

7. Initial Statement of Reasons (ISOR)

INITIAL STATEMENT OF REASONS

December, 2019

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

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 DEA-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.

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

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 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.

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

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.

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.

GENERAL COMMENTS APPLICABLE TO STATEMENT OF REASONS

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 establish and submit to the Department of Resources Recycling and Recovery (the department), either 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.

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>.

- 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, 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

§ 18972. Purpose.

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, and pharmacies pursuant to Chapter 2 (commencing with section 42030), Part 3, Division 30 of the Public Resources Code.

§ 18972.1. Definitions.

The purpose of Section 18972.1 is to define terms used in the regulations that have a meaning which is not readily apparent without further definition. This section is necessary to ensure regulatory consistency and clarity for several technical and administrative terms that appear in the Act and the regulations.

Subsection (a)

Subsection (a) explains that the definitions that follow are provided as a supplement to the definitions contained in the Act. This section is necessary to set forth the following definitions and for completeness in order to ensure the regulated community is also aware of the definitions contained in the Act.

Subsection (b)

Subsection (b) defines the term “administrative and operational costs” as used in subsection (1)(D) of section 42032.2(a) of the Public Resources Code and is necessary in order to specify which costs associated with a stewardship program must be borne by the participating covered entities. This definition ensures that covered entities, and not any other party, will be responsible for the costs of implementing the stewardship program.

Subsection (c)

Subsection (c) defines the term “homebound” as used in subsection (G)(i) of section 42032.2(a)(1) of the Public Resources Code by referring to the definition used in the Medicare Benefit Policy Manual⁸. This definition is necessary for clarity in order to provide a standard set of criteria for all stewardship programs as to which individuals qualify as “homebound” and are thus entitled to certain disposal mechanisms for their covered drugs.

⁸ Medicare Benefit Policy Manual, Chapter 15, 60.4.1

Subsection (d)

Subsection (d) defines the term “homeless” as used in subsection (G)(i) of section 42032.2(a)(1) of the Public Resources Code by referring to the definition used in the U.S. Code on Public Health and Welfare⁹. This definition is necessary for clarity in order to provide a standard set of criteria for all stewardship programs as to which individuals qualify as “homeless” and are thus entitled to certain disposal mechanisms for their covered drugs.

Subsection (e)

Subsection (e) defines the term “home-generated sharps consolidation point” as used in subsections (f) and (i) of section 18973.3 by referring to the Medical Waste Management Act¹⁰. This definition is necessary for consistency as a sharps collection receptacle program will need to abide by existing regulations related to the Medical Waste Management Act, including the requirement that each location that collects home-generated sharps waste be registered with the California department of Public Health as a “home-generated sharps consolidation point.”

Subsection (f)

Subsection (f) defines the terms “local jurisdiction” and “local agency” to mean specific local government entities. This definition is necessary in order to clarify which entities are permitted to request that program operators provide either reimbursement for or removal of home-generated sharps waste collected at their household hazardous waste facilities. This ensures that the local government entities that were intended to receive this program assistance do so and that it is clear to program operators which requests

⁹ Subsection (5)(A) of subdivision (h) of section 254b of Title 42 of the U.S. Code on Public Health and Welfare

¹⁰ Division 104, Part 14, Chapter 3, Section 117904 of the Health and Safety Code

they must address, pursuant to subsection (1)(F)(ii) of section 42032.2(d) of the Public Resources Code.

Subsection (g)

Subsection (g) defines the term “minutes, books, and records” as used in subsection (a) of section 42033.4 of the Public Resources Code as up-to-date information of a program operator’s activities. This is necessary to clarify what information needs to be recorded and maintained by program operators, so they can prepare for and support audits of the stewardship program.

Subsection (h)

Subsection (h) defines the term “prescription” by referencing an existing definition from the Business and Professions Code¹¹. This is necessary to clarify the statutory definitions of “prescription drug” and “nonprescription drug.”

Subsection (i)

Subsection (i) defines the term “point of sale” as used in subsection (F)(i) of section 42032.2(d)(1) of the Public Resources Code, and is necessary in order to clarify the situations in which an ultimate user is entitled to a free sharps waste container and mail-back materials. This definition clarifies the scope of the program by ensuring that all sales of sharps are covered by a stewardship program, including sales from retailers other than pharmacies and online sales.

Subsection (j)

Subsection (j) defines the phrase “provides or initiates distribution of a sharps waste container,” as used in subsection (F)(i) of section 42032.2(d)(1) of the Public Resources Code. This definition is necessary in order to clarify a critical component of the mechanism by which ultimate users receive sharps waste containers and mail-back

¹¹ Division 2, Chapter 9, section 4040 of the Business and Professions Code

materials and determining compliance. The definition allows program operators the option of providing these materials at the point of sale, arranging, at the point of sale, for them to be sent to an ultimate user within three business days, or proposing a different method of distribution in the stewardship plan that would not compromise convenience to the ultimate user. The department understands that program operators may prefer to arrange for sharps waste containers and mail-back materials be sent, for example via mail or delivery, to ultimate users rather than provided directly at the point of sale, and that three business days is a reasonable time frame for program operators that will not inconvenience the ultimate user. However, it is impossible for the department to predict which distribution mechanisms may be proposed by program operators, and thus allowing flexibility is crucial for providing ultimate users with the most effective disposal methods while also allowing program operators to implement their stewardship program in a less burdensome manner.

The Department considered an alternative to this definition, which is discussed on page 70.

Subsection (k)

Subsection (k) defines the term “significant change” as used in subsection (e) of section 42030 of the Public Resources Code by providing a list of five types of scenarios that are deemed significant. This is necessary in order to identify and clarify when program operators would be required to submit the change to the department in writing for approval.

Subsection (k)(1)

Subsection (k)(1) identifies an addition or discontinuation of a method of collection as a “significant change.” This is necessary because the collection methods available to ultimate users are fundamental components of an approved stewardship program and adding or discontinuing a collection method could substantially alter the effectiveness of the program.

Subsection (k)(2)

Subsection (k)(2) identifies a change to a stewardship plan due to other existing laws or regulations as a “significant change.” This is necessary for the department to effectively monitor a stewardship program for compliance.

Subsection (k)(3)

Subsection (k)(3) identifies a change to a stewardship plan due to an ordinance repeal pursuant to section 42036.2 of the Public Resources Code as a “significant change.” Subsection (e) of section 42032.2 of the Public Resources Code requires that a stewardship plan include provisions for expanding into local jurisdictions that repeal their preexisting ordinance for the disposal of covered drugs and home-generated sharps waste. Departmental approval for changes to a stewardship plan due to an ordinance repeal is essential to ensure that program operators appropriately expand the stewardship program to counties that were previously exempt from the Act.

Subsection (k)(4)

Subsection (k)(4) identifies a change to a stewardship plan regarding achievement of the minimum statutory convenience standards as a “significant change.” This is necessary because a stewardship program that does not achieve the minimum statutory convenience standards is out of compliance pursuant to section 42032.2 of the Public Resources Code. Being informed of changes to achievement of the convenience standards ensures that the department can effectively monitor stewardship programs for compliance.

Subsection (k)(5)

Subsection (k)(5) identifies a change to the facility(ies) used to dispose of covered products as a “significant change.” Disposal facilities are a critical component of a handling, transport, and disposal system, and being aware of which facilities are being utilized by a program assists the department in effectively evaluating whether the program is complying with all applicable laws and regulations pursuant to section 42032.2 of the Public Resources Code.

§ 18972.2. Criteria for Determining a Covered Entity.

Subsection (f)(2) of section 42030 of the Public Resources Code directs the department to develop regulations on the process for determining what entity is a covered entity.

Subsection (a)

Subsection (a) specifies that all manufacturers of covered products that are sold, offered for sale, or dispensed in California are considered the covered entities. This subsection is necessary to clarify the phrase “sold in or into the state,” as used in subsection (1)(A) of section 42030(f) of the Public Resources Code.

Subsection (b)

This subsection clarifies that the department is going to rely on the statutory definition for determining a covered entity. The statutory definition is clear, unambiguous, and structured in a way that accounts for the complex infrastructure that brings covered products to market. This subsection is necessary to provide clarity on who is subject to these requirements as a covered entity and uphold a competitive business environment and prevent unfair advantages for any covered entities.

§ 18973. Document Submittals: Stewardship Plan, Initial Program Budget, Annual Report, and Annual Budget.

Subsection (a)

Subsection (a) requires that a corporate officer acting on behalf of a program operator submit certain contact information to the department. This subsection is necessary because it identifies to the department the appropriate point of contact for a program operator. Requiring multiple forms of contact information ensures that the department will be able to consistently contact the program operator regarding the submittal of a stewardship plan, initial program budget, annual report, or annual budget for covered drugs or home-generated sharps waste.

Subsection (b)

Subsection (b) requires documents submitted to the department to be in compliance with website accessibility requirements applicable to state agencies in order to facilitate posting on the department's website. This subsection is necessary for program transparency, as the department is not able to post documents for public access unless they meet the accessibility requirements.

Subsection (c)

Subsection (c) identifies electronic submittal instructions and specifies that the date of electronic receipt by the department is considered the date of receipt. This subsection is necessary because electronic submittal is critical for an efficient review process and this subsection removes ambiguity regarding submittal and review deadlines.

Subsection (d)

Subsection (d) requires a hard copy submittal letter referencing an electronically submitted document containing a signature from a corporate officer. This subsection is necessary to verify compliance that a required document was submitted to the department by the required due date in the event that electronic transmission fails for any reason.

Subsection (e)

Subsection (e) requires program operators wishing to mark information in a submitted document as confidential to include a cover letter justifying the assertion of confidentiality. This provision is necessary as it upholds a program operator's right to keep proprietary information from being publicly disclosed and provides a mechanism by which the department can be explicitly informed of what information the program operator wishes to remain confidential. These requirements ensure consistency with Title 14 CCR 17041 et. seq¹².

¹² Title 14, Division 7, Chapter 1, Article 4, Section 17041 of the California Code of Regulations

§ 18973.1. Document Approvals: Stewardship Plan, Initial Program Budget, Annual Report, and Annual Budget.

Subsection (a)

Subsection (a) states that the department may request clarifying information from a program operator regarding documents submitted to the department for approval. This is necessary to ensure that the department has access to information necessary to make a proper and timely decision whether to approve, conditionally approve, or disapprove of submitted documents if the original submission contains ambiguity or is otherwise unclear.

Subsection (b)

Subsection (b) clarifies and details the timeline related to the department's initial review for a document's completeness. This subsection repeats the timelines put forth in statute, but clarifies that, if the department notifies a program operator that the submitted document is incomplete, the 30-day deadline for resubmitting the document begins upon receipt of the department's notification. This subsection is necessary to set forth the timelines in a clear manner.

Subsection (c)

Subsection (c) repeats a statutory provision in subsection (d)(2) of section 42032 of the Public Resources Code and is included for completeness here so this exception to the timelines is noted together with the above timelines to prevent confusion.

Subsection (d)

Subsection (d) clarifies and details the process for conditional approval of a stewardship plan. This subsection specifies that, upon conditional approval of a stewardship plan, the department notify a program operator within 30 days of the conditions that need to be met for approval (30 days was chosen to be consistent with other 30-day time limits

in the statute). This subsection also clarifies that a plan that has been conditionally approved may be disapproved if the outstanding conditions are not met, and that covered entities operating under a disapproved plan are considered out of compliance. These clarifications are necessary to include in the regulations to ensure that program operators implementing a conditionally approved stewardship plan are aware of the consequences of not meeting conditions in a timely manner.

Subsection (e)

Subsection (e) clarifies and details the process for disapproval of a stewardship plan. In addition to repeating statutory requirements listed in subsections (d)-(f) of section 42032 of the Public Resources Code for completeness, this subsection also clarifies that, following the notification that a submitted stewardship plan has been disapproved, a program operator shall resubmit a revised plan within 60 days of the notification. This requirement is consistent with the 60-day time limit for program operators to resubmit an annual report or program budget that has been disapproved, as described in subsection (e)(3) of section 42033.2 of the Public Resources Code. This provision is necessary to ensure that program operators are aware of the applicable compliance and submission deadlines.

Subsection (f)

Subsection (f) details the process for conditional approval of an annual report or program budget. This subsection repeats the statutory requirements listed in subsection (e) of section 42033.2 of the Public Resources Code and is included for completeness.

Subsection (g)

Subsection (g) clarifies and details the process for disapproval of an annual report or program budget. This subsection repeats statutory requirements in subsection (e)(3) of section 42033.2 of the Public Resources Code and is included for completeness so that all of the relevant time periods are in one location.

§ 18973.2. Stewardship Plan for Covered Drugs.

This section requires the program operator submitting a stewardship plan to comply with applicable laws and regulations and outlines the components included in the plan. This is necessary to make clear that there are other applicable laws that will apply to a plan.

Subsection (a)

Subsection (a) specifies the information to be submitted for a corporate officer, acting on behalf of the program operator who is the person in an organization who is held the most responsible for the actions of that organization and is responsible for submitting a stewardship plan. This subsection is necessary to provide the department information on who to contact on behalf of the covered entity or stewardship organization and how to contact that person regarding any aspect of the submitted stewardship plan, and to follow-up with compliance related activities as necessary, including posting a list of stewardship organizations with an approved stewardship plan to the department's website as required in section 42035 of the Public Resources Code.

Subsection (b)

Subsection (b) specifies the information for participating covered entities that must be submitted to the department as required by statute. This subsection is necessary so the department will know who to contact if a stewardship plan is revoked pursuant to subsection (a) of section 42035.4 of the Public Resources Code or terminated pursuant to subsection (h) of section 42032 of the Public Resources Code or if the department needs to inform a covered entity of pending compliance actions. Additionally, this subsection is necessary so that the department is able to post a list of covered entities that are compliant with this Act to the department's website as required pursuant to section 42035 of the Public Resources Code.

Subsection (c)

Subsection (c) restates the statutory requirement that the stewardship plan include each covered drug sold or offered for sale by each participating covered entity and is necessary for completeness so that all of the plan requirements are listed in one place.

Subsection (d)

Subsection (d) requires information about authorized collectors and potential authorized collectors.

Subsection (d)(1)(A) through (D)

Subsection (d)(1)(A) through (D) specifies the information that must be submitted for each authorized collector participating in the stewardship program. This information is necessary to assist the department in verifying the collection network and determine compliance with the convenience standards pursuant to subsection (F) of section 42032.2(a)(1) of the Public Resources Code. The contact name, contact title, collection site entity, and both mailing and physical addresses are required for authorized collectors in subsections (A), (B), and (C) and are necessary to allow efficient correspondence, inspections, and audits as necessary. Subsection (D) addresses the possibility of an authorized collector having numerous satellite facilities across the state. In this instance, it is necessary to know the participating authorized collection sites, by county, for purposes of calculating compliance with the convenience standards as set forth in subsection (F) of section 42032.2(a)(1) of the Public Resources Code.

Subsection (d)(2)

Subsection (d)(2) requires a list of all potential authorized collectors that were notified of the opportunity to serve as an authorized collector for the stewardship program. This subsection is necessary to assist the department in verifying that the program operator has met statutory notification obligations in each county in which the program will operate pursuant to subsection (b)(1) of section 42032.2 of the Public Resources Code.

Subsection (d)(3)

Subsection (d)(3) requires a description of the process in which negotiations with potential authorized collectors is conducted. This is necessary because subsection (b)(1) of section 42032.2 of the Public Resources Code directs a program operator to commence good faith negotiations with a potential authorized collector within 30 days of the potential authorized collector expressing interest in participating. Subsection (d)(3) enables the department to understand how the negotiation process between the program operator and potential authorized collectors occurs so the department can determine that potential authorized collectors will not be excluded even when interest in participating in a stewardship program is expressed.

Subsection (d)(4)

Subsection (d)(4) requires a description of the conditions for a program operator to exclude any potential authorized collectors from participating. This subsection is necessary for the department to determine that the reason for exclusion is valid and potential authorized collectors are not excluded from participating after statutory minimum convenience standards specified in subsection (F) of section 42032.2(a)(1) of the Public Resources Code have been met.

Subsection (e)

Subsection (e) restates the statutory requirement set forth in subsection (C) of section 42032.2(a)(1) of the Public Resources Code that the stewardship plan include agency determinations of compliance and is necessary for completeness so that all of the plan requirements are listed in one place. This requirement will inform the department that compliance with laws and regulations outside the department's authority and knowledge base are met and that any approval the department provides will not conflict with other legally binding standards.

Subsection (f)

Subsection (f) restates the statutory requirement set forth in subsection (D) of section 42032.2(a)(1) of the Public Resources Code that the stewardship plan demonstrate adequate funding for all administrative and operational costs to be borne by

participating covered entities and is necessary for completeness so that all of the plan requirements are listed in one place. The funding information for the first five calendar years of operation will provide the department with necessary data to verify the program is funded in a prudent and responsible manner.

Subsection (g)

This subsection requires information about the proposed collection, transportation, and disposal system.

Subsection (g)(1)

Subsection (g)(1) requires a description of the processes and policies to be utilized to collect, track, manage, and dispose of covered drugs. This subsection is necessary for the department to evaluate the collection, transportation, and disposal system provided for by the stewardship program as required by statute and to assist the department in verifying that the processes and policies are consistent with applicable laws and regulations.

Subsection (g)(2)

Subsection (g)(2) requires a description of how collection system convenience standards pursuant to subsection (F) of section 42032.2(a)(1) of the Public Resources Code will be met. This description includes how the geographic spread of authorized collection sites will be determined using the most up-to-date population calculations from the State of California Department of Finance and how frequently populations on which convenience standards are based will be re-evaluated. This subsection is necessary to ensure that the collection system will continuously meet statutory convenience standards statewide as populations shift over time. The department utilizes population estimates for the state, counties, and cities obtained from the California

Department of Finance¹³ because it is designated as the official source of demographic data for state planning and budgeting. Therefore, it is necessary that the stewardship program's calculations regarding achievement of the convenience standards are based on this data for consistency when populations are analyzed to ensure convenience standards are met for each county.

Subsection (g)(3)

Subsection (g)(3) requires a description of the mechanism(s) for which covered drugs will be tracked during the process of collection, transportation, and disposal. This is necessary for the department to evaluate whether the stewardship plan complies with subsection (1)(H) of section 42032.2(a) of the Public Resources Code.

Subsection (g)(4)

Subsection (g)(4) requires the name and addresses of each entity used to transport, process, and dispose of covered drugs. This subsection is necessary in the event written correspondence is necessary or for the department to perform inspections and audits as necessary. Additionally, this subsection assists the department in determining that each entity is continuously operating in a safe and secure manner and complying with applicable laws and regulations.

Subsection (g)(5)

Subsection (g)(5) requires a description of the mail-back services or alternative forms of collection and disposal system(s) provided to ultimate users through the stewardship program. This subsection is necessary so the department can evaluate whether statutory requirements related to mail-back services or alternative forms of collection and disposal are met and to verify that these systems are consistent with applicable laws and regulations. Requiring metrics to be identified in the plan is necessary so that

¹³ California Department of Finance. *Demographics*. 2019. Accessed December 11, 2019. <http://www.dof.ca.gov/forecasting/demographics/>

the department can measure program success during annual report compliance determinations. This subsection also provides program operators with the flexibility to use metrics applicable to unique forms of collection (for example, weight, volume, count).

Subsection (g)(6)

Subsection (g)(6) requires a description of any alternative form of collection and disposal system that is used as a supplemental service for any county that does not meet the minimum collection site threshold. This subsection mirrors statutory language in subsection (c) of section 42032.2 of the Public Resources Code and is necessary for completeness so that all of the plan requirements are listed in one place.

Subsection (g)(7)

Subsection (g)(7) requires a description of the method(s) of collection for covered drugs, other than controlled substances, that cannot be accepted or commingled with other covered drugs in secure collection receptacles or through a mail-back program. This subsection is necessary for the department to evaluate whether these methods are consistent with applicable laws and regulations.

Subsection (g)(8)

Subsection (g)(8) requires a description of the process in which collection receptacles will be monitored, how service schedules will be determined to ensure that collection receptacles do not reach capacity, and procedures to be followed if capacity is reached. This subsection is necessary so the department can evaluate compliance with statutory requirements specified in subsection (G)(iii) of section 42032.2(a)(1) of the Public Resources Code. It is necessary that service schedules for collection receptacles meet the needs of ultimate users by ensuring access during planned hours of operation and that receptacles are not unavailable due to exceeded capacity. Additionally, compliance with convenience standards may not be achieved for the period collection receptacles are not available to ultimate users unless collection receptacle service occurs in a timely manner.

Subsection (g)(9)

Subsection (g)(9) requires a description of how authorized collection sites are notified of their responsibility to maintain collection records and make them available to the department upon request. This subsection is necessary to ensure authorized collectors maintain appropriate records pursuant to subsection (G)(iii)(I)-(II) of section 42032.2(a)(1) of the Public Resources Code and the stewardship plan remains compliant pursuant to subsection (E) of section 42032.2(a)(1) of the Public Resources Code. The records are necessary for the department to verify that consistent and timely collection and transportation of covered drugs at authorized collection sites is occurring, and to verify that situations such as collection receptacles have not exceeded their capacity and that collection site closures have not resulted in a direct impact on the convenience standards. These records will also support the department's efforts to verify final disposal is occurring in a timely manner consistent with applicable laws.

Subsection (g)(10)

Subsection (g)(10) requires a description of corrective actions to be taken if a program operator discovers an authorized collector or service provider is not maintaining collection, transportation, and disposal compliance standards consistent with applicable laws and regulations. This subsection is necessary for the department to evaluate whether the stewardship plan complies with subsection (1)(H) of section 42032.2(a) of the Public Resources Code and to support the department's evaluation of the planned action(s) the program operator will take to ensure compliance with all applicable laws.

Subsection (g)(11)

Subsection (g)(11) requires a description of how each participating collection site will be funded or reimbursed, if applicable. This subsection is necessary in order for the department to determine that a program operator has demonstrated that anticipated costs affecting the funding necessary to implement and operate the stewardship program are managed in a prudent and responsible manner pursuant to subsection (c)(2) of section 42033.2 of the Public Resources Code.

Subsection (g)(12)

Subsection (g)(12) requires a description of standard operating procedures that address safety and security issues for an unplanned incident. This subsection is necessary for the department to evaluate the steps put in place to safeguard covered drugs during a safety or security-related incident, pursuant to subsection (1)(H) of section 42032.2(a) of the Public Resources Code.

Subsection (h)

Subsection (h) requires a description of how and where records such as policies and procedures and other documents related to collection, transportation, and disposal will be maintained. This subsection is necessary to facilitate the department's reasonable and timely access to the records during inspections and audits, pursuant to subsection (a) of section 42035.6 of the Public Resources Code.

Subsection (i)

Subsection (i) requires a description of provisions including processes, logistics, and timing of implementation that will be used to expand into jurisdictions in the event of the repeal of a local stewardship program ordinance pursuant to subsection (e) of section 42032.2 of the Public Resources Code. This subsection is necessary to ensure that all ultimate users are provided opportunities to convenient collection. This subsection also provides for completeness so that all the plan requirements are listed in one place and clarifies that "provisions" in statute means processes, logistics, and timing of implementation.

Subsection (j)

Subsection (j) requires a description of the education and outreach program pursuant to subsection (f) of section 42032.2 and section 42031.6 of the Public Resources Code. This subsection is necessary to enable the department to evaluate whether the scope of the education and outreach program is comprehensive and to ensure all ultimate users are made aware of the opportunities presented by the program operator.

Subsection (j)(1)

Subsection (j)(1) requires a description of the education and outreach activities to be conducted and is necessary to enable the department to evaluate the comprehensiveness of the education and outreach activities.

Subsection (j)(2)

Subsection (j)(2) requires a description of the materials to be utilized that will be distributed in languages suited to the local demographics in which the program is operated. Examples of methods of distribution that are to be utilized include, but are not limited to, signage for hospitals, pharmacies, and other locations, as necessary. This subsection is necessary to enable the department to evaluate whether the materials utilized will be comprehensive in their ability to reach the diverse audience of ultimate users throughout the state and to ensure all ultimate users are made aware of the opportunities presented by the program operator.

The department considered the alternative of not including this requirement in the proposed regulations, and a discussion of this alternative can be found on page 71.

Subsection (j)(3)

Subsection (j)(3) requires the establishment of an internet website that is designed with mobile platform functionality and that is maintained to ensure all information is accurate and up to date. This subsection is necessary pursuant to subsection (a)(3) of section 42031.6 of the Public Resources Code. Additionally, it is necessary for the website to function properly on mobile platforms in order to maximize access to ultimate users on the commonly used platforms, in accordance with a comprehensive education and outreach program.

Subsection (j)(3)(A)

Subsection (j)(3)(A) requires that participating authorized collection site locations are publicized on an internet website developed and maintained by the program operator. This subsection is necessary to clarify what “other information” is required pursuant to

subsection (a)(3) of section 42031.6 of the Public Resources Code. This information regarding authorized collection sites is necessary to include on the internet website for the education and outreach program to adequately “promote the use of the stewardship program” and to enable the department to determine compliance with statutory requirements.

Subsection (j)(3)(B)

Subsection (j)(3)(B) requires that participating authorized collection site telephone numbers are publicized on an internet website developed and maintained by the program operator. This subsection is necessary to clarify what “other information” is required pursuant to subsection (a)(3) of section 42031.6 of the Public Resources Code. This information regarding authorized collection sites is necessary to include on the internet website for the education and outreach program to adequately “promote the use of the stewardship program” and to enable the department to determine compliance with statutory requirements.

Subsection (j)(3)(C)

Subsection (j)(3)(C) requires that participating authorized collection site days and hours of operation are publicized on an internet website developed and maintained by the program operator. This subsection is necessary to clarify what “other information” is required pursuant to subsection (a)(3) of section 42031.6 of the Public Resources Code. This information regarding authorized collection sites is necessary to include on the internet website for the education and outreach program to adequately “promote the use of the stewardship program” and to enable the department to determine compliance with statutory requirements.

Subsection (j)(3)(D)

Subsection (j)(3)(D) requires that the internet website provides a mechanism to accept requests for mail-back materials and is necessary to ensure compliance with subsection (G)(i) of section 42032.2(a)(1) of the Public Resources Code so that all of the requirements are listed in one place.

Subsection (j)(3)(E)

Subsection (j)(3)(E) requires the internet website to provide information to promote the stewardship program, including instructions for safe handling and proper disposal of covered drugs and information on collection options. This subsection is necessary for completeness, and to clarify what “other information” is required pursuant to subsection (a)(3) of section 42031.6 of the Public Resources Code. This information regarding disposal options is necessary to include on the internet website for the education and outreach program so that the department may determine that it adequately “promote the use of the stewardship program” to ensure compliance with the statutory requirements.

Subsection (j)(4)

Subsection (j)(4) requires the establishment of a toll-free telephone number, pursuant to subsection (G)(i) of section 42032.2(a)(1) of the Public Resources Code, for the purpose of accepting mail-back materials requests, information on disposal options, and other program information for ultimate users who are homeless, homebound, or disabled. This subsection is a statutory requirement that is necessary to include for completeness so that all of the requirements are listed in one place.

Subsection (j)(5)

Subsection (j)(5) requires the program operator to establish metrics that will be used to evaluate the comprehensive education and outreach program. This subsection is necessary to ensure that the department will be able to effectively evaluate the comprehensiveness of the education and outreach program during annual report review by providing a means to measure the effectiveness of promotion efforts. Education and outreach is a budget category reported to and reviewed by the department and the established metrics will assist in determining that the funds are used in a prudent and responsible manner pursuant to subsection (c)(2) of section 42033.2 of the Public Resources Code.

Subsection (k)

Subsection (k) requires a description of how the program operator will make a good faith effort to work with other stewardship programs if multiple stewardship programs are in operation concurrently. This subsection is necessary to minimize the likelihood that ultimate user participation would be compromised by conflicting messaging or instructions from multiple stewardship programs.

Subsection (l)

Subsection (l) requires the program operator to describe the process for providing grants, loans, sponsorships, reimbursements, or other incentives, if applicable. This subsection is necessary to enable the department to determine if a program operator has demonstrated that costs and funding necessary to implement and operate the stewardship program will be managed in a prudent and responsible manner pursuant to subsection (c)(2) of section 42033.2 of the Public Resources Code.

Subsection (m)

Subsection (m) requires the program operator to describe the process used to select service providers, including any competitive procedure used, as applicable. This subsection is necessary to enable the department to determine if a program operator has demonstrated that costs and funding necessary to implement and operate the stewardship program will be managed in a prudent and responsible manner pursuant to subsection (c)(2) of section 42033.2 of the Public Resources Code. Additionally, this subsection enables the department to verify that the process provides a uniform competitive business environment to all service providers.

§ 18973.3. Stewardship Plan for Home-Generated Sharps Waste.

This section requires the program operator submitting a stewardship plan to comply with applicable laws and regulations and outlines the components included in the plan. This section is necessary to make clear that there are other applicable laws that will apply to a plan.

Subsection (a)

Subsection (a) specifies the information to be submitted for a corporate officer, acting on behalf of the program operator who is the person in an organization who is held the most responsible for the actions of that organization and is responsible for submitting a stewardship plan. This subsection is necessary to provide the department information regarding who to contact on behalf of the covered entity or stewardship organization, how to contact that person regarding any aspect of the submitted stewardship plan, and to follow-up with compliance related activities as necessary, including posting a list of stewardship organizations with an approved stewardship plan to the department's website as required in section 42035 of the Public Resources Code.

Subsection (b)

Subsection (b) specifies the information for participating covered entities that must be submitted to the department as required by statute. This subsection is necessary so the department will know who to contact if a stewardship plan is revoked pursuant to subsection (a) of section 42035.4 of the Public Resources Code or terminated pursuant to subsection (h) of section 42032 of the Public Resources Code or if the department needs to inform a covered entity of pending compliance actions. Additionally, this subsection is necessary so that the department is able to post a list of covered entities that are compliant with this Act to the department's website as required pursuant to section 42035 of the Public Resources Code.

Subsection (c)

Subsection (c) restates the statutory requirement that the stewardship plan include each covered product sold or offered for sale by each participating covered entity and is necessary for completeness so that all of the plan requirements are listed in one place.

Subsection (d)

Subsection (d) restates the statutory requirement set forth in subsection (B) of section 42032.2(d)(1) of the Public Resources Code that the stewardship plan include agency

determinations of compliance and is necessary for completeness so that all requirements are listed in one place. This requirement will inform the department that compliance with laws and regulations outside the department's authority and knowledge base are met and that any approval the department provides will not conflict with other legally binding standards.

Subsection (e)

Subsection (e) restates the statutory requirement set forth in subsection (d)(1)(C) of section 42032.2, subsection (c)(2) of section 42033.2, and 42033 of the Public Resources Code that the stewardship plan demonstrate adequate funding for all administrative and operational costs to be borne by participating covered entities and is necessary for completeness so that all requirements are listed in one place. The funding information for the first five calendar years of operation will provide the department with necessary data to verify the program is funded in a prudent and responsible manner.

Subsection (f)

This subsection requires information on the proposed collection, transportation, and disposal system for home-generated sharps waste.

Subsection (f)(1)

Subsection (f)(1) requires a description of the processes, policies, and metrics for the mail-back program that will be utilized to collect, track, transport, and dispose of home-generated sharps waste. This subsection is necessary for the department to evaluate the collection, transportation, and disposal system provided for by the stewardship program as required by statute and to assist the department in verifying that the processes and policies are consistent with applicable laws and regulations.

Subsection (f)(2)

Subsection (f)(2) requires a description of how stewardship plan implementation will provide or initiate distribution of sharps waste containers and mail-back materials at no cost to ultimate users at the point of sale and how statutory requirements will be met as

set forth in subsection (F)(i)(I)-(III) of section 42032.2(d)(1) of the Public Resources Code. This subsection is necessary for completeness so that all requirements are listed in one place.

Subsection (f)(3)

Subsection (f)(3) requires a description of how and where records will be maintained on policy and procedures for collection, transportation, and disposal. This subsection is necessary to facilitate the department's access to records during inspections and audits pursuant to subsection (a) of section 42035.6 of the Public Resources Code.

Subsection (f)(4)

Subsection (f)(4) requires the name and addresses for each entity used to transport, process, and dispose of home-generated sharps waste. This subsection is necessary in the event written correspondence is necessary and for the department to perform inspections and audits as necessary. Additionally, this subsection assists the department in determining that each entity is continuously operating in a safe and secure manner and complying with applicable laws and regulations.

Subsection (f)(5)

Subsection (f)(5) requires a description of the processes and policies to be followed by persons handling home-generated sharps waste under the stewardship plan and efforts the program operator will take to ensure that all entities participating will operate under and comply with all applicable laws and regulations. This subsection is necessary for the department to evaluate the handling processes and policies for consistency with applicable laws and regulations.

Subsection (f)(6)

Subsection (f)(6) requires a program operator that chooses to implement supplemental collection method(s) for home-generated sharps waste to include certain information about the method(s) in the stewardship plan. Although supplemental collection methods are not required by statute, if utilized, it is essential for the department to be aware of all

collection activities performed by program operators in order to effectively monitor stewardship programs for compliance, and to provide appropriate context for the information received in the annual report and program budgets regarding the mandatory mail-back program. While the department cannot predict the full scope of collection activities that may be conducted by program operators, it understands that take-back collection events and secure collection receptacles are two likely methods to be employed in order to maximize convenience to ultimate users, as they are currently used by local stewardship programs required by ordinances, such as in Alameda County.

Subsection (f)(6)(A)

Subsection (f)(6)(A) requires that the stewardship plan include information that directly parallels the plan requirements regarding secure collection receptacles at authorized collection sites for covered drugs, as applicable. This subsection is necessary for the department to effectively monitor the stewardship program for consistency with all applicable laws and regulations, including the Medical Waste Management Act, which contains requirements regarding collection receptacles placed at home-generated sharps consolidation points. Additionally, this subsection enables the department to conduct inspections and audits and request relevant records for the purpose of investigating whether the collection activities are occurring as set forth in the approved stewardship plan.

Subsection (f)(6)(B)

Subsection (f)(6)(B) requires that the stewardship plan include the date and location of take-back collection events, as applicable. This subsection is necessary to allow the department to be able to verify during compliance review that these events occurred.

Subsection (f)(7)

Subsection (f)(7) requires metrics to be identified to measure the amount of sharps waste containers and mail-back materials distributed and the weight returned. This subsection is necessary to ensure that the department can evaluate the program

operator's budgeted costs pursuant to subsection (c)(2) of section 42033.2 of the Public Resources Code and to measure program success over time. Reporting the weight of material returned is necessary to provide the department context to analyze the mail-back program since number of containers distributed alone would not be a full measure of the success of the program.

Subsection (f)(8)

Subsection (f)(8) requires metrics to be identified to measure the amount of home-generated sharps waste collected through supplemental collection methods, if applicable. This subsection is necessary so the department can evaluate the program operator's budgeted costs pursuant to subsection (c)(2) of section 42033.2 of the Public Resources Code and to measure program success over time.

Subsection (g)(1)

Subsection (g)(1) requires a description of the process for coordinating with local agencies, or an agent on behalf of a local agency, for the removal of home-generated sharps waste from local household hazardous waste facilities. This subsection is necessary to clarify subsection (F)(ii) of section 42032.2(d)(1) of the Public Resources Code. This is necessary so that the department can ensure that both parties are executing these provisions in a compliant manner.

Subsection (g)(2)(A) through (B)

Subsection (g)(2)(A) through (B) outlines the process for a local agency to request disposal of home-generated sharps waste and a program operator's responsibility to resolve the request by either providing for the removal of the home-generated sharps waste or reimbursement for proper disposal. This subsection is necessary so that a program operator will respond to a local agency's request in a reasonable timeframe. In subsection (A), 45 days was selected as a reasonable timeframe for reimbursement and is consistent with the required time state agencies are required to pay properly

submitted invoices¹⁴. Subsection (B) requires that a program operator provide for the removal of the home-generated sharps waste in a timeframe consistent with section 117904 of the Health and Safety Code or as approved by the local enforcement authority.

Subsection (h)

Subsection (h) requires a description of provisions including processes, logistics, and timing of implementation that will be used to expand into jurisdictions in the event of the repeal of a local stewardship program ordinance pursuant to subsection (e) of section 42032.2 of the Public Resources Code. This subsection is necessary to ensure that all ultimate users are provided opportunities to convenient collection. This subsection also provides for completeness so that all the plan requirements are listed in one place and clarifies that “provisions” in statute means processes, logistics, and timing of implementation.

Subsection (i)

Subsection (i) requires a description of the education and outreach program pursuant to subsection (f) of section 42032.2 and section 42031.6 of the Public Resources Code. This subsection is necessary to enable the department to evaluate whether the scope of the education and outreach program is comprehensive and to ensure all ultimate users are made aware of the opportunities presented by the program operator.

Subsection (i)(1)

Subsection (i)(1) requires a description of the education and outreach activities to be conducted and is necessary to enable the department to evaluate the comprehensiveness of the education and outreach activities.

Subsection (i)(2)

¹⁴ Division 3.6, Chapter 4.5, section 927(b) of the Government Code

Subsection (i)(2) requires a description of the materials to be utilized that will be distributed in languages suited to the local demographics in which the program is operated. Examples of methods of distribution that are to be utilized include, but are not limited to, signage for hospitals, pharmacies, and other locations, as necessary. This subsection is necessary to enable the department to evaluate whether the materials utilized will be comprehensive in their ability to reach the diverse audience of ultimate users throughout the state and to ensure all ultimate users are made aware of the opportunities presented by the program operator.

The department considered the alternative of not including this requirement in the proposed regulations, and a discussion of this alternative can be found on page 71.

Subsection (i)(3)

Subsection (i)(3) requires the establishment of an internet website that is designed with mobile platform functionality and that is maintained to ensure all information is accurate and up to date. This subsection is necessary pursuant to subsection (a)(3) of section 42031.6 of the Public Resources Code. Additionally, it is necessary for the website to function properly on commonly used platforms in order to maximize access to ultimate users, in accordance with a comprehensive education and outreach program.

Subsection (i)(3)(A)

Subsection (i)(3)(A) requires that the internet website provides a mechanism to accept requests for mail-back materials and is necessary to ensure compliance with subsection (E) of section 42032.2(d)(1) of the Public Resources Code so that all of the requirements are listed in one place.

Subsection (i)(3)(B)

Subsection (i)(3)(B) requires the internet website to provide information to promote the stewardship program, including instructions for safe handling and proper disposal of home-generated sharps waste and information on collection options. This subsection is necessary for completeness, and to clarify what “other information” is required pursuant

to subsection (a)(3) of section 42031.6 of the Public Resources Code. This information regarding disposal options is necessary to include on the internet website for the education and outreach program so that the department may determine that it adequately “promote the use of the stewardship program” to ensure compliance with the statutory requirements.

Subsection (i)(3)(C)

Subsection (i)(3)(C) requires that participating home-generated sharps consolidation point locations are publicized on an internet website developed and maintained by the program operator, if applicable. If a stewardship program includes sharps consolidation points as a supplement to the mail-back program, this subsection is necessary to clarify what “other information” is required pursuant to subsection (a)(3) of section 42031.6 of the Public Resources Code. This information regarding sharps consolidation points is necessary to include on the internet website for the education and outreach program to adequately “promote the use of the stewardship program” and to enable the department to determine compliance with statutory requirements.

Subsection (i)(3)(D)

Subsection (i)(3)(D) requires that participating home-generated sharps consolidation point telephone numbers are publicized on an internet website developed and maintained by the program operator, if applicable. If a stewardship program includes sharps consolidation points as a supplement to the mail-back program, this subsection is necessary to clarify what “other information” is required pursuant to subsection (a)(3) of section 42031.6 of the Public Resources Code. This information regarding sharps consolidation points is necessary to include on the internet website for the education and outreach program to adequately “promote the use of the stewardship program” and to enable the department to determine compliance with statutory requirements.

Subsection (i)(3)(E)

Subsection (i)(3)(E) requires that participating home-generated sharps consolidation point days and hours of operation are publicized on an internet website developed and

maintained by the program operator, if applicable. If a stewardship program includes sharps consolidation points as a supplement to the mail-back program, this subsection is necessary to clarify what “other information” is required pursuant to subsection (a)(3) of section 42031.6 of the Public Resources Code. This information regarding sharps consolidation points is necessary to include on the internet website for the education and outreach program to adequately “promote the use of the stewardship program” and to enable the department to determine compliance with statutory requirements.

Subsection (i)(4)

Subsection (i)(4) requires the establishment of a toll-free telephone number, pursuant to subsection (E) of section 42032.2(d)(1) of the Public Resources Code, for the purpose of accepting mail-back materials requests, information on disposal options, and other program information. This subsection is a statutory requirement that is necessary to include for clarity and completeness so that all of the requirements are listed in one place.

Subsection (i)(5)

Subsection (i)(5) requires the program operator to establish metrics that will be used to evaluate the comprehensive education and outreach program. This subsection is necessary to ensure that the department will be able to effectively evaluate comprehensiveness of the education and outreach program during annual report review by providing a means to measure the effectiveness of promotion efforts. Education and outreach is a budget category reported to and reviewed by the department and the established metrics will assist in determining that the funds are used in a prudent and responsible manner pursuant to subsection (c)(2) of section 42033.2 of the Public Resources Code.

Subsection (j)

Subsection (j) requires a description of how the program operator will make a good faith effort to work with other stewardship programs if multiple stewardship programs are in operation concurrently. This subsection is necessary to minimize the likelihood that

ultimate user participation would be compromised by conflicting messaging or instructions from multiple stewardship programs.

Subsection (k)

Subsection (k) requires the program operator to describe the process for providing grants, loans, sponsorships, reimbursements, or other incentives, if applicable. This subsection is necessary to enable the department to determine that a program operator has demonstrated that costs and funding necessary to implement and operate the stewardship program will be managed in a prudent and responsible manner pursuant to subsection (c)(2) of section 42033.2 of the Public Resources Code.

Subsection (l)

Subsection (l) requires the program operator to describe the process used to select service providers, including any competitive procedure used, as applicable. This subsection is necessary to enable the department to determine if a program operator has demonstrated that costs and funding necessary to implement and operate the stewardship program will be managed in a prudent and responsible manner pursuant to subsection (c)(2) of section 42033.2 of the Public Resources Code. Additionally, this subsection enables the department to verify that the process provides a uniform competitive business environment to all service providers.

§ 18973.4. Annual Report for Covered Drugs.

This section requires the program operator submitting an annual report to comply with requirements specified in section 42033.2 of the Public Resources Code.

Subsection (a)

Subsection (a) requires the contact information for the corporate officer responsible for overseeing implementation of the stewardship plan and submitting the annual report. This subsection is necessary to provide clarity as to whom is responsible and supports

the department for review, approval, compliance determination, and enforcement purposes.

Subsection (b)

Subsection (b) requires an executive summary which provides an overview of program implementation, progress, and challenges. This subsection is necessary to support the department's annual report review process and for public transparency by providing context for the information and data in the annual report.

Subsection (c)

Subsection (c) details the information to be included in the annual report regarding the collection system for covered drugs. This subsection is necessary pursuant to section 42033.2 of the Public Resources Code to clarify the required content of the Annual Report which will serve as a basis for the department to conduct compliance reviews.

Subsection (c)(1)

Subsection (c)(1) requires a description of the collection system implemented to provide ultimate users with the opportunity to dispose of their covered drugs. This subsection is necessary to support the department in the review process for determining compliance with statutory requirements of the convenience standards and collection methods specified in subsection (1)(F) and (1)(G) of section 42032.2(a) of the Public Resources Code.

Subsection (c)(2)

Subsection (c)(2) requires an update on good faith negotiations between the program operator and potential authorized collectors to establish collection sites. This subsection is necessary to protect the integrity of the program by supporting the department review process for compliance with statutory requirements, including the convenience standards specified in subsection (1)(F) of section 42032.2(a) of the Public Resources Code.

Subsection (c)(2)(A)

Subsection (c)(2)(A) requires a description of the efforts to notify potential authorized collectors of the opportunity to serve as an authorized collector. This subsection is necessary for the department to assess whether the program operator met the statutory notification obligation in each county pursuant to subsection (b)(1) of section 42032.2 of the Public Resources Code.

Subsection (c)(2)(B)

Subsection (c)(2)(B) requires a description of efforts to include authorized collectors beyond the minimum convenience standards specified in subsection (1)(F) of section 42032.2(a) of the Public Resources Code. This subsection is necessary to ensure that program operators will continue to notify potential authorized collectors of the opportunity to participate in the stewardship program regardless of whether the convenience standards have been met pursuant to subsection (b)(1) of section 42032.2. This assists the department in evaluating whether negotiations were carried out in good faith between the program operator and all potential authorized collectors.

Subsection (c)(2)(C)

Subsection (c)(2)(C) requires a description of the efforts made to achieve compliance in a county that did not achieve the convenience standards as specified in subsection (1)(F) of section 42032.2(a) of the Public Resources Code. This subsection is necessary to assist the department's evaluation of compliance with the convenience standards requirement and a program operator's inability to meet the convenience standards as specified in subsection (F) of section 42032.2(a)(1) of the Public Resources Code. An explanation of the implementation status and efforts provides context for the department to determine whether a good faith effort was made to establish the required collection sites, at the required geographic spread, or that full implementation of the mail-back program achieved the minimum convenience standards.

Subsection (c)(2)(D)

Subsection (c)(2)(D) requires a description of any known reason why a potential authorized collector was excluded from participating. This subsection is necessary for the department to understand the implementation status for compliance review purposes. This subsection requires only known reasons for exclusion because the program operator may have limited knowledge of an authorized collector's perspective.

Subsection (c)(3)

Subsection (c)(3) requires a description of updates to the methods and calculations used to meet the statutory convenience standards specified in subsection (1)(F) of section 42032.2(a) of the Public Resources Code. This subsection is necessary for the department to determine if the convenience standards were continuously met as populations shift over time. The California Department of Finance¹⁵ is the official source of demographic data for state planning and budgeting. Therefore, it is necessary that the stewardship program calculations utilize this data for consistency of analysis.

Subsection (c)(4)(A) through (D)

Subsection (c)(4)(A) through (D) requires reporting on the authorized collection sites that participated in the program. The name and physical address are necessary pursuant to subsection (b)(4) of section 42033.2 of the Public Resources Code and assist the department in verifying collection sites, conducting compliance reviews, and performing inspections or audits. Reporting the weight of covered products collected is necessary pursuant to subsection (b)(3) of Section 42033.2 of the Public Resources Code. However, covered products may be mixed with other material in a secure collection receptacle and may not be individually counted, sorted, inventoried, or

¹⁵ California Department of Finance. *Demographics*. 2019. Accessed December 11, 2019. <http://www.dof.ca.gov/forecasting/demographics/>

otherwise individually handled¹⁶. Therefore, the required metric for reporting is weight of material collected. A program operator is required to provide a service schedule that meets the needs of each authorized collection site to ensure that secure collection receptacles do not reach capacity and that collected covered drugs are transported to final disposal in a timely manner as specified in subsection (G)(iii)(I) of section 42032.2(a)(1)) of the Public Resources Code. Regulations require reporting the number of collections, number of liners collected, and number of instances, and corresponding business hours an authorized collection site was not available to the public. This is necessary to evaluate the service schedule by ensuring collection receptacles do not reach capacity pursuant to subsection (G)(iii)(I) of section 42032.2(a)(1) of the Public Resources Code and the program operator met the convenience standards pursuant to subsection (1)(F) of section 42032.2(a) of the Public Resources Code. This allows the department to evaluate if services are rendered in a manner consistent with the stewardship plan and statutory requirements.

Subsection (c)(5)(A) and (C)

Subsection (c)(5)(A) and (C) requires reporting the name and location of distribution facility(ies) and mechanism of distribution of mail-back materials related to any mail-back services offered. The name and location of the distribution facility and method of distribution are necessary to assist the department in performing inspections and audits and evaluating the program for compliance with applicable laws and regulations.

Subsection (c)(5)(B) and (D)

Subsection (c)(5)(B) and (D) requires reporting of the amount of materials distributed and weight of materials returned for any mail-back services offered. These subsections are necessary in order to provide the department context to analyze whether the authorized collection sites, mail-back activities, and alternative forms of collection provide adequate access to safe disposal for the ultimate user, and to assist the

¹⁶ Title 21, Section 1317.75 of the Code of Federal Regulations

department in preparing the report required in section 42033.6 of the Public Resources Code.

Subsection (c)(6)(A) through (C)

Subsection (c)(6)(A) through (C) requires reporting of alternative forms of collection, including covered drugs that cannot be accepted or commingled with other covered drugs, and as an alternative form of collection when the convenience standards are not met due to circumstances outside of the program operator's control. Since the alternative forms of collection and disposal will not be known by the department until its review of the stewardship plan, this subsection lists multiple potential descriptions and reporting metrics. The method of collection and name and address of location are necessary to assist the department in performing inspections and audits and evaluating the program for compliance with applicable laws and regulations. The number of collections is necessary for the department to evaluate whether the alternative form of collection fulfills statutory requirements.

Subsection (c)(6)(D) through (E)

Subsection (c)(6)(D) through (E) requires reporting of the amount of materials distributed and weight of materials collected for alternative forms of collection. This subsection is necessary to assist the department in preparing the report required in section 42033.6 of the Public Resources Code and provide the department context to analyze whether the authorized collection sites, mail-back activities, and alternative forms of collection provide adequate access to safe disposal for the ultimate user.

Subsection (d)

Subsection (d) requires a description of the transportation and disposal system. This subsection is necessary for the department to evaluate the transportation and disposal methods used to verify that the processes and policies are consistent with those set forth in the approved stewardship plan.

Subsection (d)(1)

Subsection (d)(1) requires a description of updates concerning the mechanism(s) by which covered drugs were tracked during transportation and disposal. This subsection is necessary for the department to evaluate the program for compliance with subsection (b)(6) of section 42033.2 and subsection (1)(H) of section 42032.2(a) of the Public Resources Code, and whether the tracking mechanism(s) followed are consistent with those set forth in the approved stewardship plan.

Subsection (d)(2)

Subsection (d)(2) requires the name and mailing address of each entity used to transport or process covered drugs. The name and mailing address are necessary to assist the department in evaluating compliance with applicable laws and regulations and performing inspections and audits.

Subsection (d)(3)

Subsection (d)(3) requires reporting related to each disposal facility utilized in the stewardship program. The name, mailing and physical addresses are necessary to identify each facility and its specific location if an entity has multiple disposal facilities and assists the department with inspections and audits. Reporting the weight of material received by each facility is necessary for the department to confirm whether the weight of materials received matches the weight collected and assists the department in evaluating the program for compliance with applicable laws and regulations.

Subsection (e)

Subsection (e) requires a description of the corrective actions taken if a program operator discovered that a service provider did not maintain compliance with all applicable laws and regulations. This subsection is necessary to identify instances of noncompliance and assist the department in evaluating the stewardship program for compliance with subsection (1)(H) of section 42032.2(a) of the Public Resources Code.

Subsection (f)

Subsection (f) requires a description of the updates to the processes and policies followed to safely and securely collect, track, and properly manage covered drugs in a manner compliant with all applicable laws and regulations. This subsection is necessary for the department to evaluate compliance with subsections (6) and (7) of section 42033.2(b) of the Public Resources Code. A program operator may identify the necessity to update the processes and policies followed to safely and securely collect, track, and properly manage disposal of covered drugs and provide the updates in the annual report. Reporting enables the department to verify that the updates are consistent with applicable law(s) and regulation(s).

Subsection (g)

Subsection (g) requires a description of efforts to expand into jurisdictions due to the repeal of a local stewardship program ordinance pursuant to subsection (e) of section 42032.2 of the Public Resources Code. This subsection is necessary for the department to evaluate whether program expansion efforts matched those set forth in the approved stewardship plan. In addition, this subsection is necessary for the department to evaluate program expansion efforts and in reviewing the stewardship program for compliance with the convenience standards.

Subsection (h)

Subsection (h) requires a description of any incidents concerning safety or security related to the collection, transportation, or disposal of covered drugs. This subsection is necessary to clarify subsection (7) of section 42033.2(b) of the Public Resources Code by requiring specific information about an incident be included in the description. This information is necessary to assist the department with evaluation of corrective actions taken regarding safety and security.

Subsection (i)

Subsection (i) requires a description and evaluation of the education and outreach activities. This subsection is necessary to enable the department to determine whether the comprehensive education and outreach program was compliant with the statutory

requirements as specified in section 42031.6 of the Public Resources Code and consistent with the approved stewardship plan. Submission of examples of promotional marketing materials are required to be submitted electronically along with the electronic submission of the annual report. This is necessary to support the department's efficient review process, to ensure the program is operating in a prudent and responsible manner, and for program transparency for posting the annual report to the department's website.

Subsection (j)

Subsection (j) requires a list of covered entities, covered products, authorized collectors, and authorized collection sites that participated within the specific reporting period. This is necessary for compliance with statutory requirements and to assist the department with conducting inspections, audits, and enables efficient correspondence with covered entities.

Subsection (j)(1)

Subsection (j)(1) requires a list of covered entities participating in the stewardship plan. This subsection is necessary pursuant to subsection (b)(1) of section 42033.2 of the Public Resources Code and is included for completeness and convenience so that all of the requirements are listed in one place.

Subsection (j)(2)

Subsection (j)(2) requires a list of covered products that each covered entity subject to the stewardship plan sells or offers for sale in the state. This subsection is necessary pursuant to subsection (b)(2) of section 42033.2 of the Public Resources Code and is included for completeness and convenience so that all of the requirements are listed in one place.

Subsection (j)(3)

Subsection (j)(3) requires a list of authorized collectors and their contact information. This subsection is necessary for the department to conduct inspections, audits, and enables efficient correspondence with authorized collectors.

Subsection (j)(4)

Subsection (j)(4) requires a list of authorized collection sites. This subsection is necessary pursuant to subsection (b)(4) of section 42033.2 of the Public Resources Code and is included for completeness and convenience so that all of the requirements are listed in one place.

Subsection (k)

Subsection (k) requires a description of any changes in the process for selecting service providers. This subsection is necessary for the department to evaluate whether the stewardship program is managed in a prudent and responsible manner pursuant to subsection (c)(2) of section 42033.2 of the Public Resources Code, and whether it provides a uniform competitive business environment for all service providers. In addition, it supports the department in evaluating whether the process was consistent with those set forth in the approved stewardship plan.

Subsection (l)

Subsection (l) requires a description of any changes in the process of providing grants, loans, sponsorships, reimbursements or other incentives, in the event that a program operator chooses to provide these. This subsection is necessary to demonstrate that the program operator has anticipated costs affecting the funding to implement and operate the stewardship program in a prudent and responsible manner pursuant to subsection (c)(2) of section 42033.2 of the Public Resources Code.

Subsection (m)

Subsection (m) requires a description of any changes in staffing of the stewardship program. This subsection is necessary to assist the department in evaluating whether the stewardship program was implemented in a prudent and responsible manner

pursuant to subsection (c)(2) of section 42033.2 of the Public Resources Code. This requirement ensures that the stewardship program is sufficiently staffed to adequately provide services to implement the stewardship plan in a consistent manner throughout the year.

Subsection (n)

Subsection (n) requires a description of how the program operator made a good faith effort to work with other stewardship programs to achieve the requirements of statute and regulations. This subsection is necessary to assist the department in evaluating the efforts and effectiveness of the efforts made to work with any other stewardship program(s) to minimize the likelihood that ultimate user participation would be compromised by conflicting messaging or instructions from multiple stewardship programs.

Subsection (o)

Subsection (o) requires a program operator to report any determinations of compliance or noncompliance by other federal, state, or local government entities. This requirement is necessary pursuant to subsection (1)(C) of section 42032.2(a) of the Public Resources Code and is included for completeness and convenience so that all of the requirements are listed in one place.

§ 18973.5. Annual Report for Home-Generated Sharps Waste.

This section requires the program operator submitting an annual report to comply with requirements specified in section 42033.2 of the Public Resources Code.

Subsection (a)

Subsection (a) requires the contact information for the corporate officer responsible for overseeing implementation of the stewardship plan and submitting the annual report. This subsection is necessary to provide clarity as to whom is responsible and supports the department for review, approval, compliance determination, and enforcement purposes.

Subsection (b)

Subsection (b) requires an executive summary which provides an overview of program implementation, progress, and challenges. This subsection is necessary to support the department's annual report review process and for public transparency by providing context for the information and data in the annual report.

Subsection (c)

Subsection (c) details the information to be included in the annual report regarding the collection system for home-generated sharps waste. This subsection is necessary pursuant to section 42033.2 of the Public Resources Code to clarify the required content of the Annual Report which will serve as a basis for the department to conduct compliance reviews.

Subsection (c)(1)

Subsection (c)(1) requires a description of the collection system implemented to provide ultimate users with the opportunity to dispose of their home-generated sharps waste. This subsection is necessary to support the department in the review process for determining compliance with statutory requirements specified in subsection (b)(5) of section 42033.2 of the Public Resources Code.

Subsection (c)(2)(A) through (D)

Subsection (c)(2)(A) through (D) requires the amount of sharps waste containers and mail-back materials distributed by county, and the method by which distribution took place. This subsection is necessary to support the department in the review process for compliance with statutory requirements specified in subsection (E) and (F)(i) of section 42032.2(d)(1) of the Public Resources Code and provides the department context to analyze the mail-back program.

Subsection (c)(3)

Subsection (c)(3) requires reporting the weight of material returned for the mail-back program. Reporting the weight of material returned is necessary as it provides the department context to analyze the mail-back program.

Subsection (c)(4)

Subsection (c)(4) requires a description of the supplemental collection methods used in addition to the mail-back program. This subsection is necessary to support the department in evaluating whether this process was consistent with the process outlined in the approved stewardship plan and to provide the department context to analyze the supplemental collection method.

Subsection (d)

Subsection (d) requires a description of the methods used to transport and dispose of consolidated home-generated sharps waste. This subsection is necessary for the department to evaluate the transportation and disposal methods used to verify that the processes and policies are consistent with those set forth in the approved stewardship plan.

Subsection (d)(1)

Subsection (d)(1) requires a description of updates concerning the mechanism(s) by which home-generated sharps waste were tracked during transportation and disposal. This subsection is necessary for the department to evaluate the program for compliance with subsection (b)(6) of section 42033.2 and subsection (1)(H) of section 42032.2(a) of the Public Resources Code, and whether the tracking mechanism(s) followed are consistent with those set forth in the approved stewardship plan.

Subsection (d)(2)

Subsection (d)(2) requires the name and mailing address of each entity used to transport or process home-generated sharps waste. The name and mailing address are necessary to assist the department in evaluating compliance with applicable laws and regulations and performing inspections and audits.

Subsection (d)(3)

Subsection (d)(3) requires reporting related to each disposal facility utilized in the stewardship program. The name, mailing and physical addresses are necessary to identify each facility and its specific location if an entity has multiple disposal facilities and assists the department with inspections and audits. Reporting the weight of material received by each facility is necessary for the department to confirm whether the weight of materials received matches the weight collected and assists the department in evaluating the program for compliance with applicable laws and regulations.

Subsection (e)

Subsection (e) requires a description of the corrective actions taken if a program operator discovered that a service provider did not maintain compliance with all applicable laws and regulations. This subsection is necessary to identify instances of noncompliance and assist the department in evaluating the stewardship program for compliance with subsection (1)(H) of section 42032.2(a) of the Public Resources Code.

Subsection (f)

Subsection (f) requires a description of the updates to the processes and policies followed to safely and securely collect, track, and properly manage covered drugs in a manner compliant with all applicable laws and regulations. (The version of the proposed regulations that was approved for noticing incorrectly stated 'covered drugs' in this section and this clerical error was changed to 'home-generated sharps waste' prior to commencing the formal notice period). This subsection is necessary for the department to evaluate compliance with subsections (6) and (7) of section 42033.2(b) of the Public Resources Code. A program operator may identify the necessity to update the processes and policies followed to safely and securely collect, track, and properly manage disposal of home-generated sharps waste and provide the updates in the annual report. Reporting enables the department to verify that the updates are consistent with applicable law(s) and regulation(s).

Subsection (g)

Subsection (g) requires a description of efforts to expand into jurisdictions due to the repeal of a local stewardship program ordinance pursuant to subsection (e) of section 42032.2 of the Public Resources Code. This subsection is necessary for the department to evaluate whether program expansion efforts matched those set forth in the approved stewardship plan. In addition, this subsection is necessary for the department to evaluate program expansion efforts and in reviewing the stewardship program for compliance with the convenience standards.

Subsection (h)

Subsection (h) requires a description of any incidents concerning safety or security related to the collection, transportation, or disposal of home-generated sharps waste. This subsection is necessary to clarify subsection (7) of section 42033.2(b) of the Public Resources Code by requiring specific information about an incident be included in the description. This information is necessary to assist the department with evaluation of corrective actions taken regarding safety and security.

Subsection (i)

Subsection (i) requires a description and evaluation of the education and outreach activities. This subsection is necessary to enable the department to determine whether the comprehensive education and outreach program was compliant with the statutory requirements as specified in section 42031.6 of the Public Resources Code.

Submission of examples of promotional marketing materials are required to be submitted electronically along with the electronic submission of the annual report. This is necessary to support the department's review process, to ensure the program is operating in a prudent and responsible manner, and for program transparency for posting the annual report to the department's website.

Subsection (j)

Subsection (j) requires a list of covered entities and their contact information that participated within the specific reporting period. This subsection is necessary pursuant to subsection (b)(1) of section 42033.2 of the Public Resources Code and is included for

completeness and convenience so that all of the requirements are listed in one place. In addition, this is necessary to for the department to conduct inspections, audits, and enables efficient correspondence with covered entities.

Subsection (k)

Subsection (k) requires a list of covered products that each covered entity subject to the stewardship plan sells or offers for sale in the state. This subsection is necessary pursuant to subsection (b)(2) of section 42033.2 of the Public Resources Code and is included for completeness and convenience so that all of the requirements are listed in one place.

Subsection (l)

Subsection (l) requires a description of any changes in the process for selecting service providers. This subsection is necessary for the department to evaluate whether the stewardship program is managed in a prudent and responsible manner, pursuant to subsection (c)(2) of section 42033.2 of the Public Resources Code, and whether it provides a uniform competitive business environment for all service providers. In addition, it supports the department in evaluating whether the process was consistent with those set forth in the approved stewardship plan.

Subsection (m)

Subsection (m) requires a description of any changes in the process of providing grants, loans, sponsorships, reimbursements or other incentives, in the event that a program operator chooses to provide these. This subsection is necessary to demonstrate that the program operator has anticipated costs affecting the funding to implement and operate the stewardship program in a prudent and responsible manner pursuant to subsection (c)(2) of section 42033.2 of the Public Resources Code.

Subsection (n)

Subsection (n) requires a description of any changes in staffing of the stewardship program. This subsection is necessary to assist the department in evaluating whether

the stewardship program was implemented in a prudent and responsible manner pursuant to subsection (c)(2) of section 42033.2 of the Public Resources Code. This requirement ensures that the stewardship program is sufficiently staffed to adequately provide services to implement the stewardship plan in a consistent manner throughout the year.

Subsection (o)

Subsection (o) requires a description of how the program operator made a good faith effort to work with other stewardship programs to achieve the requirements of statute and regulations. This subsection is necessary to assist the department in evaluating the efforts and effectiveness of the efforts made to work with any other stewardship program(s) to minimize the likelihood that ultimate user participation would be compromised by conflicting messaging or instructions from multiple stewardship programs.

Subsection (p)

Subsection (p) requires detailed results of the process for local agency requests for removal of or reimbursement for home-generated sharps waste. Reporting the name of the local agency, facility location, reimbursement payment amount, and weight of collected material is necessary to provide the department context to analyze if the mail-back program, supplemental collection methods, and management of home-generated sharps waste from household hazardous waste facilities provide adequate access to safe disposal for the ultimate user and assists the department in preparing the report required in section 42033.6 of the Public Resources Code. Disposal costs are a budget category and requiring the amount reimbursed to household hazardous waste facilities for these disposal costs will assist the department with audits and evaluating that the stewardship program is operating in a prudent and responsible manner pursuant to subsection (a)(2) of section 42033.2 of the Public Resources Code.

Subsection (q)

Subsection (q) requires a program operator to report any determinations of compliance or noncompliance by other federal, state, or local government entities. This requirement is necessary pursuant to subsection (1)(C) of section 42032.2(a) of the Public Resources Code and is included for completeness and convenience so that all of the requirements are listed in one place.

§ 18973.6. Program Budgets.

Section 18973.6 sets forth the content requirements of the initial stewardship program budget and annual budgets that will be submitted to the department. This section is necessary to establish the minimum requirements of the program budget and ensure that the stewardship plan's budgeted costs to operate the stewardship program are financially prudent and responsible pursuant to subsection (c)(2) of section 42033.2 of the Public Resources Code and is included so that all of the requirements are in one place.

Subsection (a)(1) through (9)

Subsections (a)(1) through (9) identify the required anticipated cost categories of the initial stewardship program budget and annual budget. This subsection is necessary to clarify the costs of implementing the stewardship program pursuant to subsection (a) of section 42033, and subsection (a)(1)(D) and subsection (d)(1)(C) of section 42032.2 of the Public Resources Code. This subsection supports the department's evaluation of the anticipated costs of implementing the stewardship program to ensure the stewardship organization is meeting the financial responsibility requirement in subsection (c)(2) of section 42033.2 of the Public Resources Code.

Subsection (a)(1)

Subsection (a)(1) requires capital costs as a separate line item of the initial stewardship program budget and annual budget. This subsection is necessary to clarify subsection (a) of section 42033, and subsection (a)(1)(D) and subsection (d)(1)(C) of section 42032.2 of the Public Resources Code. This subsection supports the department's evaluation of the anticipated costs of implementing the stewardship program to ensure

the stewardship organization is meeting the financial responsibility requirement in subsection (c)(2) of section 42033.2 of the Public Resources Code.

Subsection (a)(2)

Subsection (a)(2) requires costs of collection of covered products as a separate line item of the initial stewardship program budget and annual budget. This subsection is necessary to clarify section 42034, subsection (a) of section 42033, and subsection (a)(1)(D) and subsection (d)(1)(C) of section 42032.2 of the Public Resources Code. This subsection supports the department's evaluation of the anticipated costs of implementing the stewardship program to ensure the stewardship organization is meeting the financial responsibility requirement in subsection (c)(2) of section 42033.2 of the Public Resources Code.

Subsection (a)(3)

Subsection (a)(3) requires the costs of transportation of covered products as a separate line item the initial stewardship program budget and annual budget. This subsection is necessary to clarify section 42034, subsection (a) of section 42033, and subsection (a)(1)(D) and subsection (d)(1)(C) of section 42032.2 of the Public Resources Code. This subsection supports the department's evaluation of the anticipated costs of implementing the stewardship program to ensure the stewardship organization is meeting the financial responsibility requirement in subsection (c)(2) of section 42033.2 of the Public Resources Code.

Subsection (a)(4)

Subsection (a)(4) requires the costs of processing covered products as a separate line item of the initial stewardship program budget and annual budget. This subsection is necessary to clarify subsection (a) of section 42033, and subsection (a)(1)(D) and subsection (d)(1)(C) of section 42032.2 of the Public Resources Code. This subsection supports the department's evaluation of the anticipated costs of implementing the stewardship program to ensure the stewardship organization is meeting the financial responsibility requirement in subsection (c)(2) of section 42033.2 of the Public

Resources Code.

Subsection (a)(5)

Subsection (a)(5) requires the costs of disposal of covered products as a separate line item of the initial stewardship program budget and annual budget. This subsection is necessary to clarify section 42034, subsection (a) of section 42033, and subsection (a)(1)(D) and subsection (d)(1)(C) of section 42032.2 of the Public Resources Code. This subsection supports the department's evaluation of the anticipated costs of implementing the stewardship program to ensure the stewardship organization is meeting the financial responsibility requirement in subsection (c)(2) of section 42033.2 of the Public Resources Code.

Subsection (a)(6)

Subsection (a)(6) requires the administrative costs as a separate line item of the initial stewardship program budget and annual budget. This subsection is necessary to clarify section 42034, subsection (a) of section 42033, and subsection (a)(1)(D) and subsection (d)(1)(C) of section 42032.2 of the Public Resources Code. This subsection supports the department's evaluation of the anticipated costs of implementing the stewardship program to ensure the stewardship organization is meeting the financial responsibility requirement in subsection (c)(2) of section 42033.2 of the Public Resources Code.

Subsection (a)(7)

Subsection (a)(7) requires the costs of the education and outreach program as a separate line item of the initial stewardship program budget and annual budget. This subsection is necessary to clarify subsection (a) of section 42033, and subsection (a)(1)(D) and subsection (d)(1)(C) of section 42032.2 of the Public Resources Code. This subsection supports the department's evaluation of the anticipated costs of implementing the stewardship program to ensure the stewardship organization is meeting the requirements of the comprehensive education and outreach program requirements in subsections (1) through (5) of section 42031.6 (a) of the Public

Resources Code and the financial responsibility requirement in subsection (c)(2) of section 42033.2 of the Public Resources Code.

Subsection (a)(8)

Subsection (a)(8) requires costs related to grants, loans, sponsorships, or other incentives as a separate line item of the initial stewardship program budget and annual budget. This subsection is necessary to clarify subsection (a) of section 42033, and subsection (a)(1)(D) and subsection (d)(1)(C) of section 42032.2 of the Public Resources Code. This subsection supports the department's evaluation of the anticipated costs of implementing the stewardship program to ensure the stewardship organization is meeting the financial responsibility requirement in subsection (c)(2) of section 42033.2 of the Public Resources Code.

Subsection (a)(9)

Subsection (a)(9) requires the amount of the reserve level as a separate line item of the initial stewardship program budget and annual budget. This subsection is necessary to clarify subsection (a) of section 42033, and subsection (a)(1)(D) and subsection (d)(1)(C) of section 42032.2 of the Public Resources Code. This subsection supports the department's evaluation of the anticipated costs and funds set aside to implement the stewardship program to ensure the stewardship organization is meeting the financial responsibility requirement in subsection (c)(2) of section 42033.2 of the Public Resources Code.

Subsection (b)

Subsection (b) requires a recommended funding level and a description of how costs are apportioned and remitted from participating covered entities. This subsection is necessary to clarify subsection (b) of section 42033 of the Public Resources Code and enable the department to assess the calculated recommended funding level to ensure that program funds are managed in a prudent and responsible manner.

Subsection (c)

Subsection (c) requires a program budget to include a narrative description of the types of activities listed within each line item cost category. This subsection is necessary to enable the department to understand what is contained in each cost category during its budget review to ensure the program funds are managed in a prudent and responsible manner pursuant to subsection (c)(2) of section 42033.2 of the Public Resources Code.

Subsection (d)

Subsection (d) requires that the annual program budget include the previous program year expenses. This information is necessary to support the department's evaluation of the annual budget by enabling comparisons between program year funds and activities pursuant to subsection (b) of section 42033 and subsection (c)(2) of section 42033.2 of the Public Resources Code.

Subsection (e)(1) through (5)

Subsections (e)(1) through (5) require the program budget to include an independent financial audit of the stewardship program pursuant to subsection (b)(1) of section 42033.4 of the Public Resources Code. These subsections require the audit to be conducted in accordance with generally accepted auditing standards in the United States of America and Generally Accepted Government Auditing Standards, by an independent Certified Public Accountant. This subsection is necessary to clarify the audit standards to ensure the submitted financial audit is independently credible. These standards are generally accepted by industry as a reasonable standard. The independent financial audit is necessary to support the department's performance audit of the stewardship program, compliance consideration of the stewardship organization's financial responsibility requirement pursuant to subsection (c)(2) of section 42033.2 of the Public Resources Code, and is included so that all the requirements are in one place.

Subsection (e)(1)

Subsection (e)(1) requires the independent financial audit to include the minutes, books, and records of the activities and transactions of the program operator's stewardship

program, pursuant to subsection (b)(1) of section 42033.4 of the Public Resources Code. This information is necessary to support the department's performance audit of the stewardship program, compliance consideration of the stewardship organization's financial responsibility requirement, pursuant to subsection (c)(2) of section 42033.2 of the Public Resources Code, and is included so that all the requirements are in one place.

Subsection (e)(2)

Subsection (e)(2) requires the independent financial audit to include the stewardship program's financial statements, pursuant to the Generally Accepted Accounting Principles (GAAP) by the U.S. Securities and Exchange Commission. The GAAP are the commonly accepted ways to recording and reporting accounting information. GAAP aims to improve the clarity, consistency and comparability of the communication of financial information, which is useful to investors, lenders, and other parties that provide or may potentially provide resources to make sound decisions. Profit companies, non-profit companies, and government agencies must follow GAAP. Accurate and verifiable financial statements are necessary to support the department's performance audit of the stewardship program, compliance consideration of the stewardship organization's financial responsibility requirement, pursuant to subsection (c)(2) of section 42033.2 of the Public Resources Code, and is included so that all the requirements are in one place.

Subsection (e)(3)

Subsection (e)(3) requires the independent financial audit to include an opinion on the stewardship organization's compliance with section 42034 of the Public Resources Code and Title 14, Division 7, Chapter 11, Article 4 of the California Code of Regulations. This information is necessary to support the department's performance audit of the stewardship program, compliance consideration of the stewardship organization's financial responsibility requirement, pursuant to subsection (c)(2) of section 42033.2 of the Public Resources Code, and is included so that all the requirements are in one place.

Subsection (e)(4)

Subsection (e)(4) requires the independent financial audit to include findings and recommendations related to the financial aspects of the stewardship program. This information is necessary to support the department's performance audit of the stewardship program, compliance consideration of the stewardship organization's financial responsibility requirement, pursuant to subsection (c)(2) of section 42033.2 of the Public Resources Code, and is included so that all the requirements are in one place.

Subsection (e)(5)

Subsection (e)(5) requires the independent financial audit to include the management letter, if issued, by the stewardship organization's Certified Public Accountant. This subsection is necessary to certify the submitted financial audit is accurate and supports the department's performance audit of the stewardship program, compliance consideration of the stewardship organization's financial responsibility requirement, pursuant to subsection (c)(2) of section 42033.2 of the Public Resources Code and is included so that all the requirements are in one place.

§ 18974. Record Keeping Requirements.

Section 18974 requires that all parties required to comply with the Article, including, but not limited to, covered entities, stewardship organizations, program operators, retail pharmacies, and retail pharmacy chains maintain records to support compliance with the law, provide the timeframe that the records are to be maintained, and provide the department access to the records. This section is necessary to provide clear standards regarding recordkeeping for the regulated community.

Subsection (a)

Subsection (a) requires records are to be maintained by all parties required to comply with the requirements of this Article. This subsection further requires covered entities, stewardship organizations, program operators, retail pharmacies and retail pharmacy chains to retain the records necessary to comply with this Article, so that they are

accessible to the department for three (3) years. A three-year records retention period is consistent with requirements for other types of solid waste program record retention. The department conducts a review of the submitted annual reports yearly. If necessary, follow up audits or compliance investigations of an annual report cycle or of the records for a specific year will normally be started within three years after the submission of an annual report. The proposed language ensures records will be available for an audit or compliance investigation. This is necessary to clarify subsection (a)(2) of section 42035.6 of the Public Resources Code, and enables the department to execute its oversight responsibilities, ensure accuracy and consistency of information provided by each party, when the department conducts audits, compliance reviews, and site inspections.

Subsection (b)

Subsection (b) clarifies that each party required to comply with the Article provide the department reasonable and timely access to facilities, operations, and any relevant records necessary to determine compliance with the Article. The subsection further clarifies that covered entities, stewardship organizations, and program operators maintain and provide access to records required by this Article for three years after the submission of the annual report which rely upon those records. The department conducts a review of the submitted annual reports yearly. If necessary, follow up audits or a compliance investigation of a given annual report cycle or of the records to support compliance with the requirements of this article for a specific year will normally be started within three years after the submission of an annual reports, so the proposed language ensures records will be available for an audit or compliance investigation. Finally, the subsection clarifies subsection (a)(1) of section 42035.6 of the Public Resources Code, and enables the department to execute its oversight responsibilities, ensure accuracy and consistency of information provided by each party, when the department conducts audits, compliance reviews, and investigations.

Subsection (c)(1) through (3)

Subsections (c)(1) through (3) require participating retail pharmacies and retail pharmacy chains to provide the department access to existing records on all covered

product sold or offered for sale in the state. Retail pharmacies and retail pharmacy chains are one of the primary points at which an ultimate user obtains a covered product. It has been recommended that the department use the retail pharmacies and retail pharmacy chains as a point of entry of a covered product that may not be complying with the requirements of the law. This subsection clarifies the specific records the department will need to conduct covered product verifications. This subsection is necessary to clarify subsection (a)(2) of section 42035.6 of the Public Resources Code, and ensure the department has access to records and information regarding covered products needed to conduct compliance reviews.

Subsection (c)(1)

Subsection (c)(1) requires retail pharmacies and retail pharmacy chains to provide a list of manufacturers of covered products(s) being sold or offered for sale in the state. This list will allow the department to determine if all covered products are compliant with the law. While the department cannot prohibit the sale of the covered product, this subsection enables the department to obtain necessary information to allow for follow-up enforcement with the manufacturer identified. This subsection is necessary to protect the integrity of the program and ensure that only sales of compliant covered products are conducted in the state.

Subsection (c)(2)

Subsection (c)(2) clarifies that retail pharmacies and retail pharmacy chains are to provide the date(s) a covered product(s) was purchased from a manufacturer, distributor, and/or wholesaler. Through the development of the regulations the department has learned from manufacturers, distributors, wholesalers, retail pharmacies and retail pharmacy chains that the development, release, and discontinuation of covered products is continuous and occurs regularly. This subsection acknowledges this circumstance by requesting the date a covered product was purchased. This will help to support the department's identification of when a covered product was purchased, and when the covered product was in compliance, could be offered for sale and was initially sold. This information will support the department's efforts to protect the integrity of the program and ensure that only sales of compliant covered products are

conducted in the state

Subsection (c)(3)

Subsection (c)(3) requires retail pharmacies and retail pharmacy chains to provide the date(s) a covered product(s) was offered for sale. This will help to support the department's verification that a product that was in compliance at the time it was offered for sale, protect the integrity of the program, and ensure that only sales of compliant covered products are conducted in the state

Subsection (c)(4)

Subsection (c)(4) requires retail pharmacies and retail pharmacy chains to provide the department access to certification letters, if provided by a manufacturer. This documentation will support that a covered product offered for sale or sold was compliant. This subsection is necessary to enable the department to verify that a covered product is or was subject to an approved stewardship plan.

§ 18974.1. Administrative Fee to Department of Resources Recycling and Recovery.

Section 18974.1 identifies the process the department will use to set the administrative fee. This section is included for convenience and completeness and refers to subsections (a)(1) and (a)(2) of section 42034.2 of the Public Resources Code.

§ 18974.2. Stewardship Organization Audits of Covered Entities or Authorized Collectors.

Section 18974.2 requires a stewardship organization to provide a copy of the audit to the department within 30 days of its completion, in the event an audit of covered entities or authorized collectors is conducted. This section clarifies subsection (b)(4) of section 42034.4 and establishes a reasonable amount of time to provide a copy of the audit to the department. This section is necessary to inform the department that an audit of covered entities or authorized collectors was conducted by the stewardship organization and enables the department to confirm the administrative fees and charges are remitted properly and accurately for the implementation of the program.

§ 18974.3. Retailer, Wholesaler, Distributor Product Verification.

Section 18974.3 outlines the product verification process, applicable to distributors, wholesalers, pharmacies, and retailers of covered products, and pharmacies or retailers that sell or offer for sale or dispense a covered product. This section is necessary to enable the department to ensure only compliant covered products are sold or dispensed in the state.

Subsection (a)

Subsection (a) requires each distributor, wholesaler, pharmacy, or other retailer of a covered product to log onto the department's Internet Web site and verify whether each product sold, offered for sale, or dispensed is in compliance with the Act. This subsection is necessary to enable the department to obtain and monitor verification of compliance from covered entities.

Subsection (b)

Subsection (b) requires all identified noncompliant covered products be reported to the department's Enforcement Unit by the distributor, wholesaler, pharmacy, retailer, or designated responsible party. This reporting is consistent with subsection (c) of section 42035 of the Public Resources Code and discloses to the department the discovery of noncompliant covered products and enables the department to conduct enforcement actions against entities that sell, offer for sale, or dispense noncompliant covered products.

§ 18975. Criteria to Impose an Administrative Civil Penalty.

Subsection (a)

Subsection (a) states a covered entity is not in compliance with the Chapter if it sells or offers for sale a covered product that is not subject to an approved stewardship plan and the covered entity is subject to administrative penalties. This subsection is necessary to clarify subsection (a)(1) of section 42035.2 of the Public Resources Code and set forth the department's process for determining an administrative penalty against a noncompliant entity.

Subsection (b)(1) through (11)

Subsections (b)(1) through (11) establish a list of circumstantial criteria that the department may consider when assessing or reviewing the amount of an administrative penalty. These subsections are necessary to clarify section 42035.2 of the Public Resources Code and inform the covered entity of what elements will be considered when the department sets an administrative penalty amount and is included so that all the requirements are in one place.

Subsection (b)(1)

Subsection (b) states the nature, circumstances, extent, and gravity of the violation(s) is one of the eleven (11) criterion the department may take into consideration when assessing or reviewing the amount of an administrative penalty. This is necessary to clarify section 42035.2 of the Public Resources Code and inform the covered entity of an element that will come into consideration when the department is setting administrative penalty amount.

Subsection (b)(2)

Subsection (b)(2) states the number and severity of the violation(s) is one of the eleven (11) criterion the department may take into consideration when assessing or reviewing the amount of an administrative penalty. This is necessary to clarify section 42035.2 of the Public Resources Code and inform the covered entity of an element that will come into consideration when the department is setting administrative penalty amount.

Subsection (b)(3)

Subsection (b)(3) states evidence that the violation was intentional, knowing, or negligent is one of the eleven (11) criterion the department may take into consideration when assessing or reviewing the amount of an administrative penalty. This is necessary to clarify section 42035.2 of the Public Resources Code and inform the covered entity of an element that will come into consideration when the department is setting administrative penalty amount.

Subsection (b)(4)

Subsection (b)(4) states the size of the violator is one of the eleven (11) criterion the department may take into consideration when assessing or reviewing the amount of an

administrative penalty. This is necessary to clarify section 42035.2 of the Public Resources Code and inform the covered entity of an element that will come into consideration when the department is setting administrative penalty amount.

Subsection (b)(5)

Subsection (b)(5) states the history of the violation(s) of the same or similar nature is one of the eleven (11) criterion the department may take into consideration when assessing or reviewing the amount of an administrative penalty. This is necessary to clarify section 42035.2 of the Public Resources Code and inform the covered entity of an element that will come into consideration when the department is setting administrative penalty amount.

Subsection (b)(6)

Subsection (b)(6) states the willfulness of the violator's misconduct is one of the eleven (11) criterion the department may take into consideration when assessing or reviewing the amount of an administrative penalty. This is necessary to clarify section 42035.2 of the Public Resources Code and inform the covered entity of an element that will come into consideration when the department is setting administrative penalty amount.

Subsection (b)(7)

Subsection (b)(7) states good faith measures to comply with this chapter took place and the period of time over which these measure were taken is one of the eleven (11) criterion the department may take into consideration when assessing or reviewing the amount of an administrative penalty. This is necessary to clarify section 42035.2 of the Public Resources Code and inform the covered entity of an element that will come into consideration when the department is setting administrative penalty amount.

Subsection (b)(8)

Subsection (b)(8) states evidence of any financial gain resulting from the violation(s) is one of the eleven (11) criterion the department may take into consideration when assessing or reviewing the amount of an administrative penalty. This is necessary to clarify section 42035.2 of the Public Resources Code and inform the covered entity of

an element that will come into consideration when the department is setting administrative penalty amount.

Subsection (b)(9)

Subsection (b)(9) states the economic effect of the penalty on the violator is one of the eleven (11) criterion the department may take into consideration when assessing or reviewing the amount of an administrative penalty. This is necessary to clarify section 42035.2 of the Public Resources Code and inform the covered entity of an element that will come into consideration when the department is setting administrative penalty amount.

Subsection (b)(10)

Subsection (b)(10) states the deterrent effect that the imposition of the penalty would have on both the violator and the regulated community is one of the eleven (11) criterion the department may take into consideration when assessing or reviewing the amount of an administrative penalty. This is necessary to clarify section 42035.2 of the Public Resources Code and inform the covered entity of an element that will come into consideration when the department is setting administrative penalty amount.

Subsection (b)(11)

Subsection (b)(11) states any other factor that justice may require is one of the eleven (11) criterion the department may take into consideration when assessing or reviewing the amount of an administrative penalty. This is necessary to clarify section 42035.2 of the Public Resources Code and inform the covered entity of an element that will come into consideration when the department is setting administrative penalty amount.

§ 18975.1. Procedure for Imposing Administrative Civil Penalties.

Subsection (a)

Subsection (a) describes the applicable informal hearing process for administratively imposing civil penalties, in accordance with the procedures outlined in the Administrative Procedures Act (commencing with section 11445.10 of the Government

Code¹⁷) and is necessary so that the regulated community understands the procedures that will be used.

Subsection (b)(1) through (3)

Subsections (b)(1) through (3) describes the means of services used to notify the respondents of the accusation or complaint served on them under the law. This is necessary to inform the covered entity of what mode of communication the department will use to deliver the accusation or complaint.

Subsection (b)(1)

Subsection (b)(1) identifies personal service is one of the three (3) means of services used to notify the respondents of the accusation or complaint served on them under the law. This is necessary to inform the covered entity of what mode of communication the department will use to deliver the accusation or complaint.

Subsection (b)(2)

Subsection (b)(2) identifies substitute service procedures described in section 415.20 of the Code of Civil Procedure are one of the three (3) means of services used to notify the respondents of the accusation or complaint served on them under the law. This is necessary to inform the covered entity of what mode of communication the department will use to deliver the accusation or complaint.

Subsection (b)(3)

Subsection (b)(3) identifies certified mail or registered mail that is mailed and addressed to the respondent at the latest facility or mailing address(es) on file with the department is one of the three (3) means of services used to notify the respondents of the accusation or complaint served on them under the law. This is necessary to inform the covered entity of what mode of communication the department will use to deliver the accusation or complaint.

Subsection (c)

¹⁷ Title 2, Division 3, Part 1, Chapter 4.5, Section 11445.10 of the Government Code

Subsection (c) states civil penalties may be imposed pursuant to subsection (a)(2) of section 42035.2 of the Public Resources Code. This is necessary for completeness and is included so that all the requirements are in one place.

§ 18975.2. Procedure for Revoking, Requiring Resubmittal, or Additional Reporting of an Approved Stewardship Plan.

The department may revoke a previously approved stewardship plan, require plan resubmittal, or require additional reporting due to failure to meet a material requirement of the statute as set forth in section 42035.4 of the Public Resources Code. This is necessary to protect the integrity of the program, enable the department to execute its oversight responsibilities to ensure and maintain compliant program performance and take the necessary enforcement action to execute all material requirements in the statute, and is included so that all the requirements are in one place.

Subsection (a)

Subsection (a) sets forth that the department will hold a public hearing prior to taking non-monetary enforcement actions against a program operator or authorized collector, due to failure of meeting the material requirement of statute. This subsection is necessary to enable the department to execute its oversight responsibilities against a noncompliant program operator or authorized collector, as required in section 42035.4 of the Public Resources Code, and take the necessary enforcement action to execute material requirements in the statute.

Subsection (b)

Subsection (b) requires the department to notify the program operator of the department's intent to consider revocation, resubmittal, or requiring additional reporting of an approved stewardship plan, sixty (60) days in advance prior to the hearing. This subsection is necessary to establish a reasonable timeframe the respondent will receive the department hearing notice and enable the program operator's participation at the department hearing.

Subsection (c)

Subsection (c) establishes the means and procedure of the department's hearing to consider revoking, requiring resubmittal, or additional reporting that will be followed in accordance with the provisions of Article 10 of Chapter 4.5 of Part 1 of Division 3 of Title 2 of the Government Code. This is necessary to identify the department's due process regarding these hearings and enables the program operator's participation at the department hearing.

Subsection (d)

Subsection (d) requires the statement of the basis for responding to or rebutting the department's finding of noncompliance to be submitted within thirty (30) calendar days of receipt of the notification from the department. This subsection is necessary to establish a reasonable amount of time for the objection statement to be submitted to the department and set forth the submittal instructions. This is necessary, as part of the due process that will be followed, to enable the program operator to present any evidence or facts for the department's consideration regarding the department's finding of non-compliance that the department will take into consideration.

Subsection (e)

Subsection (e) sets forth that the Director will make the determination to revoke the stewardship plan, require a resubmittal of the stewardship plan, or require additional reporting. The determination will be communicated to the program operator, in writing, within sixty (60) working days from when the hearing was conducted. Sixty (60) days is a reasonable amount of time and provides a timeframe in which the program operator will receive the department's determination given the potential significance of these determinations. This subsection is necessary to establish how the determination will be made and provide the program operator with the process to acquire compliance.

Subsection (f)

Subsection (f) identifies the stewardship plan resubmittal process is established in accordance with the submittal process set forth in section 18973.1. This is necessary to clarify the resubmittal requirement in subsection (a) of section 42035.4 of the Public

Resources Code and provide the program operator with the resubmittal instructions to acquire compliance.

Subsection (g)

Subsection (g) defines the term “resubmittal” to mean a revised plan to correct or address the material requirement that was not met, for the purposes of section 18975.2. This subsection is necessary to clarify the resubmittal requirement in subsection (a) of section 42035.4. This is necessary to enable the program operator to discern what portions of the chapter’s material requirements was not met. This provides the program operator with the means to execute the required stewardship plan revisions to acquire compliance.

Subsection (h)

Subsection (h) defines the term “additional reporting” to mean more frequent or more detailed reports regarding the material requirement not met, for the purposes of section 18975.2. This subsection is necessary to clarify the additional reporting requirement in subsection (b) of section 42035.4 of the Public Resources Code. This is necessary to enable the program operator to discern what portions of the chapter’s material requirements was not met. This provides the program operator with the means to gather the required reporting information to acquire compliance.

REASONABLE ALTERNATIVES TO THE PROPOSED REGULATORY ACTION

The department has considered three alternatives to the proposed regulations. The first alternative, which would be more burdensome on businesses than the proposed regulations, would be 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. Thus, this alternative would result in an excess of sharps containers being distributed without significantly increasing the amount of home-generated sharps waste collected, and was consequently rejected.

The second alternative, which would be less burdensome on businesses than the proposed regulations, would be to remove the proposed regulatory requirements that education and outreach materials produced by stewardship organizations be provided in languages suited to local demographics. Under this alternative, stewardship organizations would save thousands of dollars per year in printing, translation, and IT costs, but the education and outreach campaigns would be less successful in reaching certain communities and target audiences. Consequently, Alternative 2 would result in less pharmaceutical and home-generated sharps waste collected and reduce the effectiveness of the law, which is why it was not selected.

Finally, the third alternative would be for the department to not adopt any regulations beyond what is required by subsection (f)(2) of section 42030 of the Public Resources Code. While this alternative would avoid much of the department's time and effort spent on the regulatory process, the clarity provided by the regulations is essential to minimize confusion, facilitate effective program implementation, and ensure that ultimate users have adequate access to safe and convenient disposal options for their covered drugs and home-generated sharps waste.

FINDINGS REGARDING EVIDENCE OF NO SIGNIFICANT ADVERSE ECONOMIC IMPACT ON BUSINESS

Based on the Economic Impact Assessment discussed below, the department has made the initial finding that these regulations will not have a significant adverse economic impact on business.

DUPLICATION OR CONFLICTS WITH CODE OF FEDERAL REGULATIONS

Federal law or regulations do not contain comparable requirements.

FINDING ON NECESSITY OF REPORTS [GOVERNMENT CODE SECTION 11346.3(d)]

The Pharmaceutical and Sharps Waste Stewardship Act (Pub. Res. Code § 42030-42036.4) mandates multiple reporting requirements. Program operators are required to annually submit a stewardship plan, annual budget, and annual report to the department for approval; covered entities are required to annually submit product lists to the Board of Pharmacy; and retailers of covered products as well as wholesalers and distributors are required to monitor the department's website for compliant covered entities and notify the department if they sell covered products that are not from a compliant covered entity. The proposed regulations do not require reports in addition to what is laid out in statute, but the regulations do, among other things, add clarity and specificity to some of these reporting requirements. Adding clarity and specificity is necessary to ensure that these reports fulfill their intended purpose, such as determining the program's success, determining parties' compliance with the law, and informing potential enforcement actions.

ECONOMIC IMPACT ASSESSMENT

CREATION OR ELIMINATION OF JOBS WITHIN CALIFORNIA

Approximately 40 new jobs will be created statewide as a direct result of the regulation. This number includes 17 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 job loss, 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 Regional Economic Models Inc. (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 40 jobs are expected to be lost, resulting in a total net job loss of 0 due to the 40 new jobs that are created as discussed above.

CREATION OF NEW BUSINESSES OR ELIMINATION OF EXISTING BUSINESSES WITHIN CALIFORNIA

Covered entities are likely to form a number of stewardship organizations (501(c)(3) non-profit organizations, per statutory requirements) to administer the stewardship programs. A small expansion in waste hauling and disposal is also expected, which might lead to additional businesses being created, but is more likely to result in expansion of existing businesses.

EXPANSION OF BUSINESSES CURRENTLY DOING BUSINESS WITHIN THE STATE

CalRecycle anticipates a small expansion of waste hauling and disposal businesses within the state.

BENEFITS OF THE REGULATION

CalRecycle has determined that the proposed regulation will result in the following benefits to public health and the environment:

1. Reduction of needle-stick injuries. 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 home-generated sharps waste.

2. Reduction of accidental poisonings. 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 abuse 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 toilet. The regulation will likely reduce the amount of trace pharmaceutical contamination in both surface and ground water by diverting unused covered drugs toward proper disposal methods.

TECHNICAL STUDIES, REPORTS, OR DOCUMENTS

The department relied upon the following sources of information to develop the proposed Regulations:

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. [Medicare Benefit Policy Manual, Chapter 15, 60.4.1](#)

6. [Subsection \(5\)\(A\) of subdivision \(h\) of section 254b of Title 42 of the U.S. Code on Public Health and Welfare](#)
7. [Title 2, Division 3, Part 1, Chapter 4.5, Section 11445.10 of the Government Code](#)
8. [Title 14, Division 7, Chapter 1, Article 4, Section 17041 of the California Code of Regulations](#)
9. [Title 21, Section 1317.75 of the Code of Federal Regulations](#)
10. [Architectural Paint and Recovery Program Regulations \(Title 14, Division 7, Chapter 11, Sections 18950-18958 of the California Code of Regulations\)](#)
11. [Used Mattress Recovery and Recycling Program Regulations \(Title 14, Division 7, Chapter 11, Sections 18959-18971 of the California Code of Regulations\)](#)
12. [Product Stewardship for Carpets Program Regulations \(Title 14, Division 7, Chapter 11, Sections 18940-18948 of the California Code of Regulations\)](#)
13. Alameda County Department of Environmental Health. *Safe Drug and Consumer-Generated Sharps Disposal Program*. 2019. Accessed December 11, 2019. <https://deh.acgov.org/safe-drug/index.page?>
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19. Center for Disease Control and Prevention. *National Diabetes Statistics Report, 2017*. August 8, 2017. Accessed December 11, 2019. <https://www.cdc.gov/features/diabetes-statistic-report/index.html>

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24. Pharmaceutical Research and Manufacturers of America v. County of Alameda, 967 F.Supp.2d 1339 (N.D.Cal. 2013).
<https://law.justia.com/cases/federal/district-courts/california/candce/3:2012cv06203/261433/40/>
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<https://sfenvironment.org/safe-drug-disposal-stewardship-ordinance>
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<https://www.sccgov.org/sites/rwr/hhw/Pages/Sharps%20and%20Prescription%20Drugs%20Disposal.aspx>
27. Santa Clara County Recycling and Waste Reduction Division. *Safe Drug Disposal*. 2019. Accessed December 11, 2019.
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<https://www.doh.wa.gov/ForPublicHealthandHealthcareProviders/HealthcareProfessionsandFacilities/SafeMedicationReturnProgram>