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7 **STATE OF CALIFORNIA**

8 **DEPARTMENT OF RESOURCES RECYCLING AND RECOVERY**

9  
10 **IN THE MATTER OF THE ACCUSATION)**  
**AGAINST:** )

AGENCY NO: IH26-001-PS

11 )  
12 **The Drug Takeback Solutions Foundation )**

**ACCUSATION FOR PENALTIES AND  
NOTICE OF REVOCATION OF PLAN  
APPROVAL**

13 **Respondent )**

**(Public Resources Code Sections 42030-  
42036.4 and Title 14 California Code of  
Regulations Sections 18972.1-18975.2)**

14 )  
15 )  
16 )  
17 Pursuant to the Pharmaceutical and Sharps Waste Stewardship Act (Public Resources  
18 Code (“PRC”) section 42030 *et seq.*) (the “Act”) and its implementing regulations (Title 14  
19 California Code of Regulations (“14 CCR”) section 18972.1 *et seq.*) (the “Regulations”), the  
20 California Department of Resources Recycling and Recovery (the “Department”) makes and files  
21 this Accusation (the “Accusation”) against the Drug Takeback Solutions Foundation, an exempt  
22 corporation formed in Delaware (the “Respondent”), to seek penalties totaling not less than  
23 \$1,682,375 for violations related to the Drugs Program (defined below) and \$1,687,750 for  
24 violations related to the Sharps Program (defined below) under the Act and the Regulations and  
25 to seek revocation of the approvals of both the Respondent’s home-generated sharps waste  
26 stewardship plan and covered drugs stewardship plan.  
27  
28



1 section 42035.2(a) and (b) and 14 CCR section 18975(a)). The Department conducts the  
2 proceedings on civil penalties and revocation in accordance with the procedures outlined in the  
3 Administrative Procedure Act, Chapter 4.5 (Gov. Code section 11400 et seq.).

4 7. The Act and the Regulations also authorize the Department to revoke an approved  
5 stewardship plan if a program operator fails to meet a material requirement (PRC section  
6 42035.4(a) and 14 CCR section 18975.2).

7 8. The Respondent is subject to the requirements in the Act and the Regulations because,  
8 during all relevant times, the Respondent was a program operator with approved covered drugs  
9 and home-generated sharps waste stewardship plans. The Department conditionally approved  
10 the Respondent's stewardship plan for covered drugs on February 16, 2022, maintained  
11 conditional approval on August 16, 2022, and fully approved the plan on December 20, 2022  
12 ("Drugs Plan"). The Respondent was required to fully implement the Drugs Plan by November  
13 13, 2022, within 270 days of the Department's conditional approval. The Department  
14 conditionally approved the Respondent's stewardship plan for home-generated sharps waste on  
15 February 14, 2022, maintained conditional approval on August 16, 2022, and fully approved the  
16 plan on December 20, 2022 ("Sharps Plan"). The Respondent was required to fully implement  
17 the Sharps Plan on November 11, 2022, within 270 days of the Department's conditional  
18 approval. The Respondent continues to be a program operator with approved stewardship plans  
19 for the covered drugs stewardship program ("Drugs Program") and the home-generated sharps  
20 waste stewardship program ("Sharps Program"). However, the Respondent has notified the  
21 Department of its intent to terminate both the Drugs Program and the Sharps Program, with the  
22 last day of operations being June 30, 2026.

23 **STEWARDSHIP PLAN PROPOSAL, DEPARTMENT REVIEW, AND STEWARDSHIP**

24 **PROGRAM IMPLEMENTATION**

25 9. The Act creates stewardship programs for covered drugs and home-generated sharps  
26 waste, and fundamental to any stewardship program is the stewardship plan. While the Act and  
27 the Regulations lay out the requirements for the stewardship program, it is in the stewardship  
28 plan that a program operator submits to the Department that the program operator proposes

1 how it will comply with all statutory and regulatory requirements. In other words, the statutory  
2 and/or regulatory requirements may not explicitly explain how a certain requirement shall be met  
3 and instead require a program operator to describe in its plan how a requirement will be met  
4 (see e.g., the education and outreach requirements (PRC section 42031.6, 14 CCR sections  
5 18973.2(j) and 18973.3(i)); the requirement to provide or initiate the distribution of a sharps  
6 waste containers and mail-back materials at the point of sale (PRC section 42032.2(d)(1)(F)(i)  
7 and 14 CCR section 18973.3(f)(2)); and the reasonable geographic spread requirement (PRC  
8 section 42032.2(a)(1)(F)(ii) and 14 CCR section 18973.2(g)(2)). The Act and the Regulations  
9 establish a general requirement that, in turn, elicits the program operator's proposal, in a  
10 stewardship plan, for implementing that requirement in a stewardship program (after the  
11 Department approves a stewardship plan). The program operator commits to meeting the  
12 statutory and regulatory requirements by implementing its stewardship plan. An approved  
13 stewardship plan then memorializes the requirements of the Act and the Regulations. In this  
14 way, the Act and the Regulations provide the flexibility that is a fundamental component of  
15 stewardship program law for a program operator to propose how it will meet certain  
16 requirements. The responsibility to implement a stewardship plan and run a stewardship  
17 program that complies with the statutory, regulatory, and plan requirements lies with the program  
18 operator. If a program operator wishes to modify the stewardship plan to help comply with  
19 statutory and regulatory requirements in a way different than outlined in its approved stewardship  
20 plan, it can do so via a submittal of a significant change plan amendment to the Department  
21 (PRC section 42032(e) and 14 CCR section 18973.1(i)). The significant changes in the plan  
22 amendment can then be implemented, but only after Department approval (*Id*).

## 23 **STATUTORY AND REGULATORY AUTHORITY**

### 24 **Submittal and Review of Annual Reports and Budgets**

25 10. The Act requires a program operator with an approved stewardship plan, to submit yearly  
26 annual reports and program budgets to the Department (PRC section 42033.2).

27 11. On or before March 31, 2022, and each year thereafter, a program operator shall prepare  
28 and submit to the Department a written report describing the stewardship program activities

1 during the previous reporting period of one year (PRC section 42033.2(a)(1)). An annual report  
2 must include multiple components, as described in PRC section 42033.2(b) and 14 CCR section  
3 18973.4 (specifically for covered drugs annual reports) and 14 CCR section 18973.5 (specifically  
4 for home-generated sharps waste annual reports).

5 12. The Department shall review and approve, conditionally approve, or disapprove an  
6 annual report or program budget that has been found to be complete (PRC section  
7 42033.2(e)(1)).

8 13. Conditional approval means that the Department determines that a document, including  
9 a program budget, is substantially compliant with all material requirements in relevant regulatory  
10 sections, but additional information from and/or additional actions by the program operator are  
11 necessary (14 CCR section 18973.1(e)).

12 14. If the Department conditionally approves an annual report or program budget, the  
13 Department shall identify the deficiencies in the program budget and the program operator shall  
14 comply with the conditions of the conditional approval within 60 days of the notice date, unless  
15 additional time is granted (PRC section 42033.2(e)(2)(A)). If the program operator fails to meet  
16 the conditions within 60 days, unless additional time is granted, the Department shall disapprove  
17 the program budget (PRC section 42033.2(e)(2)(B)).

18 15. Following a disapproval for failure to meet conditions of a conditional approval, a program  
19 operator can resubmit a program budget or annual report (PRC section 42033.2(e)(3)).  
20 However, a resubmittal of a program budget or annual report cannot always fix the deficiencies  
21 (e.g., if a program operator failed to collect data for a required annual report metric and cannot  
22 go back in time and collect the data).

23 **Drugs Plan, Plan Implementation, and Annual Report Requirements**

24 16. Per PRC section 42032.2(a)(1)(F), a stewardship plan for covered drugs, which a  
25 program operator must implement, must:

26 Provide for a collection system that complies with the requirements of [the Act] and meets  
27 all of the following requirements for authorized collection sites in each county in which the  
28 plan will be implemented:

1 (i) Provides for a minimum of five authorized collection sites or one authorized collection  
2 site per 50,000 people, whichever is greater.

3 (ii) Provides for a reasonable geographic spread of authorized collection sites and an  
4 explanation for the geographic spread.

5 17. (iii) Provides for a mail-back program covering any counties where there is not an  
6 authorized retail pharmacy operating as an authorized collection site. An authorized collection  
7 site is “a location where an authorized collector operates a secure collection receptacle for  
8 collecting covered [drugs]” (PRC section 42030(a)). An authorized collector is “a person or  
9 entity that has entered into an agreement with a program operator to collect covered drugs,  
10 including ...” law enforcement agencies and certain retail pharmacies (PRC section 42030(b)).

11 18. To summarize, the Act requires a covered drugs plan to commit to:

- 12 a) providing a minimum number of authorized collection sites in every required  
13 county;
- 14 b) spacing the authorized collection sites within a county to ensure reasonable  
15 geographic spread, as defined by the plan; and
- 16 c) providing a mail-back program for counties where an authorized retail pharmacy is  
17 not operating an authorized collection site.

18 19. As described above, in paragraph 9, a program operator’s stewardship plan  
19 memorializes the statutory and regulatory requirements and provides a detailed description of  
20 how these requirements will be implemented.

21 20. As required by the Act, the Respondent’s Drugs Plan committed to providing for a  
22 minimum of five authorized collection sites or one authorized collection site per 50,000 people,  
23 whichever is greater, per PRC section 42032.2(a)(1)(F)(i) and committed to providing for a mail-  
24 back program covering any counties where there is not an authorized retail pharmacy operating  
25 as an authorized collection site, per PRC section 42032.2(a)(1)(F)(iii).

26 21. With respect to reasonable geographic spread, to implement statutory and regulatory  
27 requirements, the Respondent committed, in its Drugs Plan, to a reasonable geographic spread  
28 as 90% of ultimate users living within a 15-mile drive of an authorized collection site (Section

1 VI.C.2 (page 14); Section VII.B.2. (page 22); and Section VII.D.1.(f) (page 25)).

2 22. The Act allows a program operator to “supplement service, if approved by the  
3 [D]epartment, for a county in which it operates that does not have the minimum number of  
4 authorized collection sites due to circumstances beyond the program operator’s control, by  
5 establishing ... a mail-back program. The mail-back program may include providing information  
6 on where and how to receive mail-back materials or providing the locations at which it distributes  
7 prepaid, preaddressed mailing envelopes” (PRC section 42032.2(c)).

8 23. To meet the statutory requirement in PRC section 42032.2(a)(1)(F)(ii), the Respondent  
9 committed, in its Drugs Plan, to using mail-back distribution locations if a retail pharmacy was  
10 not available as an authorized collection site in a particular county. (Section VI.C.2 (page 14);  
11 Section VII.B.1 (page 21); and Section VII.B.2. (page 22)).

12 24. The Regulations require a program operator to describe, in its annual report, “[h]ow the  
13 convenience standards pursuant to subsection (1)(F) of subdivision (a) of section 42032.2 of the  
14 PRC were met... If the convenience standards were not met, [the program operator shall]  
15 describe efforts made to achieve compliance.”

16 25. The Act and Regulations also require a program operator to establish a comprehensive  
17 education and outreach program for the covered drugs program.

18 26. The Act requires, per PRC section 42031.6(a), a program operator to “conduct a  
19 comprehensive education and outreach program intended to promote participation in the  
20 stewardship program. At a minimum, per PRC section 42031.6(a), the education and outreach  
21 program shall do all of the following:

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

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

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

1 (4) Prepare and provide additional outreach materials not specified in this section,  
2 as needed to promote the collection and proper management of covered drugs  
3 and home-generated sharps waste.

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

7 27. A program operator shall not, as part of the education and outreach program, promote  
8 the disposal of a covered product in a manner inconsistent with the services offered to ultimate  
9 users by the stewardship program (PRC section 42031.6(b)).

10 28. A stewardship plan shall include education and outreach provisions to meet the  
11 requirements of PRC section 42031.6 (PRC section 42032.2(f)).

12 29. Specific requirements for the covered drugs stewardship program are further described  
13 in the Regulations in 14 CCR section 18973.2(j) and in the Drugs Plan.

14 30. The Drugs Plan did not describe any local take-back events nor advertising for such  
15 events.

16 31. To implement the education and outreach statutory and regulatory requirements, in the  
17 Drugs Plan, Section IX.A. (page 30), the Respondent committed to providing “promotional  
18 materials, including signage, ... free of charge to hospitals, Pharmacies, and other locations, as  
19 necessary.” Additionally, the Respondent committed to the following in Section IV.A.1 of the  
20 Drugs Plan: “Easily consumable educational materials will be developed for dissemination to  
21 residents, pharmacists, retailers, and health care practitioners that will be translated into the  
22 languages based on those offered by the California Online Voter Registration website by the  
23 California Secretary of State (Spanish, Hindi, Chinese, Japanese, Khmer, Korean, Tagalog,  
24 Thai, and Vietnamese) in addition to English.” Further, the Respondent committed to the  
25 following in its Drugs Plan: “Printed materials will be easily understandable with varying levels  
26 of English proficiency, will leverage explanatory graphics to aid in comprehension, and will  
27 promote the disposal of Covered Drugs consistent with the services offered by the Program.”

28 32. To implement the education and outreach statutory and regulatory requirements, in the

1 Drugs Plan, Section IX.B. (pages 33-34), the Respondent committed to operating a website with  
2 multiple functionalities as part of its education and outreach.

3 33. Additionally, to implement the education and outreach statutory and regulatory  
4 requirements, in its Drugs Plan, the Respondent committed to provide both authorized collection  
5 sites and mail-back distribution sites with promotional brochures, per Section VII.D.3 of the  
6 Drugs Plan on page 26.

7 34. To implement the statutory and regulatory education and outreach requirements, in  
8 Section VII.A.1.b, on pages 16-18, of the Drugs Plan, the Respondent committed to having the  
9 following on its collection receptacles at authorized collection sites:

- 10 • “signage ... translated into [various languages other than English and Spanish] and  
11 be “available to Ultimate Users on their mobile devices via a QR code that will be  
12 placed on the Collection Receptacle”;
- 13 • “signage [that will] communicate how Ultimate Users can request Combination  
14 Product Mail-Back Packages for the disposal of drugs in a medical device, or a  
15 combination product containing a drug and a medical device”;
- 16 • “signage [that] will ... feature the [Drugs] Program’s website and toll-free number, so  
17 Ultimate Users can ask questions and find more information”;
- 18 • “readily recognizable images to communicate how to safety deposit Covered Drugs  
19 into the Collection Receptacle”;
- 20 • “signage [that] includes communication representing items allowed (all Covered  
21 Drugs including inhalers and schedule II-V controlled substances) and prohibited  
22 (drugs in a medical device, combination product containing a drug and a medical  
23 device such as auto-injector) for deposit into the Collection Receptacle”.

24 35. The Act requires a program operator to fully implement operation of an approved  
25 stewardship program no later than 270 days after approval ... of the stewardship plan that  
26 establishes the program (PRC section 42032(g) and 14 CCR section 18973.1(m)).

27 36. In each annual report, a program operator must describe how it complied with all  
28 elements in its covered drugs stewardship plan. (PRC section 42033.2(b)(8) and introductory

1 preamble to 14 CCR section 18973.4).

2 **Sharps Plan, Plan Implementation, and Annual Report Requirements**

3 37. Per PRC section 42032.2(d)(1)(F)(i), a stewardship plan for home-generated sharps  
4 waste, that a program operator must implement, must include a description of how the  
5 stewardship “program provides or initiates distribution of a sharps waste container and mail-back  
6 materials at the point of sale, to the extent allowable by law.”

7 38. Per the Regulations, “point of sale” means the point in time at which an ultimate user  
8 purchases a covered drug or sharp at a pharmacy or other retailer, including but not limited to  
9 an online retailer. (14 CCR section 18972.1(a)(9)).

10 39. Per the Regulations, 14 CCR section 18972.1(a)(10), “provides or initiates distribution of  
11 a sharps waste container and mail-back materials” means one of the following:

12 (A) To provide a sharps waste container and mail-back materials to the ultimate  
13 user, at the point of sale or prior, at no cost to the ultimate user; or

14 (B) To arrange, at the point of sale or prior, for a sharps waste container and mail-  
15 back materials to be sent to the ultimate user and arrive within five business days  
16 at no cost or inconvenience to the ultimate user; or

17 (C) other methods of providing a sharps waste container and mail-back materials  
18 to the ultimate user at the point of sale or prior, at no cost to the ultimate user, if  
19 the method identified in subparagraph (a) above is not allowed by law and if the  
20 method identified in subpart (B) above is not allowed by law. These methods must  
21 be approved by the [D]epartment in a stewardship plan and result in substantially  
22 the same level of convenience to the ultimate user as the methods identified in  
23 subparts (A) and (B) above.

24 40. To implement the provision and initiation requirement, the Respondent committed, in its  
25 Sharps Plan, to providing and initiating the distribution of sharps waste containers and mail-back  
26 materials at the point of sale or prior (Section VI.A.1 (pages 13-14; Section VI.A.1(b) (pages 15-  
27 16)). The Sharps Plan states:

28 The Mail-Back Program will:

- 1           • Provide Mail-Back Units at all Points of Sale where Covered
- 2           Products are sold.
- 3           ...
- 4           • Arrange, at the Point of Sale or prior, for a Mail-Back Unit to be sent
- 5           to the Ultimate User and arrive to the Ultimate User within five (5)
- 6           business days of the request.

7           The Point of Sale Location will initiate the distribution of the Mail-Back Unit(s) to  
8           the Ultimate User in the following ways:

- 9           1) Distributing the Mail-Back Unit(s) to the Ultimate User at the Point of Sale.
- 10          2) *If the Ultimate User declines the Mail-Back Unit(s)* [emphasis added],  
11          they will be offered the opportunity to have the Mail-Back Unit(s) shipped to  
12          them to arrive within five (5) days of the Point of Sale. The Point of Sale  
13          Location employee will be provided with instructions on how to request Mail-  
14          Back Unit(s) for Ultimate Users.
- 15          3) The [Respondent] will provide Point of Sale Locations with an ordering  
16          portal that will allow them to request Mail-Back Unit(s) directly from the  
17          Service Provider to be shipped to the Ultimate User. Once the Service  
18          Provider receives the request, the Sharps Waste Containers will be  
19          packaged according to the amount needed to adequately handle the  
20          amount of Sharps purchased. The Mail-Back Unit(s) will arrive to the  
21          Ultimate User within the required timeframe of five (5) business days from  
22          the Point of Sale.
- 23          4) ***Should Ultimate Users decline either option described above***  
24          [emphasis added], Point of Sale Locations will provide Ultimate Users with  
25          an information pamphlet describing additional options for requesting Mail-  
26          Back Unit(s) to be sent to them at a later date.

27          41. The Respondent committed, in its Sharps Plan, to providing both the option to receive a  
28          Mail-Back Unit and the option to have it mailed to the ultimate user at all Point of Sale Locations,

1 as evidenced by the absence of the word “OR” in the list above in paragraph 40. Moreover,  
2 Section VI.A.1.b(4), on page 16, states that “should Ultimate Users decline either option  
3 described above”, meaning that an ultimate user can make the choice, at any point of sale  
4 location, to receive the Mail-Back Unit at the Point of Sale or have it mailed to arrive within five  
5 (5) business days.

6 42. The Act and the Regulations require a program operator to establish an education and  
7 outreach program for its home-generated sharps waste program (See PRC sections 42031.6  
8 and 42032.2(f), which are described in paragraphs 25-28 above).

9 43. Specific requirements for the home-generated sharps waste stewardship program are  
10 further described in the Regulations (14 CCR section 18973.3(i)) and the Sharps Plan).

11 44. To implement the education and outreach requirements, the Respondent committed, in  
12 its Sharps Plan, to develop and distribute “easily consumable [*sic*] educational and outreach  
13 materials, including signage, ... to Point of Sale Locations participating in the Program.” (Section  
14 VIII.A.1. (page 22) of the Sharps Plan.)

15 45. Further, the Respondent committed to operating a website, stating in the Sharps Plan  
16 that “[t]he website will: ... provide information on collection options for Home-Generated Sharps  
17 Waste ... Accept requests for Mail-Back Units from Ultimate Users ... include educational and  
18 outreach materials on safe handling, storage, and proper disposal of Home-Generated Sharps  
19 Waste” (Section VIII.B of Sharps Plan, pages 24-25).

20 46. The Respondent also committed, in its Sharps Plan (Section X.B. pages 28-29), to  
21 “conduct an annual survey of Covered Entities, pharmacists, and healthcare professionals ...  
22 who interact with Ultimate Users. The goal of the survey is to measure public awareness and  
23 use of the [Sharps] Stewardship Program”. Further, the Respondent committed in its Sharps  
24 Plan to “provide survey responses to [the Department] for review in the annual report that will  
25 describe the following data points:

- 26 • Overall number of survey responses and methods of contact
- 27 • Percentage of survey respondents that were exposed to any forms of outreach  
28 provided by the Program

- Percentage of survey responses that have used the Program and which collection method was used
- The percentage of survey respondents that believe the Program is convenient.

47. In a home-generated sharps waste stewardship program annual report, a program operator must include the metric for the number of sharps waste containers and mail-back materials provided at the point of sale to ultimate users, per county, per 14 CCR section 18973.5(c)(2)(A).

48. The Act requires a program operator to fully implement operation of an approved stewardship program no later than 270 days after approval ... of the stewardship plan that establishes the program (PRC section 42032(g) and 14 CCR section 18973.1(m)).

49. In an annual report, a program operator must describe how it complied with all elements in its home-generated sharps waste stewardship plan (PRC section 42033.2(b)(8) and introductory preamble to 14 CCR section 18973.5).

**Department Audit Authority**

50. The Department has authority to conduct an audit of a program operator, per PRC section 42033.4(b)(3).

**Budget Requirements**

51. On or before March 31, 2022, a program operator shall prepare and submit to the Department a written program budget for stewardship program implementation for the upcoming calendar year. (PRC section 42033.2(a)(2)). A program budget must include, among other components, a recommended funding level necessary to cover the stewardship plan's budgeted costs and to operate the stewardship program over a multi-year period in a prudent and responsible manner (PRC section 42033.2(c)(2) and 14 CCR section 18973.6(d)). Pursuant to 14 CCR sections 18973(a) and (d), documents, including a program budget, submitted to the Department, must meet the following requirements:

- The document is required to be in compliance with section 7405 of the Government Code, and the Web Content Accessibility Guidelines 2.0 published in 2008 by the Web Accessibility Initiative of the World Wide Web Consortium at a minimum Level

1 AA success criteria to allow for posting on the department's website. The entirety of  
2 the Web Content Accessibility Guidelines 2.0 (published in 2008) are incorporated  
3 herein by reference. (14 CCR section 18973(a))

- 4 • The document shall be complete and correct. (14 CCR section 18973(d))

#### 5 **Departmental Administrative Fees and Program Budgets**

6 52. Program operators are required to pay departmental administrative fees, per PRC  
7 section 42034.2 (“Departmental Administrative Fees”). Note that PRC section 42034.2 of the Act  
8 was modified, effective July 10, 2023. *Id.* The Department invoices each program operator for  
9 the Department’s (as well as any other state agencies’) actual and reasonable costs to  
10 implement the Act. *Id.* The State Administrative Manual requires an agency to send nonpayment  
11 notices, 30 days apart, before attempting to collect the unpaid amounts (Section 8293.1 of the  
12 State Administrative Manual, renumbered from section 8776.6).

13 53. The Act requires “each covered entity, either individually or through a stewardship  
14 organization, [to] pay all administrative and operational costs associated with establishing and  
15 implementing the stewardship program in which it participates, including the cost of collecting,  
16 transporting, and disposing of covered products” (PRC section 42034). Furthermore, a program  
17 operator must demonstrate, in its plan, “adequate funding for all administrative and operational  
18 costs of the stewardship program, to be borne by participating covered entities” (PRC section  
19 42032.2(a)(1)(D) for the covered drugs stewardship program and PRC section 42032.2(d)(1)(C)  
20 for the home-generated sharps stewardship program).

21 54. Pursuant to the Act, by March 31 every year, the Respondent was required to submit a  
22 program budget for the upcoming calendar year, which includes an independent financial audit  
23 (“IFA”) for the preceding calendar year (PRC sections 42033.2(a)(2) and (c)).

24 55. Program budgets must contain the following information:

25 (c) Recommended reserve level amount and description justifying the reserve level  
26 amount indicated. The program operator shall maintain reserves in a prudent and  
27 responsible manner (14 CCR section 18976.3(c)).

28 (f) An independent financial audit of the stewardship program.... [which] shall include:

- 1 (1) Minutes, books, and records that clearly reflect the activities and transactions
- 2 of the program operator's stewardship program
- 3 (2) Stewardship program financial statements ...
- 4 (3) An opinion on the stewardship organization's compliance with all aspects of
- 5 section 42034 [of the Act] and [the Regulations] (14 CCR section 18973.6 (f)).

## 6 **Violations, Penalties, and Revocations**

7 56. The Act authorizes the Department to impose an administrative penalty on any program  
8 operator and stewardship organization for violations of the Act in an amount of up to \$10,000  
9 per day or \$50,000 per day for intentional, knowing, or reckless violations (PRC section  
10 42035.2(a) and (b) and 14 CCR section 18975(a)).

11 57. Before imposing an administrative penalty, the Department shall issue a notice of  
12 violation ("NOV"). (14 CCR section 18975.1(a)(1)). The NOV shall list and describe the nature  
13 of the violation(s). (14 CCR section 18975.1(a)(1)). The Department shall issue a NOV to the  
14 Respondent if the Department determines (1) that a program operator or a stewardship  
15 organization has violated the Regulations or the Act (14 CCR section 18975.1(a)(1)).

16 58. In assessing the administrative penalty amount, the Department shall consider the  
17 totality of the circumstances, which may include, but is not limited to, the following: (1) The  
18 nature, circumstances, extent, and gravity of the violation(s); (2) The number and severity of the  
19 violation(s); (3) Evidence that the violation was intentional, knowing, or reckless; (4) The size of  
20 the violator's business and/or the financial position of the violator; (5) History of violation(s) of  
21 the same or similar nature; (6) The willfulness of the violator's misconduct; (7) Whether the  
22 violator took good faith measures to comply with this Article [the Regulations] and Chapter 2 of  
23 Part 3 of Division 30 of the Public Resources Code and the period of time over which these  
24 measures were taken; (8) Evidence of any financial gain resulting from the violation(s); (9) The  
25 economic effect of the penalty on the violator; (10) The deterrent effect that the imposition of the  
26 penalty would have on both the violator and the regulated community; (11) Any other factor(s)  
27 that justice may require (14 CCR section 18975(c)).

28 59. Upon a written finding that a ...program operator... has not met a material requirement

1 of [the Act], in addition to any other penalties authorized under [the Act], the [D]epartment may...  
2 [r]evoke the program operator's stewardship plan approval.... (PRC section 42035.4(a)).

3 **FACTUAL ALLEGATIONS AND DISCUSSION OF VIOLATIONS**

4 60. As of the date this Accusation was signed, the Respondent is a program operator that  
5 is a stewardship organization, incorporated in Delaware with a physical address at 3929 West  
6 Point Blvd. Suite D, Winston-Salem, North Carolina, 27103. The Respondent is a program  
7 operator for both the covered drugs and home-generated sharps waste stewardship programs.

8 **2022 and 2023 Drugs Program Annual Reports and Department's 2023 Field Inspections**

9 61. After the Department disapproved the Respondent's 2022 Drugs Annual Report on  
10 August 16, 2023, the Respondent submitted the Revised 2022 Drugs Annual Report on  
11 October 15, 2023 (collectively, the "2022 Drugs Annual Reports"). The Department  
12 disapproved the 2022 Revised Drugs Annual Report on January 8, 2024 for continued failure  
13 to meet multiple requirements and for failure to cure deficiencies identified by the Department.  
14 (The disapprovals are not facts material to this Accusation.)

15 62. The Department issued an NOV on August 24, 2023, concerning the disapproval of the  
16 2022 Drugs Annual Report.

17 63. The Department issued an NOV on August 8, 2025, concerning the disapproval of the  
18 2022 Revised Drugs Annual Report.

19 64. After the Department disapproved the Respondent's 2023 Drugs Annual Report on  
20 June 27, 2024 and notified the Respondent of the deficiencies on July 29, 2024, the  
21 Respondent submitted the Revised 2023 Drugs Annual Report on September 27, 2024  
22 (collectively, the "2023 Drugs Annual Reports"). The Department disapproved the Revised  
23 2023 Drugs Annual Report on December 23, 2024, for continued failure to meet multiple  
24 requirements and for failure to cure deficiencies identified by the Department. (The  
25 disapprovals are not facts materials to this Accusation.)

26 65. Apart from the information reported by the Respondent in its covered drugs annual  
27 reports, the Department conducted field inspections in calendar year 2023 and inspected 52  
28 authorized collection sites where the Respondent reported hosting pharmaceutical collection

1 receptacles.

2 66. The Department issued an NOV on September 30, 2025, concerning the disapproval of  
3 the 2023 Drugs Annual Reports and the 2023 field inspection observations.

4 67. The Respondent admitted, in the 2022 Drugs Annual Reports, that it failed to establish  
5 the requisite number of authorized collection sites within 270 days of the Drugs Plan approval.  
6 The Respondent failed to establish enough authorized collection sites in 44 counties and failed  
7 to describe the circumstances that were beyond its control in each county in order to use the  
8 exception in PRC section 42032.2(c), in violation of PRC section 42032.2(a)(1)(F)(i). But, even  
9 if the Respondent had described these circumstances, it failed to establish any authorized  
10 collection sites or mail-back distribution sites in seven California counties. In these seven  
11 counties, the Respondent did not meet the convenience standard using authorized collection  
12 sites. Nor did the Respondent establish any mail-back distribution sites, required to use the  
13 exception. Thus, even if the Department approved the use of the exception afforded by PRC  
14 section 42032.2(c) if the Respondent described circumstances that were beyond its control,  
15 the Respondent could not have met the convenience standard in PRC section  
16 42032.2(a)(1)(F)(i) using the exception.

17 68. This failure to establish the requisite number of authorized collection sites in multiple  
18 California counties continued into calendar year 2023. In the 2023 Drugs Annual Report, the  
19 Respondent reported using a combination of authorized collection sites and mail-back  
20 distribution sites to meet the convenience standard in 22 counties. However, the Department  
21 approved the use of mail-back in only 19 counties because the Respondent established at  
22 least one authorized collection site in these counties to supplement service. Barring  
23 exceptional circumstances, the exception available in PRC section 42032.2(c) can only be  
24 used to **supplement** service, not to replace service completely. Thus, if the Respondent did  
25 not establish at least one authorized collection site in a county, the mail-back exception could  
26 not be used, unless there were exceptional circumstances beyond the Respondent's control  
27 for not establishing authorized collection sites other than at a retail pharmacy. These  
28 exceptional circumstances existed only in Sierra and Alpine counties. The Department did not

1 approve mail-back in multiple counties where the Respondent failed to establish the requisite  
2 number of authorized collection sites, in violation of PRC section 42032.2(a)(1)(F)(i). Based on  
3 information reported by the Respondent in the 2023 Drugs Annual Reports, there are 25  
4 counties where Respondent failed to establish enough combined authorized collection sites  
5 and mail-back distribution locations to meet the convenience standard in PRC section  
6 42032.2(a)(1)(F)(i).

7 69. Based on the information reported by the Respondent in the 2022 Drugs Annual  
8 Reports and 2023 Drugs Annual Reports, the Respondent failed to meet the reasonable  
9 geographic spread requirement of 90% of ultimate users living within a 15-mile drive of an  
10 authorized collection site within 270 days of the Drugs Plan approval, in violation of PRC  
11 section 42032.2(a)(1)(F)(ii). For the 2022 reporting period, the Respondent failed to meet the  
12 reasonable geographic spread requirement in 25 counties. For the 2023 reporting period, the  
13 Respondent reported that it met the reasonable geographic spread standard in 23 counties  
14 using both authorized collection sites and mail-back distribution sites. Per the Drugs Plan and  
15 the Respondent's method for implementing the reasonable geographic spread requirement,  
16 the only counties where the Respondent was able to use mail-back distribution sites to  
17 calculate reasonable geographic spread were Sierra and Alpine, where a retail pharmacy was  
18 not available. The Respondent did not meet the reasonable geographic spread in multiple  
19 other counties, where it was required to use authorized collection sites only in order to  
20 calculate the spread.

21 70. Based on the information reported by the Respondent in the 2022 Drugs Annual  
22 Reports and 2023 Drugs Annual Reports, the Respondent failed to establish a mail-back  
23 program in counties where a retailer pharmacy was not operating as an authorized collection  
24 site within 270 days of Drugs Plan approval. During both the 2022 and 2023 reporting periods,  
25 the Respondent admitted that it failed to establish a mail-back program in Alpine and Sierra  
26 counties, in which there are no retail pharmacies operating as authorized collection sites, in  
27 violation of the convenience standard requirement per PRC section 42032.2(a)(1)(F)(iii).

28 71. Based on the information reported in the 2022 Drugs Annual Reports and 2023 Drugs

1 Annual Reports, the Respondent failed to implement a comprehensive education and outreach  
2 program within 270 days of Drugs Plan approval, as discussed below. The Respondent failed  
3 to have an operational website, as required by Section IX.B. (pages 33-34) of the Drugs Plan  
4 and 14 CCR section 18973.2(j)(3) and PRC section 42031.6(a)(3). See declarations from  
5 Becky Haworth and Morgan Buchan.

6 72. In the 2022 Drugs Annual Reports, the Respondent reported that it included “local take-  
7 back events” in its education and outreach brochures even though the Respondent did not  
8 report hosting any collection events and did not identify any alternative form of collection, per  
9 14 CCR section 18973.2(g)(6). Thus, the Respondent promoted the disposal of covered drugs  
10 in a manner inconsistent with the services it offered to ultimate users, in violation of PRC  
11 section 42031.6(b) and 14 CCR sections 18973.2(j) and 18973.4(i).

12 73. During the 2023 calendar year, the Department conducted inspections at 52 authorized  
13 collection sites where the Respondent reported having a Collection Receptacle, pursuant to 14  
14 CCR section 18973.4(c)(4)(A), including hospitals, pharmacies, and other locations throughout  
15 California. Through these inspections, the Department found that none of the authorized  
16 collection sites were providing promotional materials, including easily consumable educational  
17 materials or signage. Inspectors confirmed that the Respondent did not provide education and  
18 outreach materials to display or distribute. The Respondent failed to implement a  
19 comprehensive education and outreach program, required by PRC section 42031.6, 14 CCR  
20 section 18973.2(j), and the Drugs Plan.

21 74. Moreover, through 52 inspections of the Respondent’s Collection Receptacle at  
22 authorized collection sites, the Department documented the following violations:

- 23 a) 27 collection receptacles, out of 52 inspected did not have a QR code to provide  
24 an ultimate user access to translation into languages other than English and  
25 Spanish. Additionally, even though 13 collection receptacles had a QR code, the  
26 QR code did not provide ultimate users access to translation into languages  
27 other than English and Spanish, as required by the Drugs Plan and 14 CCR  
28 section 18973.2(j).

- 1           **b)** 47 collection receptacles, out of the 52 inspected, did not have communication  
2           regarding how ultimate users can request Combination Product Mail-Back  
3           Packages for the disposal of drugs in a medical device, or a combination product  
4           containing a drug and a medical device, as required by the Drugs Plan and 14  
5           CCR section 18973.2(j).
- 6           **c)** 50 collection receptacles, out of the 52 inspected, did not have the Drugs  
7           Program’s website to allow for ultimate users to ask questions and find more  
8           information, as required by the Drugs Plan and 14 CCR section 18973.2(j).
- 9           **d)** 50 collection receptacles, out of 52 inspected, did not have the Drugs Program’s  
10           website to allow for ultimate users to ask questions and find more information, as  
11           required by the Drugs Plan and 14 CCR section 18973.2(j).
- 12           **e)** 50 collection receptacles, out of the 52 inspected, did not have the Drugs  
13           Program’s toll-free number to allow for ultimate users to ask questions and find  
14           more information, as required by the Drugs Plan and 14 CCR section 18973.2(j).
- 15           **f)** 33 collection receptacles, out of the 52 inspected, did not include recognizable  
16           images regarding how to safely deposit covered drugs into the collection  
17           receptacle, as required by the Drugs Plan and 14 CCR section 18973.2(j).
- 18           **g)** 41 collection receptacles, out of the 52 inspected, did not include signage  
19           communication representing items allowed (all Covered Drugs including inhalers  
20           and schedule II-V controlled substances) and did not include inhalers as the  
21           items allowed, as required by the Drugs Plan and 14 CCR section 18973.2(j).

22           75. Additionally, the Department’s inspection of one of the authorized collection sites  
23           demonstrated that the Respondent reported, in the 2023 Drugs Annual Reports, a collection  
24           receptacle at a site that was not part of the statewide program, but rather a MEDRETURN  
25           collection receptacle. Neither the authorized collection site representatives nor any information  
26           on the collection receptacle indicated that the collection receptacle was owned and operated  
27           by the Respondent or its service provider. The Respondent also reported a collection  
28           receptacle as being part of its program, when in fact, the collection receptacle was owned and

1 operated by another approved program operator.

2 **2022 and 2023 Sharps Annual Reports and Department's 2023 Field Inspections**

3 76. After the Department disapproved the Respondent's 2022 Sharps Annual Report on  
4 June 21, 2023, the Respondent submitted the Revised 2022 Sharps Annual Report on August  
5 21, 2023. On November 17, 2023, The Department disapproved the 2022 Revised Sharps  
6 Annual Report, submitted on August 21, 2023 (collectively, the "2022 Sharps Annual  
7 Reports"). (The disapprovals are not facts material to this Accusation.)

8 77. The Department issued an NOV on August 11, 2023, regarding violations documented  
9 in the 2022 Sharps Annual Report. ("First 2022 Sharps Annual Report NOV"). The Department  
10 issued an NOV on August 6, 2025, regarding violations documented in the 2022 Revised  
11 Sharps Annual Report ("Second 2022 Sharps Annual Report NOV").

12 78. After the Department disapproved the Respondent's 2023 Sharps Annual Report on  
13 June 27, 2024, and notified the Respondent of the deficiencies on July 29, 2024, the  
14 Respondent submitted the Revised 2023 Sharps Annual Report on September 27, 2024  
15 (collectively, the "2023 Sharps Annual Reports"). The Department disapproved the 2023  
16 Revised Sharps Annual Report on December 23, 2024, for continued failure to meet multiple  
17 requirements and for failure to cure deficiencies identified by the Department. (The  
18 disapprovals are not facts material to this Accusation.)

19 79. The Department issued an NOV on September 30, 2025, regarding violations  
20 documented in the 2023 Sharps Annual Reports and 2023 field inspections.

21 80. The Respondent reported in the 2022 Sharps Annual Reports that point of sale sites  
22 had the **option** to either provide or initiate the distribution of sharps waste containers and mail-  
23 back materials at the point of sale site, in violation of the Sharps Plan, which required the  
24 Respondent to equip point of sale sites to do both. The 2022 Revised Sharps Annual Report  
25 stated: "Point of Sale Locations were provided two different options for participation including  
26 1) Initiating the distribution of Mail-Back Units on behalf of Ultimate Users or 2) Ordering  
27 inventory to keep Mail-Back Units on-site and physically distribute them at the Point of Sale."  
28 Moreover, the 2022 Revised Sharps Annual Report stated: "[the Respondent] was able to

1 secure 127 Point of Sale Locations during the Reporting Period. Of the 127 Locations, 31  
2 Locations elected to initiate the order of Mail-Back Units on behalf of Ultimate Users. The  
3 remaining 96 Point of Sale Locations elected to keep Mail-Back Units on-site to distribute to  
4 Ultimate Users at the Point of Sale.”

5 81. The Revised 2023 Sharps Annual Report includes *Attachment C – Mail-Back Unit*  
6 *Distribution By County*, which lists the number of sharps waste containers and mail-back  
7 materials distributed in 54 counties and the method of distribution. The Respondent admitted  
8 that in 28 of the 54 counties, the Respondent did not provide sharps waste containers and  
9 mail-back materials at the point of sale. In 24 of those 28 counties, the Respondent did not  
10 initiate the distribution of a sharps waste container and mail-back materials at the point of sale.  
11 The Respondent’s 2023 Revised Sharps Annual Report states that 203 point of sale locations  
12 have the ability to provide and initiate, but the Respondent admitted to providing only 99 of  
13 these 203 locations with the ability to provide sharps waste containers and mail-back materials  
14 at the point of sale. Thus, it was not possible for an ultimate user to have the choice of being  
15 provided with a sharps waste container and mail-back materials at all locations, as required by  
16 the Sharps Plan. Therefore, the Respondent failed to fully implement its Sharps Plan within  
17 270 days of approval.

18 82. Additionally, the Respondent, in its 2023 Revised Annual Report, describes how it  
19 “continues its efforts in rural counties that have not requested Mail-Back Units”, which is an  
20 admission that the Respondent failed to provide and initiate in those counties and therefore  
21 failed to fully implement the Sharps Plan within 270 days of approval.

22 83. The Department conducted field inspections for the Sharps Program in 2023, which  
23 demonstrate that the Respondent failed to provide or initiate the distribution of sharps waste  
24 containers or mail-back materials at the point of sale. Section VII of the Respondent’s Sharps  
25 Plan requires the Respondent to provide a sharps waste container and mail-back materials to  
26 an ultimate user, and to initiate their distribution if the ultimate user declines.

27 84. Through 61 inspections of point of sale locations throughout California, where the  
28 Respondent’s Sharps Plan participating covered entities’ sharps products were offered for

1 sale, Department documented the following violations (a)-(d):

- 2 a) At all 61 point of sale locations that were inspected, sharps waste containers and  
3 mail-back materials were not provided at the point of sale, as required by the  
4 Sharps Plan. At the time of inspection, site personnel stated that they did not  
5 have any sharps waste containers and mail-back materials to provide to an  
6 ultimate user.
- 7 b) At (60) point of sale locations, out of 61 inspected, the Respondent failed to  
8 initiate distribution of a sharps waste container and mail-back materials at the  
9 point of sale. At the time of inspection, site personnel explained that they were  
10 unaware of the existence of an ordering portal to allow the point of sale site to  
11 order sharps waste containers and mail-back materials on behalf of the ultimate  
12 user to arrive to the ultimate user within five (5) business days. Staff at the point  
13 of sale sites were not aware of a mechanism to be able to order the sharps  
14 waste containers and mail-back materials on behalf of the ultimate users.
- 15 c) At all 61 point of sale locations that were inspected, there was failure to offer  
16 informational pamphlets describing additional options for requesting a sharps  
17 waste container and mail-back materials for ultimate users that declined to have  
18 these provided or initiated at the point of sale. At the time of inspection, site  
19 personnel stated that they did not have any informational pamphlets available to  
20 offer.
- 21 d) The Respondent failed to provide all of the 61 point of sale sites with education  
22 and outreach materials, including the informational pamphlets described above,  
23 to distribute to ultimate users. At the time of inspection, site personnel stated that  
24 they did not have any education and outreach materials available to provide.

25 85. The 2022 Sharps Annual Reports, 2023 Sharps Annual Reports, and the 2023 field  
26 inspections demonstrate that the Respondent failed to either provide or initiate the distribution  
27 of sharps waste containers and mail-back materials at the point of sale or prior, in violation of  
28 PRC section 42032.2(d)(1)(F) and the Sharps Plan.

1 86. The Respondent failed to have an operational website, as required by Section VIII.B.  
2 (page 24) of the Sharps Plan and 14 CCR section 18973.3(i)(3) and PRC section  
3 42031.6(a)(3). See declarations from Becky Haworth and Morgan Buchan.

4 87. Per the 2022 Revised Sharps Annual Report, the Respondent promoted the disposal of  
5 home-generated sharps waste in a manner inconsistent with the services it offered to ultimate  
6 users, in violation of PRC section 42031.6(b), 14 CCR section 18973.3(i), and 14 CCR section  
7 18973.5(i). The Respondent included “local take-back events” in its education and outreach  
8 brochures even though it did not report hosting any collecting events and did not identify any  
9 supplemental collection methods in its Sharps Plan, per 14 CCR section 18973.3(f)(5).

10 88. The Respondent failed to implement and report on its Sharps Program’s education and  
11 outreach activities, in violation of PRC section 42031.6 and 14 CCR sections 18973.3(i) and  
12 18973.5(i) as well as the Sharps Plan, as discussed below. In its 2023 Sharps Annual Reports,  
13 the Respondent failed to provide the requisite survey of its education and outreach program,  
14 as required by the Sharps Plan, which stated that the Respondent will “conduct an annual  
15 survey of Covered Entities, pharmacists, and healthcare professionals... who interact with  
16 Ultimate Users.” The Respondent did not include covered entities in the list of those surveyed,  
17 as described in its Sharps Plan, and failed to explain why it did not survey covered entities.  
18 Moreover, the Respondent failed to include the percentage of respondents that have used the  
19 program or which collection method was used, in violation of the Sharps Plan.

20 89. One of the Respondent’s survey questions, as reported by Respondent in the 2023  
21 Revised Sharps Annual Report, as part of its education and outreach program, pertained to  
22 expired and/or unwanted medicines instead of sharps, which is a failure to implement the  
23 comprehensive education and outreach program and failure to report metrics as required by  
24 the annual report. The Respondent reported that the following question was asked: “Are you  
25 aware of the program or residents to safely dispose of expired and/or unwanted medicines in  
26 California?” This question is about medicines, rather than sharps. But, the Respondent  
27 concluded, based on this question about medicines, that “67 [percent of the healthcare  
28 providers surveyed] stated that they were aware of the Program for Ultimate Users to safely

1 dispose of Sharps,” that “Only 19 [percent] stated that they were not aware of the [Sharps]  
2 Program”, and ‘14 [percent] reported that they were unsure of their awareness of the [Sharps]  
3 Program” (see page 46 of the 2023 Revised Sharps Annual Report). The survey results about  
4 the Sharps Program conflict with survey questions that pertain to expired and/or unwanted  
5 medicines.

6 90. Questions about medicine instead of sharps appeared on the Respondent’s website as  
7 well, as reported by the Respondent in its 2023 Revised Sharps Annual Report. The  
8 Respondent’s website, which must contain information to promote the use of the Sharps  
9 Program, as required by PRC section 42031.6(a)(3) and 14 CCR section 18973.3(i)(3),  
10 contained a question about unwanted medication rather than sharps. A question in a link that  
11 says “Unwanted medication at home?” does not help an ultimate user who is seeking  
12 information about proper home-generated sharps waste disposal. However, an ultimate user  
13 had to click on this link to learn about such disposal. The Respondent noted that the website,  
14 which included this link, was “utilized by [the Respondent] until the jointly operated website  
15 was available for use starting on October 26, 2023.” Thus, according to the Respondent, the  
16 only website where ultimate users could request sharps waste containers and mail-back  
17 materials for 10 months in 2023, which the Respondent was required to operate, only had a  
18 question about medicine rather than sharps.

19 91. Moreover, the Respondent failed to meet the annual report requirement to include  
20 metrics for sharps waste containers and mail-back materials provided at the point of sale to  
21 ultimate users, per county, pursuant to 14 CCR section 18973.5(c)(2)(A). The Respondent did  
22 not report this metric in its 2023 Sharps Annual Report. The Respondent’s 2023 Revised  
23 Sharps Annual Report states that “[the Respondent] intends to implement a survey for enrolled  
24 Point of Sale Locations to report this metric at intervals prescribed by [the Respondent] in  
25 order to capture this metric in future reporting,” evidencing that it was impossible for the  
26 Respondent to cure the deficiency in the 2033 Revised Sharps Annual Report because the  
27 numbers for this metric had not been recorded during the 2023 calendar year, as required.  
28

1 **2023 Covered Drugs Program Budget**

2 92. The Department conditionally approved the Respondent’s 2023 Covered Drugs  
3 Budget, per PRC section 42033.2(e)(2) and 14 CCR sections 18973.1(e) and (j).

4 93. The two conditions of the conditional approval, which the Respondent had to meet to  
5 avoid disapproval, were:

6 “a. Correct accessibility errors in the *Annual Program Budget* to make it compliant with  
7 section 7405 of the Government Code and with the Web Content Accessibility Guidelines  
8 2.0 Level AA success criteria, at a minimum. (The requirement necessitating this condition  
9 appears in 14 CCR section 18973(a)).

10 b. Use correct terminology throughout the annual program budget. (The requirement  
11 necessitating this condition appears in 14 CCR section 18973(d)).”

12 94. On February 28, 2023, the Department disapproved the Respondent’s Resubmitted  
13 2023 Drugs Budget (resubmitted on December 16, 2022) because the Respondent failed to  
14 comply with the conditions of conditional approval, per PRC sections 42033.2(e)(2)(B) and  
15 (e)(3). The Resubmitted 2023 Covered Drugs Budget continued to have accessibility errors  
16 and was incorrect because it contained mathematical errors.

17 95. On March 14, 2023, the Department issued a Notice of Violation to the Respondent for  
18 failure to meet conditions of a conditional approval, resulting in a disapproval.

19 96. The Respondent submitted a compliant covered drugs program budget 23 days after the  
20 disapproval, on March 24, 2023.

21 97. Only after the Department issued an NOV, did the Respondent correct the deficiencies.

22 **2023 Home-Generated Sharps Waste Program Budget**

23 98. The Department conditionally approved the Respondent’s 2023 Sharps Waste Budget,  
24 per PRC section 42033.2(e)(2) and 14 CCR sections 18973.1(e) and (j).

25 99. The condition of conditional approval, which the Respondent was required to meet to  
26 avoid disapproval was:

27 “a. Correct accessibility errors in the *Annual Program Budget* to make it compliant with  
28 section 7405 of the Government Code and with the Web Content Accessibility Guidelines 2.0

1 Level AA success criteria, at a minimum. (The requirement necessitating this condition  
2 appears in 14 CCR section 18973(a)).

3 100. On February 28, 2023, the Department disapproved the Respondent's Resubmitted  
4 2023 Sharps Waste Budget (resubmitted on December 16, 2022) because the Respondent  
5 failed to comply with the conditions of conditional approval, per PRC sections 42033.2(e)(2)(B)  
6 and (e)(3). The Resubmitted 2023 Sharps Waste Budget continued to have accessibility  
7 errors.

8 101. The Department issued a Notice of Violation to the Respondent on March 14, 2023 for  
9 failure to comply with the conditions of conditional approval.

10 102. The Respondent submitted a compliant home-generated sharps waste program budget  
11 23 days after the disapproval, on March 24, 2023.

12 103. Only after the Department issued an NOV, did the Respondent correct the deficiencies.

13 **Late Payments of Departmental Administrative Fees**

14 104. The Respondent failed to pay Departmental Administrative Fees on time, in violation of  
15 PRC section 42034.2.

16 105. In order for the Respondent to meet its statutory deadline of June 30, 2023, to pay its  
17 Departmental Administrative Fees, the Department issued invoice No. 1518735 on May 31,  
18 2023, to the Respondent to collect these fees for the Drugs Program and invoice No. 1518736  
19 for the Sharps Program for the October 1, 2021, through March 31, 2023, time period. The  
20 Respondent failed to pay these invoices within 30 days of issuance (June 30, 2023). Per the  
21 State Administrative Manual section 8293.1 (renumbered from section 8776.6), the Department  
22 proceeded to issue late notices for failure to pay on time. The Department issued the first late  
23 notices on June 30, 2023, requiring payment within 30 days, and the Respondent failed to pay  
24 again. The Department issued the second late notices on July 31, 2023, and the Respondent  
25 failed to pay for a third time. The Department issued the final late notices on August 31, 2023,  
26 and the Respondent failed to pay again. On November 6, 2023, the Department issued two  
27 Notices of Violation for failure to pay the Departmental Administrative Fees ("Department Drugs  
28 Fee NOV1") and ("Department Sharps Fee NOV1"). The Respondent paid the invoices on

1 November 20, 2023, 142 days late (nearly 5 months late), only after 3 notices and the  
2 Department Drugs Fee NOV1 and the Department Sharps Fee NOV1 were issued. Moreover,  
3 the Respondent failed to provide any response or explanation for the late payments.

4 106. On September 15, 2023, the Department issued invoice No. 1528404 to the Respondent  
5 to collect Departmental Administrative Fees for the Drugs Program and invoice No. 1528370 for  
6 the Sharps Program. These two invoices covered the April 1, 2023 through June 30, 2023 time  
7 period. The Respondent failed to pay these invoices by the required October 15, 2023 deadline.  
8 Per the State Administrative Manual section 8293.1 (renumbered from section 8776.6), the  
9 Department proceeded to issue late notices for failure to pay on time. The Department issued  
10 the first late notices on October 16, 2023, and the Respondent failed to pay within 30 days. The  
11 Department issued the second late notices on December 15, 2023, and the Respondent failed  
12 to pay within 30 days. The Department issued the final late notices on January 16, 2024, and  
13 the Respondent failed to pay again. On March 8, 2024, the Department issued four Notices of  
14 Violation for failure to pay the Departmental Administrative Fees (“Department Drugs Fee NOV2”  
15 and “Department Sharps Fee NOV2”). The Respondent paid invoices No. 1528404 on March  
16 19, 2024, 155 days late, and invoice No. and 1528370 on March 20, 2024, 156 days late (over  
17 5 months late), only after three late notices, the Department Drugs Fee NOV2, and Department  
18 Sharps Fee NOV2 were issued. Moreover, the Respondent failed to provide any response or  
19 explanation for the late payments of these invoices.

20 **Department’s Audit of the Respondent’s Books and Records for Calendar Year 2022,**  
21 **Program Budgets for 2025, and Independent Financial Audit for Calendar Year 2023**

22 107. The Department conducted an audit, released on March 6, 2025, of the Respondent’s  
23 books and records for the February 16, 2022, through December 31, 2022, time period  
24 (“Department Audit for Year 2022”), pursuant to PRC section 42033.4(b)(3). The Department  
25 Audit for Year 2022 was planned and performed, in part, to validate the accuracy of the financial  
26 information reported by the Respondent, including fees collected from covered entities by the  
27 Respondent, and to determine if the Respondent complied with certain recordkeeping  
28 requirements that were within the scope of the Department Audit for Year 2022. The Department

1 Audit for Year 2022 found that the Respondent committed multiple violations.

2 108. The Department Audit for Year 2022 found that:

- 3 a) [REDACTED]  
4 [REDACTED]  
5 [REDACTED].”
- 6 b) The Respondent had a negative change in net assets, failing to meet its target  
7 cash reserve amount of \$215,935 and \$300,300 and, as budgeted in the Drugs  
8 Plan and Sharps Plan, respectively.
- 9 c) The Respondent received in-kind contributions from Inmar, Rx Solutions, Inc.  
10 (“Inmar”), which is its service provider, not a covered entity in either the covered  
11 drugs or home-generated sharps waste stewardship programs. [Note that Inmar is  
12 the Respondent’s direct controlling entity, per IRS Forms 990 for years 2022 and  
13 2023, which are available for public inspection.]

14 109. Additionally, the Department Audit for Year 2022 found that the Respondent’s audited  
15 financial statements did not contain an opinion on the Drugs Program’s or Sharps Program’s  
16 compliance with aspects of PRC section 42034, which requires all stewardship program  
17 operational costs to be paid by covered entities, either individually, or through a stewardship  
18 organization.

19 110. Finally, the Department Audit for Year 2022 found that the Respondent’s financial  
20 statements [REDACTED]  
21 [REDACTED], in violation of the requirement to  
22 provide separate financial statements for each California stewardship program (namely the  
23 Drugs Program and the Sharps Program).

24 111. On April 1, 2024, the Respondent submitted a Drugs Program budget to the  
25 Department (“2025 Drugs Budget”). The 2025 Drugs Budget included an Independent  
26 Financial Audit (“IFA”) for calendar year 2023 (“2023 IFA”). On July 1, 2024, Department  
27 disapproved the 2025 Drugs Budget and issued a notice of disapproval on July 31, 2024. The  
28 Respondent submitted a revised covered drugs budget on November 22, 2024 (“2025 Revised

1 Drugs Budget”). The 2025 Revised Drugs Budget included a revised IFA for calendar year  
2 2023 (“2023 Revised IFA”). On February 18, 2025, the Department disapproved the 2025  
3 Revised Drugs Budget. (The disapprovals are not facts material to this Accusation.)

4 112. On April 1, 2024, the Respondent submitted a Sharps Program budget to the  
5 Department (“2025 Sharps Budget”). The 2025 Sharps Budget included an IFA for calendar  
6 year 2023 (“2023 IFA”). On July 1, 2024, the Department disapproved the 2025 Sharps Budget  
7 and issued a notice of disapproval on July 31, 2024. The Respondent submitted a revised  
8 sharps budget on November 22, 2024 (“2025 Revised Sharps Budget”). The 2025 Revised  
9 Sharps Budget contained a revised IFA for calendar year 2023 (“2023 Revised IFA”). On  
10 February 18, 2025, the Department disapproved the 2025 Revised Sharps Budget. (The  
11 disapprovals are not facts material to this Accusation.)

12 113. The 2023 Revised IFA includes \$3,858,138 in expenses for the Drugs Program, [REDACTED]  
13 [REDACTED]. The Respondent  
14 started calendar year 2023 with negative net assets of \$102,528 and ended calendar year 2023  
15 with negative net assets of \$2,785,303 (per IRS Form 990, which is open for public inspection).  
16 Note that information reported on the IRS Form 990 is for all of Respondent’s stewardship  
17 programs, not only the Drugs Program and the Sharps Program. For the Drugs Program, [REDACTED]  
18 [REDACTED]. The 2023 Revised IFA includes \$907,931  
19 in expenses for the Sharps Program, [REDACTED]  
20 [REDACTED]  
21 [REDACTED].

22 114. The 2023 IFA failed to provide an opinion on either the Drugs Program’s or the Sharps  
23 Program’s compliance with aspects of PRC section 42034 and the Regulations, in violation of  
24 14 CCR section 18973.6(f)(3).

25 115. Even though the Respondent clarified, in its response to the Department’s Audit for Year  
26 2022, that the cause for [REDACTED] and its negative net asset  
27 balance was due to temporary financial impact of the initial start-up costs incurred to set up the  
28 stewardship programs, it continued to have substantial negative net assets in calendar year

1 2023 (per IRS Form 990, which doesn't exclusively cover CA state programs) despite the  
2 requirement to ensure covered entities pay for all costs of the programs. Based on the foregoing,  
3 it appears that the Respondent failed to collect enough payments from covered entities to pay  
4 for both its Drugs Program and its Sharps Program.

5 116. The IFA [REDACTED]  
6 [REDACTED], which did not reflect the activities and transactions of each  
7 stewardship program and did not provide separate financial statements for each stewardship  
8 program.

9 117. Even though the Respondent explained, in its response to the Department's Audits for  
10 Year 2022, [REDACTED]  
11 [REDACTED] the 2023 IFA shows that this same, out-of-compliance  
12 reporting system was in place in 2023.

13 118. Additionally, the 2023 IFA found that the Respondent is "[REDACTED]  
14 [REDACTED]", as required by the  
15 Law. Inmar is the Respondent's [REDACTED] direct controlling entity, and service provider.  
16 [REDACTED],  
17 respectively. Inmar made cash contributions to Respondent, per the 2023 Form 990, which is  
18 open for public inspection. As stated above, the Form 990 does not exclusively cover the CA  
19 programs. The Respondent also received \$1,272,993 in year 2022 and \$1,359,987 in year 2023  
20 in donated services and use of facilities (per IRS Forms 990, available for public inspection).

21 119. Finally, with regard to reserves, the 2023 IFA did not include a reserve level amount.  
22 Moreover, as discussed above, the Respondent operated at a loss in 2022 and 2023. The Drugs  
23 Plan budget in Appendix A includes a reserve level amount of \$215,935 for year 2022 and  
24 \$175,935 for year 2023. The Sharps Plan budget in Appendix A includes a reserve level amount  
25 of \$300,300 for year 2022 and \$324,774 for year 2023. But, the Respondent ended both years  
26 with negative net assets, as discussed above, failing to meet its targeted reserve levels. Thus,  
27 there were either no reserves in years 2022 and 2023, or, at a minimum, the reserves were not  
28 maintained in a prudent and responsible manner, in violation of 14 CCR section 18973.6(c).

1 **ALLEGATIONS OF SPECIFIC VIOLATIONS**

2 120. The Statements, assertions, and allegations set forth in paragraphs 1 through 119 are  
3 incorporated by reference as if fully set forth herein.

4 121. Pursuant to PRC section 42035.2(a)(1) and 14 CCR section 18975(a), the Department  
5 has authority to impose an administrative penalty for violation(s) with the Act and the  
6 Regulations. The Department has authority to impose a penalty of up to \$10,000 per day or  
7 \$50,000 per day for intentional, knowing, or reckless violations. (PRC section 42035.2(a)(2)).

8 122. Pursuant to PRC section 42035.4(a) and 14 CCR section 18975.2, the Department has  
9 authority to revoke the approval of a stewardship plan if a program operator fails to meet a  
10 material requirement.

11 **COUNT I**

12 **RESPONDENT FAILED TO IMPLEMENT ITS COVERED DRUGS STEWARDSHIP**  
13 **PLAN WITHIN 270 DAYS OF APPROVAL AND FAILED TO MEET ANNUAL**  
14 **REPORTING REQUIREMENTS**

15 123. The statements, assertions, and allegations set forth in paragraphs 1 through 122 are  
16 incorporated by reference as if fully set forth herein.

17 124. Within 270 days of the Drugs Plan approval, the Respondent failed to: (1) meet the  
18 convenience standard requirements in PRC section 42032.2(a)(1)(F) and its Drugs Plan; (2)  
19 implement a comprehensive education and outreach program, including having correct  
20 signage on its collection receptacles, as required by the Act, the Regulations, and the Drugs  
21 Plan; and (3) meet multiple covered drugs annual reporting requirements.

22 125. The Respondent did not meet required convenience standards within 270 days of  
23 approval of the Drugs Plan by: (1) failing to establish enough authorized collection sites in  
24 every required CA county, in violation of PRC section 42032.2(a)(1)(F)(i) and the Drugs Plan,  
25 and failing to describe circumstances beyond its control per PRC section 42032.2(c); (2) failing  
26 to meet the reasonable geographic spread standard in every required CA county, in violation of  
27 PRC section 42032.2(a)(1)(F)(ii) and the Drugs Plan; and (3) failing to establish a mail-back  
28 program in counties where a retail pharmacy is not operating as an authorized collection site,

1 in violation of PRC section 42032.2(a)(1)(F)(iii) and the Drugs Plan.

2 126. In violation of the Drugs Plan, PRC section 42031.6, and 14 CCR section 18973.2(j),  
3 the Respondent failed to meet required education and outreach requirements by failing to  
4 provide promotional education and outreach materials, having a compliant, operational website  
5 within 270 days of Drugs Plan approval, and by failing to have compliant collection receptacle  
6 signage (as discussed in more detail in paragraph 74). The Respondent also promoted the  
7 disposal of covered drugs in a manner inconsistent with the services it offered to ultimate  
8 users, in violation of PRC section 42031.6(b) and 14 CCR sections 18973.2(j) and 18973.4(i).

9 127. The Respondent failed to meet multiple covered drugs annual reporting requirements  
10 by failing to describe efforts made to achieve compliance, in violation of 14 CCR section  
11 18973.4(c)(3) and failing to compliantly report regarding local take-back events, in violation of  
12 14 CCR section 18973.4(c)(6). In the 2022 Drugs Annual Report and 2022 Revised Drugs  
13 Annual Report (collectively "2022 Drugs Annual Reports"), the Respondent reported that it  
14 included "local take-back events" in its education and outreach brochures, even though the  
15 Respondent did not report hosting any collection events and did not identify any alternative  
16 form of collection, per 14 CCR section 18973.2(g)(6). In the 2022 Drugs Annual Reports,  
17 Respondent did not provide an explanation for the "local take-back event" brochures.

18 128. Thus, the Respondent has violated PRC section 42032(g), 14 CCR section  
19 18973.1(m), PRC section 42033.2(b), including 42033.2(b)(8), PRC section 42031.6, and 14  
20 CCR section 18973.4 by omitting required covered drugs annual report elements, by not fully  
21 implementing its Drugs Plan, as documented by admission in the Respondent's 2022 Annual  
22 Reports, 2023 Annual Reports, and as documented by the Department's 2023 field  
23 inspections. These are material violations, which is grounds for revocation of approval of the  
24 Drugs Plan.

25 129. For purposes of this Accusation, even though Count I includes multiple violations, the  
26 Department is counting only one violation. The Department reserves the right to count all  
27 violations in future accusations.

1 **COUNT II**

2 **RESPONDENT FAILED TO IMPLEMENT ITS HOME-GENERATED SHARPS**  
3 **WASTE STEWARDSHIP PLAN WITHIN 270 DAYS OF APPROVAL AND FAILED**  
4 **TO MEET ANNUAL REPORTING REQUIREMENTS**

5 130. The statements, assertions, and allegations set forth in paragraphs 1 through 129 are  
6 incorporated by reference as if fully set forth herein.

7 131. Within 270 days of the Sharps Plan approval, the Respondent failed to: (1) provide and  
8 initiate distribution of sharps waste containers and mail-back materials, as required by its  
9 Sharps Plan and PRC section 42032.2(d)(1)(F); (2) implement a comprehensive education and  
10 outreach program, as required by the Act, the Regulations, and the Sharps Plan; and (3) meet  
11 multiple home-generated sharps waste annual reporting requirements.

12 132. In violation of the Sharps Plan, PRC sections 42031.6, and 14 CCR section 18973.3.(i),  
13 the Respondent failed to meet required education and outreach requirements by failing to  
14 provide promotional education and outreach materials, by failing to have compliant collection  
15 receptacle signage (as discussed in more detail in paragraphs 84 and others above), and by  
16 failing to have a compliant, operational website within 270 days of Sharps Plan approval. The  
17 Respondent also promoted the disposal of home-generated sharps waste in a manner  
18 inconsistent with the services it offered to ultimate users, in violation of PRC section  
19 42031.6(b) and 14 CCR sections 18973.3(i), and 18973.5(i). Within 270 days of the Sharps  
20 Plan approval, the Respondent failed to: (1) provide and initiate distribution of sharps waste  
21 containers and mail-back materials, as required by the Sharps Plan and PRC section  
22 42032.2(d)(1)(F) and 14 CCR section 18973.3(f)(2).

23 133. The Respondent failed to meet multiple annual reporting requirements by: (1) failing to  
24 include metrics for sharps waste containers and mail-back materials provided at the point of  
25 sale to ultimate users, per county, in violation of 14 CCR section 18973.5(c)(2)(A); (2) failing to  
26 compliantly report regarding local take-back events, in violation of 14 CCR section  
27 18973.5(c)(4); and (3) failing to properly report regarding education and outreach, as  
28 evidenced by questions regarding medicines rather than sharps without an explanation for why

1 these questions are relevant for someone expecting to learn about home-generated sharps  
2 waste disposal.

3 134. Thus, the Respondent has violated PRC section 42032(g), 14 CCR section  
4 18973.1(m), PRC section 42033.2(b), including section 42033.2(b)(8), PRC section 42031.6,  
5 and 14 CCR section 18973.3 and 18973.5 by omitting required annual report elements, by not  
6 fully implementing its Sharps Plan in both its 2023 Sharps Annual Report and its 2023 Revised  
7 Sharps Annual Report as well as in the field, as documented by the Department's calendar  
8 year 2023 inspections. These are material violations, which is grounds for revocation of the  
9 approval of the Sharps Plan.

10 135. For purposes of this Accusation, even though Count II includes multiple violations, the  
11 Department is counting only one violation. The Department reserves the right to count all  
12 violations in future accusations.

### 13 **COUNT III**

#### 14 **RESPONDENT FAILED TO COMPLY WITH THE CONDITIONS OF THE** 15 **CONDITIONAL APPROVAL NOTICE FOR RESPONDENT'S COVERED DRUGS** 16 **PROGRAM BUDGET, RESULTING IN VIOLATION OF THE ACT AND** 17 **REGULATIONS**

18 136. The statements, assertions, and allegations set forth in paragraphs 1 through 135 are  
19 incorporated by reference as if fully set forth herein.

20 137. The Respondent failed to comply with the Act and the Regulations by failing to comply  
21 with the conditions of conditional approval notice of the covered drugs program budget for year  
22 2023 for the Drugs Program, in violation of sections 42033.2(e)(2)(B) and (e)(3).

23 138. Failing to comply with conditions of a conditional approval is a material violation, which  
24 is grounds for revocation of the approval of the Drugs Plan.

1 **COUNT IV**

2 **RESPONDENT FAILED TO COMPLY WITH THE CONDITIONS OF THE**  
3 **CONDITIONAL APPROVAL NOTICE FOR RESPONDENT’S HOME-**  
4 **GENERATED SHARPS WASTE PROGRAM BUDGET, RESULTING IN**  
5 **VIOLATION OF THE ACT AND REGULATIONS**

6 139. The statements, assertions, and allegations set forth in paragraphs 1 through 138 are  
7 incorporated by reference as if fully set forth herein.

8 140. The Respondent failed to comply with the Act and the Regulations by failing to comply  
9 with the conditions of conditional approval notice of the home-generated sharps waste  
10 program budget for year 2023 for the Sharps Program, in violation of sections 42033.2(e)(2)(B)  
11 and (e)(3).

12 141. Failing to comply with conditions of a conditional approval is a material violation, which  
13 is grounds for revocation of the approval of the Sharps Plan.

14 **COUNTS V AND VI**

15 **RESPONDENT FAILED TO OPERATE THE COVERED DRUGS AND THE HOME-**  
16 **GENERATED SHARPS WASTE STEWARDSHIP PROGRAMS IN A PRUDENT**  
17 **AND RESPONSIBLE MANNER**

18 142. The statements, assertions, and allegations set forth in paragraphs 1 through 141 are  
19 incorporated by reference as if fully set forth herein.

20 143. Respondent violated 14 CCR section 18973.6(f)(3) because Respondent’s audited  
21 financial statements for year 2022 did not contain an opinion on the Drugs Program’s or  
22 Sharps Program’s compliance with aspects of PRC section 42034, which requires all  
23 stewardship program operational costs to be paid by covered entities, either individually, or  
24 through a stewardship organization.

25 144. The Respondent did not operate its Drugs Program and its Sharps Program in a  
26 prudent and responsible manner in calendar years 2022 and 2023, in violation of PRC section  
27 42033.2(c) and 14 CCR sections 18973.6(c) and (d) because the Respondent: (1) did not have  
28 a reserve, as shown by the Revised 2023 IFA and the Department Audit for Year 2022; (2) did

1 not maintain the Drugs Program reserve and the Sharps Program reserve in a prudent and  
2 responsible manner [REDACTED] and operated at a loss (per IRS Form  
3 990); and (3) [REDACTED].

4 145. Based on the Department Audit for Year 2022, the 2025 Drugs Budget, the 2025 Revised  
5 Drugs Budget, the 2025 Sharps Budget, the 2025 Revised Sharps Budget (collectively, "2025  
6 Budgets"), the 2023 IFA, and the 2023 Revised IFA (collectively "2023 IFAs"), the Respondent  
7 violated PRC sections 42032.2(a)(1)(D), 42032.2(d)(1)(C), 42033.2(c), and 42034, and 14 CCR  
8 sections 18973.6(c), (d) and (f).

9 146. The 2025 Budgets, the 2023 IFAs, and the Department Audit for Year 2022 demonstrate  
10 that the Respondent violated PRC sections 42032(g), 42032.2(a)(1)(D) (concerning the Drugs  
11 Program), PRC 42032.2(d)(1)(C) (concerning the Sharps Program), 42033.2(c), and 42034 and  
12 14 CCR sections 18973.6(c) and (f) by failing to run the Drugs Program and the Sharps Program  
13 in a prudent and responsible manner (violation of PRC section 42033.2(c) and 14 CCR sections  
14 18973.6(c) and (d)), failing to provide an opinion by an independent auditor (violation of 14 CCR  
15 section 18973.6(f)), by violating the requirement that all program costs must be borne by the  
16 covered entity members of the Respondent's Drugs Plan and the Respondent's Sharps Plan,  
17 respectively (in violation of PRC sections 42032.2(a)(1)(D), 42032.2(d)(1)(C), and 42034, and  
18 by [REDACTED]

19 [REDACTED] instead of reporting specifically  
20 on the Drugs Program and specifically on the Sharps Program. With regard to [REDACTED]  
21 [REDACTED], The Respondent violated PRC section 42033.2(c)(1) and 14  
22 CCR section 18973.6(f) because the Respondent failed to provide separate independent  
23 financial audits for the Drugs Program and the Sharps Program, including failure to make  
24 findings on the financial aspects of the Drugs Program and the Sharps Program separately.

25 [REDACTED]  
26 [REDACTED]. These are  
27 material violations, which are grounds for revocation of approvals of the Drugs Plan and the  
28 Sharps Plan.

1 147. For purposes of this Accusation, even though Counts V and VI include multiple violations  
2 each, the Department is counting only one violation for Count V and one violation for Count VI.  
3 The Department reserves the right to count all violations in future accusations.

4 **COUNT VII**

5 **RESPONDENT FAILED TO PAY DEPARTMENTAL ADMINISTRATIVE FEES ON**  
6 **TIME FOR THE COVERED DRUGS STEWARDSHIP PROGRAM**

7 148. The statements, assertions, and allegations set forth in paragraphs 1 through 147 are  
8 incorporated by reference as if fully set forth herein.

9 149. The Respondent failed to pay Departmental Administrative Fees for the Drugs Program  
10 on time (approximately five months late) for two separate invoices, violating PRC sections  
11 42034 and 42034.2 of the Act. Three late payment notices and an NOV were issued before the  
12 Respondent paid the invoices. These violations are material, which is grounds for revocation of  
13 approval of the Drugs Plan.

14 **COUNT VIII**

15 **RESPONDENT FAILED TO PAY DEPARTMENTAL ADMINISTRATIVE FEES ON**  
16 **TIME FOR THE HOME-GENERATED SHARPS WASTE STEWARDSHIP**  
17 **PROGRAM**

18 150. The statements, assertions, and allegations set forth in paragraphs 1 through 149 are  
19 incorporated by reference as if fully set forth herein.

20 151. The Respondent failed to pay Departmental Administrative Fees for the Sharps  
21 Program on time (approximately five months late) for two separate invoices, violating PRC  
22 sections 42034 and 42034.2 of the Act. Three late payment notices and an NOV were issued  
23 before the Respondent paid the invoices. These violations are material, which is grounds for  
24 revocation of approval of the Sharps Plan.

25 **CIVIL PENALTIES**

26 152. The statements, assertions, and allegations set forth in paragraphs 1 through 151 are  
27 incorporated by reference as if fully set forth herein.

28 153. Pursuant to 14 CCR section 18975(c), to determine an appropriate penalty amount, the

1 Department shall consider the totality of the circumstances which may include, but is not limited  
2 to, the following:

- 3 (1) The nature, circumstances, extent, and gravity of the violation(s);
- 4 (2) The number and severity of the violation(s);
- 5 (3) Evidence that the violation was intentional, knowing, or reckless;
- 6 (4) The size of the violator's business and/or the financial position of the violator;
- 7 (5) History of violation(s) of the same or similar nature;
- 8 (6) The willfulness of the violator's misconduct;
- 9 (7) Whether the violator took good faith measures to comply with this Article [the  
10 Regulations] and Chapter 2 of Part 3 of Division 30 of the Public Resources Code and the period  
11 of time over which these measures were taken;
- 12 (8) Evidence of any financial gain resulting from the violation(s);
- 13 (9) The economic effect of the penalty on the violator;
- 14 (10) The deterrent effect that the imposition of the penalty would have on both the  
15 violator and the regulated community;
- 16 (11) Any other factor(s) that justice may require.

17 Consideration of the penalty factors, discussed in the paragraphs below, is based on  
18 information available to the Department at the time of filing of this Accusation. The Department  
19 reserves the right to amend or augment any and all penalty factor analysis after filing this  
20 Accusation, before a hearing, and based on information presented at a hearing.

21 **COUNT I PENALTY FACTORS**

22 **RESPONDENT FAILED TO IMPLEMENT ITS COVERED DRUGS STEWARDSHIP**  
23 **PLAN WITHIN 270 DAYS OF APPROVAL AND FAILED TO MEET ANNUAL**  
24 **REPORTING REQUIREMENTS**

25 154. The statements, assertions, and allegations set forth in paragraphs 1 through 153 are  
26 incorporated by reference as if fully set forth herein.

27 155. **The nature, circumstances, extent, and gravity of the violation(s) (14 CCR section**  
28 **18975(c)(1))**. The Respondent failed to implement the Drugs Plan for two consecutive years as

1 evidenced by its own admissions in annual reports and the Department's field inspections.  
2 Despite the Department's multiple notices to the Respondent about the violations, the  
3 Respondent continued to violate. The Respondent failed to provide a compliant collection  
4 system of covered drugs and failed to implement a comprehensive education and outreach  
5 program. These facts support a higher penalty amount.

6 **156. The number and severity of the violation(s) (14 CCR section 18975(c)(2)).** The  
7 Respondent failed to implement the Drugs Plan for two consecutive years as evidenced by its  
8 own admissions in annual reports and the Department's field inspections. This resulted in  
9 multiple violations and reduced access for compliant disposal options for ultimate users. Despite  
10 the Department's multiple notices to the Respondent about the violations, the Respondent  
11 continued to violate. The Respondent failed to provide a compliant collection system of covered  
12 drugs and failed to implement a comprehensive education and outreach program. These facts  
13 support a higher penalty amount.

14 **157. Evidence that the violation was intentional, knowing, or reckless (14 CCR section**  
15 **18975(c)(3)).** The Respondent knew about the violations but failed to correct them over a two-  
16 year period. These facts support a higher penalty amount.

17 **158. The size of the violator's business and/or the financial position of the violator (14**  
18 **CCR section 18975(c)(4)).** The Respondent represents about 87 covered entities in the Drugs  
19 Program. In the Drugs Plan, Respondent budgeted for \$2,094,195 for its operations plus a  
20 \$215,935 reserve for calendar year 2022 and \$2,764,751 for its operations plus a \$175,935  
21 reserve for calendar year 2023. Even though the Respondent had negative net assets in years  
22 2022 and 2023, the Respondent is financially supported by Inmar, its service provider, direct  
23 controlling entity, and [REDACTED]. Based on the information available to the Department at the  
24 time of filing of this Accusation, these facts support neither a higher nor lower penalty amount.

25 **159. History of violation(s) of the same or similar nature (14 CCR section 18975(c)(5)).**  
26 The Respondent failed to implement the Drugs Plan for two consecutive years as evidenced by  
27 its own admissions in annual reports and the Department's field inspections. Despite the  
28

1 Department's multiple notices to the Respondent about the violations, the Respondent continued  
2 to violate. These facts support a higher penalty amount.

3 **160. The willfulness of the violator's misconduct (14 CCR section 18975(c)(6)).** The  
4 Respondent knew about the violations but failed to correct them over a two-year period. These  
5 facts support a higher penalty amount.

6 **161. Whether the violator took good faith measures to comply with the Act and the**  
7 **Regulations and the period of time over which these measures were taken (14 CCR**  
8 **section 18975(c)(7)).** The Respondent's violations continued for a period of two years. The  
9 Respondent reported on its efforts to achieve compliance, but violations kept accruing. The Act  
10 requires covered entities to pay for all costs of the stewardship program, and the Respondent  
11 could have increased its membership fees for covered entities to have sufficient funds to comply  
12 with the requirements. However, the Respondent either did not have sufficient funds for  
13 compliance or was unjustly enriched by failing to spend sufficient funds on the Drugs Program.  
14 These facts support a higher penalty amount.

15 **162. Evidence of any financial gain resulting from the violation(s). (14 CCR section**  
16 **18975(c)(8)).** Failure to sufficiently fund the Drugs Program resulted in the failure to provide a  
17 compliant collection system for covered drugs and failure to implement a comprehensive  
18 education and outreach program. Thus, despite the Respondent collecting participation fees  
19 from its approximately 87 covered entity members, an insufficient amount of money was spent  
20 to achieve compliance, resulting in the Respondent's unjust enrichment. These facts support a  
21 higher penalty amount.

22 **163. The economic effect of the penalty on the violator. (14 CCR section 18975(c)(9)).**  
23 Based on information available to the Department at the time of filing of this Accusation, it is  
24 likely that the penalty will have an economic effect. Without further information, the Department  
25 is unable to determine the extent of this effect. The Department reserves the right to amend or  
26 augment any and all penalty factor analysis after filing this Accusation, before a hearing, and  
27 based on information presented at a hearing.  
28

1 164. **The deterrent effect that the imposition of the penalty would have on both the**  
2 **violation and the regulated community. (14 CCR section 18975(c)(10)).** The penalty will deter  
3 the Respondent, other program operators, and others in the regulated community. But, given  
4 that this is the first time an accusation has been brought under the Act, it is not known how the  
5 deterrent effect will affect the penalty amount.

6 165. **Any other factor(s) that justice may require (14 CCR section 18975(c)(11)).** The  
7 Department did not apply this factor because there is no information, at the time of filing of this  
8 Accusation, regarding any other matters that justice may require. The Department reserves the  
9 right to amend or augment any and all penalty factor analysis after filing this Accusation, before  
10 a hearing, and based on information presented at a hearing.

11 166. For Count I, based on the above analysis of the penalty factors and the totality of the  
12 circumstances, the Department has determined that the following penalty amounts are  
13 appropriate: (1) a \$2,150 per day penalty amount (out of \$10,000 allowed by the Act for non-  
14 knowing, non-intentional and non-reckless violations) for calendar year 2022; and (2) a \$2,250  
15 per day penalty amount (out of \$10,000 allowed by the Act for non-knowing, non-intentional and  
16 non-reckless violations) for calendar year 2023. Therefore, the Department seeks a penalty of  
17 \$105,350 for calendar year 2022 and \$821,250 for calendar year 2023 for a total to be  
18 determined at a hearing, but no less than \$926,600. The Respondent was required to fully  
19 implement its plan on November 13, 2022, which means the violations continued for 49 days in  
20 2022. A \$2,150 per day penalty multiplied by 49 days results in the 2022 penalty amount. For  
21 calendar year 2023, the \$2,250 per day penalty amount multiplied by 365 days results in the  
22 final penalty amount.

## 23 **COUNT II PENALTY FACTORS**

### 24 **RESPONDENT FAILED TO IMPLEMENT ITS HOME-GENERATED SHARPS** 25 **WASTE STEWARDSHIP PLAN WITHIN 270 DAYS OF APPROVAL AND FAILED** 26 **TO MEET ANNUAL REPORTING REQUIREMENTS**

27 167. The statements, assertions, and allegations set forth in paragraphs 1 through 166  
28 are incorporated by reference as if fully set forth herein.

1 168. **The nature, circumstances, extent, and gravity of the violation(s) (14 CCR section**  
2 **18975(c)(1))**. The Respondent failed to implement the Sharps Plan for two consecutive years as  
3 evidenced by its own admissions in annual reports and the Department's field inspections.  
4 Despite the Department's multiple notices to the Respondent about the violations, the  
5 Respondent continued to violate. The Respondent failed to provide a compliant mail-back  
6 program for home-generated sharps waste and failed to implement a comprehensive education  
7 and outreach program. These facts support a higher penalty amount.

8 169. **The number and severity of the violation(s) (14 CCR section 18975(c)(2))**. The  
9 Respondent failed to implement the Sharps Plan for two consecutive years as evidenced by its  
10 own admissions in annual reports and the Department's field inspections. This resulted in  
11 multiple violations and reduced access for compliant disposal options for ultimate users. Despite  
12 the Department's multiple notices to the Respondent about the violations, the Respondent  
13 continued to violate. The Respondent failed to provide a compliant mail-back program for home-  
14 generated sharps waste and failed to implement a comprehensive education and outreach  
15 program. These facts support a higher penalty amount.

16 170. **Evidence that the violation was intentional, knowing, or reckless (14 CCR section**  
17 **18975(c)(3))**. The Respondent knew about the violations but failed to correct them over a two-  
18 year period. These facts support a higher penalty amount.

19 171. **The size of the violator's business and/or the financial position of the violator (14**  
20 **CCR section 18975(c)(4))**. The Respondent represents about 23 covered entities in the Sharps  
21 Program. In the Sharps Plan, Respondent budgeted for \$3,407,000 for its operations plus a  
22 \$300,300 reserve for calendar year 2022 and \$5,176,640 for its operations plus a \$324,774  
23 reserve for calendar year 2023. Even though the Respondent had negative net assets in years  
24 2022 and 2023, the Respondent is financially supported by Inmar, its service provider, [REDACTED]  
25 [REDACTED], and direct controlling entity. Based on the information available to the Department at  
26 the time of filing of this Accusation, these facts support neither a higher nor lower penalty  
27 amount.  
28

1     **172. History of violation(s) of the same or similar nature (14 CCR section 18975(c)(5)).**

2     The Respondent failed to implement the Sharps Plan for two consecutive years as evidenced  
3     by its own admissions in annual reports and the Department's field inspections. Despite the  
4     Department's multiple notices to the Respondent about the violations, the Respondent continued  
5     to violate. These facts support a higher penalty amount.

6     **173. The willfulness of the violator's misconduct (14 CCR section 18975(c)(6)).** The

7     Respondent knew about the violations but failed to correct them over a two-year period. These  
8     facts support a higher penalty amount.

9     **174. Whether the violator took good faith measures to comply with the Act and the**  
10    **Regulations and the period of time over which these measures were taken (14 CCR**  
11    **section 18975(c)(7)).** The Respondent's violations continued for a period of two years. The

12    Respondent reported on its efforts to achieve compliance, but violations kept accruing. The Act  
13    requires covered entities to pay for all costs of the stewardship program, and the Respondent  
14    could have increased its membership fees for covered entities to have sufficient funds to comply  
15    with the requirements. However, the Respondent either did not have sufficient funds for  
16    compliance or was unjustly enriched by failing to spend sufficient funds on the Drugs Program.  
17    These facts support a higher penalty amount.

18    **175. Evidence of any financial gain resulting from the violation(s). (14 CCR section**  
19    **18975(c)(8)).** Failure to sufficiently fund the Sharps Program resulted in the failure to provide a

20    compliant collection system for home-generated sharps waste and failure to implement a  
21    comprehensive education and outreach program. Thus, despite the Respondent collecting  
22    participation fees from its approximately 23 covered entity members, an insufficient amount of  
23    money was spent to achieve compliance, resulting in the Respondent's unjust enrichment.  
24    These facts support a higher penalty amount.

25    **176. The economic effect of the penalty on the violator. (14 CCR section 18975(c)(9)).**

26    Based on information available to the Department at the time of filing of this Accusation, it is  
27    likely that the penalty will have an economic effect. Without further information, the Department  
28    is unable to determine the extent of this effect. The Department reserves the right to amend or

1 augment any and all penalty factor analysis after filing this Accusation, before a hearing, and  
2 based on information presented at a hearing.

3 **177. The deterrent effect that the imposition of the penalty would have on both the**  
4 **violator and the regulated community. (14 CCR section 18975(c)(10)).** The penalty will deter  
5 the Respondent, other program operators, and others in the regulated community. But, given  
6 that this is the first time an accusation has been brought for the Act, it is not known how the  
7 deterrent effect will affect the penalty amount.

8 **178. Any other factor(s) that justice may require (14 CCR section 18975(c)(11)).** The  
9 Department did not apply this factor because there is no information, at the time of filing of this  
10 Accusation, regarding any other matters that justice may require. The Department reserves the  
11 right to amend or augment any and all penalty factor analysis after filing this Accusation, before  
12 a hearing, and based on information presented at a hearing.

13 179. For Count II, based on the above analysis of the penalty factors and the totality of the  
14 circumstances, the Department has determined that the following penalty amounts are  
15 appropriate: (1) a \$2,150 per day penalty amount (out of \$10,000 allowed by the Act for non-  
16 knowing, non-intentional, and non-reckless violations) for calendar year 2022; and (2) a \$2,250  
17 per day penalty amount (out of \$10,000 allowed by the Act for non-knowing, non-intentional, and  
18 non-reckless violations) for calendar year 2023. Therefore, the Department seeks a penalty of  
19 \$109,650 for calendar year 2022 and \$821,250 for calendar year 2023, for a total to be  
20 determined at a hearing, but no less than \$930,900. The Respondent was required to fully  
21 implement its plan on November 11, 2022, which means the violations continued for 51 days in  
22 2022. A \$2,150 per day penalty multiplied by 51 days results in the 2022 penalty amount. For  
23 calendar year 2023, the \$2,250 per day penalty amount multiplied by 365 days results in the  
24 final penalty amount.



1 186. **The willfulness of the violator's misconduct (14 CCR section 18975(c)(6)).** The  
2 Respondent knew about the violations and only corrected them after an NOV was issued. These  
3 facts support a higher penalty amount.

4 187. **Whether the violator took good faith measures to comply with the Act and the**  
5 **Regulations and the period of time over which these measures were taken (14 CCR**  
6 **section 18975(c)(7)).** The Respondent knew about the violations and only corrected them after  
7 an NOV was issued. These facts support a higher penalty amount.

8 188. **Evidence of any financial gain resulting from the violation(s). (14 CCR section**  
9 **18975(c)(8)).** The Department did not apply this factor because there is no information, at the  
10 time of filing of this Accusation, regarding any other matters that justice may require. The  
11 Department reserves the right to amend or augment any and all penalty factor analysis after  
12 filing this Accusation, before a hearing, and based on information presented at a hearing.

13 189. **The economic effect of the penalty on the violator. (14 CCR section 18975(c)(9)).**  
14 The Department did not apply this factor because there is no information, at the time of filing of  
15 this Accusation, regarding any other matters that justice may require. The Department reserves  
16 the right to amend or augment any and all penalty factor analysis after filing this Accusation,  
17 before a hearing, and based on information presented at a hearing.

18 190. **The deterrent effect that the imposition of the penalty would have on both the**  
19 **violator and the regulated community. (14 CCR section 18975(c)(10)).** The penalty will deter  
20 the Respondent, other program operators, and others in the regulated community. But, given  
21 that this is the first time an accusation has been brought for the Act, it is not known how the  
22 deterrent effect will affect the penalty amount.

23 191. **Any other factor(s) that justice may require (14 CCR section 18975(c)(11)).** The  
24 Department did not apply this factor because there is no information, at the time of filing of this  
25 Accusation, regarding any other matters that justice may require. The Department reserves the  
26 right to amend or augment any and all penalty factor analysis after filing this Accusation, before  
27 a hearing, and based on information presented at a hearing.

28 192. For Count III, based on the above analysis of the penalty factors and the totality of the

1 circumstances, the Department has determined that a \$1,300 per day penalty amount is  
2 appropriate, out of \$10,000 allowed by the Act for non-knowing, non-intentional, and non-  
3 reckless violations. Therefore, the Department seeks a penalty of \$1,300 per day for 23 days,  
4 for a total to be determined at a hearing, but no less than \$29,900. This penalty amount covers  
5 23 days, which is the number of days from the Department's February 28, 2023 notice of  
6 disapproval to the Respondent's March 24, 2023 compliant covered drugs program budget  
7 submittal.

#### 8 **COUNT IV PENALTY FACTORS**

#### 9 **RESPONDENT FAILED TO COMPLY WITH THE CONDITIONS OF THE** 10 **CONDITIONAL APPROVAL NOTICE FOR RESPONDENT'S HOME-** 11 **GENERATED SHARPS WASTE PROGRAM BUDGET, RESULTING IN** 12 **VIOLATION OF THE ACT AND REGULATIONS**

13 193. The statements, assertions, and allegations set forth in paragraphs 1 through 192 are  
14 incorporated by reference as if fully set forth herein.

15 194. **The nature, circumstances, extent, and gravity of the violation(s) (14 CCR section**  
16 **18975(c)(1)).** The violations were only corrected after an NOV was issued, but the violations are  
17 not grave. These facts support a lower penalty amount.

18 195. **The number and severity of the violation(s) (14 CCR section 18975(c)(2)).** The  
19 violations are not severe. These facts support a lower penalty amount.

20 196. **Evidence that the violation was intentional, knowing, or reckless (14 CCR section**  
21 **18975(c)(3)).** The Respondent knew about the violations but failed to correct them over a two-  
22 year period. These facts support a higher penalty amount.

23 197. **The size of the violator's business and/or the financial position of the violator (14**  
24 **CCR section 18975(c)(4)).** The Respondent represents about 23 covered entities in the Sharps  
25 Program. In the Sharps Plan, Respondent budgeted for \$3,407,000 for its operations plus a  
26 \$300,300 reserve for calendar year 2022 and \$5,176,640 for its operations plus a \$324,774  
27 reserve for calendar year 2023. Even though the Respondent had negative net assets in years  
28 2022 and 2023, the Respondent is financially supported by Inmar, its [REDACTED], direct

1 controlling entity, and service provider. Based on the information available to the Department at  
2 the time of filing of this Accusation, these facts support neither a higher nor lower penalty  
3 amount.

4 **198. History of violation(s) of the same or similar nature (14 CCR section 18975(c)(5)).**

5 The Respondent had multiple opportunities to fix the deficiencies but only corrected them after  
6 an NOV was issued. These facts support a higher penalty amount.

7 **199. The willfulness of the violator's misconduct (14 CCR section 18975(c)(6)).** The

8 Respondent knew about the violations and only corrected them after an NOV was issued. These  
9 facts support a medium penalty amount.

10 **200. Whether the violator took good faith measures to comply with the Act and the**  
11 **Regulations and the period of time over which these measures were taken (14 CCR**

12 **section 18975(c)(7)).** Even though the Respondent attempted to correct the violations, a  
13 compliant budget was submitted only after an NOV was issued. These facts support a higher  
14 penalty amount.

15 **201. Evidence of any financial gain resulting from the violation(s). (14 CCR section**  
16 **18975(c)(8)).** The Department did not apply this factor because there is no information, at the

17 time of filing of this Accusation, regarding any other matters that justice may require. The  
18 Department reserves the right to amend or augment any and all penalty factor analysis after  
19 filing this Accusation, before a hearing, and based on information presented at a hearing.

20 **202. The economic effect of the penalty on the violator. (14 CCR section 18975(c)(9)).**

21 The Department did not apply this factor because there is no information, at the time of filing of  
22 this Accusation, regarding any other matters that justice may require. The Department reserves  
23 the right to amend or augment any and all penalty factor analysis after filing this Accusation,  
24 before a hearing, and based on information presented at a hearing.

25 **203. The deterrent effect that the imposition of the penalty would have on both the**  
26 **violator and the regulated community. (14 CCR section 18975(c)(10)).** The penalty will deter

27 the Respondent, other program operators, and others in the regulated community. But, given  
28

1 that this is the first time an accusation has been brought for the Act, it is not known how the  
2 deterrent effect will affect the penalty amount.

3 **204. Any other factor(s) that justice may require (14 CCR section 18975(c)(11)).** The  
4 Department did not apply this factor because there is no information, at the time of filing of this  
5 Accusation, regarding any other matters that justice may require. The Department reserves the  
6 right to amend or augment any and all penalty factor analysis after filing this Accusation, before  
7 a hearing, and based on information presented at a hearing.

8 **205.** For Count IV, based on the above analysis of the penalty factors and the totality of the  
9 circumstances, the Department has determined that a penalty amount of \$1,290 per day is  
10 appropriate, out of the \$10,000 allowed by the Act for non-knowing, non-intentional, and non-  
11 reckless violations. Therefore, the Department seeks a penalty of \$1,290 per day for 23 days,  
12 for a total to be determined at a hearing, but no less than \$29,670 This penalty amount covers  
13 23 days, which is the number of days from the Department's February 28, 2023 notice of  
14 disapproval to the Respondent's March 24, 2023 compliant home-generated sharps waste  
15 program budget submittal.

16 **COUNTS V AND VI PENALTY FACTORS**

17 **RESPONDENT FAILED TO OPERATE THE COVERED DRUGS AND THE HOME-**  
18 **GENERATED SHARPS WASTE STEWARDSHIP PROGRAMS IN A PRUDENT**  
19 **AND RESPONSIBLE MANNER**

20 **206.** The statements, assertions, and allegations set forth in paragraphs 1 through 205 are  
21 incorporated by reference as if fully set forth herein.

22 **207. The nature, circumstances, extent, and gravity of the violation(s) (14 CCR section**  
23 **18975(c)(1)).** The Respondent failed to provide a compliant independent financial audit of the  
24 Drugs Program and the Sharps Program two years in a row. Additionally, despite budgeting for  
25 a reserve for both the Drugs Program and the Sharps Program, the Respondent operated with  
26 negative net assets and the Respondent's IFA did not have a reserve amount. Thus, the  
27 Respondent failed to maintain reserves in a prudent and responsible manner. The Respondent  
28 also failed to [REDACTED], which is a fundamental part

1 of extended producer responsibility programs. Despite the Department's multiple notices to the  
2 Respondent about these violations, the Respondent continued to violate from year 2022 through  
3 year 2023. These facts support a higher penalty amount.

4 **208. The number and severity of the violation(s) (14 CCR section 18975(c)(2)).** The  
5 Respondent failed to provide a compliant independent financial audit of the Drugs Program and  
6 the Sharps Program two years in a row. Additionally, despite budgeting for a reserve for both  
7 the Drugs Program and the Sharps Program, the Respondent operated with negative net assets  
8 and the Respondent's IFA did not have a reserve amount. Thus, the Respondent failed to  
9 maintain reserves in a prudent and responsible manner. The Respondent also failed to [REDACTED]  
10 [REDACTED], which is a fundamental part of extended  
11 producer responsibility programs. Despite the Department's multiple notices to the Respondent  
12 about these violations, the Respondent continued to violate from year 2022 through year 2023.  
13 These facts support a higher penalty amount.

14 **209. Evidence that the violation was intentional, knowing, or reckless (14 CCR section**  
15 **18975(c)(3)).** The Respondent knew about the violations but failed to correct them over a two-  
16 year period. These facts support a higher penalty amount.

17 **210. The size of the violator's business and/or the financial position of the violator (14**  
18 **CCR section 18975(c)(4)).** The Respondent represents about 87 covered entities in the Drugs  
19 Program. In the Drugs Plan, Respondent budgeted for \$2,094,195 for its operations plus a  
20 \$215,935 reserve for calendar year 2022 and \$2,764,751 for its operations plus a \$175,935  
21 reserve for calendar year 2023. The Respondent represents about 23 covered entities in the  
22 Sharps Program. In the Sharps Plan, Respondent budgeted for \$3,407,000 for its operations  
23 plus a \$300,300 reserve for calendar year 2022 and \$5,176,640 for its operations plus a  
24 \$324,774 reserve for calendar year 2023. Even though the Respondent had negative net assets  
25 in years 2022 and 2023, the Respondent is financially supported by Inmar, its service provider,  
26 [REDACTED], and direct controlling entity. Based on the information available to the Department  
27 at the time of filing of this Accusation, these facts support neither a higher nor lower penalty  
28 amount.

1     **211. History of violation(s) of the same or similar nature (14 CCR section 18975(c)(5)).**

2     The Respondent failed to operate the Drugs Program and the Sharps Program in a prudent and  
3     responsible manner over a two-year period. Despite the Department's multiple notices to the  
4     Respondent about the violations, the Respondent continued to violate. These facts support a  
5     higher penalty amount.

6     **212. The willfulness of the violator's misconduct (14 CCR section 18975(c)(6)).** The

7     Respondent knew about the violations but failed to correct them over a two-year period. These  
8     facts support a higher penalty amount.

9     **213. Whether the violator took good faith measures to comply with the Act and the**  
10    **Regulations and the period of time over which these measures were taken (14 CCR**  
11    **section 18975(c)(7)).** The Respondent's violations continued for a period of two years. The

12    Respondent reported on its efforts to achieve compliance, but violations kept accruing. The Act  
13    requires covered entities to pay for all costs of the stewardship programs, and the Respondent  
14    could have increased its membership fees for covered entities to have sufficient funds to comply  
15    with the requirements. However, the Respondent either did not have sufficient funds for  
16    compliance or was unjustly enriched by failing to spend sufficient funds on the Drugs Program  
17    and the Sharps Program. These facts support a higher penalty amount.

18    **214. Evidence of any financial gain resulting from the violation(s). (14 CCR section**  
19    **18975(c)(8)).** Failure to sufficiently fund the Drugs Program and the Sharps Program resulted in

20    the failure to provide a compliant collection system for covered drugs and failure to implement a  
21    comprehensive education and outreach program. Thus, despite the Respondent collecting  
22    participation fees from its approximately 87 covered entity members in the Drugs Program and  
23    approximately 23 covered entity members in the Sharps Program, an insufficient amount of  
24    money was spent to achieve compliance, resulting in the Respondent's unjust enrichment.  
25    These facts support a higher penalty amount.

26    **215. The economic effect of the penalty on the violator. (14 CCR section 18975(c)(9)).**

27    Based on information available to the Department at the time of filing of this Accusation, it is  
28    likely that the penalty will have an economic effect. Without further information, the Department

1 is unable to determine the extent of this effect. The Department reserves the right to amend or  
2 augment any and all penalty factor analysis after filing this Accusation, before a hearing, and  
3 based on information presented at a hearing.

4 **216. The deterrent effect that the imposition of the penalty would have on both the**  
5 **violator and the regulated community. (14 CCR section 18975(c)(10)).** The penalty will deter  
6 the Respondent, other program operators, and others in the regulated community. But, given  
7 that this is the first time an accusation has been brought for the Act, it is not known how the  
8 deterrent effect will affect the penalty amount.

9 **217. Any other factor(s) that justice may require (14 CCR section 18975(c)(11)).** The  
10 Department did not apply this factor because there is no information, at the time of filing of this  
11 Accusation, regarding any other matters that justice may require. The Department reserves the  
12 right to amend or augment any and all penalty factor analysis after filing this Accusation, before  
13 a hearing, and based on information presented at a hearing.

14 218. For Count V, based on the above analysis of the penalty factors and the totality of the  
15 circumstances, the Department has determined that a \$3,000 per day penalty amount is  
16 appropriate, out of the \$10,000 allowed by the Act for non-knowing, non-intentional, and non-  
17 reckless violations. Therefore, the Department seeks a penalty of \$3,000 per day for 113 days,  
18 for a total to be determined at a hearing, but no less than \$339,000. This accounts for 113 days  
19 from the date of the Department's notice regarding the deficiencies in the budget to the date the  
20 final non-compliant budget was submitted.

21 219. For Count VI, based on the above analysis of the penalty factors and the totality of the  
22 circumstances, the Department has determined that a \$3,000 per day penalty amount is  
23 appropriate, out of the \$10,000 allowed by the Act for non-knowing, non-intentional, and non-  
24 reckless violations. Therefore, the Department seeks a penalty of \$3,000 per day for 113 days,  
25 for a total to be determined at a hearing, but no less than \$339,000. This accounts for 113 days  
26 from the date of the Department's notice regarding the deficiencies in the budget to the date the  
27 final non-compliant budget was submitted.

1 **COUNT VII PENALTY FACTORS**

2 **RESPONDENT FAILED TO PAY DEPARTMENTAL ADMINISTRATIVE FEES ON**  
3 **TIME FOR THE COVERED DRUGS STEWARDSHIP PROGRAM**

4 220. The statements, assertions, and allegations set forth in paragraphs 1 through 219 are  
5 incorporated by reference as if fully set forth herein.

6 221. **The nature, circumstances, extent, and gravity of the violation(s) (14 CCR section**  
7 **18975(c)(1)).** Failure to pay departmental administrative fees on time is a grave violation  
8 because paying these fees on time is essential for program oversight. Despite the Department's  
9 multiple notices to the Respondent about the violations, the Respondent paid the fees only after  
10 the issuance of three late notices and an NOV for each invoice, 142 and 155 days late. These  
11 facts support a higher penalty amount.

12 222. **The number and severity of the violation(s) (14 CCR section 18975(c)(2)).** Failure to  
13 pay departmental administrative fees on time is a grave violation because paying these fees on  
14 time is essential for program oversight. Two Drugs Program invoices were paid 142 and 155  
15 days late. Despite the Department's multiple notices to the Respondent about the violations, the  
16 Respondent paid the fees only after the issuance of three late notices and an NOV for each  
17 invoice. These facts support a higher penalty amount.

18 223. **Evidence that the violation was intentional, knowing, or reckless (14 CCR section**  
19 **18975(c)(3)).** The Act requires a program operator to pay for the Department's costs, as  
20 discussed above. The Respondent knew about the invoices and the fact they were late and only  
21 paid them 142 and 155 days late (approximately 5 months late). These facts support a higher  
22 penalty amount.

23 224. **The size of the violator's business and/or the financial position of the violator (14**  
24 **CCR section 18975(c)(4)).** The Respondent represents about 87 covered entities in the Drugs  
25 Program. In the Drugs Plan, Respondent budgeted for \$2,094,195 for its operations plus a  
26 \$215,935 reserve for calendar year 2022 and \$2,764,751 for its operations plus a \$175,935  
27 reserve for calendar year 2023. Even though the Respondent had negative net assets in years  
28 2022 and 2023, the Respondent is financially supported by Inmar, its [REDACTED] direct

1 controlling entity, and service provider. Based on the information available to the Department at  
2 the time of filing of this Accusation, these facts support neither a higher nor lower penalty  
3 amount.

4 **225. History of violation(s) of the same or similar nature (14 CCR section 18975(c)(5)).**

5 The Respondent failed to pay the first invoice on time. Months later, the Respondent failed to pay  
6 the second invoice on time. Thus, there was a history and pattern of non-compliance. These  
7 facts support a higher penalty amount.

8 **226. The willfulness of the violator's misconduct (14 CCR section 18975(c)(6)).** The

9 Respondent knew about the invoices and about each late notice but failed to pay on time despite  
10 multiple notices. These facts support a higher penalty amount.

11 **227. Whether the violator took good faith measures to comply with the Act and the**  
12 **Regulations and the period of time over which these measures were taken (14 CCR**  
13 **section 18975(c)(7)).** The Respondent paid the two invoices only after three notices and an  
14 NOV for each invoice. The Respondent did not communicate with the Department after the  
15 notices nor did the Respondent offer any explanations for why the payments were so late. These  
16 facts support a higher penalty amount.

17 **228. Evidence of any financial gain resulting from the violation(s). (14 CCR section**  
18 **18975(c)(8)).** The Respondent collects participation fees from its approximately 87 covered  
19 entity members in the Drugs Program. However, despite the Respondent collecting these fees,  
20 the Respondent failed to pay the departmental administrative fees on time. Thus, the  
21 Respondent was unjustly enriched. These facts support a higher penalty amount.

22 **229. The economic effect of the penalty on the violator. (14 CCR section 18975(c)(9)).**  
23 Based on information available to the Department at the time of filing of this Accusation, it is  
24 likely that the penalty will have an economic effect. Without further information, the Department  
25 is unable to determine the extent of this effect. The Department reserves the right to amend or  
26 augment any and all penalty factor analysis after filing this Accusation, before a hearing, and  
27 based on information presented at a hearing.

1 230. **The deterrent effect that the imposition of the penalty would have on both the**  
2 **violation and the regulated community. (14 CCR section 18975(c)(10)).** The penalty will deter  
3 the Respondent, other program operators, and others in the regulated community. But, given  
4 that this is the first time an accusation has been brought for the Act, it is not known how the  
5 deterrent effect will affect the penalty amount.

6 231. **Any other factor(s) that justice may require (14 CCR section 18975(c)(11)).** The  
7 Department did not apply this factor because there is no information, at the time of filing of this  
8 Accusation, regarding any other matters that justice may require. The Department reserves the  
9 right to amend or augment any and all penalty factor analysis after filing this Accusation, before  
10 a hearing, and based on information presented at a hearing.

11 232. For Count VII, based on the above analysis of the penalty factors and the totality of the  
12 circumstances, the Department has determined that the following penalty amounts are  
13 appropriate: (1) for the first violation, \$1,300 per day penalty amount (out of the \$10,000 allowed  
14 by the Act for non-knowing, non-intentional, and non-reckless violations); and (2) for the second  
15 violation, a \$1,305 per day penalty amount (out of the \$10,000 allowed by the Act for non-  
16 knowing, non-intentional, and non-reckless violations). Therefore, the Department seeks a  
17 penalty of: (1) \$1,300 per day for 142 days for the first violation, for a total to be determined at a  
18 hearing, but no less than \$184,600; and (2) \$1,305 per day for the second violation for 155 days,  
19 for a total to be determined at a hearing, but no less than \$202,275.

## 20 **COUNT VIII PENALTY FACTORS**

### 21 **RESPONDENT FAILED TO PAY DEPARTMENTAL ADMINISTRATIVE FEES ON** 22 **TIME FOR THE HOME-GENERATED SHARPS WASTE STEWARDSHIP** 23 **PROGRAM**

24 233. The statements, assertions, and allegations set forth in paragraphs 1 through 232 are  
25 incorporated by reference as if fully set forth herein.

26 234. **The nature, circumstances, extent, and gravity of the violation(s) (14 CCR section**  
27 **18975(c)(1)).** Failure to pay departmental administrative fees on time is a grave violation  
28 because paying these fees on time is essential for program oversight. Despite the Department's

1 multiple notices to the Respondent about the violations, the Respondent paid the fees only after  
2 the issuance of three late notices and an NOV for each invoice, 142 and 156 days late. These  
3 facts support a higher penalty amount.

4 **235. The number and severity of the violation(s) (14 CCR section 18975(c)(2)).** Failure to  
5 pay departmental administrative fees on time is a grave violation because paying these fees on  
6 time is essential for program oversight. Two Sharps Program invoices were paid 142 and 156  
7 days late. Despite the Department's multiple notices to the Respondent about the violations, the  
8 Respondent paid the fees only after the issuance of three late notices and an NOV for each  
9 invoice. These facts support a higher penalty amount.

10 **236. Evidence that the violation was intentional, knowing, or reckless (14 CCR section**  
11 **18975(c)(3)).** The Act requires a program operator to pay for the Department's costs, as  
12 discussed above. The Respondent knew about the invoices and the fact they were late and only  
13 paid them 142 and 156 days late (approximately 5 months late). These facts support a higher  
14 penalty amount.

15 **237. The size of the violator's business and/or the financial position of the violator (14**  
16 **CCR section 18975(c)(4)).** The Respondent represents about 23 covered entities in the Sharps  
17 Program. In the Sharps Plan, Respondent budgeted for \$3,407,000 for its operations plus a  
18 \$300,300 reserve for calendar year 2022 and \$5,176,640 for its operations plus a \$324,774  
19 reserve for calendar year 2023. Even though the Respondent had negative net assets in years  
20 2022 and 2023, the Respondent is financially supported by Inmar, its [REDACTED], direct  
21 controlling entity, and service provider. Based on information available to the Department at the  
22 time of filing of this Accusation, these factors support neither a higher nor lower penalty amount.

23 **238. History of violation(s) of the same or similar nature (14 CCR section 18975(c)(5)).**  
24 The Respondent failed to pay the first invoice on time. Months later, the Respondent failed to  
25 pay the second invoice on time. Thus, there was a history and pattern of non-compliance. These  
26 facts support a higher penalty amount.

1 239. **The willfulness of the violator's misconduct (14 CCR section 18975(c)(6)).** The  
2 Respondent knew about the invoices but failed to pay them on time despite multiple notices.  
3 These facts support a higher penalty amount.

4 240. **Whether the violator took good faith measures to comply with the Act and the**  
5 **Regulations and the period of time over which these measures were taken (14 CCR**  
6 **section 18975(c)(7)).** The Respondent paid the two invoices only after three notices and an  
7 NOV for each invoice. The Respondent did not communicate with the Department after the  
8 notices nor did the Respondent offer any explanations for why the payments were so late. These  
9 facts support a higher penalty amount.

10 241. **Evidence of any financial gain resulting from the violation(s). (14 CCR section**  
11 **18975(c)(8)).** The Respondent collects participation fees from its approximately 23 covered  
12 entity members in the Sharps Program. However, despite the Respondent collecting these fees,  
13 the Respondent failed to pay the departmental administrative fees on time. Thus, the  
14 Respondent was unjustly enriched. These facts support a higher penalty amount.

15 242. **The economic effect of the penalty on the violator. (14 CCR section 18975(c)(9)).**  
16 Based on information available to the Department at the time of filing of this Accusation, it is  
17 likely that the penalty will have an economic effect. Without further information, the Department  
18 is unable to determine the extent of this effect. The Department reserves the right to amend or  
19 augment any and all penalty factor analysis after filing this Accusation, before a hearing, and  
20 based on information presented at a hearing.

21 243. **The deterrent effect that the imposition of the penalty would have on both the**  
22 **violator and the regulated community. (14 CCR section 18975(c)(10)).** The penalty will deter  
23 the Respondent, other program operators, and others in the regulated community. But, given  
24 that this is the first time an accusation has been brought for the Act, it is not known how the  
25 deterrent effect will affect the penalty amount.

26 244. **Any other factor(s) that justice may require (14 CCR section 18975(c)(11)).** The  
27 Department did not apply this factor because there is no information, at the time of filing of this  
28 Accusation, regarding any other matters that justice may require. The Department reserves the

1 right to amend or augment any and all penalty factor analysis after filing this Accusation, before  
2 a hearing, and based on information presented at a hearing.

3 245. For Count VIII, based on the above analysis of the penalty factors and the totality of the  
4 circumstances, the Department has determined that the following penalty amounts are  
5 appropriate: \$1,300 per day penalty amount for the first violation and \$1,305 for the second  
6 violation (out of the \$10,000 allowed by the Act for non-knowing, non-intentional, and non-  
7 reckless violations). Therefore, the Department seeks a penalty of: (1) \$1,300 per day for 142  
8 days for the first violation, for a total to be determined at a hearing, but no less than \$184,600;  
9 and (2) \$1,305 per day for the second violation for 156 days, for a total to be determined at a  
10 hearing, but no less than \$203,580.

11 **PRAYER FOR RELIEF**

12 246. For the violations stated herein, the Department seeks administrative penalties against  
13 the Respondent of \$1,682,375 for violations related to the Drugs Program and \$1,687,750 for  
14 violations related to the Sharps Program.

15 247. For the violations stated herein, in the case that Respondent does not terminate both the  
16 Drugs Program and the Sharps Program, with the last day of operations being June 30, 2026,  
17 the Department seeks revocation of approvals of both the Drugs Plan and the Sharps Plan.

18  
19 Dated: 2/19/2026

**Emel G. Wadhvani** Digitally signed by Emel G. Wadhvani  
Date: 2026.02.19 14:07:45 -08'00'

20 Emel Wadhvani, Chief Counsel

21 Department of Resources Recycling and Recovery

# Declarations

**STATE OF CALIFORNIA**  
**DEPARTMENT OF RESOURCES RECYCLING AND RECOVERY**

<b>IN THE MATTER OF THE ACCUSATION)</b> <b>AGAINST:</b>	AGENCY NO: IH26-001-PS
	) <b>ACCUSATION FOR PENALTIES AND NOTICE OF REVOCATION OF PLAN APPROVAL</b>
<b>The Drug Takeback Solutions Foundation</b>	) <b>(Public Resources Code Sections 42030-42036.4 and Title 14 California Code of Regulations Sections 18972.1-18975.2)</b>
<b>Respondent</b>	)

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I, MORGAN BUCHAN, declare:

1. I have personal knowledge of the facts set forth in this declaration unless it is stated that the facts are upon information and belief, and, if called to do so, I can competently testify as to these statements.
2. I am an environmental scientist at the Department of Resources Recycling and Recovery.
3. My position involves reviewing whether program operators in the Pharmaceutical and Sharps Waste Stewardship Program have met annual reporting requirements.
4. I reviewed the calendar year 2022 covered drugs (“Drugs”) and home-generated sharps waste (“Sharps”) annual reports for the Drug Takeback Solutions Foundation (“Foundation”).
5. The review of the 2022 annual reports involved verifying whether the Foundation’s website was operational on the day of full implementation of its Drugs and Sharps programs, as required by statute. The first day of full implementation was November 13, 2022 for the Drugs program and November 11, 2022 for the Sharps program.
6. On November 14, 2022 and November 30, 2022, I tried to visit the Foundation’s website, using the URL Foundation provided in its Drugs and Sharps stewardship plans (<http://www.takebackfoundation.org/>). The website was not available on both dates.

7. On December 7, 2022, I was able to visit the Foundation's website, which was operational.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct to the best of my knowledge and belief.

**Morgan**  
Digitally signed by  
Morgan Buchan  
Date: 2026.02.13  
08:07:25 -08'00'

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Date: **Buchan**

Morgan Buchan, Declarant

**STATE OF CALIFORNIA**  
**DEPARTMENT OF RESOURCES RECYCLING AND RECOVERY**

**IN THE MATTER OF THE ACCUSATION) AGENCY NO: IH26-001-PS**  
**AGAINST:** )  
 ) **ACCUSATION FOR PENALTIES AND**  
 ) **NOTICE OF REVOCATION OF PLAN**  
 ) **APPROVAL**  
 )  
**The Drug Takeback Solutions** ) **(Public Resources Code Sections**  
**Foundation** ) **42030-42036.4 and Title 14 California**  
 ) **Code of Regulations Sections**  
 ) **18972.1-18975.2)**  
 )  
**Respondent** )

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I, BECKY HAWORTH, declare:

1. I have personal knowledge of the facts set forth in this declaration unless it is stated that the facts are upon information and belief, and, if called to do so, I can competently testify as to these statements.
2. I am an environmental scientist at the Department of Resources Recycling and Recovery.
3. My position involves reviewing whether program operators in the Pharmaceutical and Sharps Waste Stewardship Program have met annual reporting requirements.
4. I reviewed the calendar year 2022 covered drugs (“Drugs”) and home-generated sharps waste (“Sharps”) annual reports for the Drug Takeback Solutions Foundation (“Foundation”).
5. The review of the 2022 annual reports involved verifying whether the Foundation’s website was operational on the day of full implementation of its Drugs and Sharps programs, as required by statute. The first day of full implementation was November 13, 2022 for the Drugs program and November 11, 2022 for the Sharps program.
6. On November 14, 2022 and November 30, 2022, I tried to visit the Foundation’s website, using the URL Foundation provided in its Drugs and Sharps stewardship plans (<http://www.takebackfoundation.org/>). The website was not available on both dates.

7. On December 7, 2022, I was able to visit the Foundation's website, which was operational.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct to the best of my knowledge and belief.

**Becky**  
Digitally signed by  
Becky Haworth  
Date: 2026.02.13  
08:48:20 -08'00'

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Date: **Haworth**

Becky Haworth, Declarant