

SAFE DRUG DISPOSAL REGULATIONS

The Director has determined that the following Regulations are necessary to clarify, implement, administer, and enforce the provisions of Chapter XX of Division B11 of the County of Santa Clara Ordinance Code relating to Safe Drug Disposal ("Ordinance"), pursuant to the authority granted to the Director in Section 552(a) of the Ordinance. The Director hereby adopts these Regulations as of the date specified below.

Section 1 - Definitions

The following definitions shall apply to the Regulations. All capitalized terms used in the Regulations that are not defined in this Section shall have the meaning set forth in the Ordinance.

"2+ / 3+ Frequency" means the amount of Reach obtained among audiences exposed to two / three or more advertising messages.

"Annual Report" means the yearly report required to be submitted by Plan Operators under Section B11-548 of the Ordinance.

"Collection System" means the Drop-Off Kiosks, Take-Back Events, and Mail-Back Services available in Santa Clara County.

"Combined Target Reach Percent" means the percentage of adult County Residents exposed to at least one (1) outreach message across all Media used.

"Drop-Off Site" means a physical location with a secure collection receptacle for receiving Unwanted Covered Drugs from County Residents, free of charge.

"Frequency" means the number of times an adult County Resident has an opportunity to be exposed to the Promotion System within a specified time period.

"Mail-Back Distribution Site" means a convenient distribution site providing for free, prepaid, preaddressed mailers to County Residents as part of Mail-Back Services.

"Medium (plural, Media)" means a communication vehicle such as the internet, radio, magazines, mail, newspapers, billboards, television, telephone directories, etc.

"Promotion System" means the system of education and outreach required under Section B11-547 of the Ordinance.

"Reach" refers to the number or percentage of a population group exposed to the Promotion System within a given period of time.

"Safe Drug Disposal Liaison" means the contact designated by the Director for all issues relating to the Ordinance.

“Small Producer” means a Producer that employs no more than 750 employees.

“Survey” means the survey required under Section B11-547(c) of the Ordinance.

“Take-Back Event” means an event providing for the secure collection of Unwanted Covered Drugs.

“Target Rating Points” means the percentage of adult County Residents exposed to any given Medium.

“Website” means www.sccsafemeds.org.

Section 2 - Regulations

A. **Adoption and Effective Date.** Regulations adopted by the Director shall be posted on the Website upon being adopted.

B. **Notice.** The Director shall notify all Plan Operators of any Regulations within seven calendar days of their adoption. Adopted Regulations shall be effective immediately.

C. **Severability.** If any part or provision of the 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.

Section 3 - Fees

A. **Fee Schedule.** Fees shall be charged based on an hourly rate set forth in a fee schedule approved by the Board of Supervisors. The activities and hours contained in the fee schedule reflect projections and estimates. The fee schedule may from time to time be amended as approved by the Board of Supervisors.

B. **Fee Submittal.** All fees must be submitted to the mailing address provided on the Website. An initial fee submittal as set forth in the fee schedule must be made by a Plan Operator upon initial submission of a proposed Stewardship Plan. An annual fee submittal as set forth in the fee schedule must be made by a Plan Operator upon submission of each Annual Report. A Plan Operator will be periodically billed for additional fee submittals as set forth in the fee schedule to cover any Stewardship Plan-related activities requiring County staff time. Additional fee submittals must be made by a Plan Operator within 30 days of receipt of a bill.

Section 4 - Communications

A. **Safe Drug Disposal Liaison.** The contact for the Director for all issues relating to the Ordinance shall be the Safe Drug Disposal Liaison. All Stewardship Plans, petitions, and other communications required to be submitted to the Director must be submitted electronically to the

Safe Drug Disposal Liaison. All information or notices provided to Producers, Plan Operators, or other Persons related to the Ordinance may be provided by the Safe Drug Disposal Liaison on behalf of the Director. The Safe Drug Disposal Liaison is available to discuss the requirements of the Ordinance, including but not limited to Stewardship Plans, Annual Reports, and Surveys, and to assist Plan Operators in setting goals and estimates for Stewardship Plans and Annual Reports. The Safe Drug Disposal Liaison's contact information shall be available on the Website.

B. Public Documents. The County is a public agency subject to the disclosure requirements of the California Public Records Act ("CPRA"). If a Producer's or Stewardship Organization's proprietary information is contained in documents or information submitted to the County, and the Producer or Stewardship Organization claims that such information falls within one or more CPRA exemptions, the Producer or Stewardship Organization must clearly mark such information "CONFIDENTIAL AND PROPRIETARY," and identify the specific lines containing the information. In the event of a request for such information, the County will make best efforts to provide notice to the Producer or Stewardship Organization prior to such disclosure. If the Producer or Stewardship Organization contends that any documents are exempt from the CPRA and wishes to prevent disclosure, it is required to obtain a protective order, injunctive relief, or other appropriate remedy from a court of law in Santa Clara County before the County is required to respond to the CPRA request. If the Producer or Stewardship Organization fails to obtain such remedy within the time the County is required to respond to the CPRA request, the County may disclose the requested information. The Producer or Stewardship Organization further agrees that it shall defend, indemnify, and hold the County harmless against any claim, action, or litigation (including but not limited to all judgments, costs, fees, and attorney's fees) that may result from denial by the County of a CPRA request for information arising from any representation, or any action (or inaction), by the Producer or Stewardship Organization.

C. Safety and Security Incidents. The Plan Operator must notify the Safe Drug Disposal Liaison of any known security or safety incidents at Drop-Off Sites, Take-Back Events, and Mail-Back Distribution Sites, or during transportation or disposal of Unwanted Covered Drugs as soon as reasonably practicable but no later than ten business days after the incident. The notification shall include a description of what corrective or other action is being or has been taken in response to the incident and whether any law enforcement or regulatory agencies are or were involved in the incident. The Plan Operator must provide updates regarding any litigation, arbitrations, or other legal proceedings arising out of, or involving, the incident as soon as reasonably practicable but no later than ten business days after commencement of the proceedings.

Section 5 - Petitions for Exemption

A. **Requirements.** A Small Producer may submit a written petition to the Director for an exemption to engage in alternate means for supporting safe disposal of Covered Drugs in lieu of participating in a Stewardship Plan. A petition for exemption must include: the Producer's telephone number, mailing address, and email address; the trade and chemical name of each of the Producer's Covered Drugs; a projection of the quantity of each of the Producer's Covered Drugs to be sold in the County over the next three years; and a proposal for an alternate means by which the Producer will support safe disposal of Unwanted Covered Drugs in the County in lieu of participating in a Stewardship Plan.

B. **Review.** A petition for exemption submitted by a Small Producer shall toll the Small Producer's deadline for submission of a proposed Stewardship Plan through such date as the Director accepts, conditionally accepts, or rejects the petition. The Director shall have discretion to grant or deny any petition for exemption made under this Section.

C. **Term and Renewal.** Any exemption granted will specify the time period for the exemption, which may not exceed three years. A renewed petition for exemption must be submitted to the Director at least six months before the expiration date of the exemption.

Section 6 - Participation of Collectors

A. **Conditions of Participation.** A prospective Collector's participation in a Stewardship Plan shall not be conditioned on any requirements not expressly set forth in the Ordinance, including but not limited to the use of a common carrier model. A Plan Operator must make reasonable efforts to accommodate any reasonable requests made by a prospective Collector regarding their participation in the Stewardship Plan.

B. **Timing.** If a prospective Collector requests more than three months from its offer to participate in the Stewardship Plan to meet the requirements of the Ordinance, the Plan Operator shall document such request in writing for review upon request by the Director.

Section 7 - Promotion System

A. **Materials.** The educational and outreach materials required under Section B11-547(a)(5) must:

- i. Promote safe storage of all Covered Drugs before their use or disposal and promote the prompt and proper disposal of Unwanted Covered Drugs;
- ii. Convey instructions and information only for the types of disposal options offered through the Collection System; and
- iii. Provide the toll-free telephone number and website and explain how to use them to obtain information about the Collection System or to request Mail-Back Services.

B. **Marketing Plan.** The Promotion System must include a detailed marketing plan with targeted Media run dates designed to achieve a Combined Target Reach Percent of: 75% at a 3+ Frequency for the duration of one month at least three times per year over the first twelve months of Stewardship Plan operation; 50% at a 2+ Frequency for the duration of one month at least three times per year for following years; and 75% at a 3+ Frequency for the duration of one month at least three times per year for every fifth year of program operation.

C. **Language Access.** The standardized instructions, toll-free telephone number, website, educational and outreach materials, and Surveys required Section B11-547 of the Ordinance must be made available in the languages specified by the County's Language Access Guidelines and Procedures.

Section 8 - Annual Reports

A. **Report Narrative.** In addition to any other information required by the Director at the Director's discretion, the Annual Report must contain a narrative section that includes, at minimum:

- i. An executive summary that provides a broad understanding of the Stewardship Plan as a whole and context for the data and information that will follow, including a brief overview of the Stewardship Plan, proposals to improve the Stewardship Plan, challenges encountered during the reporting period, and how those challenges will be addressed in the next reporting period;
- ii. A summary of the Stewardship Plan's goals and the degree of success in meeting those goals during the reporting period, including a summary of efforts to meet the goals and any difficulties in meeting the goals, and if any goals have not been met, what efforts will be made to achieve the goals in the next reporting period;
- iii. Identification of proposed goals to be accomplished in the next reporting period, and if the proposed goals differ from the original Stewardship Plan goals, an explanation of why the goals have changed;
- iv. A description of the Promotion System and how it has been implemented, including a summary of efforts to achieve the metrics set forth in Section 7; and
- v. A clearly marked "Safety and Security Report" provided on a separate page, which must identify any known security or safety incidents at Drop-Off Sites, Take-Back Events, and Mail-Back Distribution Sites, or during transportation or disposal of Unwanted Covered Drugs. For each incident, the Safety and Security Report must describe: what, if any, corrective or other action was taken in response to the incident; whether any law enforcement or regulatory agencies were involved in the incident; and

any litigation, arbitrations, or other legal proceedings arising out of, or involving, the incident.

B. Report Data. In addition to any other information required by the Director at the Director's discretion, the Annual Report must contain a data section that includes, at minimum;

- i. Identification of any changes to a Plan Operator's contact information or its list of participating Producers;
- ii. For each Drop-Off Site: the total weight of Unwanted Covered Drugs collected, the number of times Unwanted Covered Drugs were picked up for transportation per location, and the number of times a secure collection kiosk had to be locked because it reached capacity before its scheduled pickup;
- iii. For each Take-Back Event: its time, date, and location; how and when it was advertised; the total weight of Unwanted Covered Drugs collected; whether the secure collection kiosk reached capacity before the end of the Take-Back Event; and how the Unwanted Covered Drugs collected at the Take-Back Event were handled prior to disposal;
- iv. For Mail-Back Services: the number of prepaid and preaddressed mailing envelopes distributed through the toll-free telephone number, through the website, and to each Mail-Back Distribution Site; the number of envelopes returned for disposal, including how many of these contained sharps or iodine-containing medications; and the total weight of Unwanted Covered Drugs collected;
- v. The total weight of Unwanted Covered Drugs transported by each Transporter and disposed of by each Disposal Facility;
- vi. For each Medium used in the Promotion System: Target Rating Points and documentation verifying that outreach described by the Promotion System did in fact take place, such as a photograph of a billboard, a copy of a published newspaper advertisement, reports of internet usage, or other appropriate documentation.

C. Review. If the Director finds any Annual Report to be inadequate, the Director may request additional information or a revised Annual Report. After reviewing the Annual Report, the Director will approve or modify the proposed goals for the next reporting period to be addressed in the next Annual Report.

Section 9 - Surveys

A. Approval. A Survey must be approved in writing by the Director before it may be conducted. The contents and methodology for the proposed Survey must be submitted to the Director within one year after the first year of Stewardship Plan operation. The Director shall

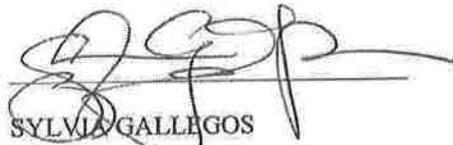
approve, conditionally approve, or reject a proposed Survey within 60 days of receiving the proposed Survey. Unless otherwise provided by the Director, a conditionally approved Survey must be conducted in accordance with all changes identified by the Director.

B. Content. Surveys must include, at a minimum, questions addressing: awareness of the Collection System and the disposal opportunities it provides; exposure to the Promotion System; understanding of the importance of promptly and properly disposing of Unwanted Covered Drugs; availability, accessibility, ease of use, frequency of use, and management of Drop-Off Sites, Take-Back Events, and Mail-Back Services; questions, concerns, or recommendations for improvements to the Stewardship Plan; and any additional issues or metrics required by the Director.

C. Methodology. The Survey's methodology must be reasonably targeted to obtain Survey responses from a representative sample of all County Residents, pharmacists, veterinarians, and healthcare professionals in the County who interact with County Residents on use of Covered Drugs.

D. Outcomes. If the results of any Survey show that less than 50% of adult County Residents are aware of the Collection System, future outreach activities must be incorporated into future goals in Annual Reports and updated Stewardship Plans to increase Reach and Frequency until awareness of at least 50% is achieved in subsequent Surveys.

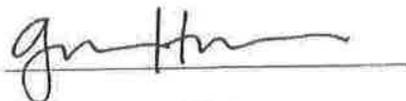
ADOPTED by the Director, Sylvia Gallegos, Deputy County Executive, on March 20, 2017:



SYLVIA GALLEGOS

Deputy County Executive

APPROVED AS TO FORM AND LEGALITY:



GRETA S. HANSEN

Chief Assistant County Counsel