

RJO Update:
Retail Industry Trade Regulation and Environmental Law

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California Offers Relief to Retailers
Seeking to Reverse Distribute Pharmaceuticals

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Waste comprised of pharmaceuticals, which has been defined to include any prescription or over-the-counter human or veterinary drugs (other than those regulated by the federal Resource Conservation and Recovery Act ("RCRA") or California's Radiation Control Law ("CRCL")), has traditionally been considered to be a subset of medical waste under California's Medical Waste Management Act ("MWMA"). As such, retailers and health service providers that generate pharmaceutical waste through disposal of such products have been required to comply with stringent requirements regarding the storage, disposal, and transport of medical waste set forth in the MWMA.

Specifically, the State of California's Department of Toxic Substances Control ("DTSC") has, until recently, considered the routine process of returning non-saleable pharmaceuticals to the manufacturer or a reclamation service, otherwise referred to as "reverse distribution," to be a violation of the MWMA. Retailers routinely reverse distribute non-saleable consumer items, including over-the-counter and prescription drugs, for credit. DTSC's interpretation of reverse distributed pharmaceuticals as medical waste has had the unfortunate effect of preventing retailers, pharmacies, and other health service providers from receiving any credit for the return of usable, but non-saleable, pharmaceuticals, resulting in significant and unnecessary monetary losses to retailers and providers, while unnecessarily diverting useable products to landfills.

In an attempt to resolve this problem, Governor Brown signed into law Assembly Bill 1442 ("AB1442") on September 28, 2012. This new legislation primarily does two things. First, it excludes from the storage, disposal, and transport requirements of the MWMA pharmaceuticals being sent to reverse distributors. Second, it relaxes hauling requirements for pharmaceutical medical waste that is not reverse-distributed if the generator meets certain conditions.

How Specifically Does AB1442 Help Retailers?

The primary benefit of AB1442 is that the definition of pharmaceutical waste under the MWMA now specifically excludes any pharmaceuticals sent to reverse distributors licensed as "wholesalers of dangerous drugs" by the California State Board of Pharmacy under the Business & Professions Code (and additionally licensed as "permitted transfer stations" if the reverse distributor is located within the State of California).

As a result, any non-saleable pharmaceutical that is returned to a licensed reverse distributor (and that is not hazardous under RCRA or radioactive under the CRCL) is not considered

pharmaceutical or medical waste, and is therefore not regulated by the MWMA. This has the effect of allowing most non-saleable pharmaceuticals to be transferred to reverse distributors without fear of violating the strict disposal and transportation requirements for medical waste.

Other Beneficial Impacts of AB1442

Retailers that employ health care professionals who generate pharmaceutical waste are also eligible for another cost-saving measure by allowing for transportation of pharmaceutical waste without use of a registered hazardous waste transporter under certain circumstances. A retailer may either (1) apply for a limited quantity-hauling exemption that would allow it to transport medical waste itself to a parent organization or another health care facility for the purpose of consolidation before treatment and disposal, or (2) utilize common carriers to transport pharmaceutical waste to a permitted medical waste treatment facility or transfer station, so long as in either case, the retailer complies with various informational and document retention requirements.

Conclusion

The new pharmaceutical waste legislation provides retailers with a welcome avenue of relief from some of the costs of compliance with the MWMA, and minimizes the ambiguity of how non-saleable pharmaceuticals should be treated.

How We Can Help Your Company

Rogers Joseph O'Donnell has assisted many retail clients in complying with applicable hazardous and medical waste laws. If you have questions or issues related to compliance with federal and state hazardous and medical waste laws, Renee D. Wasserman (rwasserman@rjo.com), Robert C. Goodman (rgoodman@rjo.com), and Walter S. Chen (wchen@rjo.com) are available to assist with any such matters. Biographies and contact information are available at www.rjo.com.