

Barry Margolin
CFO/COO
Convenience Valet

From: [Green, Sharon](#)
To: [PharmaSharps](#)
Subject: FW: LACSD Letter to CalRecycle re SB 212 draft regulations
Date: Tuesday, February 18, 2020 3:50:58 PM
Attachments: [image001.png](#)
[image002.png](#)
[image003.png](#)
[DMS-#5571258-v5-LACSD Letter to CalRecycle re SB 212 draft regulations.PDF](#)

[[EXTERNAL]]

To Whom It May Concern, please find attached our comment letter on the draft Pharmaceutical and Sharps Waste Stewardship Program Regulations. Please let me know if there are any problems with the attached file.

Thanks,
Sharon Green

Sharon N. Green

Legislative & Regulatory Programs Manager | Technical Services Department
562-908-4288 ext. 2503 | C 562-447-3871 | sgreen@lacs.org

SANITATION DISTRICTS OF LOS ANGELES COUNTY  
Converting Waste Into Resources | www.LACSD.org

From: Mays, Denise <djmays@lacs.org>
Sent: Tuesday, February 18, 2020 3:39 PM
To: Green, Sharon <SGreen@lacs.org>
Subject: LACSD Letter to CalRecycle re SB 212 draft regulations



Robert C. Ferrante
Chief Engineer and General Manager
1955 Workman Mill Road, Whittier, CA 90601-1400
Mailing Address: P.O. Box 4998, Whittier, CA 90607-4998
(562) 699-7411 • www.lacsd.org

February 18, 2020

Via Electronic Mail: pharmasharps@calrecycle.ca.gov

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

Dear Mr. Smyth:

**Comments on Proposed Regulations:
Pharmaceutical and Sharps Waste Stewardship Program**

On behalf of the Sanitation Districts of Los Angeles County, thank you for the opportunity to submit comments on the proposed regulations to implement California's Pharmaceutical and Sharps Waste Stewardship Program. We very much appreciate the pre-rulemaking process undertaken by the department and believe that process to be a helpful way to engage stakeholders and gather input. By way of background, the Sanitation Districts provide wastewater and solid waste services to approximately 5.6 million people in 78 cities and unincorporated areas in Los Angeles County. The Sanitation Districts have long been a proponent of providing safe and convenient methods for the public to dispose of unwanted and expired medications, and we have promoted that message for many years as part of our "No Drugs Down the Drain" program (www.nodrugsdownthedrain.org).

017-001

In addition to broader goals related to reducing drug abuse and diversion of unused drugs, reducing the disposal of unwanted pharmaceuticals is important because, when disposed by flushing down the drain or put out with household trash, wastewater treatment facilities and municipal solid waste facilities can serve as pathways for pharmaceutical waste residuals to enter the aquatic environment. Trace amounts of pharmaceuticals can also affect the quality of recycled water or drinking water. Furthermore, sharps that are disposed in trash or flushed down the drain pose health and safety concerns for sanitation workers, as improperly disposed sharps may cause injuries to workers at materials recovery facilities where household solid waste is sorted and to wastewater system workers when flushed. Household trash disposal also presents additional opportunities for diversion, such as by scavengers that may discover drugs in trash left at the curbside, or at materials recovery facilities, where increasingly trash is sent for sorting prior to recycling or disposal.

017-001
Continued

For all these reasons, we support the adoption of regulations to implement SB 212 in order to provide a consistent statewide approach for residents in the many local jurisdictions that have not yet established EPR programs for pharmaceuticals and sharps waste. Thank you again for providing the opportunity to submit comments on the proposed regulations. Should you have any questions about our comments, please do not hesitate to contact Sharon Green of my staff at sgreen@lacsdsd.org.

Very truly yours,



Martha Tremblay
Department Head
Technical Services Department

MT:SNG:djm

Additional Comments/Emails from Stakeholders During the 45-day Comment Period:

Inmar Questions and CalRecycle Responses:

Description: Inmar Intelligence, Inc. had emailed clarification questions pertaining to the regulatory text before the beginning of the 45-day comment period. The responses, Inmar's follow-up questions, and CalRecycle's follow-up responses continued into the 45-day comment period.

Original Questions and Responses

Question 1:

Inmar is planning to contract with each individual manufacturer and will be responsible for ensuring that they are compliant with the requirements of SB 212 and its implementing regulations. Inmar believes that as long as the company (program operator) obtains compliance with the statute and regulations, there will be no duplicative requirement for each manufacturer to individually meet the compliance standard as outlined in statute. Would CalRecycle agree with this assumption?

CalRecycle Response to Question 1:

No, CalRecycle does not agree with this assumption.

"Program operator" means a covered entity, or stewardship organization on behalf of a group of covered entities, that is responsible for operating a stewardship program (section 42030(q) of the Public Resources Code). Therefore, unless Inmar is a stewardship organization, it cannot act on behalf of a group of covered entities to operate a singular stewardship program. A covered entity is required to, either individually or through a stewardship organization of which it is a part, pay all administrative and operational costs associated with establishing and implementing the stewardship program in which it participates. All program operators implementing a stewardship program, whether they are an individual covered entity, or a stewardship organization, must adhere to the applicable regulations and statute. Unless Inmar is structured as a 501(c)(3) as required of stewardship organizations pursuant to section 42031.4(b) of the Public Resources Code, each manufacturer that contracts with Inmar will be required to comply with all statutory and regulatory requirements, including submitting individual stewardship plans, annual budgets, and annual reports, even if they are duplicative with another covered entity's documents.

Additionally, there are obligations under statute that a covered entity must follow that are outside of the requirements of a program operator as described in your scenario. A covered entity may be out of compliance with statute and regulations while a program operator is in compliance. For example, a stewardship organization may be operating its program pursuant to statute and regulations, but one of its member covered entities failed to send an annual list of covered products to the Board of Pharmacy. In this instance, the stewardship organization is compliant, and the covered entity is out of compliance.

Question 2:

Inmar will work with each manufacturer to submit a plan and an annual report to CalRecycle as required under the regulations. The company would like to discuss with CalRecycle how to most efficiently provide this information to CalRecycle so that is not duplicative and is the most easily reviewed and approved by the Department. Is CalRecycle open to further discussions to ensure manufacturer compliance but also make the process efficient and workable for the Department?

CalRecycle Response to Question 2:

See answer to question #1 regarding the statutory requirement that program operators must either be an individual covered entity or a 501(c)(3) stewardship organization operating on behalf of a group of covered entities.

We welcome your feedback if you have proposed language for an alternative we can consider for the regulations about potential plan, annual budget, and annual report efficiencies. During the formal 45-day comment period, we abstain from private discussions and address all feedback publicly. You may choose to email pharmasharps@calrecycle.ca.gov your suggested edits to the proposed regulations and a CalRecycle response will be provided on our [rulemaking webpage](#).

Question 3:

Inmar is looking for some clarification and further discussion regarding the alternative forms of collection referred to in the proposed regulations. Inmar would appreciate further direction and expectation regarding ensuring access by homebound and/or homeless individuals to take back options and the metrics by which weight measurements or other tracking of drugs received through the alternative options are needed. Is CalRecycle open to further discussions in this regard?

CalRecycle Response to Question 3:

I believe this is in reference to section 42032.2(a)(1)(G)(i) of the Public Resources Code and addressed in section 18973.2(j)(4) of the proposed regulations regarding providing a mechanism to accept requests for mail-back materials to homeless, homebound, and disabled ultimate users through an internet website and toll-free phone number. Both the development of metrics used to measure the amount of materials distributed, and the weight of material disposed, are plan requirements. See section 18973.2(g)(5)(C) in the proposed regulations.

We welcome your feedback if you have proposed language for an alternative we can consider for the regulations about take back requirements, metrics, and tracking mechanisms. During the formal 45-day comment period, we abstain from private discussions and address all feedback publicly. You may choose to email pharmasharps@calrecycle.ca.gov your suggested edits to the proposed regulations and a CalRecycle response will be provided on our [rulemaking webpage](#).

Follow-up Question following CalRecycle Responses

InMar asked CalRecycle to clarify the meaning of the following:

“each manufacturer that contracts with InMar will be required to comply with all statutory and regulatory requirements, including submitting individual stewardship plans, annual budgets, and annual reports, even if they are duplicative with another covered entity’s documents.”

CalRecycle Response to Follow-up Question

Section 42030 of the Public Resources Code:

- (f) defines “Covered entity” as the manufacturer via a tiered definition,
- (w) defines “Stewardship organization” as a 501(c)(3),
- (x) defines “Stewardship plan” to be submitted by a covered entity or stewardship organization.

First, without being represented by a 501(c)(3) stewardship organization, each covered entity will have to submit its own plan.

Second, what is meant by “even if they are duplicative with another covered entity’s documents” highlighted below, is that even if certain elements of a group of covered entities’ plans are substantially similar or the same (i.e., duplicative), such as the collection, transportation, and disposal components, unless they are represented by a 501(c)(3) stewardship organization, they must submit all plans, budgets, and reports separately. This is not to say that there cannot be efficiencies in the collection, transportation, and disposal system itself as a part of the good faith efforts you reference below. For instance, a covered entity may want to use some of the same collection sites. In that case, each individual plan would need to identify those sites, explain how they are using it, and the details on how they are sharing costs, management, etc. They wouldn’t necessarily need to use different collection sites.

Summary of Question from Sharon Green and CalRecycle Response

Sharon Green, of the Sanitation Districts of Los Angeles County, asked if CalRecycle would accept comments on February 18, 2020, and CalRecycle's response was "yes". CalRecycle accepted responses through the end of the hearing on February 19, 2020.

From: Smyth, Jason@CalRecycle <Jason.Smyth@CalRecycle.ca.gov>
Sent: Monday, January 27, 2020 3:37 PM
To: Ashley Schmidt <ashley.schmidt@inmar.com>; Dunn, Cynthia@CalRecycle <Cynthia.Dunn@CalRecycle.ca.gov>
Cc: PharmaSharps <PharmSharps@calrecycle.ca.gov>; Domingo Isasi <domingo.isasi@inmar.com>
Subject: RE: Thank you

Hi Ashley,

Thanks for your patience regarding our follow-up on this. While we appreciate your offer to meet in person, we believe that the information in this e-mail is responsive to your inquiry. We have conferred with counsel on this and offer the following clarification:

[Section 42030 of the Public Resources Code](#):

- (f) defines "Covered entity" as the manufacturer via a tiered definition,
- (w) defines "Stewardship organization" as a 501(c)(3),
- (x) defines "Stewardship plan" to be submitted by a covered entity or stewardship organization.

First, without being represented by a 501(c)(3) stewardship organization, each covered entity will have to submit its own plan.

Second, what is meant by "even if they are duplicative with another covered entity's documents" highlighted below, is that even if certain elements of a group of covered entities' plans are substantially similar or the same (i.e., duplicative), such as the collection, transportation, and disposal components, unless they are represented by a 501(c)(3) stewardship organization, they must submit all plans, budgets, and reports separately. This is not to say that there cannot be efficiencies in the collection, transportation, and disposal system itself as a part of the good faith efforts you reference below. For instance, a covered entity may want to use some of the same collection sites. In that case, each individual plan would need to identify those sites, explain how they are using it, and the details on how they are sharing costs, management, etc. They wouldn't necessarily need to use different collection sites.

Since we are in the midst of a 45-day comment period that ends February 17th (as noted on the [pharmaceutical and sharps waste stewardship rulemaking page](#) and communicated via our listserv which you can sign up for [here](#)), please clarify whether your e-mail communications in this email chain are intended to be conversational or submitted as a comment to be addressed through the formal rulemaking process in addition to the upcoming comment letter that includes proposed language that you mentioned below.

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: Ashley Schmidt <ashley.schmidt@inmar.com>
Sent: Wednesday, January 22, 2020 7:59 AM
To: Dunn, Cynthia@CalRecycle <Cynthia.Dunn@CalRecycle.ca.gov>
Cc: PharmaSharps <PharmSharps@calrecycle.ca.gov>; Smyth, Jason@CalRecycle <Jason.Smyth@CalRecycle.ca.gov>; Domingo Isasi <domingo.isasi@inmar.com>
Subject: Re: Thank you

Cynthia,

Thank you for getting back to me so quickly. We would appreciate the follow up conversation if you determine that it is ok once you are able to discuss with your legal counsel. I will actually be in Sacramento next Wednesday for some other meetings that are scattered throughout the day. I would be happy to stop by for a quick follow up discussion or we can certainly schedule a call at any time.

We will be submitting our comments and questions soon, also.

Thank you,
Ashley

Ashley Schmidt

Director, Regulatory and Compliance



Ashley.Schmidt@inmar.com

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On Tue, Jan 21, 2020 at 10:36 AM Dunn, Cynthia@CalRecycle <Cynthia.Dunn@calrecycle.ca.gov> wrote:

Good morning, Ashley:

Appreciate your follow-up e-mail. I think perhaps a phone call might be best in order to clarify our initial response, to the extent we can do so without compromising the formal rulemaking process. Our legal counsel is out of the office until 1/27, so we will need to wait until then to discuss and then get back to you. In the meantime, we absolutely welcome and appreciate written comments as part of the formal process.

Best,

Cynthia

From: Ashley Schmidt <ashley.schmidt@inmar.com>
Sent: Saturday, January 18, 2020 12:11 PM
To: PharmaSharps <PharmSharps@calrecycle.ca.gov>
Cc: Smyth, Jason@CalRecycle <Jason.Smyth@CalRecycle.ca.gov>; Dunn, Cynthia@CalRecycle <Cynthia.Dunn@CalRecycle.ca.gov>; domingo.isasi@inmar.com
Subject: Re: Thank you

Mary, Cynthia and Jason,

Thank you for your response. We certainly appreciate CalRecycle's efforts to implement this important program as it goes forward.

We'd only raise one point of clarification at this early phase for consideration. We have highlighted a portion of the response (below), which seems to suggest that absent the involvement of a 501(3)(c) entity, each manufacturer will be required to comply with all statutory/reg requirements, "even if they are duplicative" with another covered entity's documents.

The program (both in the statute and the proposed regulations) includes a reasonable "good faith" efforts concept that can apply to negotiations with collectors, as well as among all parties engaged to make the program function effectively. This would include "all covered entities, stewardship organizations, program operators, ..." as stated in proposed rule Sec. 18972. These good faith efforts could easily eliminate, for example, duplicative collection sites. The proposed rule also requires that in the event of "multiple stewardship programs," program operators must work together to most effectively achieve the requirements of the statute and regulations. Sec. 18973.2(k)

We would therefore respectfully note that through good faith efforts, many duplicative and potentially inefficient aspects of the program can be eliminated. In fact, the more good faith cooperation to implement the program statewide, the more credibility and effectiveness it can achieve, both with covered entities, as well and the citizens it is designed serve. Thus, we

would assert that current statute and proposed regulations allow for manufacturers to utilize a cooperative approach to complying with the convenience standard. In making this assertion, please note and be assured that Inmar is committed to making the California program a success, and not seeking to circumvent any aspect of the statute or regulations.

We would appreciate your thoughts on this point and, of course, we also welcome the opportunity to provide proposed language to further clarify this approach that CalRecycle can consider for the regulations and will do so during the comment period.

Thank you again.

Best Regards,

Ashley

each manufacturer that contracts with Inmar will be required to comply with all statutory and regulatory requirements, including submitting individual stewardship plans, annual budgets, and annual reports, even if they are duplicative with another covered entity's documents.

Ashley Schmidt

Director, Regulatory and Compliance



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On Fri, Jan 10, 2020 at 2:15 PM PharmaSharps <PharmSharps@calrecycle.ca.gov> wrote:

Hello Ashley,

It was a pleasure meeting with you and Domingo. The meeting was informative for CalRecycle and provided us with insight regarding Inmar's role operating in the drug distribution industry.

We appreciate the discussion regarding SB 212 and the implementation of the pharmaceutical and sharps waste stewardship program(s) for which CalRecycle is responsible for overseeing. Your questions have been addressed below in red.

Kind Regards,

Mary

The CalRecycle Pharmaceutical & Sharps Team

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

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

From: Ashley Schmidt <ashley.schmidt@inmar.com>

Sent: Monday, December 30, 2019 5:57 AM

To: Dunn, Cynthia@CalRecycle <Cynthia.Dunn@CalRecycle.ca.gov>; Smyth, Jason@CalRecycle <Jason.Smyth@CalRecycle.ca.gov>

Cc: Domingo Isasi <domingo.isasi@inmar.com>

Subject: Thank you

[[EXTERNAL]]

Dear Cynthia and Jason,

Thank you for taking the time to meet with representatives of Inmar. We were pleased to have the opportunity to share information about the company and its interest in working collaboratively with CalRecycle to institute a compliant, cost-effective and successful drug take back program in California. Inmar is committed to implementing the requirements of SB 212 and addressing the regulatory needs of the Department. Because of its long standing relationships with the key stakeholders in the drug distribution space, Inmar can be highly effective in establishing a successful and compliant take back program in California.

In an effort to start a productive dialogue regarding implementation, we wanted to send you a few items for feedback and discussion. These initial items are as follows:

1. Inmar is planning to contract with each individual manufacturer and will be responsible for ensuring that they are compliant with the requirements of SB 212 and its implementing regulations. Inmar believes that as long as the company (program operator) obtains compliance with the statute and regulations, there will be no duplicative requirement for each manufacturer to individually meet the compliance standard as outlined in statute. Would CalRecycle agree with this assumption?

No, CalRecycle does not agree with this assumption.

“Program operator” means a covered entity, or stewardship organization on behalf of a group of covered entities, that is responsible for operating a stewardship program (section 42030(q) of the Public Resources Code). Therefore, unless Inmar is a stewardship organization, it cannot act on behalf of a group of covered entities to operate a singular stewardship program. A covered entity is required to, either individually or through a stewardship organization of which it is a part, pay all administrative and operational costs associated with establishing and implementing the stewardship program in which it participates. All program operators implementing a stewardship program, whether they are an individual covered entity, or a stewardship organization, must adhere to the applicable regulations and statute. Unless Inmar is structured as a 501(c)(3) as required of stewardship organizations pursuant to section 42031.4(b) of the Public Resources Code, each manufacturer that contracts with Inmar will be required to comply with all statutory and regulatory requirements, including submitting individual stewardship plans, annual budgets, and annual reports, even if they are duplicative with another covered entity’s documents.

Additionally, there are obligations under statute that a covered entity must follow that are outside of the requirements of a program operator as described in your scenario. A covered entity may be out of compliance with statute and regulations while a program operator is in compliance. For example, a stewardship organization may be operating its program pursuant to statute and regulations, but one of its member covered entities failed to send an annual list of covered products to the Board of Pharmacy. In this instance, the stewardship organization is compliant, and the covered entity is out of compliance.

2. Inmar will work with each manufacturer to submit a plan and an annual report to CalRecycle as required under the regulations. The company would like to discuss with CalRecycle how to most efficiently provide this information to CalRecycle so that is not duplicative and is the most easily reviewed and approved by the Department. Is CalRecycle open to further discussions to

ensure manufacturer compliance but also make the process efficient and workable for the Department?

See answer to question #1 regarding the statutory requirement that program operators must either be an individual covered entity or a 501(c)(3) stewardship organization operating on behalf of a group of covered entities.

We welcome your feedback if you have proposed language for an alternative we can consider for the regulations about potential plan, annual budget, and annual report efficiencies. During the formal 45-day comment period, we abstain from private discussions and address all feedback publicly. You may choose to email pharmasharps@calrecycle.ca.gov your suggested edits to the proposed regulations and a CalRecycle response will be provided on our [rulemaking webpage](#).

3. Inmar is looking for some clarification and further discussion regarding the alternative forms of collection referred to in the proposed regulations. Inmar would appreciate further direction and expectation regarding ensuring access by homebound and/or homeless individuals to take back options and the metrics by which weight measurements or other tracking of drugs received through the alternative options are needed. Is CalRecycle open to further discussions in this regard?

I believe this is in reference to section 42032.2(a)(1)(G)(i) of the Public Resources Code and addressed in section 18973.2(j)(4) of the proposed regulations regarding providing a mechanism to accept requests for mail-back materials to homeless, homebound, and disabled ultimate users through an internet website and toll-free phone number. Both the development of metrics used to measure the amount of materials distributed, and the weight of material disposed, are plan requirements. See section 18973.2(g)(5)(C) in the proposed regulations.

We welcome your feedback if you have proposed language for an alternative we can consider for the regulations about take back requirements, metrics, and tracking mechanisms. During the formal 45-day comment period, we abstain from private discussions and address all feedback publicly. You may choose to email pharmasharps@calrecycle.ca.gov your suggested edits to the proposed regulations and a CalRecycle response will be provided on our [rulemaking webpage](#).

These are just a few key items that Inmar is reviewing and looking for direction from CalRecycle in the near future. The company is committed to implementing a successful drug take back program in California that is compliant with state law and is hopeful they can work with the Department to do so.

Hope you all have had a great holiday and we look forward to talking with you in the new year!

Best Regards,

Ashley Schmidt

Domino Isasi

Ashley Schmidt

Director, Regulatory and Compliance



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From: Smyth, Jason@CalRecycle
Sent: Friday, February 14, 2020 3:51 PM
To: sgreen@lacsdc.org
Subject: RE: Question regarding Comment deadline

Sharon,

We will accept your written comments on the SB212 rulemaking on Feb 18th. Please submit them to pharmasharps@calrecycle.ca.gov.

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: Green, Sharon <SGreen@lacsdc.org>
Sent: Friday, February 14, 2020 1:56 PM
To: PharmaSharps <PharmSharps@calrecycle.ca.gov>
Subject: Question regarding Comment deadline

[[EXTERNAL]]

Hi there, I would like to know whether it is ok to submit written comments on the SB 212 rulemaking on Feb. 18th since Feb. 17th, the published written comment deadline, falls on a state and federal holiday. Thanks!

Sharon N. Green

Legislative & Regulatory Programs Manager | Technical Services Department
562-908-4288 ext. 2503 | C 562-447-3871 | sgreen@lacsdc.org

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