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California Readies for Statewide Extended Producer Responsibility for Pharma Waste

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The sale of needles (sharps) and pharmaceutical drugs in California is estimated to be on the order of \$50 billion per year. Significant concerns have been raised about adverse impacts of wastes generated from the use of these otherwise beneficial products, including impacts on human health, public safety and the environment. However, other than a variety of different drug and sharps take-back programs established by local governments, there is no uniform coordinated program for the take back and appropriate management of these wastes in California. Although the disposal of needles in solid waste was banned in California in 2008, needles are still discovered in the handling of solid waste—posing a serious threat to workers. This is about to change—with significant penalties for noncompliance.

California Senate Bill 212 was enacted in 2018. This legislation requires all businesses involved in the marketing of drugs or home-use medical sharps in California to develop and implement a statewide drug and/or home-generated sharps waste stewardship plan for the collection and disposal of home-generated drug and sharps waste—starting on or after January 1, 2022—**less than 3 years from now**.

- For drug stewardship plans, there must be five collection sites per county or one per 50,000 people, whichever is greater.
- For home-generated sharps stewardship plans, collection is done through prepaid mail-back containers, for which distribution is made or initiated at the point of sale with no cost to the consumer.

Why Extended Producer Responsibility? Organizations like the California Product Stewardship Council (CPSC), which sponsored SB 212, argue that Extended Producer Responsibility (EPR), also known as Product Stewardship, places a shared responsibility for end-of-life product management on the producers—and all other entities involved in the product chain—instead of just local government and the end user. CPSC maintains that EPR encourages product design changes that minimize negative impacts on human health, public safety and the environment at every stage of the product's life cycle by:

- Allowing the costs of waste treatment and disposal to be incorporated into the total cost of a product

- Placing the primary responsibility on the producer, or brand owner, that makes design and marketing decisions
- Creating a setting for the emergence of markets that reflect the environmental impacts of a product . . . to which producers and consumers will respond

Because many California cities and counties have already been adopting drug and/or sharps take-back programs, SB 212 preempts a local stewardship ordinance for drug- or sharps-covered products with an effective date on or after April 18, 2018. However, SB 212 also provides that the bill does not preempt a local drug or sharp stewardship program that took effect before April 18, 2018—but such pre-April 2018 local programs may not receive funding from the statewide program unless the local program is repealed. If a pre-April 2018 ordinance is repealed, SB 212 requires compliance with the statewide program within 270 days after the date of the local repeal. It is anticipated that most local governments will repeal their pre-April 2018 ordinances to be consistent with the statewide program.

SB 212 represents a compromise among numerous stakeholders, including the governor's office, CalRecycle, industry trade associations, CPSC, the California Retailers Association, the California Hospital Association, the Healthcare Distribution Alliance and others. No stakeholder got everything it wanted, but the bill was acceptable to nearly all of those parties involved so as to minimize active opposition. Pharmaceutical companies were largely persuaded because of the preemption provisions to control the burgeoning variety of different local government programs that were being developed.

CalRecycle, a department within CalEPA, has lead responsibility for implementing the statutory and regulatory framework, as well as overseeing each stewardship plan and enforcing the requirements on plans. The California State Board of Pharmacy is also involved. CalRecycle and the Board of Pharmacy are currently seeking public input on the regulations, which must be adopted and effective by January 1, 2021—less than 2 years from now. Compliance by covered entities is not required until at least one year after those regulations are adopted. Although it's not feasible to list all aspects of the program in this article, some of the issues being discussed as part of the CalRecycle rule-making include:

- Regulatory definitions
- Criteria for determining the entities covered by SB 212 and the regulations
- Submittal of pharmaceutical lists by covered entities
- Consumer educational duties of covered entities including signage and outreach
- Requirements and submittal of the product stewardship plans
- Requirements for reports, budgeting and record-keeping
- Enforcement provisions for administrative penalties of up to **\$10,000 per day for violations and up to \$50,000 per day for violations that are intentional, knowing or reckless**

Although CalRecycle is currently in the informal discussion stage of developing the proposed regulations, the formal rule-making process is likely to begin in earnest in the fall of 2019 so that the rules can be adopted and finalized by January 1, 2021.