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NEWSLETTER

Pharma Product Stewardship Becomes Real

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The U.S. Supreme Court's May 26, 2015 decision not to reconsider the pharmaceutical industry's challenge to Alameda County, California's unwanted medicine stewardship ordinance[1] is about to have a real-world, practical effect. In February 2015, Alameda County's Department of Environmental Health approved one multiparty plan and one single company plan to comply with that ordinance, but the full impact of the multiparty plan is not scheduled before February 2016. In the meantime, however, the stage has been set for the implementation of a different multiparty "standard" stewardship plan in King County, Washington (Seattle) a month earlier.[2]

Although the case that reached the Supreme Court challenged an ordinance adopted in Alameda County in 2012,[3] King County also has been moving aggressively to implement a used drug program. Its ordinance was adopted in 2013. In both jurisdictions, drug manufacturers must bear the cost of collecting and destroying unwanted pharmaceuticals.

San Francisco, San Mateo, Santa Clara, and Marin counties also have adopted similar ordinances since the Ninth Circuit's decision.[4] In addition, at least half a dozen other California jurisdictions, including Los Angeles and San Diego, reportedly are studying proposals, and similar ordinances are expected to be presented elsewhere around the nation.

However, "product stewardship" in this arena presents a unique challenge. Few worry about the security of collected used soda bottles, batteries, carpets, or paints. But collected drugs are another matter. The Drug Enforcement Agency eased the way to implementation in September 2014, when it adopted a new rule governing collection and disposal of controlled substances.[5] Among other things, that rule authorized retail pharmacies and others to

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become "authorized collectors" of unwanted drugs, subject to a number of security requirements, and extended the time by which drug destruction is required to allow implementation of reverse-distribution systems. Another potential impediment to implementation is expected to be overcome within the next few weeks, with EPA finalization of an amendment to the Resource Conservation and Recovery Act (RCRA) "universal waste rule" that simplifies handling of used drugs that qualify as "hazardous wastes."[6]

The Alameda Ordinance

Alameda's ordinance mandates operation (and funding) of a program by "producers" to collect and destroy unwanted prescription drugs ("covered drugs").[7] "Producers" are defined as manufacturers of the drugs who sell, offer to sell, or distribute the drug in Alameda County, brand or trademark licensee or owners, or (in the absence of a person who falls into the two prior categories) the person who brings the drug into the county for sale or distribution.[8] Excluded, however, are retailers of store-brand products covered by the product's manufacturer and pharmacists.[9]

The mandated program(s) must accept all used covered drugs, regardless of who manufactured them, without charge, and arrange for the proper destruction of the drugs.[10] It authorizes both mail-back and retail collection, as well as collection at law enforcement agencies, and requires a substantial public education program.[11]

The King County Ordinance

King County's ordinance similarly imposes on "producers" the obligation to participate in (and fund) one or more collection and destruction programs. Unlike Alameda's ordinance, however, it applies to both unwanted prescription and unwanted over-the-counter "drugs" and expressly anticipates both "standard plans" and "individual plans" to collect. "Producers" are defined as manufacturers "engaged in the manufacture of a covered drug sold in or into King County, including a brand-name or generic drug," but with exclusions for retailers' store-brand products covered by the product's manufacturer, compounding pharmacists, and wholesalers.[12] "Drugs" is also broadly defined, and includes not only articles recognized by several authorities as pharmaceuticals, but also "substances intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or other (sic) animals" and "substances, other than food, intended to affect the structure or any function of the body of humans or other (sic) animals." However, medical devices and their components are excluded.[13]

Plans must provide "convenient collection" opportunities for all King County residents, potentially including secure collection at retail pharmacies and law enforcement agencies, periodic collection events and a mail-back program, as well as secure transportation of collected materials to appropriate disposal facilities and destruction of the collected drugs.[14] They must also describe public education and promotional efforts and short- and long-term goals for collection amounts, education, and promotion.[15]

Approved Alameda County Plans

Two plans have been approved in Alameda County. One, submitted by Exelixis, Inc., is narrowly limited to a collection of a single, newly developed drug currently being used in Alameda County by only one patient. The other is a multi-party plan developed by Alameda MED-Project LLC, a company established by the pharmaceutical industry's Pharmaceutical Product Stewardship Working Group.

The Alameda MED-Project plan pointed to ambiguities in the DEA's September 2014 regulation to support the need for a one-year initial implementation period that focused on collection at law enforcement agencies and a dozen public take-back events, with retail pharmacy collection to be implemented in the second year, if sanctioned by DEA. The project's first annual report, due in February 2016, is expected to more fully describe how that program has been working and will be developed.

Pending King County Plans

The King County ordinance provides an iterative process for plan development and approval. Two entities have pursued approval as the standard plan: the King County MED-Project and Return Meds LLC. No other proposals were submitted. Both sponsors' original submissions were rejected, but both also have submitted revised plans.

The King County MED-Project is an analogue to Alameda MED-Project, another limited liability company established by the Pharmaceutical Product Stewardship Working Group. Return Meds LLC is a wholly-owned subsidiary of Call2Recycle, Inc., a not-for-profit company established more than two decades ago by battery manufacturers that operates a highly-successful used battery stewardship program in the U.S. and Canada. That program originally handled only used rechargeable batteries, but in recent years has expanded to cover used primary batteries in some jurisdictions.

Both plans propose placing collection kiosks in a number of publicly-accessible locations (retail pharmacies and law enforcement agencies), sponsorship of take-back events and operation of mail-back programs, and both include provisions intended to meet other requirements of the ordinance. The Return Meds proposal appears to be somewhat more ambitious, however. For example, it identifies 112 confirmed retail pharmacy collection locations and ongoing efforts to recruit others. For its part, King County MED-Project's plan says it will "initially target approximately 30 drop-off sites, expanding to approximately 65 sites, and ultimately targeting approximately 92 sites."[16] However, King County MED Project commits itself to up to 24 take-back events (presumably annually) to supplement drop-off site collections, while Return Meds appears to view events as a stop-gap until a comprehensive collection network is established.

What Happens Next?

The next developments in Alameda County should come in early 2016, after Alameda MED-Project submits its first annual report.

There may be earlier activity in King County, however. The King County Department of Public Health is committed to acting on the two proposals by October 10, and could do so earlier. And both plans seek approval as "the" standard plan. If only one is approved, all producers will be required to support it, unless

the sponsors of the rejected plan revise it to meet whatever deficiencies justified the Department's rejection. If the rejected plan is then subsequently approved, the Department will then treat it as an "independent" plan.

If both are approved, one presumably will be approved as the "standard plan" and the other as an "independent plan," but this is uncertain. It seems most likely that, in these circumstances, the King Count MED-Project plan would be approved as the standard plan, since it appears to be supported by a substantially larger number of producers than the Return Meds plan. But the decision rests with the Department of Public Health.

If both plans are approved, however, and both submitters move to implement their programs– regardless of which plan is denominated as the "standard plan" and which as "independent"–an interesting situation will arise. There presumably will be two parallel collection and mail-in networks put in place, and a practical need for cooperation on public collection events. Inevitably, however, each network will collect used drugs that originated from sponsors of the other network, and incur the resultant costs. King County's ordinance does not address the question of how, if at all, cross-reimbursements could be arranged.

In this respect, this ordinance contrasts dramatically with Vermont's 2014 used primary battery stewardship statute, H.B. 695.[17] That statute includes both a cross-reimbursement process and a private right of action with which one program can enforce it against another, as well as against producers who are sponsoring no program whatsoever. That provision no doubt reflects the longer experience of the battery industry with product stewardship mandates. Whether future used drug ordinances pick up a similar element may well be influenced by the forthcoming experience in Seattle.

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[1] *Pharm. Research & Mfrs. of Am. v. Cnty. of Alameda, Cal.*, 135 S. Ct. 2348 (2015).
[2] King Cnty. Bd. of Health R. & Reg. 13-03.1.
[3] Alameda Cnty. Health & Safety Code § 6.53.10.
[4] *Pharm. Research & Mfrs. of Am. v. Cnty. of Alameda*, 768 F.3d 1037 (9th Cir. 2014).
[5] 79 Fed. Reg. 53,520 (September 9, 2014).
[6] *See* Proposed Rule, Amendment to the Universal Waste Rule: Addition of Pharmaceuticals, 73 Fed. Reg. 73,520 (Dec. 2, 2008).
[7] Alameda Cnty. Health & Safety Code § 6.53.030(3).
[8] *Id.* § 6.53.030(14).
[9] *Id.*
[10] *Id.* § 6.53.050(A)(1).
[11] *Id.* § 6.53.050 (5), (11), (12).
[12] King Cnty. Bd. of Health R. & Reg. 13-03.1 § 5(P).
[13] *Id.* § 5(F).
[14] *Id.* §§ 6, 7.
[15] *Id.* § 7.
[16] King County MED-Project Plan, p.10.

[17] Vt. Stat. Ann. tit. 10, §§ 7581 *et seq.* (2015).