

Alameda County Safe Drug Disposal
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Alameda County Safe Drug Disposal REGULATIONS

Section 1 – Authority for Regulations

These Regulations were developed under the authority of the Alameda County General Ordinance Code, Chapter 6.53, the Alameda County Safe Drug Disposal Ordinance (the “Ordinance”) to provide clarification and direction for its implementation.

Unless defined herein, the capitalized terms in these Regulations have the same meaning as set forth in the Ordinance.

Section 2 – Definitions

“Administrative Citation” means a citation issued by the Department for a violation of the Ordinance or Regulations.

“Alternative Plan” means a Plan imposed by the Department as a result of failure to timely submit an adequate Revised Plan.

“Annual Report” means the annual report required to be submitted by Plan Owners for each approved Plan describing the activities during the previous reporting period and other information as required by the Ordinance, Regulations and the Department.

“Annual Report Data” means the portion of the Annual Report containing numerical data relating to activities under the Plan.

“Annual Report Narrative” means the portion of the Annual Report containing descriptions, summaries and explanations of the collection efforts, other Plan efforts over the previous year, and future goals of the Plan.

“Collection Point” means a physical location with a secure drop-off kiosk to receive Unwanted Products at no cost to the individual. Collection Points may be located at hospitals, pharmacies, or other convenient physical sites.

“Department” means the Alameda County Department of Environmental Health.

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“Disposal Facility” means a facility that receives, holds or incinerates Unwanted Products collected under a Plan.

“Department Liaison” means the Environmental Health Safe Drug Disposal Liaison, who is the contact for the Department for issues relating to the Ordinance or Regulations.

“Fee Schedule” means the schedule of estimated time and cost to the Department for administration and enforcement of the Ordinance and Regulations, and includes the hourly rate which has been approved by the Alameda County Board of Supervisors.

“Law Enforcement Liaison” means the individual that will act as a liaison to law enforcement agencies for the Plan, and may be the same person as the Plan Liaison.

“Petition For Exception” means a written request to the Department for an exception from or exemption to any requirement of the Ordinance or Regulations.

“Plan Deposit” means the money lodged with the Department to be applied by the Department to cover the fees to be charged to cover the actual cost for administration and enforcement of the Ordinance and Regulations.

“Plan Liaison” means the primary contact for a Plan.

“Plan Owner” means the entity, individual or organization that submits and implements a Plan.

“Producer Contact” means the primary contact for a Producer of a Covered Drug. The Producer Contact is the person authorized to receive notices related to the Ordinance, Regulations and Plan. The Producer Contact cannot be the Plan Liaison.

“Public Hearing” means the noticed public hearing at which the Department will determine whether a Plan complies with the requirements of the Ordinance and these Regulations.

“Revised Plan” means the proposed Plan that must be submitted following rejection of an initial Plan by the Department.

“Transporter” means an individual or entity that is registered with the United States Environmental Protection Agency as a Hazardous Waste Hauler and that is permitted and authorized to haul medical waste under the California Medical Waste Management Act (Health and Safety Code Section 117600 et seq.).

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Section 3 – Fees

- A. Fees shall be charged based on an hourly rate that is approved by the Board of Supervisors. The Fee Schedule can be found at the Alameda County Environmental Health web site at <http://www.acgov.org/aceh>.
- B. The activities and estimated hours contained in the Fee Schedule may from time to time be amended by the Department and the hourly rate may from time to time be amended as approved by the Board of Supervisors.
- C. Upon request by the Department, the Plan Owner shall pay to the Department an initial sum of at least \$10,000 for a Plan Deposit to cover the actual cost for administration and enforcement of the Ordinance and Regulations. At any time a deposit is required, if the balance of the Plan Deposit is less than cost of the action(s) to be taken by the County to administer or enforce the Ordinance or Regulations (based on an estimated of hours to conduct the actions), an additional payment to bring the Plan Deposit balance to the greater of \$2500.00 or the estimated cost of the activity being requested. Failure to pay a Plan Deposit or fees or costs as required pursuant to the Fee Schedule is a violation of the Ordinance and Regulations.
- D. In addition to the fees and costs to the Department identified in the Fee Schedule, the County may also charge Producers for actual costs incurred by other departments and agencies of the County that assist in administration and enforcement of the Ordinance.
- E. The fees collected by the County pursuant to the Ordinance or Regulations shall not exceed the County's actual cost of administering and enforcing the Ordinance and Regulations.

Section 4 – Communications with Department

- A. **Department Contact Information.** The contact for the Department for all issues relating to the Ordinance and Regulations shall be the Department Liaison. All information or notices required by the Ordinance or Regulations to be sent to the Department shall be sent to the Department Liaison by e-mail, unless the Ordinance or Regulations specify otherwise.
 - i. **Written Submissions:**
 - a. All Plans and other materials should be submitted electronically to the Department Liaison at:

SafeDrugDisposalLiaison@acgov.org

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- b. The Department Liaison's mailing address is:

Safe Drug Disposal
Alameda County Environmental Health
1131 Harbor Bay Parkway
Alameda, CA 94502-6577

- ii. **Questions.** Questions regarding the Ordinance or Regulations should be directed to the Department Liaison at (510) 567-6700 or by sending an e-mail to the Department Liaison.

B. Producer Contact Information

- i. **Initial Contact.** Producers subject to the Ordinance shall identify themselves by a letter delivered to the Department prior to the date on which Plans must be submitted to the Department. The initial letter should include the e-mail address, telephone number and mailing address for the Producer Contact. The Department may request that a Producer provide the information required by this section prior to the date on which Plans are required to be submitted to the Department.
- ii. **Notification of Participation in Product Stewardship Organization.** A Producer that participates in a Stewardship Organization must notify the Department. The notification must identify the Producer and include the name, address, e-mail, telephone number and contact person for the Stewardship Organization.

- C. **Department Consultation.** The Department Liaison is available to discuss the requirements of the Ordinance and Regulations, to discuss draft Plans, to answer questions about the Ordinance and Regulations, and to assist Producers or Stewardship Organizations, including setting goals and estimates for Plans. The Department encourages Producers and Stewardship Organizations to consult with the Department Liaison prior to filing a Plan.

Section 5 – Producers

- A. **Determination of Producer.** The Department shall determine who qualifies as a Producer of a Covered Drug. The Safe Drug Disposal Ordinance is based on the principle of Extended Producer Responsibility and requires that the cost of disposal of

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Covered Drugs be borne by the person(s) who sells, offers for sale, or distributes the Covered Drugs into Alameda County.

- i. Any prescription drug sold, offered for sale, or distributed in Alameda County in any form including, but not limited to, drugs in medical devices and combination products, both brand name and generic drugs and drugs for veterinary use are considered Covered Drugs.
- ii. Medical devices and their component parts or accessories are not drugs even if there are residuals of a Covered Drug contained in or on used medical devices or their component parts or accessories.
- iii. A manufacturer or distributor of medical devices that when sold do not have covered drugs in them will not be considered a Producer, unless they also separately meet the definition of Producer.
- iv. A Producer is a person or entity that causes a Covered Drug to be manufactured. A manufacturer that does not directly sell, offer for sale, or distribute the Covered Drug in Alameda County will be considered a Producer of the Covered Drug if the Covered Drug it manufactures is sold, offered for sale, or distributed in Alameda County by another Person. Accordingly, as used in Section 6.53.030 of the Ordinance, paragraph 14(i), the terms “sells, offers for sale, or distributes” includes all sales, offers for sale, or distribution regardless of whether or not the Covered Drug is sold, offered for sale, or distributed by someone other than the manufacturer, such as by an independent wholesaler or distributor.
- v. A person or entity that has legal ownership of the brand, brand name, or co-brand under which a Covered Drug is sold, offered for sale, or distributed in Alameda County who does not directly sell, offer for sale, or distribute the Covered Drug in Alameda County will be considered a Producer of the Covered Drug if that Covered Drug is sold, offered for sale, or distributed in Alameda County by any other Person. Accordingly, as used in Section 6.53.030, paragraph 14(ii) of the Ordinance, the terms “sells, offers for sale, or distributes” includes all sales, offers for sale, or distribution regardless of whether by a Person who has legal ownership of the brand, brand name, or co-brand under which a Covered Drug is sold, offered for sale, or distributed in Alameda County or by someone else.

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- vi. The following are considered biological products which are not Covered Drugs if the Producer already has a take back program in place: vaccines derived from biological products and therapeutic serum. (Biological products are defined in 21 Code of Federal Regulation 600.3(h)).

B. Petition for Exemption

- i. A Producer whose Covered Drugs are made available exclusively to medical professionals and administered solely in a licensed hospital, medical, dental or veterinary clinic or other medical facility, with an approved Medical Waste Management Plan under the jurisdiction of the California DOHS Medical Waste Management Act, may petition the Department for an exemption from the Ordinance.
- ii. A Petition for an exemption under this section must include the following:
 - a. The petitioning Producer's name and United States business address;
 - b. The trade and chemical name of the Producer's Covered Drugs;
 - c. A description of the uses of each of the Producer's Covered Drugs;
 - d. A description of how each Covered Drug is distributed in Alameda County;
 - e. A declaration under penalty of perjury that the Producer's Covered Drugs are exclusively available to medical professionals and administered solely in a licensed hospital, medical, dental or veterinary clinic or other medical facility, with an approved Medical Waste Management Plan under the jurisdiction of the California DOHS Medical Waste Management Act and that the Covered Drugs are not dispensed directly to the public;
 - f. A showing that Producer's Unwanted Products are being safely disposed; and
 - g. A deposit for the estimated cost to the County of review, consideration and response to the petition, as set forth in the Fee Schedule.
- iii. The Department shall have the discretion to grant or deny any Petition for exemption made under this section.
- iv. Any exemption, if granted, will specify the time period for the exemption, up to three (3) years. A request for renewal of an exemption must be submitted to the

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Department at least six (6) months before the expiration date. Late requests for exemption renewals will be subject to penalties, including but not limited to late fees and costs to be determined by the Department.

Section 6 – Submission of Plans

- A. **Submission.** For Producers subject to the Ordinance on or before July 1, 2013, Plans must be submitted no later than May 1, 2014.
- B. **Petition For Later Submission Date.** A written petition may be filed for an extension of the deadline to submit a Plan to the Department. Petitions for a later submission date must be received by the Department Liaison no later than five (5) weeks prior to the deadline for submission of a Plan.
 - i. **Petition Contents.** A written petition for an extension must include the following:
 - a. The proposed extension date;
 - b. An explanation of why an extension is needed;
 - c. Justification for the proposed extension;
 - d. A brief summary of the current status of the draft Plan; and
 - e. A deposit for the estimated cost to the County of review, consideration and response to the petition.
- C. **Late Plan Submissions.** If any Producer does not submit a Plan by the date set forth in paragraph A, or has not submitted a Plan by a later date granted by the Department, such Producer(s) shall be subject to the enforcement provisions of Section 6.53.110 of the Ordinance, including penalties.
- D. **Plan Owners.** A Plan shall be submitted by its Plan Owner, which may be a Producer or any other organization, entity or individual. A Plan may be submitted for approval even if no Producers are participating in the Plan. A Product Stewardship Program may be a Plan Owner. A Product Stewardship Program may be (1) financed and operated by a Producer or Producers or (2) operated by a company, individual or other entity that is retained and compensated by a Producer or Producers to meet the obligations of the Producer or Producers under the Ordinance.
- E. **Preliminary Review of Plan.** Plan Owners may submit a draft Plan prior to the date set forth in paragraph A deadline for preliminary review and comment by the Department. Plan Owners are encouraged to contact the Department to discuss their Plan at least three months prior to the deadline for Plan submission.

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Section 7 – Plan Content

A. **General Information.** A Plan must contain the following general information:

i. **Contact Information.**

- a. **Plan Participants.** Identification of the Plan Owner(s) and the Producer Contacts for all Producers participating in the Plan. Identification of the Producer Contact shall include an e-mail address, telephone number and mailing address. Any change in Plan Owner or the Producers participating in a Plan must be provided to the Department within 30 days of the change.
- b. **Plan Liaison.** Identification of the Plan Liaison shall include an e-mail address, telephone number and mailing address. The Plan Liaison must be familiar with the Plan, the Covered Drugs of each Producer participating in a Plan, and potential issues related to implementation of the Plan. The Plan Liaison must have authority on behalf of all of the Plan Owners and all participating Producers to make binding representations and determinations related to the Plan. Notice to the Plan Liaison shall be considered notice to the Plan Owner and each Producer participating in the Plan.

ii. **Website.** A Plan must include the address of a website on which the Collection Points, educational materials, public outreach events, and other components of the Plan will be made publicly available. The website does not need to be devoted exclusively to the Plan.

iii. **Telephone Number.** All Plans must include a toll-free telephone number that will be available to Residential Generators to obtain information about Collection Points, educational materials and other aspects of the Plan.

iv. **Other.** All information required by the Ordinance.

B. **Collection Measurement and Goals.** A Plan must contain an estimate for the quantity of Unwanted Products that will be collected under the Plan and how the quantity of collected Unwanted Products will be measured.

C. **Implementation Description.** A Plan must contain a discussion of how and when the Plan will be implemented, including but not limited to:

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- i. The number of initial Collection Points and Collection Points that will be phased in over time.
- ii. The dates on which Unwanted Products will begin to be collected at each Collection Point, which must be within 90 days of Department approval of the Plan. Collection Points may include established Collection Points for which the Plan will assume responsibility.

D. Multiple Collection Components. A Plan may have multiple collection components, which may include:

- i. Collection Points with secure drop-off kiosks at hospitals, pharmacies and other convenient locations;
- ii. A mail-back program, such as providing consumers with a container in a prepaid self-addressed package for mailing Unwanted Products to be destroyed;
- iii. Public collection events, including at senior citizen facilities, health fairs, and recycling events. Plan Owners and Producers are encouraged to coordinate with community organizations, public entities, and local government regarding the Plan.

E. Transporter Information. Transportation from the Collection Points to the disposal facility must be performed by a Transporter. The Plan must include the following information for each Transporter to be used under the Plan:

- i. Name, address and phone number;
- ii. Website address;
- iii. Type of Transporter;
- iv. Environmental Protection Agency identification number;
- v. Permit status;
- vi. Record of any penalties, violations, or regulatory orders received in the previous five (5) years; and
- vii. How the Transporter will be utilized under the Plan .

F. Disposal Facility Information. The Plan must include the following information for each Disposal Facility to be used under the Plan:

- i. Name, address and phone number;
- ii. Website address;
- iii. Type of facility;
- iv. Environmental Protection Agency identification number;
- v. Permit status;

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- vi. Record of any penalties, violations, or regulatory orders received in the previous five (5) years; and
- vii. How the Disposal Facility will be utilized under the Plan.

A list of eligible Disposal Facilities that are properly permitted to dispose of Unwanted Products and information regarding such sites located in California may be obtained from the California Department of Public Health (CDPH). Information is available on its website located at www.cdph.ca.gov.

- G. **Copies of Materials.** A Plan should include copies of any educational or public outreach materials that are proposed to be used under the Plan, including a copy of any signage, with the dimensions of the proposed actual sign.
- H. **Plan Goals.** A Plan should include a proposal as to the short term and long term goals under the Plan for collection, education and public outreach. The Department may modify Plan goals as a condition of approval. As set forth below, Plan goals shall be reviewed in each Annual Report, at which time the Department, working with the Plan Liaison, will set the goals for the next reporting period.
- I. **Public Document:** Any Plan submitted to the Department or Board of Supervisors or any other governmental agency under the Ordinance or Regulations will be considered a public record. No part of the Plan should be marked as confidential or proprietary. This provision is not intended to require the disclosure of records that are exempt from disclosure under the California Public Records Act (Government Code section 6250, et seq.). If any Plan Owner or Producer participating in a Plan contends that information it is required to provide is exempt from disclosure under the California Public Records Act, such information must be accompanied by a written claim of exemption and a concise statement of reasons supporting such claim. The party seeking to protect documents, or information contained in documents, from disclosure shall bear the burden of making a showing that the documents or information are exempt from disclosure under the California Public Records Act. The County shall determine whether the documents or information are exempt from the California Public Records Act.

Section 8 – Plan Evaluation

- A. Plans will be evaluated by the Department based on the following:
 - i. **Adequate Collection.** Whether the Plan's collection program is adequate to serve the needs of Alameda County residents, including but not limited to:

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- a. Whether the Plan provides for adequate collection of Unwanted Product for each area of the County where the Covered Drugs of the participating Producer(s) are offered for sale, sold, or distributed; and
 - b. Whether residents who procure their medications outside of physical pharmacies, such as online, will be adequately served by the Plan.
- ii. **Adequacy Of Collection Points.** Whether the Plan has an adequate number of Collection Points and whether these Collection Points are accessible and located throughout Alameda County. Possible Collection Points can include, but are not limited to pharmacies, medical and veterinary offices, clinics, hospitals, law enforcement agencies, and governmental buildings. The Department encourages Plan Liaisons to contact the Department before Plans are due if they are having difficulty identifying suitable or sufficient Collection Point locations.
- iii. **Management Practices.** Whether the Plan includes adequate management and administrative practices, including but not limited to:
 - a. Training to be provided at the Collection Points;
 - b. General security procedures;
 - c. Procedures for pickup and disposal of Unwanted Products;
 - d. Frequency of pickup from Collection Points and disposal;
 - e. Procedures if a collection vessel is full prior to scheduled pick-up and disposal; and
 - f. Management and administration of alternative collection methods, such as mail-back containers.
- iv. **Tracking.** Whether the Plan provides for the collected Unwanted Products to be safely and securely tracked and handled from collection through disposal.
- v. **Controlled Substances.** Whether the Plan adequately addresses collection of Controlled Substances.
- vi. **Education and Public Outreach.** Whether the Plan complies with the public education and outreach requirements of the Ordinance, including but not limited to whether the Plan adequately provides for education regarding the safe collection and disposal of Unwanted Products for:
 - a. Medical providers and their patients;
 - b. Veterinary providers and animal owners;
 - c. Pharmacies, including education for dispensers of Covered Drugs and their patients; and
 - d. The general public.

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- vii. **Educational Materials.** Whether the Plan adequately incorporates educational materials for the public and whether such materials adequately address:
- a. The importance of promptly and properly disposing of Unwanted Products;
 - b. How to find and use Collection Points;
 - c. Alternative methods of returning Unwanted Products under the Plan (such as mail-back programs);
 - d. How to properly dispose of Unwanted Products; and
 - e. Privacy issues, such as removing Unwanted Products from labeled prescription containers, which may disclose private information, and placing them in unlabeled bags or containers.
- viii. **Public Outreach.** Whether the Plan provides for adequate public outreach, including but not limited to sufficient use of print and social media, radio, television, signage, and public events.
- ix. **Cost.** The Plan does not need to include an itemized cost breakdown for the Plan or the charges to, or financial contributions from, any Producer, so long as a statement is provided from each Producer that it is their reasoned opinion that the proposed Plan meets the criteria of Section 6.53.040(B) of the Ordinance.
- B. When considering a Plan for approval, the Department assumes the truth and accuracy of all information provided in connection with the Plan. Plan Owners and all Producers participating in a Plan are jointly and severally responsible for the truth and accuracy of their representations. If the Department determines that any information provided to it in connection with a Plan is false or inaccurate, the Plan Owner(s) and Producer(s) participating in the Plan shall, at the discretion of the Department, be subject to the penalty provisions of the Ordinance and Regulations.

Section 9 – Petitioning For Alternative Method Of Disposal

A Plan Liaison may petition for a method of disposal other than incineration as required by Section 6.53.060 (B) of the Ordinance by submitting a written petition to the Department Liaison by e-mail. The following information must be included in the petition:

- A. An explanation as to how the proposed alternative method of disposal adequately meets the requirements of the Ordinance, including Section 6.53.060 (C), and Regulations;
- B. A deposit for the estimated cost to the County to review, consider and respond to the petition, based on the Fee Schedule.

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The Department will contact the petitioner if additional information is required to make a determination on the petition. The Department shall have discretion to grant or deny any petition filed under this Section.

Section 10 – Review, Public Hearing and Approval of Plan

- A. **Review:** Following receipt of a Plan by the Department, the Department Liaison may review the Plan with the Plan Liaison. If the Department Liaison does not recommend approval of the Plan as submitted, a Revised Plan may be submitted by a date set by the Department Liaison. It is within the discretion of Department to continue a noticed public hearing to allow for submission of a Revised Plan.
- B. **Public Hearing.**
 - i. **Public Hearing:** A Public Hearing shall be noticed and conducted by the Department to determine if a Plan complies with the Ordinance and Regulations
 - ii. **Availability of Plan:** Within 10 days of the Department providing notice of the public hearing, the proposed Plan will be made available to the public by the Department at no cost on the Department website. A copy will also be made available for public viewing at the Department office.
- C. **Approval of Plan.** Within 30 days following the public hearing, the Department will notify the Plan Liaison by e-mail whether the proposed Plan has been approved or denied, whether any changes to the Plan are required for approval and/or whether additional time, information, and/or documents are needed for the Department to make a determination on the Plan. Approval of a Plan by the Department does not constitute an opinion on compliance with other federal, state, city, or county laws, ordinances, or regulations.
- D. **Posting of Approved Plan.** All approved Plans shall be posted by the Department on its website within fifteen (15) days of notification to the Plan Liaison of approval.
- E. **Rejection of a Plan.** If a Plan is rejected by the Department, the Plan Liaison must submit a Revised Plan to the Department within 60 days after receiving notice of the rejection. If a Revised plan is not timely submitted and approved, Producers participating in the rejected plan may have an Alternative Plan imposed on them.
- F. **Alternative Plan.** At the Department's discretion, an Alternative Plan may be, but is not limited to, a Plan developed by the Department, or a Plan submitted by another Plan Owner(s) or Producer(s).

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- i. All costs incurred by the County relating to an Alternative Plan shall be paid by the Producer(s) participating in the Plan. Such costs shall be determined in accordance with the Fee Schedule, Ordinance and Regulations, and shall not exceed the actual costs of the County.
- ii. The Department in its discretion may contract with a third party to create an Alternative Plan. Any fees or costs for such a consultant shall be paid by the Producer(s) participating in the Plan.
- iii. Producer Contact(s) will be sent notification of the imposition of an Alternative Plan by e-mail and first class mail, which will include a webpage where a copy of the Alternative Plan may be downloaded.

G. Appeal. A Plan Liaison or Participating Producer may appeal an Alternative Plan, or a portion of an Alternative Plan, to the Board of Supervisors within ten (10) calendar days after receiving notice of imposition of the Alternative Plan.

- i. The appeal may be initiated by filing a Notice of Appeal with the Clerk of the Board of Supervisors. A courtesy copy of the Notice of Appeal shall be sent to the Department Liaison.
- ii. The Notice of Appeal shall specify the grounds for the appeal, the specific changes requested to the Alternative Plan, and the appellant's contact information.
- iii. The appeal process before the Board of Supervisors for an Alternative Plan shall follow the procedures set forth for administrative citations in Section 6.53.110 (J) of the Ordinance. If the Board of Supervisors cannot attain a majority vote as to whether to grant or deny an appeal of an Alternative Plan, the Alternative Plan shall be upheld.

Section 11 – Request To Modify an Approved Plan

A. Only a Plan Liaison may request modifications to an approved Plan. All such requests must be made in writing and submitted to the Department Liaison with a Modification Request Fee, as set forth on the Fee Schedule. No material modifications may be made to a Plan without prior Department approval, including but not limited to:

- i. Collection Point changes;
- ii. Changes to collection methods or collection events;
- iii. Material changes to educational or public outreach efforts.

The Department must be promptly notified, in writing, of any non-material changes to the Plan, including a change in Plan Liaison, but prior Department approval is not required for such non-material changes.

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- B. The Department will notify the Plan Liaison within 30 days of receipt of a request to modify an approved Plan as to whether the requested modification has been approved, denied, approved in part, or if additional information, documents and/or time are needed to make a determination. The Department shall have discretion to determine whether to allow modifications of an approved Plan.

Section 12 – Plan Compliance

The Department may, but is not required to, monitor Plan compliance, including but not limited to visiting Collection Points or educational events or engaging a third party to do so. Costs incurred by the County in monitoring Plan compliance shall be borne by Producers participating in a Plan.

Section 13 – Enforcement and Penalties

- A. **Written Warning.** If the Department Liaison determines that a Plan is in violation of the Ordinance or Regulations or is not being implemented as approved, the Department Liaison shall send by e-mail a written warning to the Plan Liaison. Since Producers are the parties responsible for payment of all fines and penalties, all Producers participating in a Plan shall be sent a copy of the written warning at the address identified on the Plan for their Producer Contact. The written warning will be deemed received the day after it is sent by e-mail.
- B. **Recommendation for Administrative Citation.** If any violation(s) identified in the written warning is not corrected within 30 days, a recommendation will be made by the Department Liaison that the Department issue an Administrative Citation to the offending Producer(s).
- C. **Administrative Citation.** An Administrative Citation issued by the Department shall include a description of the violation, the section of the Ordinance or Regulation that has been violated, the date the warning was issued, and the administrative fines and civil penalties to be assessed against the Producer(s). The fines and penalties shall begin accruing on the 31st calendar day after the written warning. The Department has discretion as to when to issue an Administrative Citation.
- D. **Per Day Violation and Penalties.** Each day a Plan is in violation of the Ordinance or Regulations after the 30 day cure period shall constitute a separate and distinct violation, and penalties may, at the Department's discretion, be assessed on a daily basis until the violation is cured. The amount of the penalty for each violation shall be determined at the discretion of the Department, up to a maximum amount of one

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thousand dollars (\$1,000) per day per violation. Any civil penalty is separate and distinct from any fines imposed in connection with any criminal conviction.

- E. **Payment of Penalties.** All penalties shall be paid within 30 days of the date the Administrative Citation was issued. Any penalty amounts that are not paid within the 30 day period shall accrue interest at the rate of 10% per annum. Penalties shall be payable to the Department.

Section 14 – Appeal of Administrative Citations

- A. **Submission of Appeal.** Any appeal of an Administrative Citation shall follow the process set forth in the Ordinance at Section 6.53.110.
- B. **Department Review.** Appeals shall be sent to the Department Liaison for review to determine if the appeal is complete according to the requirements of Section 6.53.110 of the Ordinance.
- C. **Contact Information.** The appeal must set forth the contact person for purpose of the appeal and the appellant's telephone number, e-mail and mailing addresses.
- D. **Incomplete Appeal.** If any appeal is determined by the Department Liaison to be incomplete, it shall be returned to the appellant with the basis for the determination.
- E. **Notification of Hearing.** If the Department Liaison determines that an appeal is complete, a hearing officer will be designated, and the Department will provide written notice of the hearing as set forth in Section 6.53.110 (G) of the Ordinance.
- F. **Appeal to Board of Supervisors.** A Producer or the Department may appeal the Hearing Officer Decision to the Board of Supervisors by following the process set forth at section 6.53.110 (J) of the Ordinance. A copy of any appeal filed with the Clerk of the Board of Supervisors shall be sent by the appellant to the Department Liaison or, if filed by the Department, to the Plan Liaison.

Section 15 – Annual Reports

- A. **Submission of Reports.** An Annual Report must be submitted to the Department Liaison for each Plan on or before the annual report date set by the Department at the time the Plan is approved.
- B. **Report Format:** The Annual Report shall be in two parts: a Report Narrative section containing a narrative description of the activities under the Plan for that year and a Report Data section containing the data described below. In addition to elements

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required in the Ordinance and below, the Annual Report shall contain any changes to contact information for any Plan Owner or Producer participating in a Plan.

C. **Report Narrative.** The narrative section of the Annual Report shall include the following brief subsections:

- i. **Executive Summary.** The purpose of the Executive Summary is to provide a broad understanding of the Plan as a whole and context for the data and information that will follow. This summary should include a brief description of collection and disposal efforts during the reporting period. The executive summary should also include a description of proposals to improve collection efforts and challenges encountered during the reporting period, and how they will be addressed. (Security issues must be addressed separately as set forth below.)
- ii. **Reporting on Goals.** The Report Narrative should include a summary of the Plan goals and the degree of success in meeting those goals in the past year. The discussion should include a summary of the efforts to meet the goals, any difficulty in meeting the goals, and if any goals have not been met, what effort will be made to achieve such goals in the next year.
- iii. **Future Goals.** The Report Narrative should include proposed goals to be accomplished in the upcoming year. If the proposed goals differ from the original Plan goals, the Annual Report should include a discussion of the reasons for the suggested change(s).
- iv. **Collection Practices.** The Report Narrative shall include a brief description of the collection efforts over the past year. .
- v. **Educational Efforts and Public Outreach Activities.** The Report Narrative shall include a brief description of education and public outreach efforts over the past year.
- vi. **Safety and Security Report:** This section shall be provided on a separate page and clearly marked "Safety and Security Report". This section shall:
 - a. Identify any known security or safety incidents at Collection Points, events and during transportation or disposal. For each such incident, the report must include the following:
 1. What, if any, corrective or other action was taken in response to the incident;

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2. Any law enforcement or regulatory agencies involved in the incident; and
3. Any litigation, arbitrations or other legal proceedings arising out of, or involving, the incident.

- b. If the Plan Owner or a Producer participating in a Plan contends that information it is required to provide in the Safety and Security Report is exempt from disclosure under the California Public Records Act, this section of the Annual Report may be submitted conditionally under seal. It must be accompanied by a written claim of exemption and a concise statement of reasons supporting such claim. Submission of a written claim that the document, or information contained in a document, is exempt from disclosure under the California Public Records Act does not in itself create an exemption. The party seeking to protect documents, or information contained in documents, from disclosure shall bear the burden of making a showing that the documents or information are exempt from disclosure under the California Public Records Act. The County shall determine whether documents or information are exempt from the California Public Records Act.

D. Report Data: The data section of the annual report must contain all items required by the Ordinance and the following information:

- i. All Producers participating in the Plan;
- ii. For each Collection Point:
 - a. Location, host site name, and address;
 - b. Collected Unwanted Products by weight over the past year; and
 - c. Number of times Unwanted Products was picked up for transportation per location.
- iii. For any mail-back program:
 - a. The number of mail-back containers distributed;
 - b. The number of mail-back containers returned; and
 - c. Collected Unwanted Products by weight.
- iv. For each Disposal Facility:
 - a. The facility name, address and telephone number; and
 - b. The total weight of collected products disposed of at each Facility.

REGULATIONS

E. Failure to Submit Adequate Annual Report.

- i. If the Department finds any Annual Report to be inadequate, it may request additional information or a revised report.
- ii. If a Plan Owner does not provide an adequate Annual Report after a request by the Department for additional information or a revised report, any Producers participating in the Plan may be subject to enforcement actions and penalties under the Ordinance and Regulations.

Section 16 – Plan Renewal

Once a Plan is approved it is valid for three (3) years, unless the Department specifically sets forth a different term, which is within the Department's discretion. Plan Liaison should set up an appointment with the Department Liaison six (6) to eight (8) months prior to the end of the three (3) year term, and no later than 60 days prior to the expiration of the term of the existing Plan, to discuss renewal of the Plan and how the Plan may be improved or modified. The Department will advise the Plan Liaison within 30 days following this meeting as to whether the Plan will need to be revised prior to renewal.

The Department shall have discretion to determine whether a public hearing will be held prior to renewal of a Plan.

Section 17 – Request for Exception

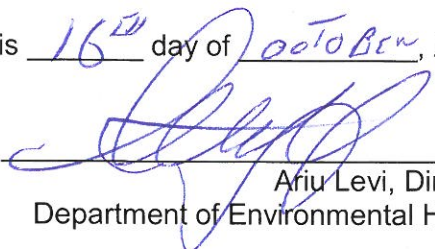
- A. **Petitions for Exception.** A Plan Liaison or a Producer may make a request of the Department for an exception, exemption, or allowance from any requirement of the Ordinance or Regulations.
- B. **Petition Content.** Any Petition for Exception must be made in writing to the Department Liaison and contain all of the following:
 - i. The name and contact information of the Plan Liaison or Producer seeking the exceptions;
 - ii. The Ordinance section or Regulation to which the request relates;
 - iii. The reason and justification for the request; and
 - iv. A deposit for the estimated cost to the County of review, consideration and response to the Petition based on the Fee Schedule.
- C. **Department Discretion.** The Department shall have the discretion to grant or deny any Petition for Exception.

REGULATIONS

Section 18 – General Provisions

- A. **Severability.** If any part or provision of these Regulations or the application thereof to any person or circumstances is held invalid, the invalid provision(s) shall be severed, and the remainder of the Regulations, including the application of such part or provision to other persons or circumstances, shall not be affected and shall continue in full force and effect.
- B. **Compliance with all Laws and Regulations.** Plan Owners and Producers participating in a Plan, and not the Department, are jointly and severally responsible for creating and maintaining a Plan that is in compliance with all federal and California laws and all city and county ordinances and regulations. Approval of a Plan by the Department does not constitute an opinion on compliance with other federal, state, city, or county laws, ordinances, or regulations. Any statement by the County, including the Department Liaison, that the Plan may contain a component that violates any federal, state, city, or county law, ordinance, or regulation shall not be interpreted as an opinion that any other component of the Plan is in compliance with any federal, state, city, or county laws, ordinances or regulations.
- C. **Separate and Distinct Compliance.** Adherence to the Ordinance and Regulations is not meant to replace or meet the requirements of any other federal, state, city, or county laws, ordinances, or regulations. Any review or approval pursuant to the Ordinance or Regulations is not meant to and shall not be indicative of compliance with or violations of any other federal, state, city, or county laws, ordinances or regulations.

These Regulations, as amended, are hereby adopted this 16th day of October, 2013.


Ariu Levi, Director
Department of Environmental Health