

16. Final Statement of Reasons (FSOR)

FINAL STATEMENT OF REASONS

PHARMACEUTICAL AND SHARPS WASTE STEWARDSHIP PROGRAM

Table of Contents

Update To The Initial Statement Of Reasons	1
Problem Addressed By And Benefits Of Regulations	1
General Comments Applicable To Statement Of Reasons.....	4
Specific Purpose And Necessity Of Regulations	6
Section 18972.1. Definitions.....	7
Section 18972.2. Criteria for Determining a Covered Entity	13
Section 18973. Document Submittals: Stewardship Plan, Initial Program Budget, Annual Report, and Annual Budget.....	14
Section 18973.1. Document Approvals: Stewardship Plan, Initial Program Budget, Annual Report, and Annual Budget.....	15
Section 18973.2. Stewardship Plan for Covered Drugs	20
Section 18973.3. Stewardship Plan for Home-Generated Sharps Waste.	35
Section 18973.4. Annual Report for Covered Drugs.	50
Section 18973.5. Annual Report for Home-Generated Sharps Waste	67
Section 18973.6. Program Budgets	79
Section 18974. Record Keeping Requirements	84
Section 18974.1. Administrative and Operational Costs	86
Section 18974.2. Stewardship Organization Audits of Covered Entities or Authorized Collectors.	88
Section 18974.3. Distributor, Wholesaler, Pharmacy, and Retailer Product Verification.	88

Section 18975. Criteria to Impose an Administrative Civil Penalty.	89
Section 18975.1. Procedure for Imposing Administrative Civil Penalties	92
Section 18975.2. Procedure for Stewardship Plan Revocation, Resubmittal, or Additional Compliance Reporting.	95
Non-Substantial Changes Made Prior To The Final Version Of The Proposed Regulatory Text	99
Documents Incorporated By Reference.....	103
Reasonable Alternatives To The Proposed Regulatory Action	104
Economic Impact Assessment Per Government Code Section 11346.3 (b).....	105
Initial Determination That The Action Will Not Have A Significant Adverse Economic Impact On Business	107
Determination That The Regulations Do Not Impose A Mandate Upon Local Agencies Or School Districts	107
Duplication Or Conflicts With Code Of Federal Regulations.....	107
Finding On Necessity Of Reports (Government Code Section 11346.3(d).....	107
Summary Of Stakeholder Comments And Department Responses	107
Technical Studies, Reports, Or Documents.....	107
Documents Removed From The List Of Documents Relied Upon.....	108

UPDATE TO THE INITIAL STATEMENT OF REASONS

Note: If a section required an update from the original text in the Initial Statement of Reasons, it is noted following the heading for each section or in the explanation that follows.

TITLE 14: NATURAL RESOURCES

DIVISION 7: DEPARTMENT OF RESOURCES RECYCLING AND RECOVERY

CHAPTER 11: PRODUCT STEWARDSHIP

ARTICLE 4: PHARMACEUTICAL AND SHARPS WASTE STEWARDSHIP PROGRAM

PROBLEM ADDRESSED BY AND BENEFITS OF REGULATIONS – Revised

To make the document accessible, footnotes have been eliminated and replaced with a reference section at the end of this section.

Home-generated sharps and pharmaceutical waste presents significant environmental and public health concerns for California and currently is not managed effectively. As outlined in a 2017 report from the California State Auditor¹, while greater than 90% of state residents live within a 20 minute drive of a home-generated sharps or pharmaceutical collection site, collection services in rural areas are limited, and approximately 4 million Californians do not have reasonable access to disposal sites. Furthermore, information on these collection sites is not readily available to consumers. Not all pharmacies, law enforcement agencies, and household-hazardous waste facilities accept pharmaceuticals and/or sharps; among facilities that do, not all accept United States Drug Enforcement Administration-controlled substances such as prescription opioids or auto-injectors such as Epi-Pens. Currently, options for proper

disposal of pharmaceuticals and sharps are complex and confusing, and as a result, these products are often disposed in the household garbage, toilets, or sinks.

State Senate Bill 212 (Jackson, Chapter 1004, Statutes of 2018), the Pharmaceutical and Sharps Waste Stewardship Act, is meant to address the above problems by expanding access to proper disposal methods for pharmaceutical and home-generated sharps waste and a robust education and outreach campaign to promote proper disposal. The Act places the cost burden of the program on the producers of certain pharmaceuticals defined as “covered drugs” and home-generated sharps waste and requires them to manage the home-generated sharps waste collected at local household hazardous waste facilities, which is typically paid for by local governments through general fund, property tax, or ratepayer revenue. The clarification provided in the proposed regulations will assist in the efficient and effective implementation of the Act and, together, the Act and the proposed regulations will lower the cost burden on individuals and local governments for the management of covered drugs and home-generated sharps waste, and will also result in the following benefits to public health and the environment:

- 1) Reduction of needle-stick injuries. Every year, California workers in waste facilities and sanitation services, as well as members of the general public, are injured by hypodermic needles that have been improperly disposed of in the household trash or in public places such as parks or beaches. Needle-stick injuries often result in time taken off from work and expensive testing for infectious disease². The regulation is anticipated to decrease the rate of needle stick injuries and reduce the associated costs by providing consumers with safe and convenient disposal methods for used sharps.
- 2) Reduction of accidental poisonings. Unused medications in the household are known to pose a health risk to children and pets if accidentally ingested³. The regulation is anticipated to reduce the incidence of accidental poisoning of children and pets from unused medications by providing consumers with

convenient disposal options and conducting education and outreach campaigns to encourage their use.

3) Reduction in abuse of prescription drugs. The stockpiling of dangerous and highly addictive prescription drugs such as opioids in household medicine cabinets is a known gateway to prescription drug abuse⁴. California is estimated to spend billions of dollars every year as a result of this public health epidemic⁵, and this regulation may make a minor contribution to reducing prescription drug abuse.

4) Water quality. Most existing water treatment infrastructure is not designed to treat or remove pharmaceuticals that have been improperly disposed of down the sink or toilet⁶. Even in trace amounts, pharmaceutical compounds are known to have adverse effects on human embryonic cells as well as fish populations and other organisms and may already be impacting public and environmental health⁷. The regulation will likely reduce the amount of trace pharmaceutical contamination in both surface and ground water by diverting household pharmaceutical waste toward proper disposal methods.

References

¹ “Home-Generated Sharps and Pharmaceutical Waste.” *California State Auditor*. 09 May 2017.

² Leigh, J. P., Wiatrowski, W. J., Gillen, M., & Steenland, N. K., “Characteristics of persons and jobs with needlestick injuries in a national data set,” *American journal of infection control*, 2008, 36(6), 414-420.

³ Bond, G. R., Woodward, R. W., & Ho, M., “The growing impact of pediatric pharmaceutical poisoning,” *The Journal of Pediatrics*, 2012, 160(2), 265-270.

⁴ Kennedy-Hendricks A, Gielen A, McDonald E, McGinty EE, Shields W, Barry CL., “Medication Sharing, Storage, and Disposal Practices for Opioid Medications Among US Adults,” *JAMA Internal Medicine*. 2016, 176(7):1027–1029.

⁵ Florence, C., Luo, F., Xu, L., & Zhou, C., “The economic burden of prescription opioid overdose, abuse and dependence in the United States 2013,” *Medical care*, 2016, 54(10), 901.

⁶ Stackelberg, P. E., Furlong, E. T., Meyer, M. T., Zaugg, S. D., Henderson, A. K., & Reissman, D. B., “Persistence of pharmaceutical compounds and other organic wastewater contaminants in a conventional drinking-water-treatment plant,” *Science of the Total Environment*, 2004, 329(1-3), 99-113.

⁷ Ferrey, M., “Pharmaceuticals and endocrine active chemicals in Minnesota Lakes,” *Minnesota Pollution Control Agency*, May 2013.
<https://www.pca.state.mn.us/sites/default/files/tdr-g1-16.pdf>.

GENERAL COMMENTS APPLICABLE TO STATEMENT OF REASONS – Revised

Revisions to the Initial Statement of Reasons in this section are identified by underlines (additions) and ~~strike-throughs~~ (deletions).

The Act creates a statewide pharmaceutical and home-generated sharps waste stewardship program. A program operator, ~~consisting of a covered entity as described in subdivision (f) of section 42030 of the Public Resources Code, to~~ must establish and submit to the Department of Resources Recycling and Recovery (henceforth referred to as CalRecycle or the department) a stewardship plan for covered drugs, home-generated sharps waste, or both, either. A program operator consists of either a covered entity that chooses to run its own stewardship program or a group of covered entities that participate individually or collectively through participation in a non-profit stewardship organization, a stewardship plan for covered drugs, home-generated sharps waste, or both.

The plan must contain specified components, including a comprehensive education and outreach campaign to promote participation in the program, a funding mechanism sufficient to carry out the plan, and payment of fees to the department for its costs and any other state agency’s costs associated with administration and enforcement activities. A stewardship plan for covered drugs is also required to provide secure

collection receptacles at authorized collection sites in the counties in which it will operate, and must fulfill the following requirements referred to as “convenience standards” in this document and specified in subsection (1)(F) of section 42032.2(a) of the Public Resources Code:

- 1) A minimum of five authorized collection sites or one authorized collection site per 50,000 people, whichever is greater.
- 2) A reasonable geographic spread of authorized collection sites.
- 3) A mail-back program covering any counties where there is not an authorized retail pharmacy operating as an authorized collection site.

A stewardship plan for home-generated sharps waste is required to provide or initiate distribution of a sharps waste container and mail-back materials at the point of sale, at no cost to the ultimate user. Upon request from a local agency, the stewardship program must either reimburse the agency for disposal costs related to home-generated sharps waste, or provide for the removal of the home-generated sharps waste from the local household hazardous waste facility.

The department is required, within 90 days after receiving a plan (with exceptions explained in section 42032 of the Public Resources Code), to review and determine whether the plan complies with the requirements laid out in sections 42031.6 and 42032.2, and 42033 of the Public Resources Code, and make a determination whether or not to approve the plan.

Each covered entity, either individually or collectively through participation in a stewardship organization, is required to prepare and submit to the department an annual report describing the stewardship program activities during the previous reporting period and a program budget for the upcoming calendar year.

SPECIFIC PURPOSE AND NECESSITY OF REGULATIONS

Please note that the section and subsection headings contained within this section reflect the proposed regulatory text as it appears in the Final Version of the regulatory text.

The First Draft Proposed Text (or First Draft) was noticed as part of the Notice of Proposed Rulemaking submittal to the Office of Administrative Law and was presented for stakeholder comment during the 45-Day Comment Period.

The Second Draft Proposed Text (or Second Draft) was noticed in July 2020 as part of the Initial 15-Day Comment Period and included revisions to the First Draft Proposed Text to address stakeholder comments received during the 45-Day Comment Period.

The Third Draft Proposed Text (or Third Draft) was noticed in August 2020 as part of the Second 15-Day Comment Period and included revisions to the Second Draft Proposed Text in response to stakeholder comments received during the Initial 15-Day Comment Period.

The Final Version of Proposed Regulatory Text includes non-substantial revisions to the Third Draft Proposed Text because the Second 15-Day Comment Period comments did not warrant further substantial changes to the regulatory text. CalRecycle describes the non-substantial changes in the section titled NON-SUBSTANTIAL CHANGES MADE PRIOR TO THE FINAL VERSION OF THE PROPOSED REGULATORY TEXT.

The “authorizing statute” or “statutory requirements” or “SB 212” refer to Chapter 2 of Part 3 of Division 30 of the Public Resources Code.

“CalRecycle” or “the department” refer to the California Department of Resources Recycling and Recovery.

Section 18972. Purpose. – Revised and Deleted in Final Version

CalRecycle revised this section in the Second Draft to delete the duplicative phrase “other retailers.” Separately, CalRecycle is making the following edit to the description of purpose and necessity included in the Initial Statement of Reasons:

The purpose of Section 18972 is to identify the reason for the regulations as a whole and to identify what the regulations will address. This section is necessary to explain why the regulations are being promulgated and what they include. It explains that the regulations will clarify existing law and establish administrative procedures to efficiently and effectively implement the department’s responsibilities under the law and to provide a uniform competitive business environment to all covered entities, stewardship organizations, program operators, distributors, wholesalers, retail pharmacies, retail pharmacy chains, other authorized collectors, and other retailers ~~and pharmacies~~ pursuant to Chapter 2 (commencing with section 42030), Part 3, Division 30 of the Public Resources Code.

The above change to the description of purpose and necessity is necessary as the Initial Statement of Reasons did not capture the full list of entities that may be affected by the proposed regulations.

CalRecycle deleted this section in the Final Version of the regulatory text because it is unnecessary. It did not make specific or interpret the authorizing statute. CalRecycle describes this non-substantial change in the section titled NON-SUBSTANTIAL CHANGES MADE PRIOR TO THE FINAL VERSION OF THE PROPOSED REGULATORY TEXT.

Section 18972.1. Definitions. – Revised

Subsection 18972.1(a) – Revised

The language in this subsection was a preamble for section 18972.1 in the First Draft, with the actual definitions starting with subsection (b). CalRecycle rearranged section 18972.1 in the Second Draft so that every definition is listed as a subsection under (a) for consistency with other regulations under CalRecycle’s purview. Separately, CalRecycle clarified the intent of this subsection by adding that the definitions listed in

section 18972.1 govern the provisions of the proposed regulations and supplement the definitions listed in the authorizing statute instead of the definitions in the regulations beings “governed by” the definitions in the authorizing statute.

Subsection 18972.1(a)(1) – Revised

CalRecycle renumbered this subsection from First Draft 18972.1(b). CalRecycle clarified this definition in the Second Draft by referencing the applicable portion of authorizing statute and by removing the department’s administrative fees from the list of administrative and operational costs. A stakeholder comment identified that the authorizing statute discusses these fees separately from the administrative and operational costs of implementing a stewardship program. Additionally, CalRecycle chose to add a separate definition for “departmental administrative fees” (subsection (a)(2) below).

Subsection 18972.1(a)(2) – New Subsection

CalRecycle added a definition for “departmental administrative fees” in the Second Draft for consistency with the authorizing statute, which discusses the department’s “administrative fees” as a separate term than the “administrative and operational costs” of implementing a stewardship program. This change was prompted by a stakeholder comment.

Subsection 18972.1(a)(3) – Revised

CalRecycle renumbered this subsection from First Draft 18972.1(c). CalRecycle made non-substantial edits in the Final Version of the regulatory text to add the year that the definition in the listed chapter of the Medicare Benefit Policy Manual was issued, effective, and implemented. In addition, CalRecycle added a sentence incorporating the Medicare Benefit Policy Manual by reference into the regulations. Please see an explanation about this in the sections titled NON-SUBSTANTIAL CHANGES MADE PRIOR TO THE FINAL VERSION OF THE PROPOSED REGULATORY TEXT and DOCUMENTS INCORPORATED BY REFERENCE.

Subsection 18972.1(a)(4) – Revised – renumbered from First Draft 18972.1(d)

Subsection 18972.1(a)(5) – Revised – renumbered from First Draft 18972.1(e)

Subsection 18972.1(a)(6) – Revised

CalRecycle added a definition of “inert” in the Second Draft as subsection (a)(6) in response to stakeholder feedback that requested explicit requirements regarding the criteria for the department to approve an alternative collection and disposal system that renders a covered drug inert. However, this definition was removed in the Third Draft following additional stakeholder feedback that the definition was inconsistent with United States Drug Enforcement Administration regulations. Thus, the department prefers to rely on other agencies’ determinations regarding alternative proposals that render a covered drug “inert.”

CalRecycle renumbered Second Draft subsection (a)(7) (the definition of “local jurisdiction” and “local agency”) to subsection (a)(6) as a result of this deletion, but did not make any edits to this definition.

Subsection 18972.1(a)(7) – Revised

CalRecycle renumbered this subsection from First Draft 18972.1(g). CalRecycle further clarified the definition of “minutes, books, and records” in the Second Draft by replacing “accurate” with “complete” and “correct” to align this definition with the added requirement in section 18973(d). Additionally, the department revised “activities” to “transactions and activities.” These edits are necessary to allow an audit by an independent certified public accountant or by the department, pursuant to section 42033.4 of the Public Resources Code.

Subsection 18972.1(a)(8) – Revised – renumbered from First Draft 18972.1(h)

Subsection 18972.1(a)(9) – Revised

CalRecycle renumbered this subsection from First Draft 18972.1(i). CalRecycle made multiple edits to clarify the “point of sale” definition in the Second Draft. Since the

definition of “provides or initiates distribution of a sharps waste container and mail-back materials” (section 18972.1(a)(10)) incorporates “point of sale” as a point in time rather than a physical location, the department deleted the use of “checkout system utilized by...” and added “the point in time at which an ultimate user purchases...” Additionally, in the Second Draft CalRecycle clarified the list of locations at which “point of sale” applies, replacing “pharmacies, stores, and other retail outlets where a covered product is sold, including online sales” with “pharmacy, other retailer, or online marketplace.” The authorizing statute does not use the terms “stores” or “retail outlets,” and “online sales” was awkward phrasing as a “sale” is not a location and thus is out of place in the list. However, in the Third Draft, in response to a stakeholder comment on the Second Draft CalRecycle replaced “marketplace” with “including but not limited to an online retailer,” which does not limit the scope of online retailers nor retailers in general. Finally, in response to another stakeholder comment, CalRecycle replaced the term “covered product” with “covered drug or sharp,” as “covered product” includes home-generated sharps waste and this definition covers new sharps before they become home generated sharps waste.

Subsection 18972.1(a)(10) – Revised

CalRecycle renumbered this subsection from First Draft 18972.1(j). CalRecycle made several edits to the definition of “provides or initiates distribution of a sharps waste container and mail-back materials.” CalRecycle added the phrase “one of the following” in the introductory statement of this definition in the Second Draft to clarify that the three subsections under this definition are each an option for fulfilling the requirement. In the Third Draft, CalRecycle added the phrase “and mail-back materials” to align with the phrasing in section 42032.2(d)(1)(F)(i) of the Public Resources Code.

Subsection 18972.1(a)(10)(A) – Revised

CalRecycle renumbered this subsection from First Draft 18972.1(j)(1). CalRecycle added the phrase “or prior” in the Second Draft to maximize flexibility for program operators to design innovative methods for distributing sharps containers and mail-back materials without compromising convenience for the ultimate user. CalRecycle also

added a comma for improved grammar and added the word “or” to further emphasize that subsections (A) through (C) each represent an option for fulfilling this requirement.

Subsection 18972.1(a)(10)(B) – Revised

CalRecycle renumbered this subsection from First Draft 18972.1(j)(2). CalRecycle added the phrase “or prior” in the Second Draft to maximize flexibility for program operators to design innovative methods for distributing sharps containers and mail-back materials without compromising convenience for the ultimate user. CalRecycle also changed “three business days” to “four business days” in response to stakeholder comments that it would be difficult, if not impossible, to ensure that ultimate users receive containers within three business days. CalRecycle further extended this deadline to “five business days” in the Third Draft in response to stakeholder comments that four business days was still not enough time. CalRecycle decided that extending the deadline to five businesses days was a reasonable solution because it largely decouples program operator compliance from common carrier reliability without compromising convenience for the ultimate user.

Subsection 18972.1(a)(10)(C) – Revised

CalRecycle renumbered this subsection from First Draft 18972.1(j)(3). In response to stakeholder confusion, CalRecycle made several edits to clarify this subsection in the Second Draft. First, the department split this subsection into two sentences and moved the language regarding department approval in a stewardship plan into the second sentence for increased readability. The department added further specificity in the Second Draft by referencing “the method identified in subpart ([A/B])” instead of relying on vague inferences to these subsections. Finally, the department added “not allowed by law” in reference to situations where option (C) may be applicable. The department made this change in response to stakeholder feedback which emphasized that the authorizing statute states that the first two options can only be used if allowed by law. In the Third Draft, CalRecycle removed “reasonably feasible” following additional stakeholder feedback that this option could hinder convenience for ultimate users. Finally, the department added additional language from options (A) and (B) (“to the

ultimate user at the point of sale or prior, at no cost to the ultimate user”) to ensure that the context of each option is interpreted consistently.

Subsection 18972.1(a)(11) – New Subsection

CalRecycle added the definition of “repeal” in the Second Draft in response to stakeholder comments seeking clarity regarding the situations where the authorizing statute applies to a local jurisdiction due to a repeal of that jurisdiction’s stewardship program ordinance. The text CalRecycle included for this new definition was suggested in a stakeholder comment, and the only modification CalRecycle made to the stakeholder’s suggestion was to adjust a reference for consistency with the authorizing statute. The department found this language to be sufficiently clear and it aligned with CalRecycle’s statutory interpretation of this issue. This definition is necessary for the regulated public to understand how the department interprets the word “repeal” in this context and to prepare for a possible repeal, as described in section 42036.2 of the Public Resources Code.

Subsection 18972.1(a)(12) – Revised

The definition of “repeal” was subsection (a)(12) in the Second Draft but became (a)(11) in the Third Draft due to other edits to section 18972.1.

Subsection 18972.1(a)(13) – Deleted

In the Second Draft, CalRecycle made several changes to clarify and expand the definition of “significant change.” The department added the phrase “a change that is not consistent with” [an approved stewardship plan] in the introductory statement because some changes could have been planned in advance in the approved plan, or reasonably expected based on how the program is implemented. CalRecycle also added “the department determines” to emphasize that the department has authority to decide what constitutes “a material impact on the stewardship program.” Furthermore, the department specified what is meant by “material impact” by noting that the significant change must impact “the operation of a stewardship program.”

In addition to these changes in the introductory statement CalRecycle adjusted the examples of changes that would be considered “significant” in the Second Draft. In subsection (E), CalRecycle revised “facility(ies)” to “services provider or facility(ies),” and changed “process or dispose” to “transport, handle, or dispose.” This change was necessary to allow the department to review and approve any changes to both disposal facilities and the service providers used to transport consolidated covered products. This ensures that the department could effectively oversee this aspect of program implementation. Additionally, in the Second Draft, CalRecycle added subsection (F): “Any changes necessitated by a substantial change in stewardship program funding.” CalRecycle made this addition to account for circumstances such as if a substantial number of covered entities were to switch programs in the middle of the year, that program funding could be significantly impacted to the detriment of collection services.

However, upon further analysis of the authorizing statute and in response to stakeholder comments that the definition was ambiguous and presented concerns for implementation, CalRecycle deleted this definition in the Third Draft. CalRecycle determined that, without knowing what is contained in a stewardship plan(s) that is yet to be written, approved, and implemented, it could not construct a definition that clearly described a significant change for that program(s). The result would be unnecessary and onerous requirements on the part of a program operator and CalRecycle in developing, resubmitting, reviewing, and approving significant changes based on a definition that is either too limiting or not inclusive enough to account for all potential changes that should be considered “significant.” Instead, the department added language in section 18973.1(i) that aligns with language in the authorizing statute. A program operator must submit any significant changes to a stewardship plan in writing for the department to review. The department will evaluate whether a program operator has made a significant change to an approved stewardship plan on a case-by-case basis, depending on the unique stewardship plan and stewardship program.

Section 18972.2. Criteria for Determining a Covered Entity. – Revised

CalRecycle edited the Criteria for Determining a Covered Entity in the Second Draft to point directly to the statutory definition. The First Draft paraphrased the authorizing statute in a way that was confusing and unnecessary. The intent for this section is simply to convey that CalRecycle will adhere to the statutory definition, and thus the Second Draft edits leave no room for ambiguity.

Section 18973. Document Submittals: Stewardship Plan, Initial Program Budget, Annual Report, and Annual Budget. – Revised

CalRecycle moved the contact information required in subsection (a) to the regulatory sections applicable to each specific document and renumbered the subsequent subsections accordingly in the Second Draft. This edit was necessary to remove duplicative requirements and clarify that the contact information must be available in each respective document rather than submitted separately from the document. Additionally, CalRecycle added a preamble to this section in the Second Draft to clarify the document submittal requirements and further specify which documents the section applies to. In the Third Draft, CalRecycle edited the preamble to specify that document submittals must adhere to all the requirements in section 18973, rather than “the following requirements.”

Subsection 18973(a) – Revised

CalRecycle renumbered this subsection from First Draft 18973(b). CalRecycle changed “documents” to “the document” in the Second Draft for consistency with the sentence structure of the preamble. CalRecycle made a non-substantial addition in the Final Version of the regulatory text, adding the year in which the Web Content Accessibility guidelines were published and incorporating the document by reference into the regulatory text. CalRecycle also deleted the phrase “or a subsequent version” in the Final Version of the regulatory text to eliminate an improper prospective incorporation by reference and any possible confusion for the regulated community. This is a non-substantial change. Please see an explanation about this in the sections titled NON-SUBSTANTIAL CHANGES MADE PRIOR TO THE FINAL VERSION OF THE

PROPOSED REGULATORY TEXT and DOCUMENTS INCORPORATED BY REFERENCE.

Subsection 18973(b) – Revised

CalRecycle renumbered this subsection from First Draft 18973(c). CalRecycle removed the phrase “according to instructions provided by the department” in the Second Draft to provide consistent requirements for document submittals.

Subsection 18973(c) – Revised: renumbered from First Draft 18973(e)

Subsection 18973(d) – Revised

CalRecycle deleted First Draft subsection (d) in the Second Draft, which included the requirement for a hard copy submittal letter. This deletion is necessary as the department determined paper copies would be an unnecessary waste of resources and a “wet signature” is not needed for compliance purposes. CalRecycle added subsection (d) in the Second Draft to specify that submitted documents must be complete and contain factually accurate information to be approved.

Subsection 18973(e) – New Subsection

CalRecycle added subsection (e) in the Second Draft to emphasize that stewardship programs are legally responsible for the information in documents they provide to the department, consistent with section 42035.6(c) of the Public Resources Code. In the Third Draft, CalRecycle further clarified this requirement by directly stating that documents must be provided under penalty of perjury, rather than implying this requirement through its inclusion in the quoted certification statement.

Section 18973.1. Document Approvals: Stewardship Plan, Initial Program Budget, Annual Report, and Annual Budget. – Revised

CalRecycle added a preamble to this section in the Second Draft to clarify the document approval requirements and further specify which documents apply to this section.

Subsection 18973.1(a) – Revised

CalRecycle added the phrase “completeness and/or” in the Second Draft to clarify that the document approval process also includes an initial review for completeness, pursuant to section 42032(c)(1) of the Public Resources Code.

Subsection 18973.1(b) – Revised

CalRecycle made multiple edits to clarify this subsection in the Second Draft. The department added the phrase “or incomplete” to emphasize that CalRecycle will make a determination and inform a program operator of its decision either way, pursuant to section 42032(c)(1) of the Public Resources Code. CalRecycle also moved the 30-day timeline to the beginning of the subsection for improved readability. Additionally, in the Second Draft CalRecycle added the criteria it will use to evaluate a document for completeness. While the authorizing statute gives the department discretion in its review process, CalRecycle decided to clarify conditions for completeness review by explaining that a complete document must contain provisions intended to fulfill each requirement in the relevant sections of the regulations, and that those provisions are sufficiently detailed for the department’s review. Both of these aspects of the completeness review are necessary, as the document would be out of compliance if it does not fulfill each applicable requirement of the regulations, and the department cannot approve a document unless it has enough information to make an informed determination. In the Third Draft, CalRecycle edited the structure of this subsection to make future references clearer.

Subsection 18973.1(b)(1) – Revised

CalRecycle reorganized the phrasing in this subsection in the Second Draft for clarity and readability.

Subsection 18973.1(b)(2) – Revised

CalRecycle reorganized the phrasing in this subsection in the Second Draft for clarity and readability. This change emphasizes that the department’s 90-day review

commences upon receipt of the resubmitted document, not the original document. This is necessary to ensure the department has enough time to review the resubmitted document.

Subsection 18973.1(c) – Revised

CalRecycle edited this subsection in the Second Draft to clarify ambiguous phrasing and include the department's statutory 30-day completeness review period.

Subsection 18973.1(d) – New Subsection

CalRecycle added this subsection in the Second Draft to specify the criteria the department will use to approve a document. The following subsections were renumbered accordingly. CalRecycle chose to add subsection (d) for consistency with subsections (e) and (f) and to emphasize that the department will look to the applicable sections of the implementing regulations when determining approval.

Subsection 18973.1(e) – New Subsection

CalRecycle added this subsection in the Second Draft to specify the criteria the department will use to conditionally approve a document. While the authorizing statute gives the department discretion in its review process, CalRecycle decided to clarify requirements surrounding conditional approval by explaining that the department will only conditionally approve a document if it determines the document would be in compliance after the program operator provides additional information and/or takes certain additional actions. This aspect of the conditional review process is necessary as the department cannot approve a document that would result in program noncompliance. However, conditional approval is a tool the department can use to allow a stewardship program to continue implementation and remain in compliance even if additional information and/or actions are needed to fully approve a document.

Subsection 18973.1(f) – New Subsection

CalRecycle added this subsection in the Second Draft to specify the criteria the department will use to disapprove a document and subsequent subsections were

renumbered accordingly. While the authorizing statute gives the department discretion in its review process, CalRecycle decided to clarify conditions requiring disapproval by explaining that the department will disapprove a document if it does not substantially comply with applicable regulatory requirements. CalRecycle cannot approve a noncompliant document, and in situations where requirements are not met and conditional approval is not warranted, the default next step is disapproval, pursuant to section 42032(d)(1) of the Public Resources Code.

Subsection 18973.1(g) – Revised

CalRecycle renumbered this subsection from First Draft 18973.1(d). CalRecycle added the phrase “of conditional approval” in the Second Draft to clarify the 30-day deadline in a manner that is consistent with the other deadlines specified in this section.

Subsection 18973.1(h) – Revised

CalRecycle renumbered this subsection from First Draft 18973.1(e). CalRecycle made multiple edits to clarify this subsection in the Second Draft. The department replaced “identify” with “explain” to better fit the context of a description provided in a written notice. The department also added the phrase “of disapproval” to clarify the 30-day deadline in a manner that is consistent with the other deadlines specified in this section. Furthermore, CalRecycle replaced “notice date” with “disapproval date the written notice was issued” to clarify the start of the subsequent 60-day deadline in a manner that is consistent with the other deadlines specified in this section.

Subsection 18973.1(i) – New Subsection

CalRecycle added this subsection in the Second Draft to specify the submittal and review processes surrounding “significant changes” to an approved stewardship plan. At the time, the department found it necessary for consistency and compliance with the authorizing statute that significant changes adhere to the same submittal and approval requirements applicable to entire stewardship plans. However, the department deleted the reference to the document approvals process in the Third Draft because applying this rigid process to each significant change eliminates flexibility and could hinder

program services by unnecessarily delaying time-sensitive changes to an approved stewardship plan. Instead, CalRecycle finds it more effective to evaluate significant changes on a case-by-case basis and tailor the review to the nature of the change. Additionally, in the Third Draft, the department included the statutory requirement related to significant changes in section 42032(e) of the Public Resources Code, and further specified that significant changes must be submitted “to the department” and shall not be implemented prior to CalRecycle’s approval. Finally, CalRecycle added a requirement in the Third Draft that significant changes include a re-certification that the stewardship plan is compliant with all applicable laws and regulations. This requirement is necessary to ensure compliance with all applicable laws and regulations since CalRecycle does not have authority to review a stewardship plan or any significant changes for compliance with laws and regulations that are outside of the department’s statutory authority.

Subsection 18973.1(j) – Revised

CalRecycle renumbered this subsection from First Draft 18973.1(f). CalRecycle made multiple changes to clarify this subsection in the Second Draft. The department replaced “deficiencies” with “condition(s) to be met for approval” to be more specific and consistent with the language regarding conditional approval in the authorizing statute and regulations. The department also added language stating that it will send the program operator written notice of the conditional approval decision within 30 days; this timeline is necessary to include so that program operators will know when to expect notice, and it is consistent with the other 30-day department notification deadlines in the authorizing statute and regulations. The department also further clarified that the program operator must comply with the conditions listed “in that written notice,” and replaced both instances of “notice date” with “the date the written notice was issued” to be consistent with the other document approval processes described in this section of the regulations. Finally, CalRecycle replaced “director” with “Director of the Department of Resources Recycling and Recovery” to provide further clarity and consistency with the authorizing statute.

Subsection 18973.1(k) – Revised

CalRecycle renumbered this subsection from First Draft 18973.1(g). CalRecycle made multiple changes to clarify this subsection in the Second Draft. The department replaced “deficiencies” with “how the annual report or program budget does not comply” to be more specific and consistent with the language regarding disapproval in the authorizing statute and regulations. The department also added language stating that it will send the program operator written notice of the disapproval decision within 30 days; this timeline is necessary to include so that program operators will know when to expect notice, and it is consistent with the other 30-day department notification deadlines in the authorizing statute and regulations. The department also replaced “submit a revised annual report” with “resubmit a revised annual report” to further clarify that this step in the process constitutes a “resubmittal” rather than an original submittal. Finally, CalRecycle replaced “notice date” with “the date the written notice was issued” to be consistent with the other document approval processes described in this section of the regulations.

Subsection 18973.1(l) – New Subsection

CalRecycle added this subsection in the Second Draft to specify the process for resubmitting a document. This subsection is necessary to provide clear conditions for document resubmittals; the department chose to match the resubmittal process with the original submittal process in order to ensure that resubmittals comply with authorizing statute, and that both program operators and the department will have sufficient time and information to fulfill their respective obligations.

Subsection 18973.1(m) – New Subsection

CalRecycle added this subsection in the Second Draft to include the statutory requirement in section 42032(g) of the Public Resources Code. This addition is necessary so that all applicable requirements are listed in the same place.

Section 18973.2. Stewardship Plan for Covered Drugs. – Revised

CalRecycle edited the preamble in the Second Draft to remove the statement regarding compliance with all applicable laws and regulations; since the department added a compliance certification requirement in subsection 18973.2(e), this statement in the preamble was duplicative. CalRecycle replaced this statement by incorporating the statutory requirement that a program operator submit its stewardship plan within six months after the regulations are adopted, which provides helpful context to the following stewardship plan requirements. Finally, CalRecycle added the phrase “to be complete” to further clarify that the subsections of section 18973.2 represent components of a complete stewardship plan.

Subsection 18973.2(a) – Revised

In the Second Draft, CalRecycle added the contact information requirements that were previously listed in section 18973 rather than just referencing that section, which was necessary to clarify what contact information is required in the stewardship plan. CalRecycle then deleted these requirements from section 18973 as they were duplicative and potentially confusing in that location. Additionally, CalRecycle deleted the initial statement (“Contact information.”) because it was duplicative and unnecessary.

Subsection 18973.2(b) – Revised

CalRecycle deleted the initial statement (“Covered Entity.”) in the Second Draft because it was duplicative and unnecessary. Additionally, CalRecycle added the word “covered” in subpart (2) to remove ambiguity and added “Covered entity” in subpart (4) to clarify that the department is not requiring the contact information of private individuals. Finally, CalRecycle added subparts (5) and (6) to the list of required pieces of covered entity contact information, rather than including them only “upon request” as described in the First Draft. CalRecycle is requiring these two items upfront rather than upon request because enforcement investigations may be time-sensitive and waiting for a program operator to provide a covered entity’s phone number and website could hinder the department’s efforts and cause unnecessary delays.

Subsection 18973.2(c) – Revised

CalRecycle deleted the initial statement (“Covered Products.”) in the Second Draft because it was duplicative and suggested that a list of all covered products was required, when only a list of covered drugs sold or offered for sale is necessary in the covered drugs stewardship plan.

Subsection 18973.2(d) – Revised: see subsections below

Subsection 18973.2(d)(1) – Revised

CalRecycle made multiple edits to clarify this subsection in the Second Draft. The department added the phrase “contact information” to provide context for the required items, and replaced “include, not limited to” with “including, but not limited to” due to improper grammar. In subpart (B), CalRecycle replaced the term “entity” with “authorized collector” to clarify the information required in a manner that is consistent with terminology used elsewhere in the authorizing statute and regulations.

Subsection 18973.2(d)(2) – Revised

In the Second Draft, CalRecycle added the appropriate statutory reference to provide the statutory context for this requirement, and also included the statutory 120-day notification deadline requirement so that all applicable requirements are listed in the same place. Additionally, CalRecycle added a requirement that the program operator describe the method(s) by which potential authorized collectors were contacted. This requirement is necessary so that the department can effectively evaluate whether outreach to potential authorized collectors was adequate and conducted in good faith.

Subsection 18973.2(d)(3) – Revised

In the Second Draft, CalRecycle added the appropriate statutory reference to provide the statutory context for this requirement, and also included the statutory “good faith negotiations” requirement so that all applicable requirements are listed in the same place. CalRecycle also replaced “is” with “were and, if applicable, continue to be” in order to better capture the timeline outlined in authorizing statute (“good faith

negotiations” commence prior to stewardship plan submittal, and then may or may not continue afterward). CalRecycle also replaced “in” with “by” for improved grammar. In the Third Draft, CalRecycle removed the duplicative statutory reference and clarified that the referenced section is contained within the Public Resources Code.

Subsection 18973.2(d)(4) – New Subsection

CalRecycle added this subsection in the Third Draft to incorporate a statutory requirement for completeness, and the subsequent subsections were renumbered accordingly. This addition is necessary so that all requirements are listed in the same place and so that the department will be able to determine compliance with this requirement when reviewing a proposed stewardship plan.

Subsection 18973.2(d)(5) – New Subsection

CalRecycle added this subsection in the Third Draft in order to incorporate a statutory requirement, and the subsequent subsections were renumbered accordingly. This addition is necessary so that all requirements are listed in the same place and so that the department will be able to determine compliance with this requirement when reviewing a proposed stewardship plan.

Subsection 18973.2(d)(6) – Revised

CalRecycle renumbered this subsection from First Draft 18973.2(d)(4). CalRecycle replaced “conditions” with “reasons” in the Second Draft for consistency with the language in the corresponding statutory requirement (Public Resources Code section 42032.2(a)(1)(B)). CalRecycle replaced “requested” with “request” in the Third Draft to clarify that the program operator must describe the reasons for exclusion of any potential authorized collectors regardless of whether a potential authorized collector is excluded: (1) prior to a stewardship plan submittal or during operation of an approved stewardship program; and/or (2) after statutory minimum convenience standards specified in section 42032.2(a)(1)(F) have been met. This is an important distinction that ensures the approved stewardship program maintains compliance with the authorizing

statute and the program operator will operate the stewardship program in good faith going forward.

Subsection 18973.2(d)(7) – New Subsection

CalRecycle added this subsection in the Second Draft in response to a stakeholder comment recommending an appeals process for potential authorized collectors who are rejected from joining a stewardship program. CalRecycle made edits to this subsection in the Third Draft to remove the appeals process, in response to a stakeholder comment that this process is unnecessary since rejected authorized collectors would be appealing the decision to the same entity that provided the rejection, and the circumstances will not have changed upon appeal. However, CalRecycle did not delete this subsection entirely, and instead revised it to align with sections 42032.2(b)(1) and (b)(3) of the Public Resources Code. While there may be legitimate reasons for rejecting an offer from a potential authorized collector (such as compliance issues with other laws and regulations), CalRecycle emphasizes that a potential authorized collector that meets all the requirements must be able to “join the stewardship program,” not just “offer to participate in the future.”

Subsection 18973.2(e) – Revised

CalRecycle edited the heading of this section in the Second Draft to clarify that it applies specifically to “State” agency determinations, pursuant to section 42032(b)(1) of the Public Resources Code. Additionally, CalRecycle added “and Compliance Certifications” due to the corresponding addition of subpart (2).

Subsection 18973.2(e)(1) – Revised

CalRecycle revised subsection (e)(1) in the Second Draft to directly include reference to section 42032.2(a)(1)(C) of the Public Resources Code instead of the sentence paraphrasing this section of the authorizing statute. This revision is necessary to ensure consistency with the authorizing statute. CalRecycle inserted language to clarify that if a stewardship plan was “initially” issued a determination of noncompliance, prior to a superseding determination of compliance, both determinations must be included in the

stewardship plan. Furthermore, the department added text from section 42032(b)(4) of the Public Resources Code to outline what a program operator must do if any state agency fails to respond to a request for stewardship plan review within 90 days of receipt, in response to a stakeholder request. Requiring a program operator to provide a certification of compliance if a state agency fails to respond is necessary for the department to determine compliance with laws and regulations outside of the department's authority. CalRecycle also made minor edits in the Second and Third Drafts to ensure sentence structure consistency with other sections in the proposed regulations and to remove ambiguity regarding the intended timing of stewardship plan submittals.

Subsection 18973.2(e)(2) – New Subsection

CalRecycle added subsection (e)(2) in the Second Draft, which requires the program operator to provide a written certification that the stewardship plan is in compliance with all applicable local, state, and federal laws and regulations. This addition is necessary to allow CalRecycle to determine compliance with laws and regulations that are outside of the department's authority during its review of a proposed stewardship plan.

CalRecycle added additional specifications in the Third Draft to clarify that the written certification certifies that the stewardship plan is in compliance "at the time of submission to the department." This revision was made in response to stakeholder confusion and is necessary to clarify that program operators must make the certification about the stewardship plan as written at the time of submittal. Additionally, CalRecycle added that the written certification includes "all aspects of the plan related to" the handling, transportation, and disposal of home-generated sharps waste. This is necessary to emphasize that the stewardship plan is required, pursuant to Section 42032.2(a)(1)(E) of the Public Resources Code, to "provide for a handling, transport, and disposal system that complies with applicable state and federal laws, including but not limited to, regulations by the United States Drug Enforcement Administration."

Subsection 18973.2(f) – Revised

CalRecycle modified subsection (f) in the Second Draft to include departmental administrative fees as part of the funding that must be accounted for in the initial program budget. This edit is necessary to provide clarity that the stewardship program, including departmental administrative fees, is solely funded by participating covered entities, pursuant to section 42032.2(a)(1)(D) of the Public Resources Code.

CalRecycle rearranged text and added commas to clarify that covered entities are to bear all program costs, not just those from the first five years of operation, in response to stakeholder confusion. CalRecycle deleted the reference to departmental administrative fees in the Final Version of the regulatory text because this change is unnecessary. It does not make specific or interpret the authorizing statute. Sections 42033, 42033.2(c)(2), 42034, and 42034.2 of the Public Resources Code are self-explanatory in requiring the program operator to budget for all costs to fund the stewardship program over a multiyear period in a responsible and prudent manner. CalRecycle describes this non-substantial change in the section titled NON-SUBSTANTIAL CHANGES MADE PRIOR TO THE FINAL VERSION OF THE PROPOSED REGULATORY TEXT.

Subsection 18973.2(g) – Revised: see subsections below

Subsection 18973.2(g)(1) – Revised

CalRecycle deleted ambiguous language from subsection (g)(1) in the Second Draft. The phrase beginning with “to ensure” served as a “reason” for the requirement that added ambiguity and unintentionally limited its scope. The department requires a description of all relevant stewardship program processes and policies related to compliance with the authorizing statute, not only the ones applicable to “local, state, and federal laws and regulations.” Statute is clear that the program operator has an ongoing responsibility to ensure compliance because all handling, transport, and disposal undertaken as part of the stewardship program “shall comply with applicable state and federal laws, including, but not limited to, regulations adopted by the United States Drug Enforcement Administration” (see Section 42035.8 of the Public Resources Code).

Subsection 18973.2(g)(2) – No Updates

Subsection 18973.2(g)(3) – No Updates

Subsection 18973.2(g)(4) – New Subsection

CalRecycle added subsection (g)(4) in the Second Draft to incorporate the requirement in subsection 42033.2(b)(3) of the Public Resources Code and subsequent subsections were renumbered accordingly. Even though this statutory requirement applies to annual reports, it is necessary to include in the stewardship plan requirements so that CalRecycle can ensure that a program operator will collect the necessary data to comply with this requirement throughout the reporting period. Additionally, CalRecycle used the phrase “including, but not limited to, weight” to allow program operators to propose other metrics in addition to the minimum statutory requirement of the weight of covered drugs collected. If a covered product is collected from an ultimate user at an authorized collection site, the program operator must report on the weight of the covered product collected, as specified in section 42033.2(b)(3) of the Public Resources Code.

Subsection 18973.2(g)(5) – Revised

CalRecycle renumbered this subsection from First Draft (g)(4) due to the insertion of Second Draft (g)(4). CalRecycle modified subsection (g)(5) in the Second Draft to replace the word “entity” with “service provider.” This edit is necessary to avoid confusion with the term “covered entity” and for consistency with terminology used elsewhere in the regulations.

Subsection 18973.2(g)(6) – Revised

CalRecycle renumbered this subsection from First Draft (g)(5). In the introductory statement of this subsection, CalRecycle added appropriate statutory references in the Second and Third Drafts to ensure consistency with the authorizing statute. Additionally, CalRecycle moved the phrase “to be provided to ultimate users” in the Third Draft for additional clarity and context regarding the mail-back program and made edits to the last sentence for improved grammar and clearer sentence structure.

Subsection 18973.2(g)(6)(A) – Revised

CalRecycle renumbered this subsection from First Draft (g)(5)(A). CalRecycle incorporated a statutory reference to an “alternative form of collection and disposal system” in the Second Draft to be consistent with the parent paragraph of subsection (g)(6), which covers both mail-back and “alternatives.” Including this description in the stewardship plan is necessary so that CalRecycle will be able to conduct annual report reviews, inspections, and audits to ensure that collection services being offered are consistent with a program operator’s proposal. CalRecycle edited this subsection in the Third Draft to provide a clearer sentence structure and to remove the reference to section 42032.2(c)(2) of the Public Resources Code, which limits the scope of situations where a program operator may propose implementing an alternative form of collection and disposal and is sufficiently covered by the reference to section 42032.2(c) in the introductory statement of subsection (g)(6).

Subsection 18973.2(g)(6)(B) – Revised

CalRecycle renumbered this subsection from First Draft (g)(5)(B). CalRecycle replaced “by request from” with “requested by” in the Second Draft for improved readability, and replaced “or” with “and” to clarify that a program operator must offer this mail-back service through both a website and toll-free telephone number, pursuant to section 42032.2(a)(1)(G)(i) of the Public Resources Code. CalRecycle incorporated this statutory reference in the Third Draft to provide context for the particular statutory scenario to which this mail-back requirement applies.

Subsection 18973.2(g)(6)(C) – Revised

This subsection was numbered 18973.2(g)(6) in the First Draft and 18973.2(g)(7) in the Second Draft. CalRecycle moved the phrase “if applicable” in the Second Draft for improved readability.

In the Third Draft, CalRecycle reorganized subsection 18973.2(g)(6), which resulted in multiple changes to subsection 18973.2(g)(6)(C). CalRecycle renumbered Second Draft subsections 18973.2(g)(7) and (8) as subsections 18973.2(g)(6)(C) and (D), properly

indented these subsections to reflect this change, and renumbered the subsequent subsections under 18973.2(g) accordingly. Concurrently, CalRecycle renumbered Second Draft subsection 18973.2(g)(6)(C) as 18973.2(g)(6)(E). These changes are necessary to include all requirements related to mail-back and alternative forms of collection and disposal for covered drugs under the same subsection, which provides a clearer logical flow for stewardship plan requirements.

CalRecycle edited subsection 18973.2(g)(6)(C), as it appears in the Third Draft, by adding “mail-back program,” incorporated the appropriate statutory reference, and adjusted the phrasing to be consistent with the language and scope of section 42032.2(c)(2) of the Public Resources Code.

Subsection 18973.2(g)(6)(D) – Revised

CalRecycle renumbered this subsection from First Draft 18973.2(g)(7). CalRecycle incorporated additional statutory language in the Second Draft for consistency with the authorizing statute in response to a stakeholder comment. CalRecycle incorporated the appropriate statutory reference in the Third Draft to provide further statutory context and replaced “method(s)” with “any alternative methods” to clarify that this requirement does not necessarily apply in all circumstances and depends on the nature of the particular covered products managed under the stewardship program.

Subsection 18973.2(g)(6)(E) – New Subsection

In the Third Draft, CalRecycle moved what used to be subsection (g)(5)(C) in the First Draft, to the end of the list under (g)(6) and renumbered it as (E) for logical consistency. CalRecycle renumbered the other subsections under 18973.2(g)(6) accordingly.

In the Second Draft, where this subsection was numbered as (g)(6)(C), CalRecycle clarified the intent of the phrase “amount of materials distributed and weight of material returned” by further specifying that “materials distributed” refers to both mail-back materials and alternative forms of collection and disposal materials, as described in the introductory statement of subsection (g)(6). Additionally, CalRecycle replaced “weight” with “amount” to provide additional flexibility to program operators in proposing metrics,

since “weight” is only required by the authorizing statute for covered drugs collected at authorized collection sites. If a covered product is collected from an ultimate user at an authorized collection site, the program operator must report on the weight of the covered product collected, as specified in section 42033.2(b)(3) of the Public Resources Code. But, since this subsection refers to mail-back or alternative forms of collection and disposal, CalRecycle is allowing for flexibility of the reporting metric.

Subsection 18973.2(g)(7) – Revised

CalRecycle renumbered this subsection from First Draft 18973.2(g)(8). CalRecycle also replaced “in” with “by” and added “explanation of” for improved grammar in the Second Draft. Additionally, the department added the opening sentence and the last sentence in this subsection to incorporate language from the corresponding statutory requirement in section 42032.2(a)(1)(G)(iii)(I) of the Public Resources Code to direct the regulated entities to the statutory requirement.

Subsection 18973.2(g)(8) – Revised

CalRecycle renumbered this subsection from First Draft 18973.2(g)(10). In the Second Draft, CalRecycle deleted language from this subsection and added the phrase “critical deviations from stewardship plan policies and procedures” in response to stakeholder comments. This edit was necessary to address stakeholder concerns surrounding reporting noncompliance with laws and regulations beyond those relevant to implementing stewardship plan policies and procedures, and provides a program operator the flexibility to determine what “corrective actions” are taken depending on the circumstances and the type of deviation. It is important to note that stewardship plan policies and procedures are based on applicable laws and regulations. CalRecycle replaced “deviations” with “instances of noncompliance” in the Third Draft in order to use consistent terminology with other sections of the regulations.

Subsection 18973.2(g)(9) – Revised

CalRecycle renumbered this subsection from First Draft 18973.2(g)(11). CalRecycle deleted First Draft subsection (g)(9) in the Second Draft because section 42035.6(b) of

the Public Resources Code requires all retail pharmacies in California to maintain records relevant to the authorizing statute, regardless of any actions taken by program operators. Collection records relevant to particular stewardship programs are already required elsewhere in the authorizing statute and regulations.

Subsection 18973.2(g)(10) – Revised

CalRecycle renumbered this subsection from First Draft 18973.2(g)(12). CalRecycle edited this subsection in the Second Draft in response to a stakeholder comment. CalRecycle deleted the reference to an “unplanned incident” because the proposed language is meant to capture any incidents related to safety and security, whether or not they were planned. The department also added the notification language to ensure that program operators will respond to incidents in a compliant manner and that the department will be able to effectively evaluate such a response. Finally, CalRecycle added the last sentence in this requirement for consistency with section 42032.2(a)(1)(H) of the Public Resources Code.

Subsection 18973.2(h) – Revised

CalRecycle revised subsection (h) in the Second Draft to specify that the records which need to be maintained are those “generated during the collection, transportation, and disposal of covered drugs.” CalRecycle also listed records that must be maintained, but used the phrase “including, but not limited to” to emphasize that the list is not exhaustive. These revisions are necessary to provide program operators with requirements regarding the records that will need to be maintained. Each listed record is necessary for the department to be able to conduct inspections and provide effective oversight for critical components of the stewardship program’s collection, transportation, and disposal system. Additionally, CalRecycle deleted the requirement to maintain records on “policy and procedures for collection, transportation, and disposal of home-generated sharps waste” from this subsection because “policies and procedures” are sufficiently addressed by other sections of the regulations and are thus redundant in this section.

Subsection 18973.2(i) – Revised

CalRecycle made multiple edits to clarify subsection (i) in the Second Draft. CalRecycle added a reference to section 42032.2(e) of the Public Resources Code to provide the appropriate statutory context and deleted the term “provisions” which is vague and substantially covered by “processes, logistics, and timing.” CalRecycle also added new language that further clarifies the requirement to describe the actions that will be “necessary for a stewardship program” to expand into jurisdictions “not previously included in the stewardship plan.” These revisions are necessary to further clarify that this requirement is mandatory in the event of a repeal of a local stewardship program ordinance, pursuant to section 42036.2(a) of the Public Resources Code.

Subsection 18973.2(j) – Revised: see subsections below

Subsection 18973.2(j)(1) – Revised

CalRecycle added language to subsection (j)(1) in the Second Draft to conform with the requirement in section 42031.6(a)(2) of the Public Resources Code. This is necessary so that all requirements are in one place.

Subsection 18973.2(j)(2) – Revised

In the Second Draft, CalRecycle added the Government Code section reference to subsection (j)(2) in response to a stakeholder comment seeking clarity on the guidelines for non-English education and outreach materials that must be made available to the public. Government Code section 7295 provides clarity by pointing program operators to a comparable benchmark applicable to local agencies, but still maintains some flexibility in proposing languages suited to each jurisdiction. Additionally, CalRecycle added language in the Second Draft that requires collection receptacle signage and labeling to be designed with explanatory graphics that will be readily understandable by all ultimate users. This requirement is necessary to uphold consumer convenience and minimize participation barriers for California’s diverse communities of ultimate users.

Subsection 18973.2(j)(3) – Revised

CalRecycle revised subsection (j)(3) in the Second Draft to require that program websites provide information in languages suited to local demographics and are accessible to disabled individuals. These insertions are necessary to uphold consumer convenience and allow diverse communities of ultimate users to access important information on the program operator's website. Similarly, CalRecycle added the reference to Government Code section 7295 in the Third Draft for consistency with the requirement in subsection (j)(2) above. CalRecycle edited subsection (j)(3)(D) in the Second Draft to clarify that accepting requests for mail-back materials through the program website is required for ultimate users that are homebound, homeless, or disabled, pursuant to section 42032.2(a)(1)(G)(i) of the Public Resources Code. Finally, CalRecycle edited the punctuation in subsection (j)(3)(E) for improved grammar.

Subsection 18973.2(j)(4) – Revised

CalRecycle revised subsection (j)(4) in the Second Draft to clarify that accepting requests for mail-back materials through the toll-free telephone number is required for ultimate users that are homebound, homeless, or disabled, pursuant to section 42032.2(a)(1)(G)(i) of the Public Resources Code. CalRecycle also clarified that the toll-free telephone number must provide disposal options and other program information to ultimate users without access to the internet, which is necessary so that this group of ultimate users will be able to take advantage of program services. CalRecycle also inserted text in the Second Draft to require language options suited to local demographics, and to accept calls via human representative and provide services for hearing-impaired and speech-impaired individuals. These additions are necessary to ensure all ultimate users have the ability to adequately access program information and disposal options. In the Third Draft, CalRecycle removed the subpart numbering from this subsection as it was unnecessary and could lead to confusing citations.

Subsection 18973.2(j)(5) – No Updates

Subsection 18973.2(j)(6) – New Subsection

CalRecycle added subsection (j)(6) in the Second Draft to conform with the requirement in section 42031.6(a)(5) of the Public Resources Code so that all applicable requirements are listed in the same place.

Subsection 18973.2(j)(7) – New Subsection

CalRecycle added subsection (j)(7) in the Third Draft to conform with the requirement in section 42031.6(b) of the Public Resources Code so that all applicable requirements are listed in the same place.

Subsection 18973.2(k) – Revised

CalRecycle made multiple edits to subsection (k) in the Second Draft in response to stakeholder comments. These edits were necessary to clarify the types of coordination efforts required and to ensure that collection services offered to the public are not negatively impacted by competitive practices between program operators or confusing discrepancies between different program materials and messaging. Rather than relying on the ambiguity of “good faith effort” and “most effectively achieve,” CalRecycle specified the goals of avoiding “conflict, duplication, and confusion to the public,” as each of these categories represent the negative effects of program operator competition on both ultimate user convenience and the cost-effectiveness of the programs. These edits also specify that coordination requirements still apply if new stewardship programs come into operation in the future, which is necessary to anticipate the negative impacts of competition under this potential scenario.

However, CalRecycle revised subsection (k) in the Third Draft to remove language requiring a description of how the program operator will coordinate with other program operators to avoid “conflict” and “duplication.” CalRecycle made this revision in response to antitrust concerns raised by stakeholder comments.

Subsection 18973.2(l) – No Updates

Subsection 18973.2(m) – Revised

CalRecycle replaced “as” with “if” in the Second Draft, since stewardship programs may not necessarily involve third-party service providers and competitive selection processes may not be necessary in all instances.

Section 18973.3. Stewardship Plan for Home-Generated Sharps Waste. – Revised

CalRecycle deleted the statement regarding stewardship plan compliance with all applicable laws and regulations in the Second Draft. Since the department added a compliance certification requirement in subsection 18973.3(d), this statement in the preamble was duplicative. CalRecycle replaced this statement by incorporating the statutory requirement that a program operator submit its stewardship plan within six months after the regulations are adopted, which provides helpful context to the following stewardship plan requirements. Finally, CalRecycle added the phrase “to be complete” in the Second Draft to further clarify that the subsections of section 18973.3 represent components of a complete stewardship plan.

Subsection 18973.3(a) – Revised

In the Second Draft, CalRecycle added the contact information requirements that were previously listed in section 18973 rather than just referencing that section, which was necessary to clarify what contact information is required in the stewardship plan. The phrase “of the corporate officer, or designee, responsible for submitting and overseeing the stewardship plan on behalf of the program operator, including, but not limited to:” was inadvertently single underlined and should be double underlined because it was added in the Second Draft (see section titled NON-SUBSTANTIAL CHANGES MADE PRIOR TO THE FINAL VERSION OF THE PROPOSED REGULATORY TEXT). The department found subsection (a) to be a more logical placement for the requirement than First Draft section 18973. As a result of this addition, CalRecycle deleted text that referenced section 18973 because it was no longer relevant. These revisions are necessary to clarify whose contact information is required in the stewardship plan, because the person submitting documents to the department may not be the person responsible for program implementation.

Subsection 18973.3(b) – Revised

CalRecycle deleted the initial statement (“Covered Entity.”) in the Second Draft because it was duplicative and unnecessary. Additionally, CalRecycle added the word “covered” in subpart (2) to remove ambiguity regarding to what type of entity this subsection refers. CalRecycle also added “Covered entity” in subpart (4) to clarify that the department is not requiring the email addresses of private individuals. This addition was made in response to stakeholder concerns about exposing private individual contact information online. Finally, CalRecycle added subparts (5) and (6) to the list of required covered entity contact information, rather than including them only “upon request” as described in First Draft subsection (b), which was deleted. CalRecycle is requiring these two items upfront rather than upon request because enforcement investigations may be time-sensitive, and waiting for a program operator to provide a covered entity’s phone number and website could hinder the department’s efforts and cause unnecessary delays.

Subsection 18973.3(c) – Revised

CalRecycle deleted the initial statement (“Covered Products.”) in the Second Draft because it was duplicative and suggested that a list of all covered products was required, when only a list of sharps sold or offered for sale is necessary in the home-generated sharps waste stewardship plan.

Subsection 18973.3(d) – Revised

CalRecycle revised the heading of this subsection in the Second Draft to clarify that it applies specifically to “State” agency determinations, pursuant to section 42032(b)(1) of the Public Resources Code. Additionally, CalRecycle added “and Compliance Certifications” due to the corresponding addition of subpart (2) below.

Subsection 18973.3(d)(1) – Revised

CalRecycle added text to subsection (d)(1) in the Second Draft to directly include reference to section 42032.2(d)(1)(B) of the Public Resources Code and deleted the

sentence paraphrasing this section of the authorizing statute. This revision is necessary to ensure consistency with the authorizing statute. CalRecycle inserted language to clarify that if a stewardship plan was “initially” issued a determination of noncompliance, prior to a superseding determination of compliance, both must be included in the stewardship plan. Furthermore, the department added language from section 42032(b)(4) of the Public Resources Code to outline what a program operator must do if any state agency fails to respond to a request for stewardship plan review within 90 days of receipt, in response to a stakeholder request. Requiring a program operator to provide a certification of compliance if a state agency fails to respond is necessary for the department to determine compliance with laws and regulations outside of the department’s authority. CalRecycle also made edits in the Third Draft to ensure sentence structure consistency with other sections in the proposed regulations and to remove ambiguity regarding the intended timing of stewardship plan submittals by specifying “at the time of submission to the department.”

Subsection 18973.3(d)(2) – New Subsection

CalRecycle added subsection (d)(2) in the Second Draft, to require the program operator to provide a written certification that the stewardship plan is in compliance with all applicable local, state, and federal laws and regulations. This addition is necessary to allow CalRecycle to determine compliance with laws and regulations that are outside of the department’s authority during its review of a proposed stewardship plan. CalRecycle added new specifications in the Third Draft to clarify that the written certification certifies that the stewardship plan is in compliance “at the time of submission to the department” in response to a stakeholder comment that the scope of the certification statement was ambiguous. This revision is necessary to clarify that program operators must provide certification for the stewardship plan as written at the time of submittal. Additionally, CalRecycle added that the written certification includes “all aspects of the plan related to” the handling, transportation, and disposal of home-generated sharps waste. This addition is necessary to emphasize that the entire stewardship plan is required, pursuant to Section 42032.2(d)(1)(D) of the Public Resources Code, to “provide for a

handling, transport, and disposal system ... that complies with applicable state and federal laws.”

Subsection 18973.3(e) – Revised

CalRecycle modified subsection (e) in the Second Draft to include departmental administrative fees as part of the funding that must be accounted for in the initial program budget. This edit is necessary to provide clarity that the stewardship program, including departmental administrative fees, is solely funded by participating covered entities, pursuant to section 42032.2(a)(1)(D) of the Public Resources Code.

CalRecycle rearranged text and added commas to clarify that covered entities are to bear all program costs, not just those from the first five years of operation, in response to stakeholder confusion. CalRecycle deleted the reference to departmental administrative fees in the Final Version of the regulatory text because this change is unnecessary. It does not make specific or interpret the authorizing statute. Sections 42033, 42033.2(c)(2), 42034, and 42034.2 of the Public Resources Code are self-explanatory in requiring the program operator to budget for all costs to fund the stewardship program over a multiyear period in a responsible and prudent manner.

CalRecycle describes this non-substantial change in the section titled NON-SUBSTANTIAL CHANGES MADE PRIOR TO THE FINAL VERSION OF THE PROPOSED REGULATORY TEXT.

Subsection 18973.3(f) – Revised: see subsections below

Subsection 18973.3(f)(1) – Revised

CalRecycle replaced subsection (f)(1) with revised text in the Second Draft. CalRecycle revised this subsection by removing the requirement for metrics to be included. This was necessary because these metrics are specified in subsections (f)(6) through (8) and including them here was duplicative. CalRecycle also deleted language that referenced the mail-back program because this requirement applies to all home-generated sharps waste. The department further revised this requirement for program operators to describe the processes and policies that will be used to “properly manage

home-generated sharps waste from collection through final disposal” rather than the processes and policies used to “transport and dispose” of this waste. This revision is necessary to ensure properly managed home-generated sharps waste through every step of the process, culminating in proper final disposal.

Subsection 18973.3(f)(2) – Revised

CalRecycle revised subsection (f)(2) in the Third Draft to ensure sentence structure consistency with other sections in the proposed regulations and deleted the internal numbering from this subsection because it was unnecessary.

Subsection 18973.3(f)(2)(A) – Revised

CalRecycle revised subsection (f)(2)(A) in the Second Draft to include “over a selected time period” in response to stakeholder comment which noted mismatched language between the authorizing statute and the proposed regulations. This edit is necessary to further clarify the amount of containers and mail-back materials that shall be distributed and to better align this proposed regulatory text with the language in Public Resources Code section 42032.2(d)(1)(F)(i).

Subsection 18973.3(f)(2)(B) – Revised

CalRecycle replaced subsection (f)(2)(B) with revised text in the Second Draft. This edit is necessary to better align this proposed regulatory text with the language in Public Resources Code section 42032.2(d)(1)(F)(i)(I). Additionally, CalRecycle specified that “all necessary information” should be included to ensure that essential information for proper home-generated sharps waste disposal is not excluded. These edits were in response to stakeholder comments that noted mismatched language between the authorizing statute and the proposed regulations.

Subsection 18973.3(f)(2)(C) – Revised

CalRecycle replaced subsection (f)(2)(C) with revised text in the Second Draft in response to a stakeholder comment which noted mismatched language between the authorizing statute and the proposed regulations. This edit is necessary to align this

proposed regulatory text with the language in Public Resources Code section 42032.2(d)(1)(F)(i)(II).

Subsection 18973.3(f)(2)(D) – No Updates

Subsection 18973.3(f)(3) – Revised

CalRecycle added a comma to the first sentence for grammatical correctness and further revised subsection (f)(3) in the Second Draft to specify that the records which need to be maintained are those “generated during the collection, transportation, and disposal of collected home-generated sharps waste.” CalRecycle also added a list of records that must be maintained, but used the phrase “including, but not limited to” to emphasize that the list is not exhaustive. These revisions are necessary to provide program operators with requirements regarding the records that will need to be maintained. Each listed record is necessary to enable the department to conduct inspections and provide effective oversight for critical components of the stewardship program’s collection, transportation, and disposal system. Additionally, CalRecycle deleted the requirement to maintain records on “policy and procedures for collection, transportation, and disposal of home-generated sharps waste” from this subsection because “policies and procedures” are sufficiently contained within other sections of the proposed regulations and are redundant in this section.

Subsection 18973.3(f)(4) – Revised

CalRecycle modified subsection (f)(4) and its subparts, (f)(4)(A) and (f)(4)(B), in the Second Draft by replacing the word “entity” with “service provider.” This edit is necessary to avoid confusion with the term “covered entity” and for consistency with terminology used elsewhere in the proposed regulations.

Subsection 18973.3(f)(5) – Revised

CalRecycle deleted First Draft subsection (f)(5) in the Second Draft and renumbered the subsequent subsections accordingly. The department deleted First Draft subsection (f)(5) to ensure that it would not have to determine compliance with laws outside its

authority and because a description of processes and policies for proper handling is included in Second Draft subsection (f)(1). CalRecycle will consult with other agencies and rely on certifications from program operators that the plan complies with all applicable laws and regulations. Statute is clear that the program operator has an ongoing responsibility to ensure compliance because all handling, transport, and disposal undertaken as part of the stewardship program “shall comply with applicable state and federal laws, including, but not limited to, regulations adopted by the United States Drug Enforcement Administration” (see Section 42035.8 of the Public Resources Code).

Subsection 18973.3(f)(5)(A) – Revised

CalRecycle renumbered this subsection from First Draft (f)(6)(A) because CalRecycle deleted subsection (f)(5) in the Second Draft. CalRecycle deleted text in subsection (f)(5)(A) in the Second Draft which stated that a receptacle-based program can supplement a program operator’s mail-back program. This deletion is necessary because stating that secure receptacle collection is a supplemental collection method is redundant with the heading in the overarching subsection (f)(5) and therefore, unnecessary. The department also deleted language in the Second Draft which specified that “the city, county, or state enforcement authority that provides oversight of the Medical Waste Management Act” has to approve and authorize home-generated sharps consolidation points. This deletion was necessary to avoid restating the definition of home-generated sharps consolidation point and instead rely on the definition in section 18972.1(a)(4) of the proposed regulations. Additionally, CalRecycle moved the phrase “authorized and approved” for sentence structure clarity and added the word “be” for grammatical correctness. However, in response to a stakeholder comment that stated it would help clarify the approval process for home-generated sharps consolidation points, CalRecycle reinserted reference to the Medical Waste Management Act in the Third Draft.

Subsection 18973.3(f)(5)(A)(i) – Revised: renumbered from First Draft 18973.3(f)(6)(A)(i)

Subsection 18973.3(f)(5)(A)(ii) – Revised

CalRecycle deleted First Draft subsection (f)(6)(A)(ii) in the Second Draft and renumbered the following subsections accordingly. This deletion is necessary because this requirement is included in subsection 18973.3(f)(1) and including it here was duplicative and unnecessary. Due to deletions, CalRecycle renumbered this subsection from First Draft (f)(6)(A)(iii) to (f)(5)(A)(ii).

CalRecycle made multiple non-substantial edits in the Second Draft for grammatical correctness, and added the phrases “will be” and “to be” to clarify that the stewardship plan represents proposed future actions, not current actions.

Subsection 18973.3(f)(5)(A)(iii) – Revised

CalRecycle renumbered this subsection from First Draft (f)(6)(A)(vi). CalRecycle deleted First Draft subsections (f)(6)(A)(iv) and (f)(6)(A)(v) in the Second Draft and renumbered the following subsections accordingly. It is necessary to delete subsection (f)(6)(A)(iv) because section 18973.3(f)(3) of the proposed regulations sufficiently clarifies the recordkeeping requirements specific to collection, transportation and disposal of covered products. It is necessary to delete First Draft subsection (f)(6)(A)(v) because CalRecycle inserted this requirement as a new subsection, subsection 18973.3(f)(9), so that the requirement applies to all elements of the stewardship program, not just supplemental collection methods.

Subsection 18973.3(f)(5)(A)(iv) – Revised

CalRecycle renumbered this subsection from First Draft (f)(6)(A)(vii) because of deletions in the Second Draft. CalRecycle modified this renumbered subsection in the Second Draft in response to a stakeholder comment that various local, state and federal agencies should be notified of an incident involving safety and security, as determined by the nature of the incident. CalRecycle modified this requirement to include processes that ensure the department and any other applicable agencies are notified if an incident occurs and to require a description of actions that will be taken to alleviate and improve the safety and security problem. These revisions are necessary to specify who must be

contacted when an incident related to safety and security occurs and to be consistent with section 42032.2(a)(1)(H) of the Public Resources Code. CalRecycle deleted language that referenced an “unplanned incident.” This deletion is necessary to ensure that all incidents related to safety and security are captured by the proposed regulations, not just “unplanned” incidents.

Subsection 18973.3(f)(5)(B) – Revised

CalRecycle renumbered this subsection from First Draft (f)(6)(B) because CalRecycle deleted subsection (f)(5) in the Second Draft. CalRecycle changed “as” to “if” in the Second Draft for grammatical correctness. In the Third Draft, the department added language requiring that take-back collection events be authorized and approved as home-generated sharps consolidation points by the appropriate city, county, or state enforcement agency in response to a stakeholder recommendation. CalRecycle also added a requirement for program operators to describe when take-back events are necessary and how they will be conducted. These additions are necessary to ensure that take-back events are conducted in a manner that the department is aware of and meet all requirements of the Medical Waste Management Act.

Subsection 18973.3(f)(6) – Revised

CalRecycle renumbered this subsection from First Draft (f)(7) because CalRecycle deleted subsection (f)(5) in the Second Draft. CalRecycle inserted new text in this subsection in the Second Draft that requires a description of the metrics that will be used to measure the amount of home-generated sharps waste returned, rather than the “weight” as specified in the First Draft. This edit is necessary because the potential variety of supplemental collection methods warrants additional flexibility for a program operator to select reporting metrics most appropriate to its program. It is necessary to report the amount of material returned using appropriate metrics to measure results of the mail-back program.

Subsection 18973.3(f)(7) – Revised

CalRecycle renumbered this subsection from First Draft (f)(8) because CalRecycle deleted subsection (f)(5) in the Second Draft. CalRecycle replaced the word “weight”

from the First Draft with “amount” in the Second Draft because the potential variety of supplemental collection methods warrants additional flexibility in reporting metrics. This revision is necessary to allow a program operator to select and propose its own metrics, applicable to unique collection systems in its stewardship program. It is necessary to report the amount of material collected through supplemental collection methods using appropriate metrics to measure programmatic results over time.

Subsection 18973.3(f)(8) – New Subsection

CalRecycle added subsection (f)(8) in the Second Draft to include a requirement to describe the metrics that will be used to measure the amount of home-generated sharps waste collected by the household hazardous waste facilities operated by local agencies. This addition is necessary to address household hazardous waste facilities as a method of collection, provide an appropriate metrics to measure programmatic results over time, and to ensure conformity with section 42033.5 of the Public Resources Code.

Subsection 18973.3(f)(9) – Revised

CalRecycle deleted First Draft subsection 18973.3(f)(6)(A)(v) and added a related requirement as subsection (f)(9) in the Second Draft. This requirement specifies that only corrective actions for critical deviations from established stewardship plan policies and procedures should be described. The stewardship plan policies and procedures are based on applicable laws and regulations. This edit is necessary because this requirement applies to all home-generated sharps waste collection, transportation, and disposal activities, not just those that occur under supplemental collection methods. In the Third Draft, CalRecycle replaced “deviations” with “instances of noncompliance” to use consistent terminology with other sections of the proposed regulations and the authorizing statute.

Subsection 18973.3(g) – Revised: see subsections below

Subsection 18973.3(g)(1) – No Updates

Subsection 18973.3(g)(2) – Revised

CalRecycle inserted new text in this subsection in the Second Draft that requires a local agency to include an invoice with its request. This addition is necessary to ensure the program operator is aware of how much a local agency is requesting for reimbursement before selecting reimbursement or arranging for removal of home-generated sharps waste from a household hazardous waste facility as the method to resolve the request. The department replaced “in a timely manner” from the First Draft with “within 14 days” in the Second Draft in response to stakeholder feedback that a time requirement was needed to ensure program success. This revision is necessary to specify the time frame in which program operators must respond to local agency requests, with 14 days being a reasonable interval for correspondence. The department added a reference to the requirements in section 42032.2(d)(1)(F)(ii) of the Public Resources Code in the Third Draft in response to a stakeholder recommendation to incorporate the statutory requirement in the proposed regulations.

Subsection 18973.3(g)(2)(A) – Revised

CalRecycle added language to this subsection in the Second Draft to clarify that a program operator will issue a reimbursement payment to a local agency within 45 days of “receipt of the local agency’s invoice.” This edit is necessary to provide clarity to the regulated community regarding when the 45-day timeline to provide payment begins.

Subsection 18973.3(g)(2)(B) – Revised

CalRecycle modified this subsection in the Second Draft to say that home-generated sharps waste removal from household hazardous waste facilities shall occur as often as required according to Section 117904 of the Health and Safety Code “and”/or by the local enforcement authority. CalRecycle inserted “and” in the Second Draft to ensure that home-generated sharps waste would be removed in a timely manner no matter the circumstances. However, the department removed this “and” in the Third Draft in response to a stakeholder comment that it was inconsistent with state law. This revision is necessary because either the seven-day timeline set in Section 117904 of the Health and Safety Code controls *or* another timeline controls if authorized by the local enforcement authority.

Subsection 18973.3(h) – Revised

CalRecycle modified subsection (h) in the Second Draft by adding a reference to section 42032.2(e) of the Public Resources Code to provide the appropriate statutory context for requirements related to ordinance repeals. The department deleted the term “provisions” which is vague and substantially covered by “processes, logistics, and timing.” CalRecycle also added new language that further clarifies the requirement to describe the actions that will be “necessary for a stewardship program” to expand into jurisdictions “not previously included in the stewardship plan.” These revisions are necessary to further clarify that this requirement is mandatory in the event of a repeal of a local stewardship program ordinance, pursuant to section 42036.2(a) of the Public Resources Code.

Subsection 18973.3(i) – Revised: see subsections below

Subsection 18973.3(i)(1) – Revised

CalRecycle added language to subsection (i)(1) in the Second Draft to better align the proposed regulations with the requirement in section 42031.6(a)(2) of the Public Resources Code. This is necessary so that all requirements are listed in the same place for completeness.

Subsection 18973.3(i)(2) – Revised

CalRecycle added the Government Code section reference to this subsection in the Second Draft in response to a stakeholder comment seeking clarity on the guidelines for non-English education and outreach materials that must be made available to the public. Government Code section 7295 provides clarity by pointing program operators to a comparable benchmark applicable to local agencies, but still maintains some flexibility in proposing languages suited to each jurisdiction. Additionally, in response to a stakeholder recommendation that imagery be included on signage to further reduce barriers to program participation, CalRecycle added language in the Second Draft that requires collection receptacle signage and labeling to be designed with explanatory graphics that will be readily understandable by all ultimate users. This is necessary to

uphold consumer convenience and minimize participation barriers for California's diverse audience of ultimate users.

Subsection 18973.3(i)(3) – Revised

CalRecycle inserted new text in subsection (i)(3) in the Second Draft to require that stewardship program websites provide information in languages suited to local demographics and are accessible to disabled individuals in response to stakeholder comments. These additions are necessary to uphold consumer convenience and allow diverse communities of ultimate users to access important information on the program operator's website. Similarly, in the Third Draft, CalRecycle added reference to Government Code section 7295, which outlines guidelines for non-English language determinations, to be consistent with the requirement in subsection (i)(2) above.

Subsection 18973.3(i)(3)(A) – Revised

CalRecycle edited subsection (i)(3)(A) in the Second Draft to clarify that requests from ultimate users accepted through the website must include both sharps waste containers and mail-back materials. It is necessary to include sharps waste containers in this requirement to align the proposed regulations with section 42032.2(d)(1)(E) of the Public Resources Code.

Subsection 18973.3(i)(3)(B) – Revised

CalRecycle edited subsection (i)(3)(B) in the Second Draft to be more complete by clarifying that information provided through the website should include collection options for home-generated sharps waste. CalRecycle deleted "if applicable" because this is not an optional requirement.

Subsection 18973.3(i)(3)(C) – No Updates

Subsection 18973.3(i)(3)(D) – Revised

CalRecycle edited subsection (i)(3)(D) in the Second Draft to include "if applicable" because home-generated sharps consolidation points are a supplemental collection

option that may be offered, but is not a requirement. If this option applies to a program operator's stewardship plan, the program operator must provide the information for the department to evaluate the plan and stewardship program.

Subsection 18973.3(i)(3)(E) – No Updates

Subsection 18973.3(i)(4) – Revised

CalRecycle added language in the Second Draft requiring one of the options that must be available through the toll-free telephone number is a means to accept requests for sharps waste containers and mail-back materials from ultimate users pursuant to section 42032.2(d)(1)(E) of the Public Resources Code. This is necessary to align the regulatory text with the authorizing statute. CalRecycle inserted text in the Second Draft to require language options suited to local demographics and to accept calls via human representative and provide services for hearing-impaired and speech-impaired individuals in response to stakeholder comments that the stewardship program's telephone service should be accessible to a wide range of ultimate users and that hearing impaired and speech-impaired individuals should have the same access to information and services available to others. These additions are necessary to ensure all ultimate users can adequately access information about the stewardship program and the ability to request sharps waste containers and mail-back material regardless of disability constraints. CalRecycle deleted the internal numbering from this subsection in the Third Draft as it was unnecessary and could lead to confusing citations.

Subsection 18973.3(i)(5) – No Updates

Subsection 18973.3(i)(6) – New Subsection

CalRecycle added subsection (i)(6) in the Second Draft to conform with the requirement in section 42031.6(a)(5) of the Public Resources Code, so that all applicable requirements are listed in the same place for completeness.

Subsection 18973.3(i)(7) – New Subsection

CalRecycle added subsection (i)(7) in the Third Draft in response to a stakeholder recommendation to restate the requirement in section 42031.6(b) of the Public Resources, so that all applicable requirements are listed in the same place for completeness.

Subsection 18973.3(j) – Revised

CalRecycle revised subsection (j) in the Second Draft in response to a stakeholder comment requesting additional clarity was needed. Rather than relying on the ambiguity of “good faith effort” and “most effectively achieve,” CalRecycle modified this subsection to specify the goals of avoiding “conflict, duplication, and confusion to the public.” Each of these categories represent the negative effects of program operator competition on both ultimate user convenience and the cost-effectiveness of the programs. These edits were necessary to ensure that collection services offered to the public are not negatively impacted by competitive practices between program operators or confusing discrepancies between different stewardship program materials and messaging. CalRecycle also added language to clarify that coordination should occur between program operators, which are not always stewardship programs. Additional edits in the Second Draft specify that coordination requirements still apply if new stewardship programs come into operation in the future, which is necessary to anticipate the negative impacts of competition under this potential scenario.

However, CalRecycle deleted text in subsection (j) in the Third Draft that required a description of how the program operator will coordinate with other program operators to avoid “conflict” and “duplication.” CalRecycle made this revision in response to antitrust concerns raised by stakeholders.

Subsection 18973.3(k) – No Updates

Subsection 18973.3(l) – Revised

CalRecycle replaced “as” with “if” in the Second Draft for grammatical correctness. Since stewardship programs may not necessarily involve third-party service providers, competitive selection processes may not be necessary in all instances.

Section 18973.4. Annual Report for Covered Drugs. – Revised

CalRecycle inserted a more instructive preamble in the Second Draft describing when a program operator must submit an annual report for covered drugs to the department pursuant to section 42033.2(a) of the Public Resources Code. CalRecycle added the phrase “to be complete” to further clarify that the subsections of section 18973.4 represent components of a complete annual report, consistent with section 42033.2(b) of the Public Resources Code. The department further revised the subsection in the Second Draft to require a description of “how the program operator complied with all elements of the stewardship plan,” rather than only requiring a description of the activities. This edit is necessary to allow the department to conduct a more complete review of program implementation. CalRecycle made Third Draft edits to correct sentence structure.

Subsection 18973.4(a) – Revised

CalRecycle modified subsection (a) in the Second Draft by deleting language from the First Draft that described whose contact information is required in the annual report. CalRecycle instead revised the requirement for annual reports to include contact information “pursuant to section 18973.2(a).” This revision is necessary to avoid confusion by including a direct reference to the stewardship plan regulatory text section that includes this requirement and not relying on paraphrased regulatory language. CalRecycle deleted the initial statement (“Contact information.”) because it is duplicative and unnecessary. Additionally, in the Second Draft, CalRecycle added a requirement to include “any changes or updates” to contact information. This addition is necessary to ensure that the department maintains the most up-to-date contact information for the person responsible for submitting and implementing the stewardship plan on behalf of the program operator.

Subsection 18973.4(b) – Revised

CalRecycle slightly modified subsection (b) in the Second Draft from “how” to “ways in which” for grammatical correctness.

Subsection 18973.4(c) – Revised: see subsections below

Subsection 18973.4(c)(1) – No Updates

Subsection 18973.4(c)(2) – Revised

CalRecycle modified subsection (c)(2) in the Second Draft by adding “but not limited to” for sentence structure consistency with terminology used elsewhere in the regulations and to emphasize that the description required is not limited to the information specified in the subsequent subparts. CalRecycle made further revisions in the Third Draft to replace “Good faith negotiations” with “Efforts” to add specificity as to what is required. Additionally, CalRecycle deleted “and the results of the negotiations” for phrasing consistency. CalRecycle moved the “good faith negotiations” component of the requirement to subsection (c)(2)(B). CalRecycle revised subsection (c)(2)(E) to include the reason(s) for each rejection of a potential authorized collector that offered to join the stewardship program to replace the deleted text in (c)(2). CalRecycle made these Third Draft edits because not all the requirements in the subsequent subparts of subsection (c)(2) require descriptions of good faith negotiations or the results of the negotiations.

Subsection 18973.4(c)(2)(A) – Revised

CalRecycle revised subsection (c)(2)(A) in the Second Draft to add the authorizing statutory reference for this requirement. CalRecycle deleted this addition in the Third Draft and instead inserted the reference to the corresponding requirement in section 18973.2(d)(2) of the stewardship plan. The referenced stewardship plan requirement includes the specific authorizing statute reference; therefore, the deletion was necessary to eliminate duplicity. CalRecycle inserted language in the Third Draft to conform with the language in section 18973.2(d)(2) of the stewardship plan.

Subsection 18973.4(c)(2)(B) – Revised

CalRecycle inserted new text in this subsection in the Third Draft to require a description of the negotiation process between a program operator and a potential authorized collector. This subsection is necessary for completeness and to conform with

the corresponding subsection 18973.2(d)(3) in the stewardship plan (which conforms with the requirement in the authorizing statute in Public Resources Code, section 42032.2(b)(1)). The text in First Draft subsection (c)(2)(B) was moved to subsection (c)(2)(D) in the Third Draft, due to insertions.

Subsection 18973.4(c)(2)(C) – Revised

CalRecycle replaced First Draft subsection (c)(2)(C) and inserted a revised subsection (c)(2)(C) in the Third Draft. CalRecycle rephrased the First Draft subsection (c)(2)(C) in the Third Draft to be consistent with the other subsection (c)(2) subparts in describing the requirement as it relates to the corresponding stewardship plan subsection 18973.2(d)(4). This edit provides greater specificity of the authorizing statutory reference that a program operator must fulfill to meet the requirement. The subsection requires a description of the efforts taken by a program operator to work with retail pharmacies and retail pharmacy chains to fulfill the requirement in section 42032.2(b)(2) of the Public Resources Code. This requirement is necessary to enable the department to evaluate the efforts by retail pharmacies and retail pharmacy chains to meet participation requirements in counties where the minimum convenience standard threshold is not being met.

Subsection 18973.4(c)(2)(D) – Revised

CalRecycle renumbered this subsection from First Draft (c)(2)(B) to (c)(2)(D) due to Third Draft insertions of (c)(2)(B) and (c)(2)(C) requirements. CalRecycle revised subsection (c)(2)(D) in the Third Draft to conform with the requirement added in the corresponding subsection 18973.2(d)(5) in the stewardship plan.

CalRecycle modified First Draft subsection (c)(2)(D) in the Second Draft in response to stakeholder recommendations to require a description of the efforts made between a program operator and retail pharmacies and retail pharmacy chains to meet the requirement in section 42032.2(b)(2) of the Public Resources Code. CalRecycle moved this requirement to subsection (c)(2)(C) in the Third Draft, as described in the subsection above.

Subsection 18973.4(c)(2)(E) – New Subsection

CalRecycle inserted subsection (c)(2)(E) in the Second Draft in response to a stakeholder recommendation to require program operators to list potential authorized collectors that requested to join the stewardship program and were rejected, and the reason(s) for each rejection. This is necessary to enable the department to evaluate the rejections preventing a potential authorized collector from participating and determine if the reasons provided are valid. CalRecycle further revised this subsection in the Third Draft for additional sentence structure clarity and to conform to the corresponding subsection 18973.2(d)(6) in the stewardship plan.

Subsection 18973.4(c)(2)(F) – New Subsection

CalRecycle inserted subsection (c)(2)(F) in the Third Draft to conform to the corresponding requirement in subsection 18973.2(d)(7) in the stewardship plan. This requirement is necessary for the department to verify during the review process that potential authorized collectors were notified of the reasons they were rejected from inclusion so that authorized collectors will have the opportunity to make corrections in order to join the stewardship program.

Subsection 18973.4(c)(3) – Revised

CalRecycle made a Third Draft addition to Subsection (c)(3) to require a program operator to provide a description of what efforts were taken to achieve compliance if convenience standards were not met. This addition is necessary for the department to determine the level of effort made to achieve the convenience standards and informs CalRecycle for potential enforcement actions.

Subsection 18973.4(c)(4) – Revised: see subsections below

Subsection 18973.4(c)(4)(A) – No Updates

Subsection 18973.4(c)(4)(B) – Revised

CalRecycle revised subsection (c)(4)(B) in the Second Draft to conform with the corresponding requirement in subsection 18973.2(g)(4) of the stewardship plan, where “weight” was changed to “amount.” This revision provides a program operator the flexibility to select and propose metrics that make sense for its particular stewardship program in addition to the statutory requirement to report the weight of covered drugs collected from ultimate users at each authorized collection site in section 42033.2(b)(3) of the Public Resources Code. This revision is necessary so that CalRecycle can ensure that a program operator collected and reported the data specified in subsection 18973.2(g)(4) of the approved stewardship plan and provides the department a metric to evaluate the collection of covered drugs.

Subsection 18973.4(c)(4)(C) – Revised

CalRecycle revised subsection (c)(4)(C) in the Second Draft to require the “number of instances that collected covered drugs were picked up for disposal” rather than number of collections. This edit is necessary to avoid confusion about which “collections” are to be reported. The intent is to collect information about the number of times the contents of the receptacle were picked up for disposal versus the number of times someone drops their unwanted covered drugs into the receptacle.

Subsection 18973.4(c)(4)(D) – Revised

CalRecycle split subsection (c)(4)(D) from First Draft subsection (c)(4)(C) and inserted it as a new subsection in the Second Draft. The department made edits in the Second Draft to require the number of liners from each “receptacle” that are “picked up for disposal” rather than “number of liners collected.” This edit is necessary to add specificity regarding the liner and to align with the subsection (c)(4)(C) language.

Subsection 18973.4(c)(4)(E) – Revised

CalRecycle renumbered First Draft subsection (c)(4)(D) to subsection (c)(4)(E) in the Second Draft. CalRecycle revised the subsection in the Second Draft by replacing “number of” with “amount of time” while moving “business hours” regarding the duration of time a receptacle is not available to the end of the sentence. This is necessary to

improve readability. CalRecycle also replaced “authorized collection site” with “secure collection receptacle.” This is necessary to clarify that CalRecycle needs information about the secure collection receptacle specifically. These edits provide clarity to the regulated community about the information the department requires in the annual report. This information is necessary for the department: (1) to evaluate whether the program operator has maintained a level of service that meet the needs of each authorized collector, pursuant to section 42032.2(a)(1)(G)(iii)(I) of the Public Resources Code; and (2) to ensure the minimum convenience standards are met, pursuant to section 42032.2(a)(1)(F) by maintaining operational collection receptacles available to the public. CalRecycle made additional revisions in response to a stakeholder recommendation to require a description of why a collection receptacle was not available. This requirement is necessary for the department to evaluate the reasons a collection receptacle is not available to the public and to determine that a collection site is serviced as often as necessary to avoid reaching capacity pursuant to section 42032.2(a)(1)(G)(iii)(I) of the Public Resources Code.

Subsection 18973.4(c)(5) – Revised

CalRecycle revised subsection (c)(5) in the Second Draft in response to a stakeholder comment to require the program operator to distinguish between each type of mail-back service that may be utilized. This revision is necessary due to state and federal guidelines, which require separation of distinct types of covered drugs dosage forms, such as inhalers and pre-filled injector products.

Subsection 18973.4(c)(5)(A) – Revised

CalRecycle deleted text in subsection (c)(5)(A) in the Third Draft that required program operators to include the name of the distribution “facility” for mail-back services. These deletions are necessary because the location where mail-back materials are distributed might not be considered a “facility” and providing the name of such a location is unnecessary. A list of distribution locations is necessary to assist the department in performing inspections and audits and to evaluate the program for compliance with applicable laws and regulations.

Subsection 18973.4(c)(5)(B) – Revised

CalRecycle renumbered subsection (c)(5)(B) to (c)(5)(C) and subsection (c)(5)(C) became (c)(5)(B) in the Second Draft. This renumbering is necessary because it is more logical to list the mechanism of distribution before the amount of materials distributed. CalRecycle made a pluralization edit to Second Draft subsection (c)(5)(B) in the Third Draft to indicate that each type of distribution mechanism is required to be listed if multiple mechanisms are utilized.

Subsection 18973.4(c)(5)(C) – Revised

CalRecycle revised subsection (c)(5)(C), formerly First Draft subsection (c)(5)(D), in the Second Draft to conform with the corresponding requirement in subsection 18973.2(g)(6)(E) of the stewardship plan. CalRecycle made a Third Draft edit to correct the stewardship plan subsection reference.

Subsection 18973.4(c)(5)(D) – Revised

CalRecycle revised subsection (c)(5)(D) in the Second Draft to conform with the corresponding requirement in subsection 18973.2(g)(6)(E) in the stewardship plan where “weight” was changed to “amount.” Under section 42033.2(b)(3) of the Public Resources Code, weight is only required as a metric for covered products collected from ultimate users at authorized collection sites. This edit is necessary to provide program operators the flexibility to select and propose their own metrics to include in the annual report on the mail-back program, if applicable. This revision is necessary so that CalRecycle can ensure that a program operator collected and reported the data as specified in subsection 18973.2(g)(6)(E) of the approved stewardship plan and provides the department a metric to evaluate the mail-back program. CalRecycle made a Third Draft edit to correct the stewardship plan subsection reference.

Subsection 18973.4(c)(6) – Revised

CalRecycle edited subsection (c)(6) in the Third Draft for consistency with the remainder of subsection 18973.4(c).

Subsection 18973.4(c)(6)(A) – Revised

CalRecycle made a Third Draft edit in subsection (c)(6)(A) that recognizes an alternative form of collection and disposal may have multiple methods of collection.

Subsection 18973.4(c)(6)(B) – Revised

CalRecycle made a Third Draft edit in subsection (c)(6)(B) that recognizes an alternative form of collection and disposal may have multiple locations.

Subsection 18973.4(c)(6)(C) – No Updates

Subsection 18973.4(c)(6)(D) – Revised

CalRecycle revised subsection (c)(6)(D) in the Second Draft to conform with the corresponding requirement in subsection 18973.2(g)(6)(E) of the stewardship plan. CalRecycle made a Third Draft edit to correct the stewardship plan subsection reference.

Subsection 18973.4(c)(6)(E) – Revised

CalRecycle revised subsection (c)(6)(E) in the Second Draft to conform with the corresponding requirement in subsection 18973.2(g)(6)(E) in the stewardship plan where “weight” was changed to “amount.” This edit is necessary to provide program operators the flexibility to select and propose their own metrics to include in the annual report on each alternative form of collection. If a covered product is collected from an ultimate user at an authorized collection site, the program operator must report on the weight of the covered product collected, as specified in section 42033.2(b)(3) of the Public Resources Code. But, because a covered product can be collected in a different way, CalRecycle is allowing for flexibility of the reporting metric. This revision is necessary so that CalRecycle can ensure that a program operator collected and reported the data as specified in subsection 18973.2(g)(6)(E) of the approved stewardship plan and provides the department a metric to evaluate each alternative form of collection. CalRecycle made a Third Draft edit to correct the stewardship plan subsection reference.

Subsection 18973.4(d) – Revised: see subsections below

Subsection 18973.4(d)(1) – Revised

CalRecycle edited subsection (d)(1) in the Second Draft to include transportation and disposal. This edit is necessary so the requirements in the annual report align with stewardship plan requirements.

Subsection 18973.4(d)(2) – Revised

CalRecycle modified subsection (d)(2) in the Second Draft to replace the word “entity” with “service provider.” This is necessary to avoid confusion with the term “covered entity” and for consistency with terminology used elsewhere in the regulations.

Subsection 18973.4(d)(3) – Revised

CalRecycle edited subsection (d)(3)(A) in the Second Draft to replace the word “entity” with “disposal facility.” This is necessary to avoid confusion with the term “covered entity” and for consistency with terminology used elsewhere in the regulations.

CalRecycle modified subpart (C) to replace “material received” with “covered drugs disposed.” The edit provides specificity that the metric required to be reported is the actual amount of covered product disposed rather than any material received that may not be related to covered drug disposal. This is necessary for the department to confirm whether the weight of covered drugs disposed matches the weight collected from authorized collection sites.

Subsection 18973.4(e) – Revised

CalRecycle revised subsection (e) and inserted language in the Third Draft to ensure requirements in this subsection conform with section 42033.2(b)(6) of the Public Resources Code. This is necessary to provide clarity to the regulated community about policies and procedures that must be included in the annual report.

Subsections 18973.4(e)(1) and (e)(2) – New Subsections

CalRecycle inserted subsections (e)(1) and (e)(2) in the Third Draft, which require a description of whether stewardship plan policies and procedures were followed during the reporting period and a description of each instance of noncompliance with stewardship plan policies and procedures. These subsections mirror the requirements in section 42033.2(b)(6) of the Public Resources Code. This addition is necessary to ensure that these statutory requirements are listed in the same place in the regulations for easy reference for the regulated community and to enable the department to determine compliance with authorizing statutory requirements when reviewing the annual report.

Subsection 18973.4(e)(3) – Revised

CalRecycle revised subsection (e)(3), formerly First Draft subsection (e), in the Second Draft, by deleting text that referenced compliance with all applicable laws and regulations. This deletion was necessary because the statutory requirement on which this subsection was based (section 42033.2 (b)(6) of the Public Resources Code) requires the program operator to report compliance with stewardship plan policies and procedures, rather than laws and regulations. CalRecycle replaced the requirement for “compliance with laws and regulations” with a requirement to describe corrective actions taken when the program operator discovers “critical deviations from stewardship plan policies and procedures” and a requirement to describe “each critical deviation” in response to stakeholder feedback.

In the Third Draft, CalRecycle replaced the Second Draft language, emphasizing that the program operator must report on the corrective actions taken if a program operator discovers critical instances of noncompliance with stewardship plan policies and procedures. The revisions are necessary to provide clarity regarding the requirement that the program operator must list all instances of noncompliance with the stewardship plan policies and procedures, not just critical deviations. CalRecycle replaced the phrase “critical deviations” with “critical instances of noncompliance,” which is necessary to align with statutory language in section 42033.2(b)(6) of the Public

Resources Code. CalRecycle added the phrase “or that will be taken” after “corrective actions taken” to emphasize that some corrective actions might not be taken right away.

Subsection 18973.4(f) – Revised

CalRecycle revised subsection (f) in the Second Draft to specify that this requirement must include a description of updates “that have been made or will be made” to processes and policies related to safety and security. This revision is necessary to align with authorizing statutory language from section 42033.2(b)(7) of the Public Resources Code. CalRecycle further revised the subsection by deleting the statement regarding compliance with all applicable laws and regulations in the Second Draft for consistency with revisions made in the corresponding subsection 18973.2(g)(1) of the stewardship plan. These modifications are necessary to provide clarity to the regulated community on processes and policies regarding safety and security that need to be reported and to avoid repetition that all aspects of the stewardship program must comply with applicable laws and regulations. Statute is clear that the program operator has an ongoing responsibility to ensure compliance because all handling, transport, and disposal undertaken as part of the stewardship program “shall comply with applicable state and federal laws, including, but not limited to, regulations adopted by the United States Drug Enforcement Administration” (see Section 42035.8 of the Public Resources Code). CalRecycle may consult with other agencies to ensure all aspects of a stewardship program comply with applicable laws and regulations.

Subsection 18973.4(g) – Revised

CalRecycle revised this subsection in the Second Draft by changing the requirement from a “description of efforts to expand into jurisdictions” to a “description of processes, logistics, and timing of implementation that will be necessary for the stewardship program to expand into jurisdictions.” This revision is necessary to provide the department more specificity of what implementation actions, rather than simply “efforts,” the program operator undertook to expand into jurisdictions, pursuant to section 42032.2(e) of the Public Resources Code, and to be consistent with updates to section 18973.3(h). CalRecycle inserted additional language in the Second Draft to clarify that

the description shall include how the stewardship program will meet the convenience standard in section 42032.2(a)(1)(F). This is necessary for the department to review the stewardship program for compliance with convenience standards.

Subsection 18973.4(h) – Revised

CalRecycle edited subsection (h) in the Second Draft, in response to a stakeholder concern of potential confidentiality risks regarding safety or security failures. The revision clarifies that the description of any safety or security incidents be “general” in nature to minimize sensitive information that is required to be submitted with the annual report. CalRecycle made additional edits in the Third Draft to clarify that explanations of what corrective actions were taken “or will be taken” shall be included. This is necessary because corrective actions shall also address and improve safety and security issues that have been identified but have not been implemented at the time the annual report is submitted to the department. CalRecycle made edits to require additional “specific” incident information to be provided upon request by the department. The revised phrasing of this subsection in the Second Draft and the Third Draft is necessary to clarify to the regulated community what is required to be included in the annual report and what only has to be made available to the department upon request.

Subsection 18973.4(h)(1) – No Updates

Subsections 18973.4(h)(2) and (h)(3) – Revised

CalRecycle revised subsections (h)(2) and (h)(3) in the Second Draft to include the term “specific.” This edit was made in response to a stakeholder comment about potential confidentiality risks regarding including descriptions of safety or security failures in public documents. This revision is necessary to clarify that specific information about any safety and security incident that occurs shall be provided to the department upon request. Pursuant to the edits made to subsection (h) above, the department only requires general descriptions of any safety or security incidents, with more specific information required only upon request. This edit will reduce the reporting burden on a

program operator by minimizing the amount of specific and potentially sensitive information provided in the annual report.

Subsection 18973.4(h)(4) – No Updates

Subsection 18973.4(h)(5) – No Updates

Subsection 18973.4(i) – Revised

CalRecycle edited subsection (i) in the Second Draft by inserting “but not limited to, the following.” This is necessary because the program operator must include the listed information but can include additional information based on the components of the education and outreach program.

Subsection 18973.4(i)(1) – Revised

This subsection was originally part of subsection (i) in the First Draft and was renumbered to (i)(1) in the Second Draft. This is necessary because the department added additional examples of education and outreach activities as subparts (2) through (4).

Subsection 18973.4(i)(2) – New Subsection

CalRecycle inserted subsection (i)(2) in the Second Draft in response to a stakeholder recommendation to require program operators to establish metrics for evaluating the outreach and education program listed in the stewardship plan and to conform with the Second Draft revisions made in the corresponding stewardship plan subsection 18973.2(j)(5) of the proposed regulations. This is necessary to enable the department to determine whether the education and outreach program was conducted comprehensively, pursuant to Public Resources Code section 42031.6.

Subsection 18973.4(i)(3) – New Subsection

CalRecycle inserted subsection (i)(3) in the Second Draft in response to a stakeholder recommendation to require program operators to establish metrics for evaluating the

outreach and education program in the stewardship plan and to conform with the Second Draft revisions made in the corresponding stewardship plan section 18973.3(i)(5) of the proposed regulations. CalRecycle made further edits in the Third Draft to clarify that the metrics discussion is to be based on the numerical results described in subsection 18973.4(i)(2). These additions are necessary for the department to determine whether the education and outreach program was conducted comprehensively pursuant to Public Resources Code section 42031.6.

Subsection 18973.4(i)(4) – New Subsection

CalRecycle inserted subsection (i)(4) in the Third Draft in response to a stakeholder recommendation that the proposed regulatory text include a requirement to conform with the requirement in section 42031.6(b) of the Public Resources Code. This subsection is necessary to prevent the promotion of disposal options that are inconsistent with the services offered by the stewardship program, is inserted for completeness so that all requirements are listed in the same place, and to enable the department to determine compliance with this requirement when reviewing the annual report.

Subsection 18973.4(j) – Revised: see subsections below

Subsection 18973.4(j)(1) – Revised

CalRecycle revised subsection (j)(1)(A) in the Second Draft for increased specificity and clarity to the regulated community that the names of the “covered” entity participating are to be included in the annual report. This is necessary to avoid confusion as to which entity is to be listed pursuant to this requirement and for consistency with terminology used elsewhere in the regulations. No other edits were made to subsection (j)(1).

Subsection 18973.4(j)(2) – Revised

CalRecycle revised subsection (j)(2) in the Second Draft in response to a stakeholder comment that asserts the provision should be consistent with the corresponding statutory language. This edit is necessary to avoid ambiguity regarding the list of

covered products required in the annual report pursuant to section 42033.2(b)(2) of the Public Resources Code and clarifies that the list submitted should be consistent with the requirement in section 42031(a)(2) of the Public Resources Code.

Subsection 18973.4(j)(3) – Revised

CalRecycle replaced “entity” with “authorized collector” in subsection (j)(3)(A) in the Second Draft to increase specificity and clarify to the regulated community that the entity to be included is the “authorized collector.” This edit is necessary to avoid confusion with the term “covered entity” and for consistency with terminology used elsewhere in the regulations. No revisions were made in subsections (j)(3)(B) through (j)(3)(D).

Subsection 18973.4(j)(4) – Deleted

CalRecycle deleted subsection (j)(4) in the Second Draft to eliminate duplicity with subsection 18973.4(j)(3).

Subsection 18973.4(k) – Revised

CalRecycle revised subsection (k) in the Second Draft to require a description “and evaluation” of the process for selecting service providers, rather than just requiring a description “of changes in” this process. This modification is necessary to enable the department to determine consistency with the process described in the stewardship plan.

Subsection 18973.4(l) – Revised

CalRecycle revised subsection (l) in the Second Draft to require a description of “any” grants, loans, sponsorships, reimbursements, or other incentives provided, rather than changes in the process for providing these incentives. These modifications are necessary to provide the department with a more complete understanding for how incentives are provided to ensure anticipated costs affecting funding to implement and operate the stewardship program is demonstrated, pursuant to the department’s responsibilities as required by section 42033.2(c)(2) of the Public Resources Code.

Subsection 18973.4(m) – No Updates

Subsection 18973.4(n) – Revised

CalRecycle moved the requirement from program budget section 18973.6(f) in the Second Draft to the annual report sections in the Third Draft. The requirement for a program operator to list actual expenses incurred over the previous reporting period is necessary to support the department's evaluation of the program budget by enabling comparisons between program year funds and activities that were incurred to determine if expenses adhered to the approved budget during the reporting period and comply with section 42033(b) of the Public Resources Code and to evaluate whether the program operator has operated the stewardship program in a prudent and responsible manner, as required in section 42033.2(c)(2) of the Public Resources Code. CalRecycle moved this requirement under the annual report section of the regulations because the annual report includes information pertaining to the previous reporting period. The program budget section, where this requirement appeared previously, includes information about the upcoming calendar year. Thus, expenses incurred over the previous reporting period are more logically placed under the annual report, rather than the program budget section.

Subsection 18973.4(o) – Revised

CalRecycle renumbered this subsection from First Draft (n) to (o) in the Third Draft due to the insertion of the new subsection (n) requirement above. CalRecycle revised this subsection in the Second Draft by inserting language to clarify that coordination should occur with program operators and not stewardship programs. This edit is necessary because the term "stewardship program" was incorrectly used in the First Draft. CalRecycle made further edits by deleting First Draft text to remove ambiguity as to how good faith efforts are achieved. These revisions are necessary to clarify this requirement to list the types of implementation issues that the description should address, rather than relying on the term "good faith effort," which was ambiguous. In the Second Draft, CalRecycle deleted the "most effectively" phrase in response to a stakeholder comment to provide clarity to the regulated community regarding the types

of conditions the department seeks to avoid. These edits are necessary to clarify the types of coordination efforts that are required and to ensure that collection services offered to the public are not negatively impacted by competitive practices between program operators or confusing discrepancies between different stewardship program materials and messaging. The Second Draft edits also clarify that the required description should account for not only existing stewardship programs, but also for the possibility of new stewardship programs arising in the future.

CalRecycle revised subsection (o) in the Third Draft by removing language that required a description of how a program operator will coordinate with other program operators to avoid “conflict” and “duplication” in response to a stakeholder comment. This revision is necessary to avoid raising federal and state antitrust concerns among program operators.

Subsection 18973.4(p) – Revised

CalRecycle renumbered this subsection from First Draft (o) to (p) in the Third Draft due to a new requirement insertion elsewhere in the section. CalRecycle revised this subsection in the Second Draft to clarify that the determinations required in the annual report are the state agency determinations required pursuant to section 42032.2(a)(1)(C) of the Public Resources Code. Requiring a program operator to provide a certification of compliance if a state agency fails to respond is necessary for the department to determine compliance with laws and regulations outside of the department’s authority.

In the Second Draft, CalRecycle added language to require program operators to certify that the approved stewardship plan remained compliant with all applicable laws and regulations. CalRecycle deleted this certification requirement in the Third Draft to avoid confusion and respond to stakeholder feedback that this requirement was duplicative. Statute is clear that the program operator has an ongoing responsibility to ensure compliance because all handling, transport, and disposal undertaken as part of the stewardship program “shall comply with applicable state and federal laws, including, but

not limited to, regulations adopted by the United States Drug Enforcement Administration” (see Section 42035.8 of the Public Resources Code).

Subsection 18973.4(q) – Deleted

CalRecycle inserted subsection (q) in the Second Draft to ensure that authorized collectors provided certifications about their compliance with all applicable laws and regulations through the program operator. CalRecycle removed this certification requirement in the Third Draft in response to a stakeholder comment that compiling such certifications may be unworkable in practice. Statute is clear that the program operator has an ongoing responsibility to ensure compliance because all handling, transport, and disposal undertaken as part of the stewardship program “shall comply with applicable state and federal laws, including, but not limited to, regulations adopted by the United States Drug Enforcement Administration” (see Section 42035.8 of the Public Resources Code).

Section 18973.5. Annual Report for Home-Generated Sharps Waste. – Revised

CalRecycle inserted a more instructive preamble in the Second Draft describing when a program operator must submit an annual report for home-generated sharps waste to the department pursuant to section 42033.2(b) of the Public Resources Code. CalRecycle added the phrase “to be complete” to further clarify that the subsections of section 18973.5 represent components of a complete annual report, consistent with section 42033.2(b) of the Public Resources Code. The department further revised the subsection in the Third Draft to require a description of “how the program operator complied with all elements of the stewardship plan,” rather than only requiring a description of the activities. This edit is necessary to allow the department to conduct a more complete review of program implementation and to align with language in section 18973.4 of the proposed regulations.

Subsection 18973.5(a) – Revised

CalRecycle modified subsection (a) in the Second Draft by deleting language from the First Draft that described whose contact information is required in the annual report, and

replacing it with the requirement for annual reports to include contact information “pursuant to section 18973.3(a).” This revision is necessary to avoid confusion by including a direct reference to the stewardship plan regulatory text section that includes this requirement and not relying on paraphrased regulatory language. CalRecycle also deleted the initial statement (“Contact information.”) because it was duplicative and unnecessary. CalRecycle added a requirement in the Third Draft to include “any changes or updates” to contact information. This addition is necessary to ensure that the department always has the most current contact information for the person responsible for submitting and overseeing the stewardship plan on behalf of the program operator.

Subsection 18973.5(b) – Revised

CalRecycle revised this subsection in the Second Draft by replacing the word “how” with “ways in which” for grammatical correctness.

Subsection 18973.5(c) – Revised: see subsections below

Subsection 18973.5(c)(1) – Revised

CalRecycle deleted a period at this end of this subsection to be consistent with other subsections in 18973.5(c) of the proposed regulations.

Subsection 18973.5(c)(2) – Revised

CalRecycle revised this subsection in the Second Draft to include a reference to section 18973.3(f)(6) of the proposed regulations. This edit is necessary to direct the regulated community to the corresponding stewardship plan requirement.

Subsection 18973.5(c)(3) – Revised

CalRecycle replaced subsection (c)(3) in the Second Draft to align with changes made to section 18973.3(f)(6), where “weight” was changed to “amount.” This edit is necessary for consistency with terminology used elsewhere in the regulations. The revision to “amount” allows a program operator flexibility to select and propose its own

metrics. This revision is necessary so that CalRecycle can ensure that a program operator collected and reported the necessary data specified in subsection 18973.3(f)(6) of the approved stewardship plan and provides the department a metric to evaluate the return of home-generated sharps waste.

Subsection 18973.5(c)(4) – Revised

CalRecycle modified subsection (c)(4) in the Second Draft by replacing the phrase “substituted for” with “in lieu of.” These edits are necessary for consistency with terminology used elsewhere in the regulations. CalRecycle made the reference to section 18973.3(f) more specific in the Second Draft by adding references to subparts (5) and (7), which relate to supplemental collection methods. However, the department deleted the reference to section 18973.3(f)(7) in the Third Draft because it was not relevant to the description of supplemental collection methods. CalRecycle moved the requirement to include the date and location of take-back collection events from section 18973.3(f)(5)(B) to this subsection in the Third Draft. The department revised this requirement to also reference section 18973.3(f)(5)(B), which describes take-back events as a supplemental collection method. This revision is necessary since the date and location of take-back events may change year-to-year. Thus, the annual reports section is a more appropriate location for this requirement than the stewardship plan section.

Subsection 18973.5(c)(5) – New Subsection

CalRecycle added subsection (c)(5) in the Second Draft to require that, when applicable, the amount of home-generated sharps waste collected through supplemental collection methods must be described in the annual report. This subsection is necessary to ensure that the amount of home-generated sharps waste collected through supplemental collection methods is properly accounted for and reported annually.

Subsection 18973.5(d) – Revised

CalRecycle revised the phrasing of this subsection in the Second Draft to be consistent with the style of other subsections.

Subsection 18973.5(d)(1) – Revised

CalRecycle modified this subsection in the Second Draft to include collection. This modification is necessary so the requirements in the annual report align with stewardship plan requirements.

Subsection 18973.5(d)(2) – Revised

CalRecycle revised subsection (d)(2) in the Third Draft to replace the word “entity” with “service provider.” This is necessary to avoid confusion with the term “covered entity” and for consistency with terminology used elsewhere in the regulations.

Subsection 18973.5(d)(3) – Revised

CalRecycle modified subsection (d)(3)(A) in the Second Draft to replace the word “entity” with “facility.” This is necessary for consistency with terminology used elsewhere in the regulations.

Subsection 18973.5(e) – Revised

CalRecycle added text to this subsection in the Third Draft to ensure the requirements in this subsection conform with section 42033.2(b)(6) of the Public Resources Code. This is necessary to clarify what information about policies and procedures must be included in the annual report.

Subsections 18973.5(e)(1) and (e)(2) – New Subsections

CalRecycle added subsections (e)(1) and (e)(2) in the Third Draft, which require a description of whether stewardship plan policies and procedures were followed during the reporting period and a description of each instance of noncompliance with stewardship plan policies and procedures. These subsections mirror the requirements in section 42033.2(b)(6) of the Public Resources Code. This addition is necessary to

ensure that these statutory requirements are listed in the same place in the regulations and to assist the department in evaluating the stewardship program for compliance with the authorizing statute.

Subsection 18973.5(e)(3) – Revised

CalRecycle revised subsection (e)(3), formerly First Draft subsection (e), in the Second Draft, by deleting text that referenced compliance with all applicable laws and regulations. This deletion is necessary because the statutory requirement on which this subsection was based (section 42033.2 (b)(6) of the Public Resources Code) requires the program operator to report compliance with stewardship plan policies and procedures, rather than applicable laws and regulations. In response to stakeholder feedback, CalRecycle replaced the requirement for “compliance with laws and regulations” with a requirement to describe corrective actions taken when the program operator discovers “critical deviations from stewardship plan policies and procedures” and a requirement to describe “each critical deviation.”

In the Third Draft, CalRecycle replaced the Second Draft language, emphasizing that the program operator must report on the corrective actions taken if a program operator discovers critical instances of noncompliance with stewardship plan policies and procedures. This revision is necessary to clarify that the program operator must list all instances of noncompliance with the stewardship plan policies and procedures, not just critical deviations. CalRecycle replaced the phrase “critical deviations” with “critical instances of noncompliance,” which is necessary to align with statutory language in section 42033.2(b)(6) of the Public Resources Code. CalRecycle added the phrase “or that will be taken” after “corrective actions taken” to emphasize that some corrective actions might not be taken right away.

Subsection 18973.5(f) – Revised

CalRecycle inserted new text in subsection (f) in the Second Draft to specify that a program operator must include a description of updates “that have been made or will be made” to processes and policies related to safety and security. This revision is

necessary to better incorporate statutory language from section 42033.2(b)(7) of the Public Resources Code and to minimize confusion for the regulated community. The department further revised this subsection in the Second Draft by deleting the statement regarding compliance with all applicable laws and regulations because it is repetitive. Statute is clear that the program operator has an ongoing responsibility to ensure compliance because all handling, transport, and disposal undertaken as part of the stewardship program “shall comply with applicable state and federal laws, including, but not limited to, regulations adopted by the United States Drug Enforcement Administration” (see Section 42035.8 of the Public Resources Code). CalRecycle may consult with other agencies to ensure all aspects of a stewardship program comply with applicable laws and regulations.

Subsection 18973.5(g) – Revised

CalRecycle revised this subsection in the Second Draft by changing the requirement from a “description of efforts to expand into jurisdictions” to a “description of processes, logistics, and timing of implementation that will be necessary for the stewardship program to expand into jurisdictions.” This revision is necessary to provide the department more specificity of what implementation actions, rather than simply “efforts,” the program operator undertook to expand into jurisdictions in the event of the repeal of a local stewardship program ordinance. CalRecycle also added a reference to section 42032.2(e) of the Public Resources Code to direct the regulated community to this statutory requirement.

Subsection 18973.5(h) – Revised

CalRecycle revised subsection (h) in the Second Draft in response to a stakeholder comment regarding the potential risk of including descriptions of safety or security failures in public documents. The revision specifies that this requirement is to include a description of the “general” nature of any safety or security incidents to minimize sensitive information that is required to be submitted with the annual report. The word “home-generated” was added before “sharps waste” to be more specific.

In the Third Draft, CalRecycle added language to require that an explanation of what corrective actions were taken “or will be taken” be included. This is necessary because corrective actions shall also address and improve safety and security issues that have been identified but have not been implemented at the time the annual report is submitted to the department. CalRecycle also made edits to require that additional “specific” incident information be provided upon request by the department. The revisions to this subsection are necessary to clarify to the regulated community what is required in the annual report and what only must be made available to the department upon request.

Subsection 18973.5(h)(1) – No Updates

Subsections 18973.5(h)(2) and (h)(3) – Revised

CalRecycle revised subsections (h)(2) and (h)(3) in the Second Draft to include the word “specific.” This edit was made in response to a stakeholder comment about the potential confidentiality risk of including descriptions of safety or security failures in public documents. This addition is necessary to clarify that only upon request shall a description and cause of the specific incident in question be provided to the department. Pursuant to the edits made to subsection (h) above, the department only requires general descriptions of any safety or security incidents, with more specific information required only upon request. These edits will reduce the reporting burden on a program operator by minimizing the amount of specific and potentially sensitive information provided in the annual report.

Subsection 18973.5(h)(4) – No Updates

Subsection 18973.5(h)(5) – No Updates

Subsection 18973.5(i) – Revised

CalRecycle modified subsection (i) in the Second Draft by inserting “but not limited to, the following.” This addition is necessary because the program operator must include

the listed information but can include additional information, based on the components of the education and outreach program.

Subsection 18973.5(i)(1) – Revised

This subsection was originally part of subsection (i) in the First Draft and was renumbered to (i)(1) in the Second Draft. This is necessary because the department added additional examples of education and outreach activities as subparts (2) through (4).

Subsection 18973.5(i)(2) – New Subsection

CalRecycle inserted subsection (i)(2) in the Second Draft, in response to a stakeholder recommendation that the annual report be consistent with the corresponding stewardship plan, section 18973.3(i)(5) of the proposed regulations, which requires program operators to establish metrics for evaluating the outreach and education program. This addition is necessary to assist the department's evaluation of whether the education and outreach program was conducted comprehensively, pursuant to section 42031.6 of the Public Resources Code.

Subsection 18973.5(i)(3) – New Subsection

CalRecycle inserted subsection (i)(3) in the Second Draft, in response to a stakeholder recommendation that the annual report be consistent with the corresponding stewardship plan, section 18973.3(i)(5) of the proposed regulations, which requires program operators to establish metrics for evaluating the outreach and education program. This addition is necessary to enable the department to understand how the program operator views the performance of the education and outreach program and to help the department determine whether the education and outreach program was conducted comprehensively. CalRecycle added language in the Third Draft that is necessary to clarify that the metrics discussion is to be based on the numerical results "described above in section 18973.4(i)(2)."

Subsection 18973.5(i)(4) – New Subsection

The department added this subsection in the Third Draft to state that a program operator must describe how the requirement in section 42031.6(b) of the Public Resources Code was met in response to a stakeholder comment that the statutory requirement should be restated in the regulatory text. This addition is necessary to prevent the promotion of disposal options that are inconsistent with the services offered by the stewardship program, for completeness so that all requirements are listed in the same place, and to enable the department to determine compliance with this requirement when reviewing the annual report.

Subsection 18973.5(j) – Revised

CalRecycle inserted new text in subsection (j)(1) in the Third Draft to specify that the name of the “covered” entity is required in reporting. This is necessary to clarify what entity is being referred to and for consistency with terminology used elsewhere in the proposed regulations.

Subsection 18973.5(k) – Revised

CalRecycle inserted new text in subsection (k) in the Second Draft to clarify that the list submitted should be consistent with the requirement in section 42031(a)(2) of the Public Resources Code. This edit was made in response to stakeholder comments that stated additional clarity was needed regarding the submittal of covered product lists in the annual report pursuant to section 42033.2(b)(2) of the Public Resources Code.

Subsection 18973.5(l) – Revised

CalRecycle revised subsection (l) in the Second Draft to require a description “and evaluation” of the process for selecting service providers, rather than just requiring a description “of changes to” this process. This modification is necessary to enable the department to ensure consistency with the process described in the stewardship plan.

Subsection 18973.5(m) – Revised

CalRecycle revised subsection (m) in the Second Draft to require a description of “any” grants, loans, sponsorships, reimbursements, or other incentives provided, rather than

requiring a description of “changes in the process for providing” these incentives. These modifications are necessary to provide the department with a more complete understanding of the incentives that were provided, and to ensure the program operator has anticipated costs affecting the funding to implement and operate the stewardship program in a prudent and responsible manner.

Subsection 18973.5(n) – No Updates

Subsection 18973.5(o) – Revised

CalRecycle revised this subsection in the Second Draft by adding language to clarify that coordination should occur between program operators not stewardship programs. This edit is necessary because the term “stewardship program” was incorrectly used in the First Draft. CalRecycle made further edits by deleting First Draft text in response to a stakeholder comment which found the phrases “good faith effort” and “most effectively” ambiguous. CalRecycle added language in the Second Draft listing the types of implementation issues that the description should address, and specifying why program operators should coordinate in the event that multiple stewardship programs operate concurrently. These edits are necessary to clarify the types of coordination efforts that are required, and to ensure that collection services offered to the public are not negatively impacted by competitive practices between program operators, or confusing discrepancies between different program materials and messaging. Furthermore, CalRecycle added text to clarify that the required description should account for not only existing stewardship programs, but also for the possibility of new stewardship programs arising in the future.

CalRecycle revised subsection (o) in the Third Draft by removing language that required a description of how the program operator will coordinate with other program operators to avoid “conflict” and “duplication.” This revision is necessary in response to stakeholder comments to avoid raising federal and state antitrust concerns among program operators.

Subsection 18973.5(p) – Revised

CalRecycle deleted “the following:” in the Second Draft to match other lists in the regulatory text. The department revised this subsection in the Third Draft by adding a reference to the requirements in section 42032.2(d)(1)(F)(ii) of the Public Resources Code in response to a stakeholder recommendation that the department incorporate the statutory requirement in the regulatory text. This addition is necessary to align with revisions to section 18973.3(g)(2) of the proposed regulations.

Subsection 18973.5(p)(1) – No Updates

Subsection 18973.5(p)(2) – Revised

CalRecycle replaced subpart (C) of subsection (p)(2) in the Second Draft to align with changes made to section 18973.3(f)(8), where CalRecycle inserted a requirement to describe the metrics that will be used to measure the amount of home-generated sharps waste collected by the household hazardous waste facilities operated by local agencies. This edit is necessary for consistency with terminology used elsewhere in the proposed regulations and so that CalRecycle can ensure that a program operator collected and reported the necessary data specified in subsection 18973.3(f)(8). This information allows the department to evaluate the collection of home-generated sharps waste from household hazardous waste facilities. CalRecycle fixed a section reference in the Third Draft to the correct subsection, 18973.3(f)(8).

Subsection 18973.5(p)(3) – New Subsection

CalRecycle added subsection (p)(3) to the Second Draft in response to a stakeholder recommendation to include a requirement for a program operator to list any local agency requests that were rejected in the annual report and indicate the reason(s) why each request was rejected. This subsection is necessary to enable the department to verify whether a program operator’s rejection of the local agency request was valid, pursuant to Public Resources code sections 42032.2(d)(1)(F)(ii)(I) through (IV).

Subsection 18973.5(p)(4) – New Subsection

CalRecycle added subsection (p)(4) to the Second Draft in response to a stakeholder recommendation that the annual report be required to include any local agency requests where responses, removal, or reimbursement was performed outside of the required timelines. This subsection is necessary to ensure the department is aware of any instances where a program operator does not meet the timeline specified in section 18973.3(g)(2) of the proposed regulations.

Subsection 18973.5(q) – Revised

CalRecycle moved the requirement from the Second Draft program budget section 18973.6(f) to the annual report sections in the Third Draft. The requirement for a program operator to list actual expenses incurred over the previous reporting period is necessary to support the department's evaluation of the program budget by enabling comparisons between program year funds and activities that were incurred to determine if expenses adhered to the approved budget during the reporting period and comply with section 42033(b) of the Public Resources Code. CalRecycle must evaluate whether the program operator has operated the stewardship program in a prudent and responsible manner, as discussed in section 42033.2(c)(2) of the Public Resources Code. CalRecycle moved this requirement under the annual report section of the regulations because the annual report includes information pertaining to the previous reporting period. The program budget section, where this requirement appeared previously, includes information about the upcoming calendar year. Thus, expenses incurred over the previous reporting period are a more logical fit under the annual report, rather than the program budget section.

Subsection 18973.5(r) – Revised

This subsection was renumbered from First Draft (q) to (r) in the Third Draft because CalRecycle moved a requirement from the program budget section to subsection (q). CalRecycle revised this subsection in the Second Draft to provide additional clarity to the regulated community by specifying that "State" Agency Determinations are required in the annual report. Requiring a program operator to provide a certification of compliance if a state agency fails to respond is necessary for the department to

determine compliance with laws and regulations outside of the department's authority. CalRecycle also added a reference to section 42032.2(d)(1)(B) of the Public Resources Code to direct the regulated community to this statutory requirement.

CalRecycle added subsection (r) in the Second Draft to require program operators to certify that the approved stewardship plan remained compliant with all applicable laws and regulations. But, in response to stakeholder feedback that this requirement may be unworkable in practice and to avoid confusion, CalRecycle deleted this certification requirement in the Third Draft. Statute is clear that the program operator has an ongoing responsibility to ensure compliance because all handling, transport, and disposal undertaken as part of the stewardship program "shall comply with applicable state and federal laws, including, but not limited to, regulations adopted by the United States Drug Enforcement Administration" (see Section 42035.8 of the Public Resources Code).

Section 18973.6. Program Budgets. – Revised

CalRecycle revised this subsection preamble in the Second Draft to reference authorizing statute sections 42033 and 42033.2 requiring that a program operator must submit an initial stewardship program budget for the first five calendar years and an annual budget, which provides the statutory requirement to the program operator. The insertion is necessary to communicate the deadlines by which program operators must submit the initial and annual program budget. The additional language complements First Draft language which conveys that subsequent components must be described for the submitted document to be considered complete.

Subsection 18973.6(a) – Revised

CalRecycle revised subsection (a) in the Second Draft by inserting the requirement for the initial and annual program budgets to include contact information of the corporate officer, or designee, responsible for submitting and overseeing the program budget on behalf of the program operator. These requirements were moved from section 18973 of the First Draft. This revision is necessary to avoid confusion and convey to the program

operator that contact information must be available in each respective document rather than submitted separately from the document.

Subsection 18973.6(b) – Revised

CalRecycle renumbered this subsection from First Draft (a). In the Initial Statement of Reasons, CalRecycle is making the following revision to the purpose and necessity explanation under subsections (a)(1) through (9) starting on page 53: “stewardship organization” should be “stewardship organization or covered entity.” The authorizing statute does not require a covered entity to join a stewardship organization – it can choose to operate its own stewardship program.

Subsection 18973.6(b)(1) – Revised

CalRecycle renumbered this subsection from First Draft (a)(1). CalRecycle revised this subsection in the Second Draft in response to stakeholder comments stating that items such as receptacles do not fall under the category of capital assets. The examples provided in the capital costs category were deleted and replaced by “fixed, one-time, tangible purchases” to avoid confusion by the program operator when designing the initial and annual budget and ensure that all parties understand which category certain costs should fall under.

Subsection 18973.6(b)(2) – Revised

CalRecycle renumbered this subsection from First Draft (a)(2). CalRecycle revised this subsection in the Second Draft to include transportation, processing, and disposal costs in response to stakeholder comments expressing concern regarding separation of specific budget cost categories listed in the First Draft. Several stakeholders expressed that it would pose an undue burden to separate costs of covered products collection, transportation, processing, and disposal and that consolidating these categories would facilitate reporting to the department. In response, CalRecycle combined the categories of collection, transportation, processing, and disposal of covered products into one. The category of processing costs was deleted from the regulatory text because processing costs are normally billed as part of disposal costs. This resulted in deletion of First Draft

subsections (a)(3) through (a)(5) and renumbering of subsequent subsections accordingly.

Subsection 18973.6(b)(3) – Revised

CalRecycle renumbered this subsection from First Draft (a)(6). CalRecycle modified the description of administrative costs in the Second Draft by adding that departmental administrative fee costs shall be included. This addition is necessary to avoid confusion and to facilitate the program operator's initial and annual budget development by specifically detailing where the departmental administrative fee shall be included as part of the budget. CalRecycle deleted the reference to departmental administrative fee costs in the Final Version of the regulatory text because this addition was unnecessary. It does not make specific or interpret the authorizing statute. Sections 42033, 42033.2(c)(2), 42034, and 42034.2 of the Public Resources Code are self-explanatory in requiring the program operator to budget for all costs to fund the stewardship program over a multiyear period in a responsible and prudent manner. CalRecycle describes this non-substantial change in the section titled NON-SUBSTANTIAL CHANGES MADE PRIOR TO THE FINAL VERSION OF THE PROPOSED REGULATORY TEXT.

Subsection 18973.6(b)(4) – Revised

This subsection was numbered as (a)(7) in the First Draft. CalRecycle modified this requirement by adding the word "costs" to the budget category in the Second Draft. This revision is necessary for consistency and clarity to convey that the intent of the category is to capture costs associated with the comprehensive outreach and education program required pursuant to the stewardship plans detailed in sections 18973.2 and 18973.3 of the proposed regulations.

Subsection 18973.6(b)(5) – Revised: renumbered from First Draft 18973.6(a)(8)

Subsection 18973.6(c) – Revised

CalRecycle moved the requirement to provide a reserve level from subsection (a)(9) in the First Draft to subsection (c) in the Second Draft, renumbered subsequent subsections, and added that program operators must include a description justifying the reserve level amount stated. The separation from the list of cost categories was necessary because a reserve level was recognized as different from a direct cost category. The purpose of a reserve level is to ensure that a program operator is able to financially adapt to unforeseen financial emergencies and maintain the level of service proposed in the stewardship plan. In accordance with statutory language, CalRecycle edited this subsection by adding that reserves shall be maintained in a prudent and responsible manner.

Subsection 18973.6(d) – Revised

CalRecycle renumbered First Draft subsection (b) to subsection (d) in the Second Draft because of the addition of subsection (c) above. CalRecycle modified this subsection to clarify requirements of a recommended funding level. The section specifies that the recommended funding level must cover the stewardship plan's budgeted costs and should be sufficient to operate the program over a multi-year period in a prudent and responsible manner as required by the authorizing statute. The additional language is necessary to clarify a connection between the recommended funding level, future budgets, and the statutory requirement to operate the program in a prudent and responsible manner pursuant to section 42033.2(c)(2) of the Public Resources Code. The language also enables the department to assess the recommended funding level to ensure that program funds are managed properly.

Subsection 18973.6(e) – Revised

CalRecycle renumbered this subsection from First Draft (c). CalRecycle modified this language by specifying that the required description should be relative to each line items cost category previously identified in section 18973.6(b) of the proposed regulations. This change is necessary to avoid different interpretations of what constitutes a sufficient description and to ensure CalRecycle receives a sufficiently

detailed description so that the review and approval process can be conducted effectively.

Subsection 18973.6(f) – Revised

This subsection was numbered as (e) in the First Draft, renumbered to (g) in the Second Draft due to two subsection additions, and renumbered to (f) in the Third Draft due to deletion of First Draft subsection (d).

First Draft subsection (d), which became subsection (f) in the Second Draft, was moved to subsections 18973.4(n) and 18973.5(q) in the Third Draft because the annual report sections are a more logical place for this requirement. The annual report includes information pertaining to the previous reporting period while the program budget section includes information about the upcoming calendar year. Thus, the requirement for expenses incurred over the previous reporting period should be under the annual report sections, rather than the program budget section.

CalRecycle further revised this subsection in the Second Draft by inserting clarifying language that the “member” covered entities of the stewardship organization are required to pay for the independent financial audit, and that covered entities that operate their own stewardship programs must fund an independent financial audit of those programs. The word “member” was inadvertently single underlined but should be double underlined because it was added in the Second Draft (See section titled NON-SUBSTANTIAL CHANGES MADE PRIOR TO THE FINAL VERSION OF THE PROPOSED REGULATORY TEXT). CalRecycle added the language to clarify who is responsible for funding the independent financial audit. CalRecycle removed the requirement that the independent audit must be performed in accordance with Generally Accepted Government Auditing Standards. The deletion was made in response to stakeholder comments that Generally Accepted Government Auditing Standards should not apply to this program since this program is not government-funded, and therefore the stringent auditing standards of Generally Accepted Government Auditing Standards were not applicable.

In the Initial Statement of Reasons, CalRecycle is making the following revision to the purpose and necessity explanation under subsection (e)(1) through (5) starting on page 57: “stewardship organization’s” should be “stewardship organization’s or covered entity’s.” The authorizing statute does not require a covered entity to join a stewardship organization – it can choose to implement and operate its own stewardship program.

Subsection 18973.6(f)(1) – Revised: renumbered from First Draft 18973.6(e)(1)

Subsection 18973.6(f)(2) – Revised: renumbered from First Draft 18973.6(e)(2)

Subsection 18973.6(f)(3) – Revised

CalRecycle renumbered this subsection from First Draft (e)(3). CalRecycle deleted the California Code of Regulations reference to these regulations and instead references “this Article” in the Second Draft. This modification was made for brevity and consistency with references to “this Article” in other sections of the proposed regulations.

Subsection 18973.6(f)(4) – Revised

CalRecycle renumbered this subsection from First Draft (e)(4). In the Second Draft, CalRecycle deleted the word “organization” in this subsection. This modification was needed to clarify that a stewardship organization is not the only entity that can implement a stewardship program. Authorizing statute allows for covered entities to design and implement their own stewardship program without joining a stewardship organization.

Subsection 18973.6(f)(5) – Revised: renumbered from First Draft 18973.6(e)(5)

Section 18974. Record Keeping Requirements. – Revised: see subsections below

Subsection 18974(a) – Revised

CalRecycle added references to the authorizing statute throughout this subsection in the Second Draft to indicate that records must be maintained in compliance with both

the regulations and authorizing statute. CalRecycle also replaced the term “regulations” with “this Article” to be consistent with how the regulations are referred to in the rest of the proposed regulations. Additionally, the department added the phrase “a minimum of” to the three-year requirement to be consistent with section 42035.6(b) of the Public Resources code. This is necessary to direct the regulated community to these statutory requirements.

Subsection 18974(b) – Revised

In the Second Draft, CalRecycle moved the phrase “upon request” from the end of the first sentence to the beginning for emphasis. CalRecycle added references to the authorizing statute in this section to indicate that records must be maintained and provided to the department as necessary to determine compliance with and pursuant to both the regulations and the authorizing statute. CalRecycle also added “a minimum of” to the three-year requirement to keep records for consistency with section 42035.6(b) of the Public Resources Code. This is necessary to direct the regulated community to this statutory requirement. The department replaced “the annual report” with “a document” in the Second Draft. This revision is necessary because records should be kept at least three years after submission of all documents as required by the regulations and the authorizing statute, regardless if the annual report relies on the records.

CalRecycle deleted the first sentence of this subsection in the Final Version of the regulatory text because it does not make specific or interpret the authorizing statute. The statutory language in section 42035.6(a) of the Public Resources Code is self-explanatory. CalRecycle describes this non-substantial change in the section titled NON-SUBSTANTIAL CHANGES MADE PRIOR TO THE FINAL VERSION OF THE PROPOSED REGULATORY TEXT.

Subsection 18974(c) – Revised

In the Second Draft, CalRecycle added “stewardship” to program to be more specific about what program is referenced and avoid ambiguity. CalRecycle added the phrase

“or dispensed” to avoid being more restrictive than section 42030(e)(1) of the Public Resources Code, which includes covered products sold, offered for sale, or dispensed.

Subsection 18974(c)(1) – No Updates

Subsection 18974(c)(2) – No Updates

Subsection 18974(c)(3) – Revised

CalRecycle revised subsection 18974(c)(3) in the Second Draft to avoid being more restrictive than section 42030(e)(1) of the Public Resources Code, which includes covered products sold, offered for sale, or dispensed.

Subsection 18974(c)(4) – Revised

The statutory reference was moved to the beginning of subsection (c)(4) in the Second Draft to specify which certification letters from the department must be provided. The term “manufacturer” was replaced with “covered entity or stewardship organization” to align with the authorizing statute terminology. CalRecycle replaced the slash symbol with the word “and” to specify that both the retail pharmacy and retail pharmacy chain must provide documentation when requested. “To demonstrate” was added to clarify the need for access to a certification letter. CalRecycle deleted the last part of the sentence because entities can always sell pharmaceuticals and sharps regardless of penalties (pursuant to section 42035.6(e) of the Public Resources Code) and the intent of the certification letter is to show compliance.

Section 18974.1. Administrative and Operational Costs. – Revised

CalRecycle revised the title of section 18974.1 in the Second Draft to include administrative and operational costs in addition to the departmental administrative fee. This edit was necessary so that CalRecycle could add the statutory requirements for administrative and operational costs to this section in the Second Draft. CalRecycle deleted the reference to departmental administrative fees in the title in the Final Version of the regulatory text due to the deletion of subsections (b) and (c), which discussed these fees. The statutory language in section 42034.2 of the Public Resources Code is

self-explanatory. CalRecycle describes this non-substantial change in the section titled NON-SUBSTANTIAL CHANGES MADE PRIOR TO THE FINAL VERSION OF THE PROPOSED REGULATORY TEXT.

Subsection 18974.1(a) – New Subsection

The First Draft text for section 18974.1 simply stated that the department shall set the administrative fee pursuant to the authorizing statute. However, because the authorizing statute includes separate requirements for administrative fees and administrative and operational costs, CalRecycle added subsections (a) through (c) in the Second Draft to more closely align with the authorizing statute.

CalRecycle added this subsection in the Second Draft to include direct statutory language from section 42034 of the Public Resources Code to clarify who shall pay all administrative and operational costs of the stewardship program.

Subsection 18974.1(b) – Added and Deleted

CalRecycle added this subsection in the Second Draft to include statutory language from section 42034.2(a)(1) of the Public Resources Code to clarify who shall pay the departmental administrative fee. The statutory references from the First Draft language were revised in the Second Draft to specifically reference subsection 42034.2(a)(1) of the Public Resources Code and remove an incorrect reference to section 42034.4. These edits are necessary to direct the regulated community to the statutory requirements regarding how the department shall set the departmental administrative fee and who shall pay it. CalRecycle deleted this subsection in the Final Version of the regulatory text because it does not make specific or interpret the authorizing statute. The statutory language in section 42034.2 of the Public Resources Code is self-explanatory. CalRecycle describes this non-substantial change in the section titled NON-SUBSTANTIAL CHANGES MADE PRIOR TO THE FINAL VERSION OF THE PROPOSED REGULATORY TEXT.

Subsection 18974.1(c) – Added and Deleted

CalRecycle added this subsection in the Second Draft to include statutory language from section 42032.2(a)(2) regarding departmental administrative fees for stewardship organizations. This addition is necessary to direct the regulated community to this statutory requirement. CalRecycle deleted this subsection in the Final Version of the regulatory text because it does not make specific or interpret the authorizing statute. The statutory language in section 42034.2 of the Public Resources Code is self-explanatory. CalRecycle describes this non-substantial change in the section titled NON-SUBSTANTIAL CHANGES MADE PRIOR TO THE FINAL VERSION OF THE PROPOSED REGULATORY TEXT.

References – Revised

In the Final Version of the regulatory text, CalRecycle corrected an inadvertent deletion error reference to section 42034 of the Public Resources Code made in the Second Draft of the proposed regulations which carried over to the Third Draft. See a description of this change in the section titled NON-SUBSTANTIAL CHANGES MADE PRIOR TO THE FINAL VERSION OF THE PROPOSED REGULATORY TEXT.

Section 18974.2. Stewardship Organization Audits of Covered Entities or Authorized Collectors. – No Updates

Section 18974.3. Distributor, Wholesaler, Pharmacy, and Retailer Product Verification. – Revised

CalRecycle revised the title of this section in the Second Draft by rearranging the words for consistency with the order of these entities as listed in section 42035(c) of the Public Resources Code.

Subsection 18974.3(a) – Revised

CalRecycle added the preamble from First Draft section 18974.3 to subsection (a) in the Second Draft because it did not relate to subsection (b). The word “internet” was made lowercase and “Website” was capitalized for consistency with the rest of the regulatory text. CalRecycle added text to specify that a distributor, wholesaler, pharmacy, and

retailer are required to determine compliance by monitoring CalRecycle’s website to verify “that the covered entities providing the covered product(s) are in compliance with the law.” This addition is necessary to clarify that each distributor, wholesaler, pharmacy, and retailer must identify non-compliant covered entities, not non-compliant covered products.

Subsection 18974.3(b) – Revised

In the Second Draft, CalRecycle replaced “product” with “entity” to clarify that it is the covered entity or stewardship organization that would be considered non-compliant under the authorizing statute, not covered products. CalRecycle deleted “Enforcement Unit” because it was not defined and no specific contact information was provided. These details are not necessary to specify in the regulations and allow the responsible party to report to CalRecycle, not a specific unit within CalRecycle. CalRecycle added “for any of the foregoing” to clarify that the term “designated responsible party” applies to any of the entities listed in this subsection. Finally, CalRecycle added “within 30 days” to specify a timeline for this requirement that is consistent with other notification deadlines in the authorizing statute and proposed regulatory text.

Section 18975. Criteria to Impose an Administrative Civil Penalty. – Deleted First Draft Text and Revised

CalRecycle deleted the First Draft text and replaced it with Second Draft text. The reason for the deletion of all text and replacement with new text is that CalRecycle made significant changes to the regulatory text. Marking each change would have made it difficult for a reader to follow. CalRecycle made further edits in the Third Draft, as indicated in the explanations below. The descriptions of purpose and necessity in this section of the Final Statement of Reasons will replace the same descriptions in the Initial Statement of Reasons.

Subsection 18975(a) – Deleted First Draft Text and Revised

The purpose of this subsection is to explain that CalRecycle has the statutory authority to impose penalties on any of the following entities if the entity has violated a

requirement of the authorizing statute or its implementing regulations: covered entity, program operator, stewardship organization, and authorized collector. This subsection is necessary to inform the above-mentioned entities that CalRecycle may impose penalties on them if CalRecycle determines that they have violated a requirement of the authorizing statute or its implementing regulations.

CalRecycle replaced the First Draft text in this subsection with Second Draft text. This is necessary because the Second Draft text aligns with the authorizing statute (section 42035.2(a)(1) of the Public Resources Code) and is easier to understand. The Second Draft includes references to violations of the implementing regulations in addition to the authorizing statute. This is necessary to clarify that CalRecycle has authority to impose penalties not only for violations of requirements in the authorizing statute, but also violations of the requirements in the implementing regulations.

CalRecycle made minor changes to the text in the Third Draft for clarity. CalRecycle added a reference to “California” to highlight that CalRecycle’s jurisdiction is limited to covered products that are sold, offered for sale, or provided in or into California and the entities (that are listed in this subsection) that are involved in managing these covered products. CalRecycle also replaced “in violation of” with “has violated” to clarify that the imposition of penalties follows a violation that has occurred.

Subsections 18975(b) – New Subsection

CalRecycle added this subsection in the Third Draft because it closely aligns with a section in the authorizing statute (section 42035.6(d) of the Public Resources Code) which lists imposition of penalties as one of the options for punitive actions. The purpose of this subsection is to inform respondents that if they fail to provide CalRecycle with access to information required by section 42035.6(a) of the Public Resources Code or section 18974 of the implementing regulations, CalRecycle can either impose penalties or post a notice in accordance with section 42035.6(d)(2) of the Public Resources Code. This subsection is necessary for consistency with the authorizing statute and to inform a respondent about CalRecycle’s authority to impose

penalties, post a notice, or take both of the actions if a respondent fails to provide CalRecycle with necessary access to information.

Subsection 18975(c) – Deleted First Draft Text and Revised

This section was numbered subsection (b) in the First Draft and Second Draft and became subsection (c) in the Third Draft. Subsections (c)(1) through (c)(11) provide 11 criteria CalRecycle may take into consideration when assessing or reviewing the amount of an administrative penalty. These criteria are necessary to clarify section 42035.2(b) of the Public Resources Code and inform the respondent of the criteria CalRecycle may use when setting the administrative civil penalty amount. Even though CalRecycle deleted and replaced the criteria list in the Second Draft to help the reader follow the changes, the criteria list did not change considerably from the First Draft.

For ease of understanding, the purpose and necessity explanations in the Final Statement of Reasons replace the purpose and necessity explanations in the ISOR. Because the criteria list did not change considerably, the following is a list of changes CalRecycle made from the First to the Second Draft text. First, CalRecycle changed the subsection (c)(3) (which was (b)(3) in the First Draft and Second Draft), criterion to “intentional, knowing, and reckless” from “intentional, knowing, and negligent” in the First Draft. This is necessary because “intentional, knowing, and *reckless*” violations can increase penalty amounts up to \$50,000 per day while penalty amounts for *negligent* violations shall not exceed \$10,000 per day (see section 42035.2(a)(2) of the Public Resources Code). Intentional, knowing, and reckless violations are more severe than negligent violations. Second, CalRecycle changed the subsection (c)(4) (which was (b)(4) in the First Draft and Second Draft) criterion to clarify that the criterion (the size of the violator) is referring to the size of the violator’s business and/or the financial position of the violator. Third, in criterion (c)(7) (which was (b)(7) in the First Draft and Second Draft), CalRecycle added a reference to both the authorizing statute and the regulatory text. This is necessary to clarify that an entity must comply with requirements in the authorizing statute as well as the requirements in the implementing regulations.

Section 18975.1. Procedure for Imposing Administrative Civil Penalties. – Deleted First Draft Text and Revised

CalRecycle deleted the First Draft text in this subsection and replaced it with Second Draft text. The reason for the deletion of all text and replacement with new text is that CalRecycle made significant changes to the regulatory text. Marking each change would have made it difficult for a reader to follow. CalRecycle made further edits in the Third Draft, as indicated in the explanations below. The descriptions of purpose and necessity in this section of the Final Statement of Reasons will replace the same descriptions in the Initial Statement of Reasons.

Subsection 18975.1(a) – Deleted First Draft Text and Revised

The First Draft included references to the Administrative Procedures Act (commencing with section 11445.10 of the Government Code) and the informal hearing procedures it outlines. CalRecycle deleted this subsection in the Second Draft. This is necessary because CalRecycle prefers to allow maximum flexibility for all parties in the informal hearing process. The authorizing statute did not prescribe a formal hearing process nor a specific informal hearing process. The Administrative Procedure Act “Bill of Rights” (Gov. Code 11425.10 through 11425.60) still applies to hearings conducted under these regulations, even though these procedures are not expressly listed in this section of the regulations.

CalRecycle added new text in this subsection in the Second Draft. This new text discusses a notice of violation, by which CalRecycle will notify a respondent about a violation of a material requirement of the authorizing statute or its implementing regulations. This is necessary to inform a respondent that CalRecycle will provide notice to the respondent (describing the nature of the violation(s)), after determining that a violation has occurred, to afford the respondent an opportunity to possibly address the violation(s) before CalRecycle commences the process to take a disciplinary action. The notice of violation is meant to encourage respondents to correct violations to avoid disciplinary actions.

CalRecycle revised this subsection in the Third Draft, adding subparts (1) and (2) and changing placement of text. Addition of the subparts is necessary to reference the statutory text that allows CalRecycle to impose penalties on respondents. This text is consistent with regulatory text in subsection 18975(a). Due to reorganization, changes in text placement are necessary for sentences to be grammatically correct. Addition of the phrase “if the department determines” is necessary to clarify that, in accordance with the authorizing statute, the department must determine that a violation has occurred before issuing a notice of violation.

Subsection 18975.1(b) – Deleted First Draft Text and Revised

CalRecycle added this subsection in the Second Draft to describe the contents of an accusation. An accusation shall inform the respondent regarding a respondent’s right to a hearing and state the legal and factual basis for imposing penalties, including a description of how CalRecycle applied the criteria in section 18975(c). This is necessary to inform the respondent that an accusation begins the formal process for imposition of penalties and to outline the contents of an accusation (as stated in the regulatory text). The contents of an accusation are necessary to provide the necessary information for a respondent to rebut CalRecycle’s findings. In the Third Draft, the reference to subsection 18975(b) changed to (c) due to insertion of a new text for subsection 18975(b). The text that was listed as subsection (b) in the First Draft was renumbered to subsection (c) and replaced in the Second Draft. Please see subsection (c) below for a purpose and necessity explanation regarding service of an accusation.

Subsection 18975.1(c) – Deleted First Draft Text and Revised

Subparts (c)(1) through (c)(4) identify personal service, substitute service, certified mail or registered mail, or electronic means with respondent’s consent as options for service to notify respondents of the accusation against them. These subsections are necessary to inform the respondent regarding the possible modes of service CalRecycle will use to deliver the accusation.

CalRecycle deleted the First Draft text in this subsection in the Second Draft. In the First Draft, this subsection stated that penalties may be imposed pursuant to Public Resources Code, section 42035.2. This deletion is necessary because it is redundant with the added text in section 18975(a).

In the First Draft, subsection (b) described the service requirements for an accusation, and CalRecycle moved these requirements to this subsection in the Second Draft.

CalRecycle replaced this text with text outlining the procedure for serving an accusation on a respondent. Deletion of the First Draft text was necessary due to reorganization. CalRecycle shortened subpart (3) for clarity in the Second Draft. This subpart allows for certified or registered mail as a means of service. It is not necessary to describe the process CalRecycle will use to identify a mailing address in the regulations. CalRecycle will determine the appropriate mailing address for a respondent if and when it decides to use certified or registered mail. It is also unnecessary to identify what shall constitute as proof of service and what section of the Government Code shall govern the mailing by certified or registered mail. Certified and registered mail are well-established mailing options. CalRecycle will comply with requirements in applicable laws and regulations to ensure proper service. The Second Draft also added electronic service (if respondent consents) as a possible option for CalRecycle to serve the accusation. This is necessary to allow more flexibility for both CalRecycle and the respondent.

Subsection 18975.1(d) – New subsection

CalRecycle added this subsection in the Second Draft to alert the respondent about the right to request a hearing and describe how the respondent shall make such a request. This subsection also alerts the respondent about the consequences of failure to submit a timely hearing request. This subsection is necessary so that the regulated parties are aware of their due process rights and the procedures available to challenge an action by CalRecycle.

Subsection 18975.1(e) – New subsection

CalRecycle added this subsection in the Second Draft to describe the informal hearing process, inform the respondent of the right to present evidence, and inform the respondent about the evidence that will be admitted at the hearing. This subsection is necessary to inform the respondent that the hearing will be held in front of the Director of CalRecycle, that parties may present any relevant evidence, and that any relevant evidence (as outlined in the regulatory text) will be admitted.

Subsection 18975.1(f) – New subsection

CalRecycle added this subsection in the Second Draft. The purpose is to let respondents know that the Director of CalRecycle will issue a written decision after a hearing and that this will happen sixty (60) days from the date of conclusion of the hearing. This is necessary so the regulated parties are aware of their due process rights and the procedures available to challenge an action by CalRecycle.

Section 18975.2. Procedure for Stewardship Plan Revocation, Resubmittal, or Additional Compliance Reporting. – Deleted First Draft Text and Revised

CalRecycle deleted the First Draft text in this subsection and replaced it with Second Draft text. The reason for the deletion of all text and replacement with new text is that CalRecycle made significant changes to the regulatory text. Marking each change would have made it difficult for a reader to follow. CalRecycle made further edits in the Third Draft, as indicated in the explanations below. The descriptions of purpose and necessity in this section of the Final Statement of Reasons will replace the same descriptions in the Initial Statement of Reasons.

Subsection 18975.2(a) – Deleted First Draft Text and Revised

The purpose of this subsection is to inform the respondent that if CalRecycle determines that a respondent has not met a material requirement of the authorizing statute or its implementing regulations, in addition to imposing penalties, CalRecycle can take one or more of the following disciplinary actions, as described by the authorizing statute: revoke a previously approved stewardship plan, require resubmittal of a stewardship plan, and/or require more compliance reporting. This subsection is

necessary to inform the respondent of possible disciplinary actions and enable CalRecycle to execute its oversight responsibilities to ensure and maintain compliant program performance.

CalRecycle deleted this subsection in the Second Draft and replaced it with language that closely aligns with statutory language in section 42035.4 of the Public Resources Code. This is easier for a reader to understand. CalRecycle also added references to the authorizing statute and the implementing regulations because CalRecycle has authority to take all of the disciplinary actions outlined in this subsection for violations of not only the authorizing statute but also the implementing regulations. The First Draft stated that CalRecycle can take a disciplinary action only after holding a public hearing. However, a public hearing is only necessary if the respondent requests one. The respondent has the right to request a hearing but does not need to request a hearing. A respondent can rebut CalRecycle's findings outside of a hearing.

CalRecycle clarified the text to align even more closely with the authorizing statute (Section 42035.4 of the Public Resources Code) in the Third Draft. The phrase "if the department finds" is necessary to clarify that the department must determine that a violation has occurred before taking a disciplinary action. CalRecycle added the word "and" to subpart (2) to clarify that CalRecycle can take one or more of the disciplinary actions outlined in subparts (1) through (3) or take all of them as allowed by the authorizing statute. CalRecycle also rearranged some language, which is necessary for grammatical purposes.

Subsection 18975.2(b) – Deleted First Draft Text and Revised

CalRecycle added new text in this subsection in the Second Draft. This subsection discusses the notice which CalRecycle will provide to the respondent which will inform the respondent of CalRecycle's intent to take the disciplinary actions outlined in subsection (a). The notice will state the legal and factual basis for the proposed disciplinary action. This is necessary to inform the respondent of the disciplinary actions and allow the respondent to rebut CalRecycle's determinations.

CalRecycle revised this subsection to align more closely with statutory language in section 42035.4 of the Public Resources Code in the Second Draft. This is easier for a reader to understand than the language in the First Draft. CalRecycle also deleted the requirement to provide notice at least sixty days prior to the hearing to allow maximum flexibility in the timing. If the respondent requests a timely hearing after receiving notice of CalRecycle's intent to take a disciplinary action, CalRecycle will schedule a hearing during a time that will serve both parties.

CalRecycle revised the text from "upon making the finding" to "before revoking a previously approved plan..." in the Third Draft. This is necessary to clarify that CalRecycle will provide notice to the respondent before taking these disciplinary actions. CalRecycle also changed "program operator" to "respondent" to match language in subsection 18975.1(b) of the proposed regulations.

Subsection 18975.2(c) – Deleted First Draft Text and Revised

Subsection (c) in the Third Draft describes the options for service of the notice (described in subsection (b)). Subparts (c)(1) through (c)(4) identify personal service, substitute service, certified mail or registered mail, or by electronic means with respondent's consent, as options for service of the notice. This is necessary to inform the respondent regarding the modes of service CalRecycle will use to deliver the notice.

The First Draft included references to the Administrative Procedures Act (commencing with section 11445.10 of the Government Code) and the informal hearing procedures. CalRecycle deleted this subsection in the Second Draft. This is necessary because CalRecycle prefers to allow maximum flexibility for all parties in the informal hearing process. The authorizing statute did not prescribe a formal hearing process nor a specific informal hearing process. The Administrative Procedure Act "Bill of Rights" (Gov. Code 11425.10 through 11425.60) still applies to hearings conducted under these regulations, even though these procedures are not expressly listed in this section of the regulations.

CalRecycle added the phrase “described in subdivision (b)” in the Third Draft, which is necessary to clarify that this refers to the notice described in subsection 18975.2(b).

Subsection 18975.2(d) – Deleted First Draft Text and Added New Text

CalRecycle deleted the First Draft text in this subsection. This is necessary because CalRecycle significantly changed and rearranged the language in this subsection and added a requirement for a timely hearing request. The regulatory text requirement to describe the basis to contest CalRecycle’s intended disciplinary action(s) was the same in the First Draft.

CalRecycle added this subsection in the Second Draft to alert the respondent about the right to request a hearing and describe how the respondent shall make such a request. The respondent must request a hearing within 30 days of receipt of the notice described in subsection (b). This subsection also alerts the respondent about the consequences of failure to submit a timely hearing request. This subsection is necessary so that regulated parties are aware of their due process rights and the procedures available to challenge an action by CalRecycle.

CalRecycle replaced “program operator” with “respondent” in the Final Version of the regulatory text for consistency with subsection 18975.2(b). This is a non-substantial change because it does not add a requirement that is not already provided for in the regulations and is consistent with the authorizing statute.

Subsection 18975.2(e) – Deleted First Draft Text and Added New Text

In the First Draft, this subsection informed the respondent that the CalRecycle Director will issue a determination about CalRecycle’s course of action within sixty working days of the hearing. CalRecycle moved this language (with changes) to subsection 18975.2(f) of the proposed regulations.

CalRecycle added this subsection in the Second Draft to describe the informal hearing process, inform the respondent of the right to present evidence, and inform the respondent about the evidence that will be admitted at the hearing. This subsection is

necessary so that regulated parties are aware of their rights and the procedures available to challenge an action by CalRecycle.

Subsection 18975.2(f) – Deleted First Draft Text and Added New Text

In the First Draft, subsection 18975.2(e) informed the respondent that CalRecycle’s Director will issue a determination about CalRecycle’s course of action within sixty working days of the hearing. The Second and Third Draft language in this subsection (f) revised the date of issuance to sixty calendar days after conclusion of the hearing. The revision from working to calendar days is necessary for consistency with other timing requirements in this section (which use calendar days).

CalRecycle added this subsection in the Second Draft. The purpose is to let respondents know that the Director of CalRecycle will issue a written decision sixty calendar days from the date of conclusion of the hearing. This is necessary so that regulated parties are aware of their due process rights and the procedures available to challenge an action by CalRecycle.

Subsection 18975.2(g) – Deleted

CalRecycle deleted this subsection in the Second Draft. The term “resubmittal” is commonly understood and not necessary to define.

Subsection 18975.2(h) – Deleted

CalRecycle deleted this subsection in the Second Draft. The term “additional reporting” is commonly understood and not necessary to define.

NON-SUBSTANTIAL CHANGES MADE PRIOR TO THE FINAL VERSION OF THE PROPOSED REGULATORY TEXT

Errors discovered in the Third Draft that CalRecycle corrected in the Final Version of the Proposed Regulations:

- 1) Page 12, line 38 – the phrase “nonstewardship plan” is shown. The word has been corrected to delete “non” as it was an inadvertent addition and the word “nonstewardship” does not exist.
- 2) Page 15, lines 14-16 – the second “contact information” was incorrectly double underlined and should be single underlined because it was added in the First Draft. The phrase “of the corporate officer, or designee, responsible for submitting and overseeing the stewardship plan on behalf of the program operator, including, but not limited to:” was inadvertently single underlined and should be double underlined because it was added in the Second Draft.
- 3) Page 33, line 23 – the word “member” is single underlined and should be double underlined because it was added in the Second Draft.
- 4) Page 36, line 2 – a double strikethrough of “, 42034” in the reference section was corrected because “, 42034” was inadvertently deleted.

Errors discovered in the Second Draft specific to underline and strikethrough to demonstrate additions and deletions:

- 1) Page 8, line 23 and page 14, line 29 – the letter “l” in the word “internet” is double stricken and double underlined and should not have appeared in the text.
- 2) Page 9, line 29 – the letter “i” in the word “if” is double stricken and double underlined and should not have appeared in the text.
- 3) Page 11, line 17 – the word “mail-back” is double stricken and double underlined and should not have appeared in the text.
- 4) Page 11, line 34 – the phrase “and procedures” is double stricken and double underlined and should not have appeared in the text.
- 5) Page 14, line 14 – the phrase “contact information” is double stricken and double underlined and should be single underlined and double stricken. The second “contact information” is double underlined and should be single underlined.
- 6) Page 26, line 27 – the reference to 18973.3(f)(5) and (7) is double underlined, but should also have demonstrated (6) and (8) in double strikethrough.

Other non-substantial changes reflected in the Final Version of the Proposed Regulatory Text. One can compare the Third Draft and the Final Version to see these changes.

- 1) Third Draft, Page 1, lines 12-22 (subsection 18972) – CalRecycle deleted this section because it did not make specific or interpret the authorizing statute. Therefore, this section is unnecessary.
- 2) Third Draft, Page 2, lines 3-4 (subsection 18972.1(a)(3)) – CalRecycle inserted the following after the definition of “Homebound” into the Final Version: “(Chapter revised July 12, 2019, definition issued, effective, and implemented in 2014). The Medicare Benefit Policy Manual, Chapter 15, Section 60.4.1 is incorporated herein by reference.” This is a non-substantial change because it simply adds an incorporation by reference tag; it does not add or alter any requirements already provided for in the proposed regulations.
- 3) Third Draft, Page 4, lines 33-34 and Page 5, lines 1-3 (subsection 18973(a)) – CalRecycle added “published in 2008” and the following sentence at the end of this subsection into the Final Version: “The entirety of the Web Content Accessibility Guidelines 2.0 (published in 2008) are incorporated herein by reference.” This is a non-substantial change because it simply adds an incorporation by reference tag; it does not add or alter any requirements already provided for in the proposed regulations. CalRecycle also deleted the phrase “or a subsequent version” to eliminate an improper prospective incorporation by reference and any possible confusion for the regulated community. This is a non-substantial change because it does not alter any requirements already provided for in the proposed regulations.
- 4) Third Draft, Page 10, lines 33-34 (subsection 18973.2(f)) – CalRecycle deleted the reference to departmental administrative fees in the Final Version of the regulations. This is a non-substantial change because the authorizing statute is self-explanatory. The deleted language does not make specific or interpret the statute. It also does not alter any requirements in the statute or regulations. Therefore, the change is non-substantial.

- 5) Third Draft, Page 16, lines 27-28 (subsection 18973.3(e)) – CalRecycle deleted the reference to departmental administrative fees in the Final Version of the regulations. This is a non-substantial change because the authorizing statute is self-explanatory. The deleted language does not make specific or interpret the statute. It also does not alter any requirements in the statute or regulations. Therefore, the change is non-substantial.
- 6) Third Draft, Page 33, line 4 (subsection 18973.6(b)(3)) – CalRecycle deleted the reference to departmental administrative fees in the Final Version of the regulations. This is a non-substantial change because the authorizing statute is self-explanatory. The deleted language does not make specific or interpret the statute. It also does not alter any other requirements in the regulations. Therefore, the change is non-substantial.
- 7) Third Draft, Page 34, lines 24-27 (subsection 18974(b)) – CalRecycle deleted the first sentence of this subsection in the Final Version of the regulatory text because the statutory language is self-explanatory. This is a non-substantial change because the deletion does not alter any requirements in the authorizing statute or regulations.
- 8) Third Draft, Page 35, lines 19-20 (subsection 18974.1 heading) – CalRecycle deleted the reference to departmental administrative fees in the title in the Final Version of the regulatory text due to deletion of subsections (b) and (c), which discussed these fees. This is a non-substantial change because the deletion does not alter any requirements in the authorizing statute or regulations.
- 9) Third Draft, Page 35, lines 26-37 (subsections 18974.1(b) and (c)) – CalRecycle deleted subsections (b) and (c) in the Final Version of the regulatory text because the statutory language is self-explanatory. This is a non-substantial change because the deletion does not alter any requirements in the authorizing statute or regulations.
- 10) Third Draft, Page 42, lines 24 and 28 (subsection 18975.2(d)) – The phrase “program operator” appears on these lines and is a syntax error. CalRecycle replaced “program operator” with “respondent” in the Final Version of the regulations for consistency with subsection 18975.2(b). This is a non-substantial

change because it does not add a requirement that is not already provided for in the regulations and is consistent with the authorizing statute.

11) Underlining Error. In May 2020, the Proposed Regulations were modified by underlining the new sections to be added to the California Code of Regulations as these sections were inadvertently noticed to the public without use of underlining in the Notice of Proposed Rulemaking (See Rulemaking File, Tab 6 for both versions). The underlining was designed to show the sections that are proposed to be added to the California Code of Regulations. CalRecycle found these modifications to be non-substantial or solely grammatical in nature, as those terms are used in Government Code section 11346.8(c), and as defined in Section 40 of Title 1 of the California Code of Regulations, since they merely clarify without materially altering the requirements, rights, responsibilities, conditions, or prescriptions contained in the original text.

DOCUMENTS INCORPORATED BY REFERENCE

Subsequent to the second 15-day formal public comment period, CalRecycle made additional non-substantial edits to the proposed regulatory text to mark the following two sources referenced in the text as “documents incorporated by reference:”

- 1) The Medicare Benefit Policy Manual, Chapter 15, 60.4.1.
- 2) The Web Content Accessibility Guidelines 2.0 published in 2008 by the Web Accessibility Initiative of the World Wide Web Consortium at a minimum Level AA success criteria.

Both of these documents are easily accessible through a standard internet web search, and they are both impractically lengthy for inclusion in our proposed regulatory text and the California Code of Regulations. Including these documents at length would also be confusing and burdensome for stakeholders seeking specific regulatory requirements.

REASONABLE ALTERNATIVES TO THE PROPOSED REGULATORY ACTION –
REVISED – See Revised Economic and Fiscal Impact Statement

CalRecycle considered alternatives to the proposed regulation (discussed below), and determined that no alternative considered by CalRecycle: (1) would be more effective in carrying out the purpose for which the regulation is proposed; (2) would be as effective and less burdensome to affected private persons than the adopted regulation; or (3) would be more cost effective in implementing the statutory policy or other provision of law. Separately, CalRecycle's determination that the regulations will not have an adverse economic impact on small businesses did not change.

CalRecycle edited the Economic Impact Assessment to include CalRecycle staff costs for a new enforcement unit that was approved in the 2020-21 California Budget. These additional costs for the state are reflected in the primary analysis as well as in the analysis of each alternative. Additionally, CalRecycle adjusted the narrative explanation of alternatives in the Economic Impact Assessment to better reflect proposed regulatory text. Thus, CalRecycle is replacing the description of alternatives listed in the Initial Statement of Reasons with the following text:

Alternative 1

Alternative 1 is to clarify in regulation the phrase “provides or initiates distribution of a sharps waste container and mail-back materials at the point of sale” to mean that every customer is given a sharps container and mail-back materials at each individual sale sufficient to accommodate the volume of sharps purchased. However, some customers who purchase syringes (and associated medications) on a frequent and routine basis may prefer not to receive a sharps container every time they purchase sharps. For example, a self-injector may prefer to receive a 1-gallon sharps container which could accommodate the amount of sharps they use over the course of nine months and enable them to make multiple purchases of syringes without incurring the additional burden of receiving and transporting a sharps container during that period of time.

Alternative 1 may also create a burden on pharmacies that have limited floor space to store sharps containers. Alternative 1 is estimated to cost covered entities \$115 million per year, which exceeds the cost of the regulation (\$22.1 million per year) and is not anticipated to result in significantly more sharps collected from ultimate users.

Alternative 1 was not selected as it does not significantly increase the quantity of sharps that would be collected and is more costly than the proposed regulation.

Alternative 2

The proposed regulation requires that a program operator's education and outreach activities and materials contain language translations suitable to local demographics and certain considerations related to accessibility. Eliminating this requirement was considered as a lower cost Alternative 2. Under Alternative 2, a program operator would save thousands of dollars per year in printing, translation, and IT costs, but its education and outreach efforts would be less successful in reaching certain communities and target audiences. Consequently, Alternative 2 would result in less pharmaceutical and sharps waste collected and reduce the effectiveness of the law, which is why it was not selected.

ECONOMIC IMPACT ASSESSMENT PER GOVERNMENT CODE SECTION 11346.3

(b) – REVISED

CREATION OR ELIMINATION OF JOBS WITHIN CALIFORNIA – Revised: See Revised Economic and Fiscal Impact Statement

CalRecycle edited the Economic Impact Assessment to include CalRecycle staff costs for a new enforcement unit that was approved in the 2020-21 California Budget. Since these increased state costs will be reimbursed by covered entities, CalRecycle re-ran the Regional Economic Models Inc. (REMI) economic model to account for the effects of increased spending on state employment and other economic metrics. Changes in state employment were minimal and consistent with a minimal increase in program costs due to the new enforcement unit. Due to these changes, CalRecycle is replacing

the description of “CREATION OR ELIMINATION OF JOBS WITHIN CALIFORNIA” section, found on pg. 72-73 in the Initial Statement of Reasons with the following text:

Approximately 50 new jobs will be created statewide as a direct result of the regulation. This number includes 24 new jobs for CalRecycle and the State Board of Pharmacy, with the remainder being jobs in newly-formed stewardship organizations. In order to calculate potential changes in employment due to indirect effects of the regulation, staff had to consider how much of the costs to operate the stewardship programs may be passed on to consumers through retail price increases. It is important to note that statute requires stewardship plans demonstrate adequate funding for all administrative and operational costs of the stewardship program, to be borne by participating covered entities. However, determining whether a change in retail prices for the thousands of covered products in the marketplace will occur as a result of the regulation or the number of the other factors that go into a manufacturer’s determination of product price will be exceedingly difficult, if not impossible. Therefore, although it is expected that manufacturers will not increase prices consistent with the law, staff ran the REMI economic model under three different assumptions regarding how much of program costs may be passed on to consumers in order to prepare as conservative an economic analysis as possible. Under the most conservative assumption that 100% of the program costs could be passed on to consumers, around 7 jobs are expected to be gained, resulting in a total net job gain of 57 due to the 50 new jobs that are directly created as discussed above. See Table 1 below. Table 1 is available under section A.6. of the Economic and Fiscal Impact Statement.

**CREATION OF NEW BUSINESSES OR ELIMINATION OF EXISTING BUSINESSES
WITHIN CALIFORNIA – No Updates**

**EXPANSION OF BUSINESSES CURRENTLY DOING BUSINESS WITHIN THE
STATE – No Updates**

BENEFITS OF THE REGULATION – No Updates

INITIAL DETERMINATION THAT THE ACTION WILL NOT HAVE A SIGNIFICANT ADVERSE ECONOMIC IMPACT ON BUSINESS – No Updates

As described in the Notice of Proposed Rulemaking, CalRecycle continues to find that the proposed regulations will not have a significant adverse economic impact on business.

DETERMINATION THAT THE REGULATIONS DO NOT IMPOSE A MANDATE UPON LOCAL AGENCIES OR SCHOOL DISTRICTS – No Updates

DUPLICATION OR CONFLICTS WITH CODE OF FEDERAL REGULATIONS – No Updates

Federal law or regulations do not contain comparable requirements.

FINDING ON NECESSITY OF REPORTS (GOVERNMENT CODE SECTION 11346.3(d) – No Updates

SUMMARY OF STAKEHOLDER COMMENTS AND DEPARTMENT RESPONSES

Stakeholder comments received during the comment periods and Department responses are included in the matrices as items ‘d’ under Tabs 8, 11, and 13 of the rulemaking binder and incorporated by reference herein. Additional comment and response documents noted as items ‘f’ in Tabs 8, 11, and 13 of the rulemaking binder and incorporated by reference herein include comments regarding the rulemaking process and CalRecycle responses.

TECHNICAL STUDIES, REPORTS, OR DOCUMENTS – Revised

In addition to the documents listed in the Initial Statement of Reasons, CalRecycle relied upon the following documents to develop the proposed regulations and publicly noticed them during the two 15-day public comment periods:

Documents noticed during the first 15-day public comment period:

1. United States Postal Service. 2018. *What Are the Guidelines for Mailing Priority Mail*. <https://faq.usps.com/s/article/What-are-the-Guidelines-for-Mailing-Priority-Mail>
2. Division 7, Chapter 17.5, Section 7295 of the Government Code. https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=GOV§ionNum=7295.

This document was removed from the list of “Documents Relied Upon” because it is a statute. Please see the next section for an explanation.

Documents noticed during the second 15-day public comment period:

3. American Institute of Certified Public Accountants. Audit and Attest Standards, including Clarified Standards. <https://www.aicpa.org/research/standards/auditattest.html>
4. American Institute of Certified Public Accountants. General Accepted Auditing Standards. <https://www.aicpa.org/Research/Standards/AuditAttest/DownloadableDocuments/AU-00150.pdf>
5. Financial Accounting Standards Board. General Accepted Accounting Principles. <https://fasb.org/home>
6. Mattress Recycling Council 2017 California Annual Report. <https://mattressrecyclingcouncil.org/wp-content/uploads/MRC-2017-California-Annual-Report-for-web.pdf>
7. U.S. Government Accountability Office. Generally Accepted Government Auditing Standards. <https://www.gao.gov/yellowbook/overview>
8. World Wide Web Consortium. 2008. Web Content Accessibility Guidelines 2.0. <https://www.w3.org/TR/WCAG20/>

DOCUMENTS REMOVED FROM THE LIST OF DOCUMENTS RELIED UPON

The following documents were identified in the Initial Statement of Reasons as technical studies, reports, or documents relied upon in proposing this rulemaking action. After further review, the Department has determined that these documents are either existing laws and regulations that CalRecycle did not need to make publicly available as a part of this rulemaking package, or were only used for general background information and were not relied upon by the Department in developing the proposed regulatory text.

Therefore, the Department is removing them from the list of such documents contained in the Initial Statement of Reasons.

1. [The Pharmaceutical and Sharps Waste Stewardship Act \(Jackson, Chapter 1004, Statutes of 2018\)](#)
2. [Division 2, Chapter 9, Section 4040 of the Business and Professions Code](#)
3. [Division 3.6, Chapter 4.5, section 927\(b\) of the Government Code](#)
4. [Division 104, Part 14, Chapter 3, Section 117904 of the Health and Safety Code](#)
5. [Subsection \(5\)\(A\) of subdivision \(h\) of section 254b of Title 42 of the U.S. Code on Public Health and Welfare](#)
6. [Title 2, Division 3, Part 1, Chapter 4.5, Section 11445.10 of the Government Code](#)
7. [Title 14, Division 7, Chapter 1, Article 4, Section 17041 of the California Code of Regulations](#)
8. [Title 21, Section 1317.75 of the Code of Federal Regulations](#)
9. [Architectural Paint and Recovery Program Regulations \(Title 14, Division 7, Chapter 11, Sections 18950-18958 of the California Code of Regulations\)](#)
10. [Used Mattress Recovery and Recycling Program Regulations \(Title 14, Division 7, Chapter 11, Sections 18959-18971 of the California Code of Regulations\)](#)
11. [Product Stewardship for Carpets Program Regulations \(Title 14, Division 7, Chapter 11, Sections 18940-18948 of the California Code of Regulations\)](#)
12. California State Board of Pharmacy. *California Pharmacy Law Book*. 2016. Accessed December 11, 2019. https://www.pharmacy.ca.gov/laws_regs/pharmacy_lawbook.shtml
13. Division 7, Chapter 17.5, Section 7295 of the Government Code. https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=GOV§ionNum=7295.