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California Department of Resources Recycling
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Senate Bill 212 Team
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Sent via PharmSharps@calrecycle.ca.gov

INFORMAL RULEMAKING – COMMENTS ON ARTICLES 1- 7 OF SENATE BILL 212 DRAFT REGULATORY CONCEPTS

The Los Angeles County Solid Waste Management Committee/Integrated Waste Management Task Force (Task Force) supports Senate Bill 212 (SB 212) Pharmaceutical and Sharps Waste Stewardship Program (2018) and is grateful for the opportunity to comment in CalRecycle's Informal Rulemaking process to develop a Draft Regulatory Text.

<https://www2.calrecycle.ca.gov/publicnotices/details/3577>

<https://www2.calrecycle.ca.gov/PublicNotices/Details/3622>

As passed, SB 212 requires “covered entities” to create a stewardship program, either individually or through a stewardship organization, and that the program plan has to be approved by CalRecycle. The law expands upon much needed safe and convenient disposal options for home-generated pharmaceutical drug and sharps waste.

It is our understanding that CalRecycle will begin the SB 212 Formal Rulemaking in October of 2019 with an adoption deadline of January 1, 2021.

As required by SB 212, the Stewardship Plans are due to CalRecycle by July 1, 2021, and Stewardship Organization(s) are to provide CalRecycle their 1st Annual Report by March 31, 2022.

The Task Force would like to offer the following comments regarding the subject Draft Regulatory Concepts:

Article 1. Definitions

“Covered Entity”: § 42030.(f)(1)(A)–(E). Online pharmaceutical and sharps sellers ought to be included and ought to have to pay for a stewardship program or into a stewardship organization.

“Significant Change”: § 42032.(e). The definition from the mattress program needs improvement. We suggest this include any changes to the education program, collection frequency, disposal methods, etc.

“Good faith negotiations”: § 42032.2.(b)(1). The definition ought to ensure no barriers to entry into the program by potential authorized collectors and ought to be demonstrated by a concerted effort to contact potential and interested authorized collectors by efforts including but not limited to, email, mail, phone and site visits to assist and encourage a convenient path to participation. Counties and State representatives, and stakeholders, ought to have the opportunity to review these efforts for accountability. These entities should also need to have the opportunity to review material(s) provided to potential and interested authorized collectors to evaluate that it clearly presents participation benefits and obligations and does not suggest obstacles to participation in contradiction to the statute and regulations.

Article 2. Covered Entities and Stewardship Organizations

A. Criteria for Determining a Covered Entity § 42030(f)(2).

Online sales could potentially be monitored by a stewardship organization as it would be in their best interest to have participation from all the online retailers to ensure there are no free riders not paying their fair share of stewardship programming. Online sales of pharmaceuticals would be eligible for any drop-off bins, and those businesses that complete online sales would be “covered entities” that would pay for a stewardship program. Online sales of sharps into California would need to be accompanied with an appropriate mail back kit.

B. Education and Outreach Program § 42031.6(a)

A successful comprehensive education and outreach program is achieved with proven results (i.e. surveys/data showing the program’s success with pre- and post- campaign data). Increasing awareness of proper methods of disposal ought to include through educational presentations at schools, senior centers, and public health facilities. Each program ought to have a toll-free number to call and receive help and public education

materials in the 13 threshold languages in California. A sharps program ought to include targeted education and access for the homeless population.

Other outreach materials could include:

- Media ads in various locations (multiple languages) – local newspapers, community newsletters, billboards, bus stop benches
- Social Media ads: Facebook, Snapchat, Instagram, and neighborhood apps such as Nextdoor (and any other future social media avenues)
- Share quick facts
- Brochures
- Flyers
- Videos including YouTube
- Internet interfaces and bilingual materials in the 13 threshold languages of LA County,
- An easy to navigate search engine allowing residents to quickly locate participating drop off locations, their current status, or alternative methods for proper disposal, truly in the various languages (often translation is not true, complete, nor interactive equal to the English version)
- An app to quickly locate a drop off location and their current status, truly in the various languages
- Work with influencers in communities, big names, to get the word out
- Child friendly outreach material

Article 3. Stewardship Plans

CalRecycle recommends eight processes related to the Stewardship Plans require clarification in the Regulations. We recommend that in addition to the stated eight processes, CalRecycle ought to adopt a ninth process and timelines for submissions, reviews, and decisions on “significant changes” submitted by a program operator for approval. “Significant changes” to this public health and solid waste management program ought to be made public and properly vetted by all stakeholders, i.e. local jurisdictions, before CalRecycle decides on approval.

A. Submittal of Proposed Pharmaceutical and Sharps Waste Stewardship Plan(s) to Board, and Other Applicable Agencies § 42032(b)(1)

It is the responsibility of the stewardship operator to be aware of and comply with all regulations that apply to it. However, since CalRecycle is the lead agency that is responsible to make sure that all aspects of the process are coordinated with all other agencies, as a courtesy, CalRecycle ought to contact all state and federal agencies to see if they have authority, their relevance, the process for submitting, and the standards for approval from that agency. CalRecycle ought to make available a checklist of this

information to stewardship operators for their reference, however, the information is subject to change without notification, and again, it is the responsibility of the stewardship operator to be aware of and comply with all regulations that apply to it.

B. Program Operator Certification that Plan Meets Applicable Laws and Regulations
§ 42032(b)(3)

CalRecycle ought to make it very clear that while a program operator can self-certify for lack of response from an agency after 90 days, if they are in fact found to be not in compliance, for whatever reason, they will still be held accountable the day after the one-year date from the adoption of the Regulations, and all applicable fines will apply.

C. Pharmaceutical and Sharps Waste Stewardship Plan Submittal to Department. Plan Completeness Process:
§ 42032(c)(1)

A plan ought to be limited to two submittals. CalRecycle ought to make it very clear that while a program operator can resubmit a plan, they are still accountable to fully implement operations in compliance one-year from the adoption of Regulations, and if they are not in compliance by that date, for whatever reason, all applicable fines will apply.

D. Plan Requirements for Covered Drugs
§ 42032.2.(a)(1)

Why would all drugs not be accepted? Comingling restrictions ought to be determined by the manufacturer based on safety and identify any potential chemical reactions. The analysis ought to be included in the plan to provide the necessary information for making an approval decision.

E. Reimbursement of Costs to Local Jurisdictions.
§ 42032.2(d)(1)(f)(ii)

A stewardship program can provide for the removal of the home-generated sharps waste from a local household hazardous waste (HHW) facility, otherwise, upon request by a local jurisdiction, the program must provide for reimbursement to local agencies for disposal costs related to home-generated sharps waste. Program operators ought to coordinate with local jurisdictions and each HHW facility to determine which option is more effective and this ought to be included in the stewardship plan and annual reports. Regulations need to allow for local jurisdictions to determine and specify the frequency of collection required based on quantities received at each HHW facility. Transportation of

sharps collected at and from mobile events to permanent facilities ought to be eligible for reimbursement.

Article 4. Reports, Budgets, and Records

A. Initial Pharmaceutical and Sharps Waste Stewardship Organization Program Budget § 42033.

The Regulations ought to include that a stewardship organization has to maintain and safeguard reports, budgets and records for CalRecycle to ensure its program is being operated in a fair and equitable manner. Details and budget costs ought to be clarified as is usual and customary for a 501(c)3 non-profit organization for public transparency, effective oversight by CalRecycle and all other applicable regulatory agencies, and for efficient and effective operation including individual bidding and better cost control. A program operator is to submit an initial budget for the first five years and annually with reporting of collection, transportation, processing, disposal, capital costs, etc.

B. Annual Pharmaceutical and Sharps Waste Stewardship Organization Program Budget § 42033.2 (c)

The budget's reserve level should be set such that the program will not be interrupted by financial issues, thereby causing a disruption in the service being provided to the consumer. Whether that reserve level be set at six months or one year of operating expenses should be assessed and maintained to guarantee seamless disposal service at optimum levels. This assessment could draw upon best practice modeling and include contingency for continuance of service through a transition period from one stewardship organization to another, should that transition be necessary.

C. Pharmaceutical and Sharps Waste Stewardship Organization Annual Report § 42033.2 (b)

The Stewardship organization ought to report on their progress towards the convenience standard and explain in writing as to the cause when they are not complying with the standard. The organization should provide as much education and outreach materials as possible to show they are informing the public of the existence of the bins, where they are located, and how to use them. They should also provide CalRecycle with education and outreach materials for recruitment of bin hosts to show they are reaching out to all pharmacies and how they are portraying the program. Annual Report ought to include accessibility and effectiveness measurements: for Pharmaceuticals progress towards convenience standards, and for Sharps distribution of mail-back kit comprehensiveness,

and for both other mandated elements such as education and outreach, and effective rates of collection.

D. Records
§ 42033.4

In addition to maintaining minutes, books, and records that clearly reflect the activities and transactions of the stewardship program, documentation ought to include all records specifically relevant for all applicable regulatory agencies such as is required with the Medical Waste Management Act and Chain of Custody for pharmaceuticals. A copy of the audit should be provided each calendar year upon submittal of the annual report, or as determined by CalRecycle to be most prudent.

Article 5. Financial Provisions

C. Stewardship Organization Audit of Covered Entities
§ 42034.4.(a)(1)

CalRecycle as part of setting up a data system for information related to this program should include a log-in user profile type interface that will track what pages and documents have been accessed/viewed by the user and record such actions for future reference. This log-in process should be mandatory for any entities that are subject to compliance under this program.

Article 6. Enforcement

§ 42035., § 42035.2., § 42035.6., § 42035.8.

Ensure that all expectations, specifics for compliance, and timelines for correcting violations to compliance are clearly identified. CalRecycle to review other applicable agencies such as the Board of Pharmacy, FDA, and DTSC requirements for recordkeeping and access to determine requirements for this regulation along with applicable agencies to determine what aspects and process ought to be included for consistency.

Pursuant to Chapter 3.67 of the Los Angeles County Code and the California Integrated Waste Management Act of 1989 (Assembly Bill 939), the Task Force is responsible for coordinating the development of all major solid waste planning documents prepared for the County of Los Angeles and the 88 cities in Los Angeles County with a combined population in excess of ten million. Consistent with these responsibilities and to ensure a coordinated and cost-effective and environmentally sound solid waste management system in Los Angeles County, the Task Force also

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addresses issues impacting the system on a countywide basis. The Task Force membership includes representatives of the League of California Cities-Los Angeles County Division, County of Los Angeles Board of Supervisors, City of Los Angeles, waste management industry, environmental groups, the public, and a number of other governmental agencies.

We respectfully request CalRecycle address these comments, concerns, and recommendations in the first Draft Regulatory Text. If you have any questions regarding these comments, please contact Mr. Mike Mohajer, a member of the Task Force, at MikeMohajer@yahoo.com or at (909) 592-1147.

Sincerely,



Margaret Clark, Vice-Chair
Los Angeles County Solid Waste Management Committee/
Integrated Waste Management Task Force and
Mayor Pro Tem, City of Rosemead

EC:pg:cso

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cc: Senator Jackson
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California State Association of Counties
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South Bay Cities Council of Governments
Gateway Cities Council of Governments
Westside Cities Council of Governments
Each City Mayor and City Manager in the County of Los Angeles
Each City Recycling Coordinator in Los Angeles County
Each Member of the Los Angeles County Solid Waste Management Committee/
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