

5. Public Meeting for Approval to Formally Notice  
Proposed Regulation (10/15/2019)

- a. Request for Approval
- b. Monthly Public Meeting Agenda
- c. Listserv Notice

## REQUEST FOR APPROVAL

**To:** Scott Smithline  
Director

**From:** Matt Henigan  
Deputy Director  
Materials Management and Local Assistance Division

**Request Date:** October 15, 2019

**Decision Subject:** Request for Approval to Initiate Formal Rulemaking for  
Pharmaceutical and Sharps Stewardship Program

**Action By:** October 18, 2019

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### Summary of Request:

Staff request approval to begin the formal rulemaking process and formally notice the proposed regulations pursuant to the Pharmaceutical and Sharps Waste Stewardship Act [[Chapter 1004, Statutes of 2018 \(Jackson, Senate Bill 212\)](#)]<sup>1</sup>.

### Recommendation:

Staff recommend that the Director approve the proposed regulations for the Pharmaceutical and Sharps Waste Stewardship Act, and, upon approval of the Economic and Fiscal Impact Statement by the Department of Finance, direct staff to complete and file the rulemaking documents with the Office of Administrative Law (OAL) to initiate the formal rulemaking process.

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### Action:

On the basis of the information and analysis in this Request for Approval, and contingent upon the completion of the economic analysis required by the Department of Finance, I hereby approve the proposed regulations for the Pharmaceutical and Sharps Waste Stewardship Act and direct staff to forward the regulatory packet to the Office of Administrative Law to initiate the formal rulemaking process.

  
\_\_\_\_\_  
Scott Smithline  
Director

11-6-19  
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Dated

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<sup>1</sup> [http://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill\\_id=201720180SB212](http://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201720180SB212)

## **Attachments:**

Attachment 1 – Proposed Pharmaceutical and Sharps Waste Stewardship Regulations, available at: <https://www2.calrecycle.ca.gov/PublicNotices/Details/3777>

Attachment 2 – Comments in Response to CalRecycle’s First and Second Informal Rulemaking Workshops available at: <https://www2.calrecycle.ca.gov/Docs/Web/115746>

Attachment 3 – Comments in Response to CalRecycle’s Third and Fourth Informal Rulemaking Workshops available at: <https://www2.calrecycle.ca.gov/Docs/Web/115734>

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## **Background Information, Analysis, and Findings:**

Senate Bill (SB) 212 (Chapter 1004, Statutes of 2018) established the Pharmaceutical and Sharps Waste Stewardship Act (Act). The Act requires covered entities<sup>2</sup>, or stewardship organizations on behalf of a group of covered entities, to design, fund, and implement a stewardship program for the collection and end-of-life management of covered drugs and home-generated sharps waste. Covered entities or stewardship organizations (referred to as “program operators”) must submit stewardship plans, initial and annual program budgets, and annual reports to CalRecycle for review and approval. Prior to submittal to CalRecycle, program operators must submit stewardship plans to the State Board of Pharmacy (BOP), and any other applicable agency, for a determination of compliance or noncompliance with applicable rules and regulations under its purview. Lists of covered products and a list and description of any drugs or sharps that are not covered products, which are offered for sale in the state, must also be reported annually to the BOP.

Statute requires that a stewardship plan for covered drugs provides for a minimum of five authorized collection sites per county or one authorized collection site per 50,000 people, whichever is greater. A mail-back program must be provided for any counties where there is not a retail pharmacy operating as a collection site. Either prepaid, preaddressed mail-back materials or an alternative form of collection and disposal must be provided upon request from ultimate users who are homeless, homebound, or disabled. Additionally, alternative methods of collection must be provided to ultimate users of any 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.

Statute requires that a stewardship plan for home-generated sharps waste provides or initiates distribution of a sharps waste container and mail-back materials at the point of sale, at no cost to the ultimate user. All stewardship plans for sharps and/or pharmaceutical waste must include a comprehensive education and outreach program. Program operators are required to pay to the department a quarterly administrative fee

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<sup>2</sup> Covered entities are statutorily-defined in the following order as either a manufacturer of covered drug or sharp, distributor that is licensed as a wholesaler, repackager, owner or licensee of a trademark, or importer, responsible for selling covered products in or into the state.

adequate to cover any costs incurred by a state agency in administering and enforcing the provisions of the law, including CalRecycle and the BOP.

CalRecycle is required to adopt regulations for the implementation of the Act with an effective date of no later than January 1, 2021. Under the Act, the department is responsible for reviewing and approving, disapproving, or conditionally approving stewardship plans, initial stewardship program budgets covering the first five years of operations, annual reports, and annual budgets submitted by program operators. Fulfilling these responsibilities will require coordination with the BOP and other applicable agencies. CalRecycle will post on its website a list of all stewardship organizations, covered entities, authorized collection sites, retail pharmacies, and retail pharmacy chains, in compliance with the law. CalRecycle will also provide oversight and enforcement to ensure compliance with the law. CalRecycle will develop and post on its website, a report analyzing whether the program operator's stewardship program provides adequate access to safe disposal of home-generated sharps waste or covered drugs, as applicable, for the ultimate user within 12 months of a program operator submitting three complete annual reports.

Regulations are necessary to clarify and establish administrative procedures related to items as such as: definitions, criteria to determine a covered entity, and submittal instructions for stewardship plans, program budgets, and annual reports. The regulations also clarify recordkeeping requirements, the process to pay administrative fees to the department, product verification requirements for retailers, wholesalers, and distributors, and the process and criteria for imposing administrative penalties or revoking a plan for failure to meet a material requirement of the statute.

Staff initiated informal rulemaking activities immediately upon the law's effective date of January 1, 2019. Staff established a Pharmaceutical and Sharps Waste Stewardship web page and listserv to facilitate communication with interested stakeholders. Staff conducted informal public workshops on January 30, 2019 and February 27, 2019 to solicit stakeholder input regarding statutory terms and processes that might benefit from further definition and clarification through rulemaking. The input gathered through these workshops and from focused stakeholder meetings was taken into consideration in the preparation of the informal draft regulatory text. Staff conducted two additional informal public workshops on May 17, 2019 and June 17, 2019 to solicit feedback on the informal draft regulatory text. Comments received at the workshops, along with comments submitted during the public comment period, helped inform the proposed Pharmaceutical and Sharps Waste Stewardship Regulations (Attachment 1).

As part of the informal rulemaking process, staff also conducted extensive focused meetings with external stakeholders to better understand existing statutory, regulatory, and operational aspects of pharmaceuticals and sharps management and to understand different stakeholder perspectives and concerns. Staff met with state agencies including the BOP, the Department of Toxic Substances Control, the Department of Public Health, and several local jurisdictions that currently implement drug and/or sharps waste

disposal ordinances. Comments received during the informal regulatory period are posted on CalRecycle's pharmaceutical and sharps rulemaking webpage<sup>3</sup>.

The comments expressed most frequently by stakeholders regarding the draft informal regulatory text and staff's response are briefly summarized below:

- **Definitions.** Stakeholders suggested modifications, deletions, and additions of various definitions to more accurately describe aspects of the program. The tiered definition of a covered entity and criteria for determining a covered entity were the two most common clarification requests. The proposed regulations refer to the criteria for determining a covered entity set forth in the tiered definition of covered entity in statute. The term "Home-generated sharps waste" was included in the informal draft regulatory text and not included in the proposed regulations because the term caused confusion for stakeholders who work with elderly care facilities that are regulated by the Department of Public Health. "Significant change" was another statutory term of concern, as stakeholders do not want to be burdened by requirements that necessitate frequent reporting to CalRecycle for approval. The proposed regulations include a definition of "significant change" to provide needed clarity regarding when reporting to the department is required. The proposed regulatory text also clarifies the statutory phrase "provides or initiates distribution of a sharps waste container" in response to stakeholder comments that the phrase required clarification.
- **Protection of proprietary information.** Stakeholders expressed concerns regarding the security of confidential and proprietary information in documents provided by program operators to the department. Staff modified the proposed regulations to further clarify state policies and procedures regarding handling of proprietary, confidential, and trade secret information. The proposed regulations clarify that the submission of any program document that is believed to contain proprietary information shall be accompanied by a cover letter stating the justification for requesting confidentiality. CalRecycle will treat documents containing proprietary information as confidential to the extent allowed under Title 14 of the California Code of Regulations.
- **Budgets.** The proposed regulations contain nine separate budget categories that must be included in both the five-year initial program budget and subsequent annual budgets. The budget categories are included to clearly identify the expenses and revenues needed for the department to determine if the stewardship program's funding level is sufficient to operate over a multiyear period in a prudent and responsible manner. Some stakeholders commented that they would prefer fewer aggregated cost categories because they believe fewer cost categories sufficiently capture the core aspects of the program and that existing contracts do not include reporting requirements at this level of detail. Staff considered this comment and concluded that the cost categories are needed for the department to conduct its statutorily required review and determine whether the funding level is sufficient to operate the program over a multiyear period in a prudent and responsible manner.

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<sup>3</sup> <https://www.calrecycle.ca.gov/laws/rulemaking/pharmasharps>

- **Accessibility Standards.** Stakeholders expressed concern regarding submittal of compliant documents due to regulatory references to accessibility standards that were considered ambiguous. The proposed regulations address this concern by including a reference to the Web Content Accessibility Guidelines 2.0, or subsequent versions, which provides further clarity regarding the standards that are required for submitting compliant documents to CalRecycle.
- **Education and Outreach.** Some stakeholders commented that inclusion of the term “maximize” in the proposed regulations in reference to “maximize education and outreach efforts” goes above and beyond “comprehensive,” exceeds the department’s statutory authority, and may lead to an unattainable compliance obligation. Staff considered the comment and determined the term “maximize” is appropriate and necessary to ensure the education and outreach program meets the statutory requirements.
- **Mail-Back Materials Distribution.** Statute requires a stewardship program for home-generated sharps waste to provide or initiate distribution of mail-back containers and materials at the point of sale. Some stakeholders stated it is burdensome for retail pharmacies to maintain the supply of sharps waste containers and mail-back materials necessary for distribution at point of sale due to a lack of space and suggested the regulations provide flexibility regarding how a program could provide or initiate distribution. The proposed regulations clarify the term “provides or initiates distribution of a sharps waste container” so that a sharps waste container and mail-back materials are provided at the point of sale to the ultimate user, arranged at the point of sale to be sent to the ultimate user, or, if those options are not feasible, provided via other methods that are approved by the department in a stewardship plan. All methods emphasize convenience for and must be at no cost to the ultimate user.
- **Enforcement and verification.** Some stakeholders expressed concern that the requirements for retail pharmacies are overly burdensome. The informal regulatory text required retail pharmacies to monitor the department’s website for a list of compliant covered entities and stewardship organizations, obtain and keep a proof of website monitoring certificate, and report any covered products sold or offered for sale from non-compliant covered entities. To address this concern, the proposed regulations allow for a designated responsible party on behalf of a retail pharmacy to identify noncompliant covered products and to report the discovery to the department.

Subsequent to the Director's approval of the proposed regulations and pending the approval of the required Economic and Fiscal Impact Statement, staff will submit the complete regulatory package to the OAL. Once the OAL approves the regulatory package, staff will initiate formal rulemaking, beginning with a 45-day comment period. CalRecycle is required to adopt regulations with an effective date of no later than January 1, 2021.

Key dates for program implementation include:

- January 1, 2021 – Regulations must be effective
- July 2021 – Stewardship plans must be submitted to CalRecycle

- August 2021 – 30-day completeness review by CalRecycle
- November 2021 – 90-day review of a complete stewardship plan by CalRecycle
- Aug 1, 2022 – Programs must be fully implemented 270 days after stewardship plan approval

The length of the plan approval process will depend on whether stewardship plans are complete and sufficiently meet all statutory and regulatory requirements upon submittal. Staff anticipate that programs to collect and properly manage covered drugs and home-generated sharps waste will be in place statewide in late 2022/early 2023 at the earliest.

## Monthly Public Meeting

10:00 A.M., October 15, 2019  
Cal/EPA Building – Byron Sher Auditorium

### A. DIRECTOR'S REPORT

*Presentations or discussions by the Director and/or Executive Offices regarding department matters, legislative updates, public affairs, or initiatives.*

### B. PUBLIC COMMENT\*

*People may speak on any matter concerning CalRecycle with the exception of items appearing elsewhere on this agenda or items related to pending adjudicative (certification or enforcement) proceedings.*

\*Please note that while CalRecycle affords members of the public the opportunity to participate by Webcast, CalRecycle strongly encourages public comments to be made in person.

### C. PROGRAM AND ISSUE UPDATES

#### Action Items

No actions at this time

#### Information Items

Nothing to report at this time

### D. POLICY MANDATES/WORKSHOPS/RULEMAKING PROCEEDINGS

*Possible decisions or discussions by department staff regarding any order instituting a rulemaking proceeding to develop and adopt regulations and/or policy guidelines specifying the procedures to implement or revise program guidelines or requirements such as Product Stewardship, Commercial Recycling, Organics Roadmap or the 75% initiative.*

#### Action Items

1. Request for Approval to Initiate Formal Rulemaking for the Pharmaceutical and Sharps Waste Stewardship Program  
Department Staff Contact: [Jason.Smyth@CalRecycle.ca.gov](mailto:Jason.Smyth@CalRecycle.ca.gov)  
[Public Notice](#)

#### Information Items

1. Public Hearing on Regulations Concerning Designated Approved Collectors  
November 27, 2019 9:30AM-11:30AM ([Sacramento](#))  
Department Staff Contact: [Ana-Maria.Stoian-Chu@CalRecycle.ca.gov](mailto:Ana-Maria.Stoian-Chu@CalRecycle.ca.gov)



2. The Truth About Textiles Workshop  
December 3, 2019 10AM – 4:30PM (Sacramento) CalEPA Byron Sher Auditorium  
Department Staff Contact: [Tracey.Harper@CalRecycle.ca.gov](mailto:Tracey.Harper@CalRecycle.ca.gov)
3. The Request for Proposals for two 2020 Waste Characterization Studies (Disposal-Based Study and Commercial Generator-Based Edible Food Waste Study) are currently advertised and are due on November 8<sup>th</sup> at 2 pm. More information can be found on the [Contracts Home Page](#).  
Staff contact: [Jennifer.HaynesWhite@calrecycle.ca.gov](mailto:Jennifer.HaynesWhite@calrecycle.ca.gov)

#### **E. BEVERAGE CONTAINER RECYCLING PROGRAM**

***Possible decisions or announcements regarding BCRP matters including fund condition, rates, approval of new/renewed certifications, or enforcement actions.***

##### **Action Items**

No actions at this time

##### **Information Items**

1. Quarterly Certification & Registration Report  
Department Staff Contact: [Jennifer.Akins@calrecycle.ca.gov](mailto:Jennifer.Akins@calrecycle.ca.gov)
2. Recycling Program Enforcement Report  
Department Staff Contact: [Ben.Shelton@calrecycle.ca.gov](mailto:Ben.Shelton@calrecycle.ca.gov)
3. Quarterly Operations Report  
Department Staff Contact: [Mike.Miller@calrecycle.ca.gov](mailto:Mike.Miller@calrecycle.ca.gov)

#### **F. GRANT AND LOAN PROGRAMS**

***Possible decisions or overview regarding matters related to the used oil and household hazardous waste programs.***

##### **Action Items**

1. Eligibility Criteria and Evaluation Process for the Local Government Waste Tire Enforcement Grant Program (Tire Recycling Management Fund, Fiscal Years 2019-20 and 2020–21)  
Department Staff Contact: [Phanessa.Fong@CalRecycle.ca.gov](mailto:Phanessa.Fong@CalRecycle.ca.gov)  
[Public Notice](#)

##### **Information Items**

1. Awards and Distribution of Payments for the Used Oil Payment Program (Used Oil Recycling Fund, Fiscal Year 2019–20)  
Department Staff Contact: [Annabel.Farrall@CalRecycle.ca.gov](mailto:Annabel.Farrall@CalRecycle.ca.gov)  
[Public Notice](#)
2. Awards for the Tire Incentive Program Grants (Tire Recycling Management Fund, Fiscal Year 2019–20)  
Department Staff Contact: [Nicholas.Amante@CalRecycle.ca.gov](mailto:Nicholas.Amante@CalRecycle.ca.gov)  
[Public Notice](#)

3. Approval of Scope of Work for the Tire Market Analysis and Support Contract (Tire Recycling Management Fund, Fiscal Years 2019/20, 20/21, 21/22)  
Department Staff Contact: [Nathan.Gauff@calrecycle.ca.gov](mailto:Nathan.Gauff@calrecycle.ca.gov)  
[Public Notice](#)

## G. SOLID WASTE AND TIRE FACILITIES

***Possible decisions or reconsiderations to petitions for a facility or landfill permit or modification; and, possible determinations of enforcement actions, clean-up requirements; or LEA training.***

### **Action Items**

1. Mountain View Organic Waste Processing Facility – Ventura County, New Solid Waste Facilities Permit, Action Needed October 25, 2019  
Department Staff Contact: [Megan.Emslander@CalRecycle.ca.gov](mailto:Megan.Emslander@CalRecycle.ca.gov)  
[Public Notice](#)
2. CVT Regional Material Recovery Facility and Transfer Station – Orange County, Modified Solid Waste Facilities Permit, Action Needed November 3, 2019  
Department Staff Contact: [Megan.Emslander@CalRecycle.ca.gov](mailto:Megan.Emslander@CalRecycle.ca.gov)  
[Public Notice](#)

### **Information Items**

1. Awards for the Solid Waste Disposal and Codisposal Site Cleanup Program (Solid Waste Disposal Trust Fund, Fiscal Year 2018-2019)  
Department Staff Contact: [Rebecca.Oliver@CalRecycle.ca.gov](mailto:Rebecca.Oliver@CalRecycle.ca.gov)  
[Public Notice](#)

## H. COMPLIANCE AND ENFORCEMENT HEARINGS

***Hearings for Compliance and Enforcement matters and Administrative Appeals which are required to have a public hearing prior to the Department taking action***

### **Action Items**

No actions at this time

### **Information Items**

Nothing to report at this time

## I. LOCAL ASSISTANCE

***Possible approval or discussion of locally adopted planning documents, bi-annual reviews, compliance and enforcement actions, or other program-related proceedings.***

### **Action Items**

No actions at this time

**Information Items**

1. Approval of the 2016-17 Jurisdiction Review Cycle Findings For The Source Reduction And Recycling Element, Household Hazardous Waste Element, Mandatory Commercial Recycling Program, Mandatory Commercial Organics Recycling Program, And Approval Of Transformation Claim For The City of Garden Grove  
Departmental Staff Contact: [Jennifer.Caldwell@Calrecycle.ca.gov](mailto:Jennifer.Caldwell@Calrecycle.ca.gov)  
[Public Notice](#)

**J. ELECTRONIC WASTE RECYCLING PROGRAM**

***Possible decisions or overview regarding the reuse, recycling, and handling of covered electronic devices; including matters related to fees, recyclers, enforcement, claim reviews and adjustments.***

**Action Items**

No actions at this time

**Information Items**

Nothing to report at this time

**K. OTHER**

***Possible decisions or discussions regarding the development or implementation of a new or an amendment to policies and procedures for grants, loans and contracts. Please note that grants, loans, or scopes of work will be agendized specific to program area unless otherwise noted here.***

**Action Items**

No actions at this time

**Information Items**

Nothing to report at this time

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We want to assure all of our stakeholders that transparency and stakeholder involvement remains a high priority for CalRecycle. In keeping with a history of providing stakeholders with information about programs, activities, and departmental decisions, CalRecycle has a public noticing site. To review Final CalRecycle Decisions and other department activities, please go to: <http://www.calrecycle.ca.gov/Actions/> or <http://www.calrecycle.ca.gov/BevContainer/Notices>. For meeting participation, listserv, and feedback information, please go to: <http://www.calrecycle.ca.gov/PublicMeeting/>

## List Archive Message Details

### Pharmaceutical and Sharps Waste Stewardship

#### Message Details

**Sent On**

10/9/2019 9:12 AM

**Priority**

Normal

**From**

pharmasharps@calrecycle.ca.gov

**Subject**

Approval to Formally Notice Proposed Pharmaceutical and Sharps Waste Stewardship Regulations

#### Message

CalRecycle staff will present the Request for Approval (RFA) to initiate the formal rulemaking process and Proposed Regulations for the Pharmaceutical and Sharps Waste Stewardship Program at the October 15, 2019 CalRecycle Monthly Public Meeting, from 10:00 a.m. to 1:00 p.m. in the Bryon Sher Auditorium at the CalEPA Headquarters in Sacramento.

The RFA and Proposed Pharmaceutical and Sharps Waste Stewardship Regulations are posted at the following link:

(<https://www2.calrecycle.ca.gov/PublicNotices/Details/3777>)

The Pharmaceutical and Sharps Rulemaking page (<https://www.calrecycle.ca.gov/laws/rulemaking/pharmasharps>) contains related rulemaking information.

The monthly public meeting agenda will be posted on the Public Meeting page (<https://calrecycle.ca.gov/PublicMeeting/>), along with the link to the webcast and details for public participation.

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>.

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

Contact: Public Affairs Office (916) 341-6300