

CLIENT ALERT

Pharmaceutical Take-Back Program Deadlines Are Here

Nov.12.2014

Less than one week remains before the November 14 deadline for drug producers—including veterinary drug producers—to comply with the first stages of Washington State's King County drug take-back and disposal program. This program is one of two first-in-the-nation programs to require drug manufacturers to shoulder the costs of organizing and implementing a drug take-back and disposal program for all county residents. Its progress will likely encourage more laws that place the primary responsibility on manufacturers for end-of-life management of products, whether pharmaceuticals or other consumer goods.

In late September, the plan's path forward was cleared of several obstacles that previously delayed implementation. First, the DEA published a final rule allowing the return of controlled substances. Then, the Ninth Circuit Court of Appeals issued a decision upholding a similar [take-back program in California's Alameda County](#). In response, King County lifted the voluntary hold on its own program.

Pharmaceutical producers that have delayed registering for either program must take immediate action. In particular, manufacturers that have not registered in Alameda County should do so as soon as possible. Non-compliant drug producers will be subject to written warnings and civil penalties of up to \$1,000 or \$2,000 per day in Alameda and King Counties respectively. Below, we discuss the recent developments and what they mean.

Ninth Circuit Decision

On September 30, the federal Ninth Circuit Court of Appeals [unanimously upheld Alameda County's Safe Drug Disposal ordinance as constitutional](#). The Court found there was no violation of the dormant Commerce Clause succinctly concluding:

The parties agree that the Alameda County Safe Drug Disposal Ordinance constitutes a "first-in-the-nation" ordinance. Opinions vary widely as to whether adoption of the Ordinance was a good idea. We leave that debate to other institutions and the public at large. We needed only to review the Ordinance and determine whether it violates the dormant Commerce Clause of the United States Constitution. We did; it does not.

The U.S. Supreme Court's two-tiered test for dormant Commerce Clause violations formed the basis of this analysis. In looking at whether the law impeded interstate commerce, they found no discrimination since the law applied uniformly to all manufactures selling in Alameda County. In applying the balancing test, they weighed the burden against the benefits and found that the industry would not be prevented from selling pharmaceuticals in the county.

Recent Happenings in APRM November 2014

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- [Pharmaceutical Take-Back Program Deadlines Are Here](#)
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- [FTC Invokes "Deception" Authority Under Section 5 to Try to Curb "Patent Troll" Behavior](#)
- ["Made in America": Qualified Claims and New Class Actions in California](#)

Intersection with King County's Take-Back Program

Because the Alameda County lawsuit was similar to another lawsuit filed regarding King County's program, King County had extended certain deadlines until after the Alameda case decision. However, King County wasted no time in proceeding with its program once the Ninth Circuit decision was issued.

On October 2, King County officials sent an email notice setting the new implementation deadlines for the King County Secure Medicine Return Regulations. The program is proceeding with the following deadlines despite another pending lawsuit:

November 14, 2014: identify plan operator and notify pharmacies

This deadline is for producers or groups of producers to (a) identify in writing a stewardship plan operator, including contact information, and (b) notify all retail pharmacies and law enforcement agencies in King County of the opportunity to participate as a drop-off-site and the process to form an agreement with the stewardship plan. (BOH Section 11.50.040.D.1 and 2.)

February 12, 2015: submit plan and fee

This deadline is for producers to submit a proposed stewardship plan and plan review fee. (BOH Section 11.50.040.D.3 and 11.50.120.A.)

The DEA final rule

The Ninth Circuit decision came less than a month after the Drug Enforcement Administration's release of its Secure and Responsible Drug Disposal Act regulation. Published on September 9, this rule expands collection options for unused controlled substances and medicines, including at pharmacies, mail-back, and drop-boxes at long-term care facilities. The Alameda County take-back program is expected to expand to encompass controlled substances in the wake of these regulations.

Comparing the county programs

The two county programs are similar in their intent and general requirement that all "producers" manufacturing covered drugs sold in the county develop or contribute to a privately administered drug take-back program. There are two notable differences, however.

Although King County's deadlines were delayed, Alameda's were not. The Alameda program required producers to submit annual stewardship plans by May 1, 2014. Failure to submit a plan by the deadline could trigger a written warning, an administrative citation and a per-day fine of up to \$1,000. As the Alameda case was pending since that registration date, we believe that no fines were imposed on unregistered manufacturers. However, unregistered manufacturers should do so now that the Ninth Circuit has rendered its decision upholding the program.

In addition, while both counties' programs cover prescription drugs and most veterinary medicines, King County's program also includes all over-the-counter drugs.

Key points of both counties' laws include:

- Residents will be encouraged to drop, free-of-charge, their leftover and expired medicines in secure boxes conveniently located in retail pharmacies or law enforcement offices throughout the county;
- Collected medicines would then be destroyed by incineration;
- Drug manufacturers selling medicines for residential use in the county would be required to run and pay for the program; and
- The county would oversee the program to ensure its effectiveness and safety.

Veterinary Pharmaceuticals Included

What may have escaped the notice of some covered drug manufacturers is that veterinary pharmaceuticals are not exempted. King County's program includes veterinary pharmaceuticals in the definition of "covered drugs." Specifically, "drugs" are defined to include "substances used for the diagnosis, care, mitigation, treatment of prevention of disease in humans or other animals" (emphasis added). The regulators defined "covered entities" to generally mean residents of King County, so pet prescription products "used" by these residents on their pets are arguably included (except for pet pesticide products such as flea collars or powders or topical applications, which are specifically excluded).

Alameda County's program defines "drugs" similarly to include veterinary pharmaceuticals, and it includes parallel exclusions for pet pesticide products.

What this means

Accordingly, the pharmaceutical industry must prepare for compliance with the take-back programs in Alameda and King Counties. This decision will encourage more laws that place the primary responsibility for end-of-life management of products on manufacturers. With this Ninth Circuit opinion, we expect to see many more pharmaceutical take-back initiatives in California and across the country, as well as additional extended producer responsibility laws for a vast array of consumer products.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

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