Senate Bill 212 Pharmaceutical and Sharps Waste Stewardship Program
January 30, 2019 Informal Rulemaking Workshop #1

Discussion Document

Governor Brown signed **Senate Bill (SB) 212 (Jackson, Chapter 1004, Statutes of 2018)** on September 30, 2018 to establish safe and convenient disposal options for home-generated pharmaceutical drug and sharps waste. CalRecycle is required to adopt regulations for the implementation of SB 212.

This document is intended to guide initial stakeholder discussion to solicit input regarding statutory terms and processes that should be defined and clarified through rulemaking within Articles 1-3. Text in a gray box contains the statutory reference and is followed by questions for stakeholder input. In some cases, examples of existing regulatory language is provided to guide discussion. A second informal rulemaking workshop will be held on February 27, 2019 to solicit stakeholder input on Articles 4-7. CalRecycle will use the input provided from the January and February workshops to prepare the draft regulatory text.

The outline below includes an initial list of statutorily-mandated elements that may need clarification:

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- Timeline
- Article 1. Definitions
- Article 2. Covered Entities and Stewardship Organizations
    - Submittal of Manufacturer Product Lists
    - Criteria for Determining Covered Entity
    - Education and Outreach
- Article 3. Stewardship Plans
    - Plan Submittal to Board, Department, et al
    - Requirements and Process for Plan Approval

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- Article 4. Reports, Budgets, and Records.
- Article 5. Financial Provisions
- Article 6. Enforcement
- Article 7. Miscellaneous Provisions

I. ARTICLE 1. DEFINITIONS

CalRecycle staff identified the following terms that may benefit from further clarification in regulations and have included some definitions from other Programs as examples. Additionally, terms that are not defined in statute are described within the context of the statutory citation where they are located.

- **Covered Entity**: § 42030.(f)(1)(A)–(E). See page 4

- **Administrative and Operational Costs**: § 42032.2.(a)(1)(D). Demonstrate adequate funding for all administrative and operational costs of the stewardship program, to be borne by participating covered entities.

  Examples of existing related definitions include:
  Used Mattress Recovery and Recycling Program 14 CCR § 18960(d): "**Operational costs**" means costs to operate a mattress recycling organization's mattress recycling program, including, but not limited to, collection, transportation, processing, disposal, and education and outreach costs.

  Architectural Paint Recovery Program 14 CCR § 18951(b): "Administrative fee" means the fee imposed by the department on the architectural paint manufacturer or stewardship organization in order to cover the costs of administering and enforcing the statute.

  Product Stewardship for Carpets 14 CCR § 18941(b): "**Administrative fee**" means payments from the carpet assessment to the department that cover the costs of its administrative, oversight, and enforcement services necessary for manufacturers or stewardship organizations to effectively implement carpet stewardship plans. The administrative fee will be paid by the individual manufacturer or stewardship organizations submitting a stewardship plan.

- **Significant Change**: § 42032.(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.

  Example of an existing definition:
  Used Mattress Recovery and Recycling Program 14 CCR § 18960(e): "Significant or material change" includes a change in a required element of the used mattress recovery and recycling plan that affects the organization's costs or revenues, such as a change that results in a modification of the recycling charge, a change that requires a party other than the mattress recycling organization to make a major change in how it participates in the program, or a change that reduces the goals set for the organization in the existing approved recycling plan.

- **Homebound**: § 42032.2.(a)(1)(G)(i). Permit an ultimate user who is a homeless, homebound, or disabled individual to request prepaid, preaddressed mailing envelopes, or an alternative form of a collection and disposal system, as described in paragraph (2) of subdivision (c), that would render the covered drug inert. A program operator shall accept that request through an Internet Web site and toll-free telephone number that it shall maintain to comply with the requests.

  Example of an existing definition:
  Medicare Definition of Homebound: Normally unable to leave home unassisted. To be homebound means that leaving home takes considerable and taxing effort. A person may leave home for medical treatment or short, infrequent absences for non-medical reasons, such as a trip to the barber or to attend religious service. A need for adult day care doesn't keep you from getting home health care.

- **Technically feasible**: § 42032.2.(a)(1)(G)(ii). Provide alternative methods of collection from ultimate users for 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, to the extent **technically feasible** and permissible under applicable state and federal law, including, but not limited to, United States Drug Enforcement Administration regulations.

- **Good faith negotiations**: § 42032.2.(b)(1). At least 120 days before submitting a stewardship plan to the department, the operator of a stewardship program for covered drugs shall notify potential authorized collectors in the county or counties in which it operates of the opportunity to serve as an authorized collector for the proposed stewardship program. 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.

- **Reasonable effort**: § 42032.2.(b)(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. If the minimum threshold described in clause (i) of subparagraph (F) of paragraph (1) of subdivision (a) is not met in each county in which a retail pharmacy chain has store locations, the retail pharmacy chain shall have at least one location or 15 percent of its store locations, whichever is greater, in that county serve as authorized collectors in a stewardship program.

Questions for Stakeholders

1. Are there other terms from Articles 1-3 that will need to be clarified and/or defined?
2. Are any of the examples provided here sufficient? Do you have revisions that would make any of the examples sufficient?
3. Do you have suggested example definitions?

II. PROPOSED REGULATORY SECTIONS (IN ADDITION TO DEFINITIONS)

Several elements of the law will require clarification and processes outlined in order for successful development, implementation, oversight, and enforcement of the pharmaceutical and sharps stewardship program(s). This will include clarifying the appropriate responsible entities and the roles and responsibilities of the oversight agencies, as well as the identified Stewardship Organizations.

A. Article 2. Covered Entities and Stewardship Organizations

1. Submittal of Covered Product Lists to the State Board of Pharmacy[1]

§ 42031.(a)–(g): requires that covered entities submit a list of covered products to the Board of Pharmacy to be reviewed and verified, and outlines a process for manufacturers to appeal the determination that their product(s) be included in a Stewardship Plan.

Remarks to be made from Tom Lenox, Board of Pharmacy

[1] Submittal of Covered Products will not be part of the CalRecycle regulatory process but is included here as it is part of the overall statutory process.

2. Criteria for Determining a Covered Entity

§ 42030(f)(2). The department shall adopt regulations on the process for determining what entity is a covered entity following the priority order set forth in paragraph (1).

§ 42030(f)(1)(A)–(E) "Covered entity" means the manufacturer of covered products that are sold in or into the state.

(B) If no entity that meets the definition in subparagraph (A) is in the state, "covered entity" means the distributor of covered products that are sold in or into the state that is licensed as a wholesaler, as defined in Section 4043 of the Business and Professions Code, but ***does not include a warehouse of a retail pharmacy chain that is licensed as a wholesaler if it engages only in intracompany transfers between any division, affiliate, subsidiary, parent, or other entity*** under complete common ownership and control.

(C) If no entity that meets the definition in subparagraph (A) or (B) is in the state, "covered entity" means a repackager, as defined in Section 4044 of the Business and Professions Code, of covered products that are sold in or into the state.

(D) If no entity that meets the definition in subparagraph (A), (B), or (C) is in the state, "covered entity" means the owner or licensee of a trademark or brand under which covered products are sold in or into the state, regardless of whether the trademark is registered.

(E) If no entity that meets the definition in subparagraph (A), (B), (C), or (D) is in the state, "covered entity" means the importer of the covered products that are sold in or into the state.

Questions for Stakeholders

1. Are there terms within the tiered definition above that should be clarified?
2. Does this definition adequately address online sales?
3. Where do Reverse Distributors[2] fit in this process? Under what circumstances should a Reverse Distributor be considered a Manufacturer of covered drugs?
4. Where would a retail pharmacy chain that is also a "repackager[3]" of covered drugs fall within the tiered definition?

[2] **Section 4043** of the Business and Professions Code - "Wholesaler" means and includes a person who acts as a wholesale merchant, broker, jobber, customs broker, **reverse distributor**, agent, or a nonresident wholesaler, who sells for resale, or negotiates for distribution, or takes possession of, any drug or device included in Section 4022. Unless otherwise authorized by law, a wholesaler may not store, warehouse, or authorize the storage or warehousing of drugs with any person or at any location not licensed by the board.

[3] **Section 4044** of the Business and Professions Code - "Repackager" means a person or entity that is registered with the federal Food and Drug Administration as a repackager and operates an establishment that packages finished drugs from bulk or that repackages dangerous drugs into different containers, excluding shipping containers.

3. Education and Outreach Program

§ 42031.6(a) A program operator shall conduct a **comprehensive education and outreach program** intended to promote participation in the stewardship program. At a minimum, the education and outreach program shall do all of the following:

(1) Promote its stewardship program to ultimate users by providing signage for hospitals, pharmacies, and other locations, as necessary.

(2) Provide educational and outreach materials for persons authorized to prescribe drugs, pharmacies, pharmacists, ultimate users, and others, as necessary.

(3) Establish an Internet Web site that publicizes the location of authorized collectors and provides other information intended to promote the use of the stewardship program.

(4) Prepare 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.

(5) Encourage ultimate users to separate products that are not covered products from covered products, when appropriate, before submitting the covered products to an authorized collection site or mail-back program.

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?

B. Article 3. Stewardship Plans

Program operators are required to submit a complete stewardship plan to the Department within 6 months of the adoption of regulations (approx. 6/30/2021). The Department suggests the following eight processes related 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. Self-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

§ 42032(a)(1) Within six months of the adoption date of regulations by the department pursuant to Section 42031.2, a program operator shall submit to the department for approval a complete stewardship plan that meets the requirements of Section 42032.2 for the establishment and implementation of a stewardship program**, in a format determined by the department.**

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

(a) A corporate officer, acting on behalf of a mattress recycling organization, shall submit as part of the used mattress recovery and recycling plan (plan) the following information:
(1) Contact information of the corporate officer responsible for submitting the plan to the department and for overseeing used mattress recycling program activities, including, but not limited to:
(A) Contact name
(B) Title
(C) Name of mattress recycling organization
(D) Mailing address
(E) Phone number
(F) E-mail address
(G) Web address, if applicable
(2) List contact information for each manufacturer, renovator, and retailer the mattress recycling organization is composed of, including, but not limited to:
(A) Name of Company
(B) Mailing or corporate address
(C) Upon request by the department, the following information shall be provided, if available: individual Web address, contact name, title, phone number, and e-mail address of participating manufacturers, renovators, and retailers. The requested information shall be submitted within 30 days of the request unless extended as determined by the department.
(3) List of brands covered under the plan.
(4) Any changes to the information in subsections (1), (2), and (3) of subdivision (a) of this section shall be submitted to the department quarterly, or more frequently as the mattress recycling organization desires, according to instructions provided by the department.
(b) The plan may be submitted electronically according to instructions provided by the department. If the plan is submitted electronically, the date of electronic submittal will be considered the date of receipt by the department, provided that the organization also submits to the department a hard copy submittal letter referencing the plan electronic document with the signature of a corporate officer of a mattress recycling organization.

Questions for Stakeholders

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

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

§ 42032(b)(1) Prior to submittal of a plan to the Department, a program operator must submit its proposed plan to the Board, and to **any other applicable state agencies**.

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 Administration?
    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[4]

§ 42032(b)(3) A program operator may submit an updated proposed plan to an agency that issued a determination of noncompliance, and must include any determinations when it submits the plan to the CalRecycle.

Consideration for Stakeholders

1. CalRecycle observes that statute does not specify a timeline for the resubmittal of an updated proposed plan (e.g., 30 or 60 days) to an agency that issued a determination of noncompliance.

5. Program Operator Certification that Plan Meets Applicable Laws and Regulations

§ 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. § 42032(b)(4) states that a program operator may submit a certification:

[4] Timeline for resubmittal of proposed plans will not be part of the CalRecycle regulatory process but is included here as it is part of the overall statutory process.

a. Should an entity other than the program operator issue the certification? If so, who should/could issue certifications?

2. What information should 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. Pharmaceutical and Sharps Waste Stewardship Plan Submittal to Department

a. Plan Completeness Process:

§ 42032(c)(1) The department shall determine if a stewardship plan is complete, including the determinations required pursuant to subdivision (b), and notify the submitting program operator within 30 days of receipt.
(2) If the department finds that the stewardship plan is complete, the department's 90-day review period for consideration of approval of the plan set forth in subdivision (d) shall commence upon the original date of receipt.
(3) If the department determines the stewardship plan is incomplete, the department shall identify for the program operator the required additional information, and the program operator shall resubmit the plan within 30 days.
(4) If the department determines upon resubmission that the stewardship plan is complete, the department's 90-day review period for consideration of approval of the plan shall commence upon the date of receipt of the resubmitted plan.

Questions for Stakeholders

1. Should there be a limit on how many times a plan can be returned for completeness deficiencies?

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.

The Department will have 90-days to determine if the Plan will be approved, conditionally approved, or disapproved.

Examples of process and timing for the department to make similar determinations under the Mattress and Paint Stewardship Programs:

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.

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.

Questions for Stakeholders

1. Additionally, CalRecycle observes the need for a timeline and process for resubmittal following conditional approval or disapproval for a stewardship plan, similar to the examples provided above.
    a. Are the example(s) above 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 approval timelines?

7. **Plan Requirements for Covered Drugs.** In order to be approved, the stewardship plan for covered drugs must adequately address all of the following elements:

§ 42032.2.(a)(1)
(A) Identify and provide contact information for the stewardship organization, if applicable, and each participating covered entity, and identify each covered drug sold or offered for sale by each participating covered entity.
(B) Identify and provide contact information for the authorized collectors for the stewardship program, as well as the reasons for excluding any potential authorized collectors from participation in the program.
(C) Include any determinations provided by a state agency pursuant to subdivision (b) of Section 42032. Any determination of noncompliance shall be accompanied by a superseding determination of compliance.
(D) Demonstrate **adequate funding for all administrative and operational costs** of the stewardship program, to be borne by participating covered entities.
(E) Provide for a handling, transport, and disposal system that complies with applicable state and federal laws, including, but not limited to, regulations adopted by the United States Drug Enforcement Administration.
(F) Provide for a collection system that complies with the requirements of this chapter and meets all of the following requirements for authorized collection sites in each county in which the plan will be implemented:
(i) Provides for a minimum of five authorized collection sites or one authorized collection site per 50,000 people, whichever is greater.
(ii) Provides for a reasonable geographic spread of authorized collection sites and an explanation for the geographic spread.
(iii) Provides for a mail-back program covering any counties where there is not an authorized retail pharmacy operating as an authorized collection site.
(G) Require a program operator to do all of the following:
(i) Permit an ultimate user who is a homeless, **homebound**, or disabled individual to request prepaid, preaddressed mailing envelopes, or an alternative form of a collection and disposal system, as described in paragraph (2) of subdivision (c), that would render the covered drug inert. A program operator shall accept that request through an Internet Web site and toll-free telephone number that it shall maintain to comply with the requests.
(ii) Provide **alternative methods** of collection from ultimate users for 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, to the extent **technically feasible** and permissible under applicable state and federal law, including, but not limited to, United States Drug Enforcement Administration regulations.
(iii) (I) Provide a service schedule that meets the needs of each authorized collection site to ensure that each secure collection receptacle is serviced as often as necessary to avoid reaching capacity and 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. The authorized collection site shall maintain and make available to the department this documentation.
(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.
(H) Provide the policies and procedures for the safe and secure collection, transporting, and disposing of the covered drug, describe how and where records will be maintained 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 to improve safety and security.

§ 42032.2(e) A stewardship plan shall include provisions to expand into jurisdictions not included in the stewardship plan pursuant to Section 42036.2, in the event a jurisdiction repeals its local stewardship program ordinance.
(f) A stewardship plan shall include educational and outreach provisions to meet the requirements of Section 42031.6.

Questions for Stakeholders:

1. How will the stewardship organization identify which drugs cannot be accepted or commingled with other covered drugs?
    a. Should 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 should be provided?

4. Regarding § 42032.2(e):
    a. What provisions are necessary to consider for expansion into a jurisdiction in the event the ordinance is repealed?

a. Authorized Collectors

§ 42032.2(b)(1) At least 120 days before submitting a stewardship plan to the department, the operator of a stewardship program for covered drugs shall notify potential authorized collectors in the county or counties in which it operates of the opportunity to serve as an authorized collector for the proposed stewardship program. 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. If the minimum threshold described in clause (i) of subparagraph (F) of paragraph (1) of subdivision (a) is not met in each county in which a retail pharmacy chain has store locations, the retail pharmacy chain shall have at least one location or 15 percent of its store locations, whichever is greater, in that county serve as authorized collectors in a stewardship program.

Questions for Stakeholders

1. What form of documentation should be submitted to demonstrate "good faith" and "reasonable effort?"

8. **Plan Requirements for Home-Generated Sharps Waste.** In order to be approved, the stewardship plan for covered sharps must adequately address all of the following elements:

§ 42032.2(d)(1)
(A) Identify and provide contact information for the stewardship organization, if applicable, and each participating covered entity, and identify each covered product sold or offered for sale by each participating covered entity.
(B) Include any determinations provided by a state agency pursuant to subdivision (b) of Section 42032. Any determination of noncompliance shall be accompanied by a superseding determination of compliance.
(C) Demonstrate **adequate funding** for all administrative and operational costs of the stewardship program, to be borne by participating covered entities.
(D) Provide for a handling, transport, and disposal system, at no cost to the ultimate user, that complies with applicable state and federal laws.
(E) Maintain an Internet Web site and toll-free telephone number for purposes of providing information on the program, including disposal options, and to receive requests for sharps waste containers from ultimate users.
(F) Provide that a stewardship program for home-generated sharps waste shall be a mail-back program for home-generated sharps waste that complies with this chapter and that meets all the following requirements:
(i) The program provides or initiates distribution of a sharps waste container and mail-back materials at the point of sale, **to the extent allowable by law**. Containers and mail-back materials shall be provided at no cost to the ultimate user. The program operator shall select and distribute a container and mail-back materials sufficient to accommodate the volume of sharps purchased by an ultimate user over **a selected time period**.
(I) For any sharps, the packaging, an insert or instructions, or separate information provided to the ultimate user shall include information on proper sharps waste disposal.
(II) 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 Web site and toll-free telephone number.
(III) All sharps waste containers shall include prepaid postage affixed to the container or to the mail-back packaging.
(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.
(I) A local agency shall not knowingly request reimbursement for disposal expenses pursuant to this subparagraph for disposal costs resulting from a municipal needle exchange program or a medical waste generator.
(II) Reimbursement costs shall be limited to the actual costs of transportation from the household hazardous waste facility and for the actual costs of disposal.
(III) A request for reimbursement pursuant to this clause shall be submitted with a declaration under penalty of perjury that the local agency has not knowingly requested reimbursement for expenses prohibited by this section.
(IV) A cost is eligible for reimbursement pursuant to this clause if the cost is incurred 270 days or more after the approval of a stewardship plan for home-generated sharps waste.
(2) Paragraph (1) shall apply only with regard to home-generated sharps waste.

§ 42032.2(e) A stewardship plan shall include **provisions to expand** into jurisdictions not included in the stewardship plan pursuant to Section 42036.2, in the event a jurisdiction repeals its local stewardship program ordinance.
(f) A stewardship plan shall include educational and outreach provisions to meet the requirements of Section 42031.6.

Questions for Stakeholders:

1. Regarding § 42032.2(d)(1)(F)(i):
   a. What are examples of when mail-back materials would not be permitted under the law?
   b. Is clarification needed regarding container volumes and corresponding "sufficient time periods"?
2. Regarding § 42032.2(e):
   a. 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)?

a. Reimbursement of Costs to Local Jurisdictions

§ 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.

(I) A local agency shall not knowingly request reimbursement for disposal expenses pursuant to this subparagraph for disposal costs resulting from a municipal needle exchange program or a medical waste generator.
(II) Reimbursement costs shall be limited to the actual costs of transportation from the household hazardous waste facility and for the actual costs of disposal.
(III) A request for reimbursement pursuant to this clause shall be submitted with a declaration under penalty of perjury that the local agency has not knowingly requested reimbursement for expenses prohibited by this section.
(IV) A cost is eligible for reimbursement pursuant to this clause if the cost is incurred 270 days or more after the approval of a stewardship plan for home-generated sharps waste.

Questions for Stakeholders

1. Do any of the processes here require clarification in regulation or should the Department require the Stewardship Organization to establish reimbursement requirements in its Plan? E.g., How often should 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?