

SB 212:

Informal Rulemaking

PHARMACEUTICAL AND SHARPS WASTE STEWARDSHIP

PUBLIC WORKSHOP #2: ARTICLES 4-7

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
 - Meds: at least 1 drug collection site for every 50,000 residents
 - Sharps: free mail back container at point of purchase
4. Annual Budgets:
5. Annual Reports:
6. Reimbursement of local jurisdiction collection 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 4. Reports, Budgets, and Records

A. Initial and Annual Budget

The law requires a program operator to submit an initial budget for the first five years and annually.

➤ CalRecycle Questions and Stakeholder Input:

1. Budget categories?

- Yes - collection, transportation, processing , disposal, capital costs, etc.

2. “Prudent and responsible” - Include a specific reserve level?

- Yes

B. Annual Report

The law requires a program operator to submit an Annual Report

➤ **CalRecycle Questions and Stakeholder Input:**

1. **What are all the elements needed in the report?**

- **Pharmaceuticals - Number and size of bins, distribution locations, volume/weight.**
- **Sharps – Number of mail-back kits/containers provided and returned, return rates, distribution locations of kits.**

C. Records

The law requires a program operator shall keep minutes, books, and records - audited by an independent CPA.

- **CalRecycle Questions and Stakeholder Input:**
 1. Keep records as required by the Medical Waste Management Act, and Chain of Custody.

D.-F. Audits, Local Reimbursement, CalRecycle Analysis & Reports

- CalRecycle does not suggest that these sections require clarification; it is included here for purposes of reviewing the article in its entirety.

Article 5. Financial Provisions

A. Costs and Fees

Covered entities/stewardship organization pay all costs including collecting, transporting, and disposing of covered products.

Program operator to pay to CalRecycle a set administrative fee which may be used for all costs for regulating this bill.

- CalRecycle does not suggest that this section requires clarification; it is included here for purposes of reviewing the article in its entirety.

B. Stewardship Organization Audit of Covered Entities

The law requires a stewardship organization may conduct an audit of covered entities and authorized collectors to verify the fees and charges submitted are proper and accurate.

An audit shall (1) Hire an independent third-party auditor to conduct the audit. (2) Provide a copy of the audit to the department.

➤ CalRecycle Questions and Stakeholder Input:

1. An audit ought to be conducted on an annual basis, and provided to CalRecycle within 90-120 days after it is completed.

Article 6. Enforcement

A. Monitoring

The Law requires all distributors/wholesalers/retailers shall monitor CalRecycle's Web site to determine which covered entities and stewardship organizations are identified and in compliance.

- CalRecycle Questions and Stakeholder Input:
 - CalRecycle ought to establish a Login Portal for entities that tracks their usage time.
 - Require entities to check at least twice per year.

B. Inspection

All covered entities shall provide CalRecycle with access to its facilities and operations, and relevant records necessary to determine compliance for a minimum of three years.

- **CalRecycle Questions and Stakeholder Input:**
 1. Most inspection done via records keeping.
 2. Are there other oversight agencies with requirements for recordkeeping?
 3. On site inspections can utilize the existing federal label tracking system to double-check.

C. Penalties

CalRecycle may impose penalties on any covered entity, program operator, stewardship organization, retailer, or authorized collector.

- Shall not exceed ten thousand dollars (\$10,000) per day unless the violation is intentional, knowing, or reckless, in which case the administrative penalty shall not exceed fifty thousand dollars (\$50,000) per day.
- CalRecycle Questions and Stakeholder Input:
 1. Make sure everything is clear, what is expected and penalties. Develop criteria.

D. Handling, Transport and Disposal

All handling, transport, and disposal undertaken as part of a stewardship program under this chapter shall comply with applicable state and federal laws.

➤ CalRecycle Questions and Input from Stakeholders

1. There are various Federal (FDA, Fed. EPA) and State (BoP, DTSC, etc.) entities that provide regulatory oversight of both the pharmaceutical and sharps industries.
2. CalRecycle ought to work with applicable agencies.

Article 7. Miscellaneous Provisions

A. Preemption

- Under section 42036.2. (a) This chapter does not apply to an ordinance that took effect before April 18, 2018, but may continue without reimbursement.
- (b) This chapter shall preempt a local stewardship program on or after April 18, 2018.
- CalRecycle does not suggest that this section requires clarification; it is included here for purposes of reviewing the article in its entirety.

CalRecycle Regulatory Process

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Next Steps:

- ▶ 4-5/2019 Informal Rulemaking Workshop #3: Draft Regulatory Text Northern California
- ▶ 5-6/2019 Informal Rulemaking Workshop #4: Draft Regulatory Text Southern California
- ▶ 10/2019 Begin Formal Rulemaking
- ▶ 1/1/2021 Adopt Final Regulations

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