

SB 212: Informal Rulemaking

PHARMACEUTICAL AND SHARPS WASTE STEWARDSHIP

PUBLIC WORKSHOP #1: ARTICLES 1-3

A PRESENTATION FOR THE LOS ANGELES COUNTY SOLID WASTE TASK FORCE BY

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Key Components of SB 212:

SB 212 accomplished a

1. **Industry-operated and funded collection & disposal programs**
2. **Stewardship Plans**
3. **Minimum Convenience Standards**
 - A. Meds: at least 1 drug collection site for every 50,000 residents
 - B. Sharps: free mail back container at point of purchase
4. **Annual Budgets:** Can be audited to ensure assets are being used for specific purposes
5. **Annual Reports:** Annual filings are publicly disclosed
6. **Reimbursement of local jurisdiction collection programs**
7. **First to prevent promotion of disposal not in the program such as trashing or flushing!**
 - A. Covered entities cannot promote alternative disposal and undercut the stewardship programs.

SB 212 Implementation Timeline:

- ▶ 9/30/2018 SB 212 signed into law by the Governor
- ▶ 1/1/2019 Informal Rulemaking Begins
- ▶ 4/1/2019 Industry to Provide Lists of Covered Entities and Products to Board of Pharmacy
- ▶ 1/1/2021 CalRecycle to Adopt Regulations
- ▶ 7/1/2021 Stewardship Plans Due to CalRecycle
- ▶ 3/31/2022 Stewardship Organization to provide CalRecycle 1st Annual Report
- ▶ 1/2/2023 CalRecycle sets Administrative Fee for Agencies' Costs by FY 2022/2023

Outline of Draft Regulatory Concepts:

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Article 1. Definitions

Article 2. Covered Entities and Stewardship Organizations

Article 3. Stewardship Plans

Article 4. Reports, Budgets, and Records

Article 5. Financial Provisions

Article 6. Enforcement

Article 7. Miscellaneous Provisions

Article 1. Definitions

1. **Covered entity** – § 42030.(f)(1)(A)-(E)
 - A. (A) Manufacturer, (B) Distributor, (C) Repackager, (D) Owner/Licensee, (E) Importer
2. **Administrative and Operational Costs** – § 42032.2.(a)(1)(D)
 - A. Demonstrate adequate funding for all administrative and operational costs of the stewardship program, to be borne by participating covered entities.
3. **Significant change** – § 42032.(e)
4. **Homebound** – § 42032.2.(a)(1)(G)(i)
5. **Technically feasible** – § 42032.2.(a)(1)(G)(ii)
6. **Good faith negotiations** – § 42032.2.(b)(1)
7. **Reasonable effort** – § 42032.2.(b)(2)

Article 1. Questions for Stakeholders:

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1. Are there other terms from Articles 1-3 that will need to be clarified and/or defined?
2. Regarding “covered entity” are there terms within the tiered definition that should be clarified?
3. Are any of the examples provided here sufficient?
 1. Mattress, Paint, Carpet, Medicare, etc.
4. Do you have revisions that would make any of the examples sufficient?
5. Do you have suggested example definitions?

Article 2. Covered Entities and Stewardship Organizations

Criteria for Determining Covered Entity – Questions for Stakeholders

1. Where do online sales fit in this process?
2. Where do Reverse Distributors fit in this process? Under what circumstances should a Reverse Distributor be considered a Manufacturer of covered drugs?
3. Where would a retail pharmacy chain that is also a “Repackager” of covered drugs fall within the tiered definition?

Article 2. Covered Entities and Stewardship Organizations

Outreach and Education – Questions for Stakeholders:

1. Is any additional clarification to “comprehensive education and outreach program” needed?
2. What other outreach materials may be necessary? E.g., media ads, bilingual materials, video, etc. Does this need to be specified in regulation?

Article 3. Stewardship Plans:

CalRecycle suggests the following eight processes relating to Stewardship Plans require clarification in regulation:

1. Format of Submittal
2. Submittal of Proposed Pharmaceutical and Sharps Waste Stewardship Plan(s) to Board, and Other Applicable Agencies
3. Agency Determinations
4. Timeline for Resubmittal of Proposed Plans
5. Certification that Plan Meets Applicable Laws and Regulations
6. Pharmaceutical and Sharps Waste Stewardship Plan Submittal to Department
7. Plan Requirements for Covered Drugs
8. Criteria for Plan Approval of Home-Generated Sharps Waste

1. Format of Submittal

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1. Example of format requirements from Used Mattress Recovery and Recycling Program 14 CCR § 18961:

1. Name of Stewardship organization
2. Contact Information for each manufacturer (e.g., name and mailing address, Web address, etc.)
3. Electronic submittal, accompanied by a hard copy submittal letter with signature
4. Other information, upon request from the department, including contact information for all participating stewardship organization members.

Questions for Stakeholders:

1. Are there other elements that ought to be included in the format of the Plan submittal?
2. Are there formats from existing local ordinances that the department ought to consider?

2. Submittal of Proposed Pharmaceutical and Sharps Waste Stewardship Plan(s) to Board, and Other Applicable Agencies

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§ 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

Questions for Stakeholders:

1. **What other applicable agencies may have authority relative to the Plan?**
 - A. **Department of Public Health?**
 - B. **Department of Toxic Substance Control?**
 - C. **United States Drug Enforcement Agency?**
 - D. **Other Law Enforcement Agencies?**

3. Agency Determinations

§ 42032.(b)(2) An agency that receives a plan shall review the plan for compliance with state and federal laws and regulations related to the agency's respective authority. The agency shall determine compliance or noncompliance with those laws and regulations, and provide to the program operator that **determination** and an explanation for any finding of noncompliance, within 90 days of receipt of the plan.

Questions for Stakeholders:

1. What information should be included in a determination and what is an acceptable form (e.g, a letter from the Director of the applicable agencies)?

4. Timeline for Resubmittal of Proposed Plans

§ 42032.(b)(3) A program operator may submit an updated proposed plan to an agency that issued a determination of noncompliance to attempt to obtain a determination of compliance. A program operator shall submit any determination received from an agency when it submits its stewardship plan to the department.

5. Certification that Plan Meets Applicable Laws and Regulations

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§ 42032.(b)(4) 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.

Questions for Stakeholders:

1. Ought an entity other than the program operator issue the certification? If so, who ought to issue certifications?
2. What information ought to be included in a certification submitted by a Program Operator and what is an acceptable form (e.g, a letter, e-mail, etc.)?
 - A. What are specific laws and regulations that a plan may need to certify compliance with for pharmaceutical and sharps plans that may need to be included in the certification?
3. What happens if the department or Board determines that the certification was made in error and the plan is not applicable with another law or regulation?

6.a. Pharmaceutical and Sharps Waste Stewardship Plan Submittal to Department

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Questions for Stakeholders:

Ought there be a limit on how many times a plan can be returned for completeness deficiencies?

6.b. Plan Approval Process

Questions for Stakeholders:

CalRecycle observes the need for a timeline and process for resubmittal following conditional approval or disapproval for a stewardship plan, similar to the Mattress and Paint Recovery Programs

1. Do the Mattress and Paint Recovery Program provide a good basis for the plan approval and process timelines in § 42032(d)(1)?
2. Do you have revisions that would improve either of the examples?
3. Do you have another suggested approach for the plan resubmittal timelines?

7.a. Plan Requirement for Covered Drugs

Questions for Stakeholders:

1. How will the stewardship organization identify which drugs cannot be accepted or commingled with other covered drugs?
 - A. Ought the process used to conduct this analysis be included in a stewardship plan?
2. Does the term “technically feasible” need to be further defined?
3. What are examples of when an alternative method would be necessary?
 - A. How many alternative methods of collection ought be provided?
4. What provisions are necessary to consider for expansion into a jurisdiction in the event the ordinance is repealed?

7.b. Authorized Collectors

§ 42032.2(b)(1) ...If a potential **authorized collector** expresses interest in participating in a stewardship program, the program operator shall commence **good faith** negotiations with the potential authorized collector within 30 days.

(2) A retail pharmacy shall make a **reasonable effort** to serve as an authorized collector as part of a stewardship program in the county in which it is located.

Questions for Stakeholders:

1. What form of documentation ought to be submitted to demonstrate “good faith” and “reasonable effort?”

8.a. Plan Requirements for Home-Generated Sharps Waste

Questions for Stakeholders:

1. What are examples of when mail-back materials would not be permitted under the law?
2. Is clarification needed regarding container volumes and corresponding “sufficient time periods”?
3. What provisions are necessary to consider for expansion into a jurisdiction in the event the ordinance is repealed? (note: this question applies to both pharmaceutical and sharps plans)

8.b. Reimbursement of Costs to Local Jurisdictions

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§ 42032.2(d)(1)(F)(ii) 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.

Questions for Stakeholders:

1. Do any of the processes here require clarification in regulation or ought the Department require the Stewardship Organization to establish reimbursement requirements in its Plan? E.g., How often ought a request for reimbursement be allowed? Monthly? Quarterly? What information needs to be included in the reimbursement request?
2. What services must the program offer to provide to remove home-generated sharps waste from a household hazardous waste facility?

CalRecycle Regulatory Process

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Next Steps:

- ▶ 2/27/2019 Informal Rulemaking Workshop #2: Articles 4-7
- ▶ 4-5/2019 Informal Rulemaking Workshop #3: Draft Regulatory Text
- ▶ 5-6/2019 Informal Rulemaking Workshop #4: Draft Regulatory Text
- ▶ 10/2019 Begin Formal Rulemaking
- ▶ 1/1/2021 Adopt Final Regulations

- ▶ PharmaSharps@CalRecycle.ca.gov
- ▶ <https://www2.calrecycle.ca.gov/Listservs/Subscribe/73>

6.b. Plan Approval Process

§ 42032.(d)(1) The department shall review a complete submitted stewardship plan and shall approve, disapprove, or conditionally approve the plan within 90 days of receipt of the complete plan.

(2) The department may consult with, or submit a stewardship plan for review to, the state board or another state agency it determines is necessary to determine the completeness of the stewardship plan or for making a determination on the approval of the stewardship plan or an amendment to the stewardship plan. The duration of time that the department takes to review a stewardship plan pursuant to this paragraph shall not count toward the 90-day time limit specified in paragraph (1).

(e) A program operator shall submit any significant changes to a stewardship plan in writing for approval by the department, and shall not implement the changes prior to that approval.

(f) (1) If the department disapproves a submitted stewardship plan pursuant to subdivision (d), the department shall explain, in writing within 30 days, how the plan does not comply with this chapter, and the program operator shall resubmit a revised plan to the department.

(2) If the department finds that the revised stewardship plan submitted by the program operator does not comply with the requirements of this chapter and disapproves the plan, the covered entity operating its own stewardship program, or the stewardship organization and the covered entities that are members of the stewardship organization, are not in compliance with this chapter until the program operator submits a plan that the department approves.

6.b. Example: Used Mattress Recovery and Recycling Program

14 CCR § 18962(d) If the department conditionally approves a plan, the department shall identify the deficiencies in the plan and the mattress recycling organization shall comply with the conditions of approval within not less than 60 days or as determined by the director of the notice date. If the conditions are met, the department shall approve the plan.

(e) If the department conditionally approves a plan and the conditions are not met, the department shall disapprove the plan.

(f) If the department disapproves a plan, the department shall identify the deficiencies in the plan and the mattress recycling organization shall resubmit a plan or provide supplemental information requested within not less than 60 days of the notice date or as determined by the director.

(g) The mattress recycling plan shall be submitted for re-approval upon any significant or material change, as defined. The department shall review the revised plan within 90 days of receipt. The department may approve, disapprove, or conditionally approve the revised plan. The department may also require the mattress recycling organization to resubmit a revised mattress recycling budget if there is a significant or material change, as defined.

6.b. Example: Architectural Paint Recovery Program

14 CCR § 18953(B) If the department conditionally approves a plan, the department shall identify the deficiencies in the plan and the manufacturer or stewardship organization shall comply with the conditions of approval within 60 days of the notice date. If the conditions are met, the department shall approve the plan.

(C) If the department disapproves a plan, the department shall identify the deficiencies in the plan and the manufacturer or stewardship organization shall resubmit a plan or provide supplemental information requested by within 60 days of the notice date.

(D) If the department conditionally approves a plan and the conditions are not met, the department shall disapprove the plan.

(4) The stewardship plan must be submitted for re-approval upon any significant or material change, as defined. The department shall review the revised stewardship plan within 90 days of receipt and make a determination whether or not to approve the plan.