

California Adopts Statewide Producer-Funded Pharmaceutical Household Drug and Sharps Take-Back Program



On September 30, 2018, Governor Brown signed SB 212, an act amending the California Integrated Waste Management Act to create a statewide takeback program for pharmaceuticals and sharps from households. California joins Washington and New York in implementing statewide pharmaceutical takeback programs. By enacting SB 212, California also adds to existing producer-funded stewardship programs operating in the State for products ranging from paint to mattresses.

The Act requires manufacturers of “covered products” to create and operate a stewardship program that provides for the takeback of covered drugs and home-generated sharps waste from households. The Act also imposes various requirements on a covered entity or stewardship organization that operates a stewardship program, including submitting a proposed stewardship plan, an initial stewardship program budget, an annual budget, annual report, and other specified information to the California Department of Resources Recycling and Recovery (CalRecycle). CalRecycle is required to adopt implementing regulations no later than January 1, 2021. Cal. Pub. Resc. Code § 42031.2(a). “Program operators” must submit their proposed programs within six months of CalRecycle adopting relevant implementing regulations.

Covered Products

Under the Act, “covered product” means a covered drug or home-generated sharps waste. § 42030(g). A “covered drug” is defined as a drug, including a brand name or generic drug, sold, offered for sale, or dispensed in the State. § 42030(e)(1). Covered drugs also

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include a drug in a medical device, or a combination product containing a drug and a medical device. *Id.* Covered drugs exclude vitamins, supplements, herbal-based remedies, cosmetics, household cleaning products, drugs that are used for animal medicines, and medical devices, or component parts or accessories of medical devices, if they do not contain a covered drug. § 42030(e)(2).

Home-generated sharps waste means hypodermic needles, pen needles, intravenous needles, lancets and other devices that are used to penetrate the skin for the delivery of medications. § 42030(l) (incorporating Health and Safety Code § 117671).

Covered Entities and Entities Involved in the Collection of Covered Products

A “covered entity” is the manufacturer of covered drugs or sharps that are sold in or into the state. § 42030(f)(1)(A). If no entity meets this “manufacturer” definition, the Act then identifies four other potential elements of the supply chain as “covered entities”, ranging from the distributor of covered products that is licensed as a wholesaler, to a repackager, to the owner or licensee of a trademark or brand under which the covered products are sold in or into the state, to ensure that an entity is responsible for managing all covered products. § 42030(f)(1)(B)-(E).

A “stewardship organization” is a non-profit organization, which must be a 501(c)(3) entity under the federal Internal Revenue Code, that is established by a group of covered entities to develop, implement, and administer a stewardship program for covered drugs and/or home-generated sharps waste. § 42030(w). A “program operator” means a covered entity, or stewardship organization acting on behalf of a group of covered entities, that is responsible for operating a stewardship program. § 42030(q).

The Act creates a statewide pharmaceutical takeback program.

An “authorized collector” means a person or entity that has entered into an agreement with a program operator to collect covered drugs, which can include a law enforcement agency, a retail pharmacy, or other collector registered with the U.S. Drug Enforcement Agency (DEA) that is authorized to collect controlled substances for the purpose of destruction. § 42030(b). An “authorized collection site” means a location where an authorized collector operates a secure collection receptacle for collecting covered products. § 42030(a).

A “retail pharmacy” is a pharmacy possessing a license from the California Board of Pharmacy to operate a pharmacy. § 42030(s). A “retail pharmacy chain” means a retail pharmacy with five or more stores in the state. § 42030(t). As discussed below, the Act places certain collection obligations on retail pharmacy chains.

Schedule for Submittal of Initial Information to CalRecycle

Within 90 days of the Act’s effective date, a covered entity must identify all covered products, and identify any drugs or sharps that are not covered products, that it sells or offers for sale in the state. § 42031(a)(1). A covered entity, or the stewardship organization on behalf of covered entities, must update this list by January 15th of each year. § 42031(a)(2).

Within 90 days of the Act's effective date, a retail pharmacy that sells a covered product under its own label must identify the covered entity from which the retail pharmacy obtains a covered product that the retail pharmacy sells under its store label. § 42031(b). The California Board of Pharmacy shall verify the information collected pursuant to this and the prior paragraph, and make it available to CalRecycle. § 42031(c).

If an entity receives a letter of inquiry as to what drugs and sharps it distributes in California from the California Board of Pharmacy, it must respond within 60 days. § 42031(d). If the entity does not believe it is a covered entity, it must state the basis for that belief, a list of any drugs and sharps it sells, distributes, repackages, or otherwise offers for sale in California, and identify the name and contact information of the manufacturer for each drug identified. *Id.* Information provided pursuant to this requirement may be shared with CalRecycle, but is otherwise deemed proprietary and exempt from disclosure. *Id.*

Program Proposals, Schedule, and Process for Plan Approval

Within six months of the adoption date of regulations, a program operator must submit a complete stewardship plan for the establishment and implementation of a stewardship program to CalRecycle for approval. § 42032(a)(1). Prior to submitting a stewardship plan to CalRecycle, a program operator must submit its proposed stewardship plan for review to the California Board of Pharmacy and also to any other state agency with areas of authority relative to the stewardship plan. § 42032(b)(1).

An agency that receives a plan shall review the plan for compliance with state and federal laws and regulations related to the agency's respective authority. § 42032(b)(2). The agency shall determine compliance or noncompliance with those laws and regulations within 90 days of receipt of the plan, and provide to the program operator that determination and an explanation for any finding of noncompliance. *Id.*

CalRecycle must review the submitted plan and determine if it is complete within 30 days of receipt, and notify the program operator. § 42032(c)(1). If CalRecycle determines that a plan is incomplete, it shall identify for the program operator the required additional information, and the program operator shall resubmit the plan within 30 days. § 42032(c)(3).

CalRecycle must review the plan and approve, disapprove, or conditionally approve the plan within 90 days of receipt of a complete plan. § 42032(d)(1). This timeline shall be extended if CalRecycle consults with or submits a plan to another state agency. § 42032(d)(2). If CalRecycle disapproves a submitted stewardship plan, it must explain in writing how the plan does not comply with the Act within 30 days of disapproving the plan. § 42032(f)(1).

A program operator is required to fully implement the operation of an approved stewardship program no later than 270 days after CalRecycle approves the stewardship plan. § 42032(g).

The law identifies the information required for plan proposals, including information about each participating covered entity, each covered drug, the method for handling, transporting, and disposing of collected products, and a demonstration of adequate funding. § 42032.2. All handling, transport, and disposal undertaken as a part of a stewardship program must comply with all applicable state and federal laws, including, but not limited to, regulations adopted by the DEA. § 42035.8.

Convenience Standard and Supplemental Services for Covered Drugs

A stewardship plan for covered drugs must provide for a collection system meeting the “convenience standard,” which is defined as providing in each county in which the plan shall be implemented: (i) a minimum of five authorized collection sites or one authorized collection site per 50,000 residents, whichever is greater; (ii) a “reasonable geographic spread” of authorized collection sites and an explanation for the geographic spread; and (iii) a mail-back program covering any counties where there is not an authorized retail pharmacy operating as an authorized collection site. § 42032.2(a)(1)(F).

In addition, a plan must permit homeless, homebound, or disabled individuals to request prepaid, preaddressed, mailing envelopes or alternative forms of a collection and disposal system that would render a covered drug inert. § 42032.2(a)(1)(G)(i). Moreover, a plan must provide alternative methods of collection for any covered drugs, other than controlled substances, that cannot be accepted or commingled with other covered drugs in secure collection receptacles or through a mailback program, to the extent technically feasible and permissible under state and federal law. § 42032.2(a)(1)(G)(ii).

At least 120 days before submitting a stewardship plan for covered drugs, the program operator shall notify potential authorized collectors in the county or counties in which it operates of the opportunity to serve as an authorized collector for the proposed stewardship program. § 42032.2(b)(1). If a potential authorized collector expresses interest in participating in a stewardship program, the program operator shall commence good faith negotiations with the potential authorized collector within 30 days. *Id.*

After a stewardship plan for covered drugs has been approved, the program operator may supplement service, if approved by CalRecycle, for a county in which it operates that does not have the minimum number of authorized collection sites due to circumstances beyond the program operator’s control, by establishing (1) a mail back program, which may include providing information on where and how to receive mail-back materials or providing the location at which it distributes prepaid, preaddressed mailing envelopes (locations shall be proposed as part of the stewardship plan) (note that prepaid mailing envelopes may be mailed to an “ultimate user” upon request), and/or (2) an alternative form of collection and disposal of covered drugs that complies with applicable state and federal laws, including DEA regulations. § 42032.2(c).

Mail Back Stewardship Plan for Home-Generated Sharps Waste

A stewardship plan for home-generated sharps waste must provide for a mail back handling, transport, and disposal system, at no cost to the end-user, that complies with applicable state and federal laws. § 42032.2(d)(1). The program must provide or initiate distribution of a sharps waste container and mail-back materials at the point of sale, to the extent allowable by law. § 42032.2(d)(1)(F). The program operator shall select and distribute a container and mail-back materials sufficient to accommodate the volume of sharps purchased by an ultimate user over a selected time period, and all sharps waste containers shall include prepaid postage affixed to the container or to the mail-back packaging. § 42032.2(d)(1)(F). All sharps waste containers shall include the program operator’s website address and toll-free telephone number affixed to a label on the container or packaging, or on a separate insert included in the container or packaging. § 42032.2(d)(1)(F)(i)(II). The program must also demonstrate

adequate funding for all administrative and operational costs of the sharps waste stewardship program. § 42032.2(d)(1)(C).

Upon request, a stewardship plan must provide for reimbursement to local agencies for actual costs of transport and disposal related to home-generated sharps waste, unless the program operator provides for the removal of the home-generated sharps waste from the local household hazardous waste facility. § 42032.2(d)(1)(F)(ii). When a local jurisdiction requests removal of home-generated sharps waste, cost recovery, or reimbursement for removal of home-generated sharps, the local jurisdiction must provide information on home-generated sharps waste to the covered entity or program operator, within a reasonable time upon request by the covered entity or program operator. § 42033.5. A local agency shall not knowingly request reimbursement for expenses for disposal costs resulting from a municipal needle exchange program or a medical waste generator. § 42032.2(d)(1)(F)(ii)(I). Any request for reimbursement shall be submitted with a declaration under penalty of perjury that the local agency has not knowingly requested reimbursement for prohibited expenses. § 42032.2(d)(1)(F)(ii)(III).

Obligations for Retail Pharmacies

A retail pharmacy must make a reasonable effort to serve as an authorized collector as part of a stewardship program in the county in which it is located. § 42032.2(b)(2). If the “convenience standard” requiring a minimum of five authorized collection sites or one authorized collection site per 50,000 people is not met in a county in which a retail pharmacy chain has store locations, the retail pharmacy chain must have at least one location or 15 percent of its store locations, whichever is greater, in that county serve as authorized collectors in the stewardship program. § 42032.2(b)(2).

Record-Keeping, Fees, and Reporting

On or before March 31, 2022, and annually thereafter, a program operator must submit a written report describing the stewardship program activities during the previous reporting period. § 42033.2(a)(1). This annual report must include a list of covered entities participating in the stewardship organization; the updated and verified list of covered products that each covered entity subject to the stewardship plan sells or offers for sale; the amount, by weight, of covered products collected from ultimate users at each authorized collection site; the name and location of authorized collection sites at which covered drugs were collected; information about the home-generated sharps waste mail-back program; a description of any noncompliance with policies and procedures for collecting, transporting, and disposing of covered products, as established in the stewardship plan; whether any safety or security problems occurred during collection, transportation, or disposal of collected covered products during the reporting period and what changes have been made to alleviate the problem and to improve safety and security; and any other information CalRecycle reasonably requires. § 42033.2(b).

In addition, on or before March 31, 2022, and annually thereafter, a program operator must submit to CalRecycle a written program budget for stewardship program implementation for the upcoming calendar year. § 42033.2(a)(2). This annual program budget must include an independent financial audit of the stewardship program, funded by the stewardship organization from the charge paid from its member covered entities. § 42033.2(c)(1). The annual program budget must also include anticipated costs and the recommended funding level necessary to implement the stewardship program, including costs to cover the stewardship plan’s budgeted costs and to operate the stewardship program over a multiyear period in a “prudent and responsible manner.” § 42033.2(c)(2).

CalRecycle has 30 days to determine whether an annual report and program budget are complete and to notify the program operator of its determination. § 42033.2(d)(1). If complete, CalRecycle has 90 days for review. § 42033.2(d)(2). If they are not complete, CalRecycle must identify the required additional information in 30 days, and the program operator has 30 days from that date to resubmit. § 42033.2(d)(3). At that point, CalRecycle can conditionally approve the annual report and budget, and call for additional resubmissions. § 42033.2(e)(2).

A program operator must maintain minutes, books, and records that clearly reflect the activities and transactions of the program operator's stewardship plan. § 42033.4(a). The minutes, books, and records of a program operator must be audited by an independent certified public accountant at least once annually at the program operator's expense. § 42033.4(b)(1).

Proprietary information submitted to CalRecycle shall be protected by all parties as confidential and shall be exempt from public disclosure under the California Public Records Act. § 42036.4.

Covered entities are required to pay all administrative and operational costs associated with establishing and implementing the stewardship program in which it participates, including the cost of collecting, transporting, and disposing of covered products. § 42034. On or before the end of the 2022-2023 fiscal year, and once every three months thereafter, a program operator shall pay CalRecycle an administrative fee, set by CalRecycle, which is adequate to cover CalRecycle's and other state agencies' costs of administering and enforcing this chapter. § 42034.2(a)(1). These costs may include the actual and reasonable costs associated with regulatory activities before submission of stewardship plans. § 42034.2(a)(1). The administrative fees shall be deposited into a Pharmaceutical and Sharps Stewardship Fund. § 42034.2(b).

Education and Promotion

Each program operator must conduct a comprehensive education and outreach program intended to promote participation in the stewardship program. § 42031.6(a). The law requires each program to, at a minimum: promote its stewardship program to ultimate users by providing signage for hospitals, pharmacies, and other locations; provide educational and outreach materials for persons authorized to prescribe drugs, pharmacies, pharmacists, ultimate user, and others, as necessary; establish a website that publicizes the location of authorized collectors and provides other information intended to promote the use of the stewardship program; prepare and provide additional materials to promote the collection and proper management of covered products; and encourage ultimate users to separate materials that are not covered products before disposing of the covered products. § 42031.6(a).

Preemption

Drugs and sharps take-back ordinances already exist in a number of California counties, including Alameda (drugs and sharps), Contra Costa, Marin, San Francisco, San Mateo, Santa Barbara, Santa Clara (drugs and sharps), and Santa Cruz (drugs and sharps). This Act does not apply to a drug or sharp within a jurisdiction that is subject to a local stewardship program pursuant to an ordinance that took effect before April 18, 2018. § 42036.2(a). If that ordinance is repealed in the jurisdiction, the drug or sharp shall be subject to this statewide law within 270 days after the date on which the ordinance is repealed. *Id.* This Act preempts a local stewardship program for drugs or sharps enacted by an ordinance with an effective date of April 18, 2018 or later. § 42036.2(b).

A local stewardship program for covered products enacted by a local ordinance that has an effective date before April 18, 2018 may continue in operation, but such program and its participants cannot receive or benefit from moneys from the Pharmaceutical and Sharps Stewardship Fund or the Pharmaceutical and Sharps Stewardship Penalty Account established pursuant to the Act, including funds collected as administrative fees or enforcement costs. § 42036.2(c).

Enforcement

CalRecycle may impose penalties on any covered entity, program operator, stewardship organization, or authorized collector that sells, offers for sale, or provides a covered product in violation of the law. § 42035.2(a)(1). The amount of the administrative penalty cannot exceed \$10,000 per day unless the violation is intentional, knowing, or reckless, in which case the penalty shall not exceed \$50,000 per day. § 42035.2(a)(2). Any penalties collected pursuant to these authorities shall be deposited in the Pharmaceutical and Sharps Stewardship Penalty Account. § 42035.2(c).

Upon a written finding that a covered entity, program operator, stewardship organization or authorized collector has not met a material requirement of the Act, CalRecycle may, after affording the covered entity, program operator, stewardship organization or authorized collector a reasonable opportunity to respond to, or rebut, the finding, revoke a program operator's approval or require the program operator to resubmit a plan, or to require additional reporting relating to compliance with the material requirement of the Act that was not met. § 42035.4.

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