

## Outside Counsel

## Expert Analysis

# DEC Initiative Targets Hazardous Waste At Pharmacy, Grocery, Big-Box Entities

In late 2014, the New York State Department of Environmental Conservation (DEC) announced a compliance initiative that will focus on Resource Conservation and Recovery Act (RCRA)<sup>1</sup> compliance at pharmacies, grocery stores, and big-box retail stores with respect to their handling of certain returned products, obsolete inventory, and other materials and wastes that are or may be regulated as hazardous wastes. But rather than just relying on traditional enforcement strategies that focus on unannounced inspections and formal enforcement actions for violations, the DEC has undertaken significant outreach and is making a concerted effort to work collaboratively to help the regulated community achieve compliance.

### RCRA Background

Waste materials are regulated hazardous wastes if they are specifically listed in the RCRA regulations or exhibit certain hazardous characteristics.<sup>2</sup> Listed wastes include, for example, certain pesticides and pharmaceuticals (such as warfarin and nicotine). Characteristic wastes include, for example, wastes that are ignitable (such as certain lighter fluids, alcohols, and acetone-based nail polish remover) or corrosive (such as household cleaning products that contain strong



By  
**Leslie M.  
Mauro**



And  
**Thomas M.  
Tuori**

acids or bleach). Another category of regulated hazardous wastes—universal wastes—includes fluorescent lightbulbs and batteries.<sup>3</sup>

As these examples illustrate, many everyday products sold at retail establishments may be regulated as hazardous wastes when they are disposed of. Thus, retailers could be subject to RCRA requirements if they handle and dispose of these types of materials. Depending on the volume of regulated hazardous waste an establishment generates, the requirements can include obtaining a RCRA identification number from the U.S. Environmental Protection Agency, using hazardous waste manifests (i.e., required shipping papers that identify the generator, type and volume of hazardous waste, and treatment, storage or disposal facility to which the wastes are being shipped) when shipping regulated hazardous waste, providing employee training, and, in New York State, paying certain hazardous waste fees and assessments.

In addition, there are certain storage and handling requirements, some of which are specific to universal wastes

(such as provisions requiring storage and handling of batteries to prevent leakage, storage and handling of fluorescent lightbulbs to prevent breakage, marking and labelling of universal waste containers, and compliance with accumulation time limitations).<sup>4</sup> Non-compliance with universal waste requirements is a common hazardous waste problem in both the retail sector and the broader regulated community generally.

Expired, unusable, and/or returned products become wastes when they are discarded or intended to be discarded. This is important to keep in mind in the context of “reverse distribution” and “reverse logistics” arrangements. Reverse distribution is, generally, the process by which retailers (and others, such as wholesalers and health care facilities) send expired, unusable or otherwise unwanted pharmaceuticals to third-party reverse distributors, who in turn determine if the pharmaceuticals can or should be returned to the manufacturers, sold for re-use, donated for re-use, or processed for disposal.<sup>5</sup> “Reverse logistics” is the name used for this same general process when non-pharmaceuticals are involved.<sup>6</sup>

In these types of arrangements, the generator—i.e., the retail establishment—may not be intending to discard such materials if they are being shipped to third parties for potential recycling pursuant to reverse distribution/logistics arrangements. The waste status of other materials handled by retail establishments may be clearer, especially when those materials are inherently waste-like, such as spilled products and

LESLIE M. MAURO is a partner at Harter Secrest & Emery and chairperson of the firm's environmental, land use and zoning practice group. THOMAS M. TUORI is an associate at the firm and was an environmental consultant for 16 years prior to law school. They are based in the Rochester office of the firm.

spill cleanup residues.

In the reverse distribution scenario, which is regulated by the federal Drug Enforcement Administration in addition to the potential regulation under RCRA, it is often the reverse distributor—not the retail establishment—that determines whether the pharmaceuticals are wastes or can be legitimately re-used. Reverse logistics arrangements are less regulated and controlled than reverse distribution arrangements, and the wide array of materials handled in the reverse logistics context means that it is more likely that retail establishments will have to make waste determinations as compared to the reverse distribution scenario.

### DEC's Compliance Initiative

The initial phase of the DEC's compliance initiative—the information outreach phase—began in November 2014 and is ongoing. The DEC hosted two briefing sessions for the regulated community to describe the new initiative, and it has issued guidance to assist retail establishments with their RCRA compliance efforts. The new DEC guidance documents are available on the DEC website.<sup>7</sup> These documents pertain to “facility compliance plans,” “facility employee training plans,” “reverse distribution/reverse logistics,” and “universal waste management,” and they are specifically tailored to the retail sector.

The second phase of the initiative—the voluntary compliance phase—is pending. During this phase, the DEC will encourage the regulated community to come into compliance with applicable RCRA requirements. The DEC has indicated that it will issue letters to pharmacies and other retailers advising them to bring their hazardous waste management activities into compliance and/or to seek assistance from the DEC with their compliance efforts under the DEC's new “commissioner policy 59—environmental audit incentive policy” (the audit policy).<sup>8</sup>

Pursuant to the audit policy, the DEC may reduce or waive penalties for eligible violations discovered dur-

ing an internal environmental audit or by the DEC as a result of compliance assistance efforts, promptly (generally within 30 days of discovery) and voluntarily disclosed, and then promptly (generally within 60 days of disclosure to the DEC) corrected.

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The DEC typically, but not always, seeks penalties in enforcement proceedings—especially when the violations or alleged violations are significant or when there have been similar compliance issues in the past. DEC penalties are comprised of two components: the “gravity” component and the “economic benefit” component.<sup>9</sup> The gravity component is based on the seriousness of the violations, the degree of harm caused by the violations, and the importance of the compliance issues in the overall regulatory scheme. The economic benefit component is based on the economic benefit that resulted from non-compliance, such as the present value of deferred capital or operating expenses.

If violations are eligible under the audit policy, the DEC will waive the “gravity” component of penalties and will consider waiving the “economic benefit” component if it is de minimis (less than \$5,000) or to the extent offset by pollution prevention expenditures that are not required by law. These are significant incentives and, as a result, self-reporting may be the best option in many circumstances.

The final phase of the initiative—the enforcement phase—will likely begin later in 2015. It will involve targeted RCRA compliance inspections at retail establishments and formal enforcement actions by the DEC if violations

are uncovered. This is the DEC's traditional enforcement approach. In this case, however, the DEC is relying on it as an option of last resort to force compliance at retail establishments that do not take advantage of the outreach and compliance assistance overtures.

Given the DEC's commitment to this new initiative and the real possibility of RCRA inspections in the near future—and enforcement actions if violations are uncovered—pharmacies, grocery stores, big-box retail stores, and other retail establishments in New York should review their waste streams and their reverse distribution and reverse logistics arrangements to determine whether they are properly managing regulated hazardous waste in full compliance with applicable RCRA requirements. If there are compliance gaps, the retailers should take the steps necessary to come into compliance and consider self-reporting any violations to the DEC pursuant to the audit policy.

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1. 42 U.S.C. §6901, et seq.
2. See 40 C.F.R. Part 261; 6 N.Y.C.R.R. Part 371.
3. See 40 C.F.R. Part 273; 6 N.Y.C.R.R. Subpart 374-3.
4. See 6 N.Y.C.R.R. §§374-3.2, 374-3.3.
5. See DEC's “RCRA-C Compliance—Reverse Distribution/Reverse Logistics” guidance document referred to in footnote 7.
6. See DEC's “RCRA-C Compliance—Reverse Distribution/Reverse Logistics” guidance document referred to in footnote 7.
7. See the following DEC websites:
  - “RCRA Compliance Information for Pharmacies and Other Retail Facilities,” <http://www.dec.ny.gov/chemical/99555.html>;
  - “RCRA-C Compliance—Facility Compliance Plans,” <http://www.dec.ny.gov/chemical/99580.html>;
  - “RCRA-C Compliance—Facility Employee Training Plans,” <http://www.dec.ny.gov/chemical/99639.html>;
  - “RCRA-C Compliance—Reverse Distribution/Reverse Logistics,” <http://www.dec.ny.gov/chemical/99644.html>;
  - “RCRA-C Compliance—Universal Waste Management,” <http://www.dec.ny.gov/chemical/99650.html>.
8. The DEC audit policy was issued in October 2013 and is available via the following DEC website: <http://www.dec.ny.gov/regulations/93791.html>.
9. See “Commissioner Policy DEE-1: Civil Penalty Policy,” dated June 20, 1990, and available via the following DEC website: <http://www.dec.ny.gov/regulations/25227.html>.