

NEWMOA Hazardous Waste Conference Call January 13, 2015

Topic: Results of a Survey of Hazardous Waste Management Practices at Small Independent Pharmacies in New Hampshire

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Participants: CT DEEP (8 people); MassDEP (2 people); ME DEP (1 person); NH DES (8 people); NJ DEP (3 people); NYS DEC (10 people); VT DEC (3 people); EPA Region 1 (2 people); EPA HQs (2 people); NEWMOA (1 person)

Call leader: New Hampshire DES

Note-taker: Mike Hudson, ME DEP with assistance from Terri Goldberg, NEWMOA

Background

Susan Francesco, NH DES presented the following summary of the results of a survey of HW management practices at small independent pharmacies in NH. During the summer of 2014, interns from NH DES visited or called 48 non-notified independent pharmacies in order to provide outreach and guidance. NH DES was interested in independent pharmacies due to issues found at NH hospitals, large numbers of chains notifying, previously notified chains regularly generating hazardous waste, and a large shipment from a non-notified independent pharmacy. A list of pharmacies with active licenses was extracted from the NH Pharmacy Boards website and any without active EPA ID#s were contacted by the interns. The list was primarily independent pharmacies, pill distribution/delivery companies, and one chain (Price Chopper). NH DES regulates Conditionally Exempt Small Quantity Generators (CESQGs), so the Agency wanted the playing field to be level. NH DES is interested in learning about how other states regulate independent pharmacies (if at all) and if they have anything helpful to share (i.e., experience, handouts, fact sheets, websites, tools, and others).

NH DES shared the checklist the interns used in the outreach initiative, a letter emailed prior to the visits, and a checklist for the facility prior to the call. The interns were not always able to get the questions answered or even speak with knowledgeable representative, but they left behind a package with informational handouts and ways to help them identify their hazardous waste. Of the 48 locations visited, 8 did not appear to be generating hazardous waste. After the intern visits, 15 have notified as hazardous waste generators (an additional two submitted SQG Self-Certification forms instead of Notification Forms). DES believes at least 21 more should also notify.

Because DES assumed that empty P-listed containers (e.g., warfarin) would require facilities to notify, the project focused on this. 28 of the visited pharmacies confirmed that they were disposing of empty warfarin (POO1) containers in the garbage or sending offsite for recycling. A few pharmacies (i.e., compounding, infusion services, and oncology) did not have warfarin, some used blister packs, and a couple had other ways of getting rid of their empty bottles. One location was sending back one warfarin pill in each empty container for reverse distribution, so they did not have any empty containers. For example, they may send back 10 empty warfarin bottles for reverse distribution, each with one pill inside. A couple other pharmacies said they would dispense warfarin to a customer in a bulk bottle and put the prescription label on that bottle (so they had no empty bottles as waste).

While nicotine (P075) usually makes the larger chains have to notify as LQGs, none of the independent pharmacies accepted returns of nicotine.

Some larger pharmacies have machines that automatically dispense the top 200 drugs. After a while, there is a tray at the bottom that catches pills that "miss". The one pharmacy that DES spoke with about this said that those pills go into infectious waste containers. Most of the other pharmacies said that dropped pills also go into the infectious waste, but the majority said they don't drop pills.

DES found that out of the 35 pharmacies that used reverse distribution, they used one or more of 10 different companies (including EXP-CA, GenCo-WI, Guaranteed Returns-NY, McKesson-CA, MEDTURNS-IN, Northeast Returns-ME, One Box Returns-?, Regis-?, Return Solutions-TN, and Rx Reverse Distributors-FL). It was hard getting information on this, but some reverse distributors bring boxes and shipping labels directly to the pharmacy and mail the returns back to the drug manufacturer from the pharmacy. Others send all returns back to the reverse distributor and have them go through it off-site. Sometimes they could document credit, sometimes they couldn't. Most of the materials shipped back are not hazardous, but the pharmacies were not tracking that or following through with credits.

Similar to reverse distribution for pharmaceuticals, 26 pharmacies that had retail waste used their wholesaler to return expired, returned, or damaged retail products. Some pharmacies used the same reverse distributor, some did not know who they used, and some used a different company. The seven DES discovered that took back retail waste were Burlington Drug-VT, EXP-CA, Guaranteed Returns-NY, HD Smith-NH, McKesson-CA?, Regis-?, Rx

Reverse Distributors-FL. The majority of them used HD Smith in NH. The interns were told that the pharmacies receive credit for anything returned, regardless of its condition.

One of the facilities that the interns visited was a doctors' office that specialized in oncology services. While they did not dispense any pharmaceuticals, they treated patients in the office. The interns found that they had been disposing of empty and expired P-listed materials in their infectious waste (illegal disposal). This office happened to have a licensed pharmacist, and there are probably many more like this one.

This initiative is still ongoing and more formal outreach and training should follow. DES would like to visit the wholesale (non-pharmaceutical) reverse distributor that we know of in NH (HD Smith). Since they are not notified as a hazardous waste generator in NH, DES would like to know what happens to any hazardous returns.

NH indicated that the survey was strictly a compliance assistance outreach effort and did not result in any enforcement actions. They may conduct inspections in the future and if they find problems they could do enforcement.

DES held a training event with HW coordinators at LQGs in the retail sector. The session went well. Most of the participants were from CVS.

Questions for Other States

Each state addressed the following questions:

1. Does your state regulate CESQGs?
2. Have you focused any outreach, inspection, or enforcement initiatives on independent pharmacies? Any plans to do so?
3. Does your state have any notified independent pharmacies that are shipping off hazardous waste pharmaceuticals and/or retail waste? If yes, do you know what types of hazardous wastes?
4. Does your state provide technical assistance fact sheets targeted toward pharmacies?
5. Do you have any strategies to deal with this sector as they are different then the larger retail chains?
6. Do you have any partnerships with your State Board of Pharmacy or another group that might be helpful?
7. Do you have any retail wholesalers in your state? Have you visited/inspected any? Results?
8. Any interesting or specific issues your state has with independent pharmacies that would be helpful to share?

CT DEEP

1. CT regulates CESQGs.
2. Outreach to pharmacies has occurred as CT has proceeded with its State Universal Waste Rule proposal and rule-making. CT has had stakeholder meetings on the proposed rule that include pharmacy representatives.
3. CT has received notifications from retailers, such as Price Chopper and Stop n Shop stores, apparently for pharmaceutical wastes as well as off-the-shelf product wastes.

4. CT does not have fact sheets specific to the pharmacy sector.
5. CT does not have a strategy for small independent retail pharmacies, other than the Universal Waste proposed rule. They are considering developing a strategy for this sector once the rule is in place.
6. CT has had stakeholder meetings as part of its rulemaking on its proposed Universal Waste rule. The State Board of Pharmacies and the Department of Health are involved in the stakeholder group for the rulemaking.
7. CT indicated it was not aware of any retail wholesalers. They have wholesalers for independent pharmacies that includes front end products. They call these “forward distributors” that also use reverse distribution.

ME DEP

1. ME regulates CESQGs.
2. ME is considering plans for outreach to corporate environmental representatives or contact persons listed in the Notification of Regulated Waste Activity (Handler information) for the retail pharmacies that have notified to provide compliance assistance information and assist the retail pharmacies in understanding and complying with Maine’s Hazardous Waste Management Rules and notification requirements. ME has received large quantity generator (LQG) notifications from 35 retail stores, per Biennial Reporting System (BRS) 2013 data, including 22 CVSs, 5 Targets, 5 Shaws, and 23 Kmart. These are not targeted during FY2015, but under the EPA 20 percent of the universe commitment requirements, some may be subject to inspection in FY2016. Maine has conducted a few inspections at retail pharmacies in the past, but those inspections were focused on waste photographic fixer from film development activities, which were common at that time.
3. ME’s manifest database is currently back-logged to 2013 and as a result current information is unavailable and has not been reviewed to determine if pharmacies, including small independents, have shipped hazardous waste pharmaceuticals or waste products.
4. ME does not have technical assistance fact sheets specific to the pharmacy sector.
5. ME has not developed sector-specific strategies for small pharmacies but is considering a compliance assistance outreach initiative.
6. There has not been a sector-specific initiative targeted towards pharmacies or associated partnerships, although a compliance assistance effort is under consideration.
7. ME has one Walmart Distribution Center that might operate similar to a retail wholesaler. ME has inspected this distribution center several years ago in response to a complaint involving an alleged discharge of waste.

MA DEP

No report available.

NJ DEP

1. NJ regulates CESQGs the same as the federal regulations; implements federal rules by reference.
2. NJ has 300+ regulated pharmacies, with the majority being CVSs, Rite Aids, and Walgreens. A handful of independent pharmacies are registered. Enforcement actions

have been taken against CVS, Walgreens, Rite Aid, and ShopRite. Enforcement actions include compliance assistance provisions. NJ has done compliance assistance outreach, advising pharmacies on Notification issues, including LQG /generator status determinations, and that for P-listed wastes, like Warfarin. Generators do not need to count the weight of containers toward generator status. No outreach planned for independent pharmacies.

3. No information on waste shipments is available.
4. NJ does not have technical assistance fact sheets targeted to the pharmacy sector. The NJ Department of Health has a “no flush” rule for pharmaceuticals and associated guidance.
5. NJ does not have a sector specific strategy for retail pharmaceuticals.
6. NJ does not have a partnership with the Board of Pharmacy.
7. NJ had a few reverse distributors, but it is believed that three of those have shut down; one might still exist.
8. Retail pharmacies have not been specifically targeted as a sector.

NYS DEC

1. NY regulates CESQGs like the EPA.
2. Have had meetings with the Retail Council – encouraging retailers to enter NY’s environmental audit program for inspection deferrals.
3. Some independent pharmacies have shipped hazardous waste.
4. Technical assistance for retail sector under development and being shared with sector.
5. Strategies for small pharmacies different from large?
6. Partnership with other state agencies in addressing this sector and pharmaceutical wastes, including Attorney General’s Office, Department of Corrections, and others. There is a State Pharmaceutical Workgroup of these agencies. The group meets regularly to coordinate activities. Does not have a partnership with the Board of Pharmacies.
7. Retail Wholesalers – NY refers to reverse distributors as reverse logistics. There is one major reverse distributor in the State that they have inspected. NY has not targeted this sector. NY has experience with reverse logistics company “Guaranteed Returns”. For controlled substances there is a lockdown area, hazardous waste determinations, and credit vs. non-credit assessment. NY assesses product-like vs. waste-like criteria for legitimate reverse distribution. Reverse Distributors return waste-like items to generators, for handling as waste. Product-like items must be in original containers. Not being too stringent on product-like vs. waste-like assessments in gray area circumstances.

NYS DEC Region 2 commented that it inspected Guaranteed Returns in 2012 and found boxes and bags of pills and sharps, not in original containers, out-of-compliance. Draft Order issued.

VT DEC

1. Regulates CESQGs.
2. VT has not focused on this sector. Has one independent pharmacy with an EPA ID #.
3. Similar answers to Maine (ME) in regards to questions posed by NH.
4. No technical assistance developed for this sector.
5. May consider some future initiatives after EPA adopts its pharmaceutical rule.

EPA Headquarters

- CVS enforcement cases in Midwest, MN, and NM.

- Drug Quality Security Act (DQSA), which is implemented by FDA ensures pedigree of drug.
- CVS claiming DQSA pre-empts RCRA. US FDA has indicated that the DQSA preemption is limited to state pedigree. FDA indicates that the preemption provisions intent is not to preempt RCRA. Google DQSA (Sections 525 and 526).
- EPA not doing much on independent pharmacies; focusing on rulemaking. The trade group for independent pharmacies visited EPA HQs before the DEA rule was finalized. They focused on discussing collection.

FDA

- Hazardous waste compounds in products – Men's Hair coloring agents (lead acetate), mercury in vaccines.
- Thimerosal – FDA website information.
- Mercuric acetate as preservative in nasal spray and eye drops may be high enough to be hazardous waste for TCLP.