



New California Medical Waste Law Impacts Out-of-State Manufacturers and Distributors with Costly Compliance Mandates

In late 2018, California passed a new law that will, in the near future, present sweeping changes to the pharmaceutical industry and certain medical device manufacturers. The new law amends the existing California Integrated Waste Management Act and is expected to be a boom for medical waste disposal companies who stand to obtain significantly more business. While the law was signed by the California Governor nearly two years ago, the regulations will go into effect in a few months (by January 1, 2021). The original bill, dubbed the “California Sharps and Drug Takeback Bill”, requires a manufacturer of covered drugs or home-generated sharps waste, to offer safe disposal methods for their customers’ used and unused products. The law has potentially sweeping affect because it encompasses all covered drugs and home generated sharps waste that are sold or offered for sale in California.

California lawmakers championed the new law by citing to information from CalRecycle that nearly a billion sharps are used by California consumers every year, and approximately a third of them are improperly disposed of in the trash. Another study conducted by the University of Massachusetts Lowell, estimated that nearly seven percent of sharps are flushed down a plumbing fixture. If those figures are correct, it means that every year in California alone, there are nearly 400 million sharps that have the heightened risk of injuring sanitation workers and/or the general public because they are not being properly disposed. In addition, many households dispose of prescription and nonprescription drugs by throwing them in the garbage or flushing them down the toilet, causing further health concerns.

Who does this new law affect? "Covered Entities" under the law include pharmaceutical and medical device manufacturers and distributors who sell or offer for sale their products the State of California. "Covered Products" include prescription and nonprescription drugs and home generated sharps waste, such as needles, lancets and other devices used to pierce the patient's skin for the delivery of medication. Under the new law, Covered Entities are obligated to engage in a complex and costly stewardship plan for the takeback of covered drugs and home-generated sharps waste from households that also requires an annual payment and report to CalRecycle, and registering its covered products. Once the stewardship plan is submitted, CalRecycle will review the plan and has the ability to approve, disapprove, or conditionally approve the plan. The stewardship plans must be submitted to CalRecycle by July 2021 and the take back programs are anticipated to be in place in late 2022 or early 2023.

The law does provide for a mail back program of the applicable sharps waste for any counties where there is not an authorized collection site. The Covered Entity must make appropriate arrangements for the mail-back container to be of a sufficient size to hold all of the affected product purchased by the customer and the container must be provided for free, be preaddressed and include prepaid postage.

CalRecycle has the ability to impose stiff penalties against those companies who violate the law, which include penalties of up to \$50,000 per day if a violation is intentional, knowing or reckless (or otherwise up to \$10,000 per day).

While the California law potentially has wide-spread effects, medical device and pharmaceutical companies are not obligated to comply with the law with respect to sales that occur outside of the State of California. Nonetheless, the standards set by the California legislature may quickly become an industry best practice for medical waste disposal and other states may also follow suit.

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