

NEWMOA Hazardous Waste Conference Call January 10, 2017

Topic: Pharmaceutical Waste – Education and Outreach to Pharmacies and Health Care Facilities on Compliance

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Any comments expressed by participants should not be considered legal opinions or official EPA or State positions on a particular rule, site-specific matter, or any other matters. Participants' comments do not constitute official agency decisions and are not binding on EPA or the States. For exact interpretations of a State's or EPA's RCRA regulations, rules, and policies, NEWMOA recommends that readers of these notes contact the appropriate hazardous waste program in the State's environmental agency or EPA Headquarters or EPA Regional RCRA staff.

Participants: CT DEEP (4 people); ME DEP (1 person); Mass DEP (5 people); NH DES (9 people); NJ DEP (3 people); NYS DEC (16 people); RI DEM (1 person); VT DEC (3 people); EPA HQ (1 person); EPA Region 1 (1 person); NEWMOA (2 people)

Call leader: New Hampshire DES
Note-taker: New Jersey DEP

States represented during this teleconference included Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York and Vermont. EPA Region I and Headquarters were also on the call.

Topic was chosen as there continues to be increased attention on the proper management of pharmaceuticals and health care facility compliance. EPA published a proposed rule on the Management of Hazardous Waste Pharmaceuticals on September 25, 2015, and has received many comments that need to be addressed (including the NEWMOA comment letter dated December 22, 2015). The purpose of this call is to review what NEWMOA states are doing with this sector in terms of outreach, technical assistance, compliance, and enforcement.

Note: NEWMOA has held numerous calls related to the health care facility sector and pharmaceuticals over the years that can be reviewed on the "members only" section of the website. In addition, a handout from the 2013 NEWMOA's EPA Region 1 live training presentation on "Common Violations at Health Care Facilities" is available on the website.

Question 1: Education/Outreach provided to this sector?

NHDES: The New Hampshire Hospital Association and New Hampshire Hospitals for a Healthy Environment (NH3E), has had NHDES staff present to their members over the years at their quarterly meetings. Presentations have included hazardous waste management, top violations at hospital inspections, questions and answers on hazardous waste, and the NH Solvent wipes rules. NH3E has these meeting presentations on their website available to the public. In addition, the NHDES P2 Program has worked with NH3E and has provided guidance as questions come up on pharmaceutical waste.

As NHDES regulates this sector as any other hazardous waste generator, health care facilities that are notified as large quantity generator (LQG) or small quantity generator (SQG) are required to attend the annual Hazardous Waste Coordinator training and become certified. Although specific training on pharmaceuticals is not provided, NHDES trains attendees on proper hazardous waste determinations, generator calculations, and hazardous waste storage. Current certified coordinators have the option to attend an advanced retail module that is held four times a year; this module has a presentation/discussion on pharmacy wastes that includes waste counting/container weight.

Question 2: Technical assistance for this sector?

The NHDES P2 Program maintains a healthcare webpage with guidance on pharmaceuticals, hazardous waste classifications, and frequently asked questions (FAQs). NHDES and EPA interpretative letters (e.g., epi salts, returned pharmaceuticals) can also be found on this webpage. NHDES maintains a Hazardous Waste Assistance Hotline for the regulated community to call with questions (603-271-2942) to provide additional technical assistance on questions.

Question 3: Compliance inspections of this sector?

NHDES has inspected all of the health care facilities (e.g., 13 acute care hospitals) that have notified as LQGs. NHDES has cited some health care facilities for failing to identify certain pharmaceutical wastes as hazardous wastes (i.e., inadequate hazardous waste determination) and shipping hazardous waste pharmaceuticals to unauthorized facilities (i.e., solid waste, sewer, infectious waste). Fines and penalties have been the result of some of these inspections.

Question 4: Given that EPA has a proposed rule, has your state handled this sector and waste stream any differently than the current regulations for compliance purposes?

NHDES handles this sector and this wastestream under the current regulations. NHDES inspects 10 percent of the LQG universe and health care facilities that are LQGs are subject to these inspections. Since the proposed rule has yet to be finalized, NHDES regulates this sector under the current regulations.

Question 5: Enforcement actions/penalties to this sector for this wastestream?

NHDES

Concord Hospital – 2009 inspection. Failed to identify certain pharmaceuticals as hazardous waste and shipped to an unauthorized facility (i.e., solid waste incineration, infectious waste facility), \$205,000 penalty in 2012.

Catholic Medical Center – 2010 inspection. Failed to identify certain pharmaceuticals prior to 2010 as hazardous waste, and shipped to unauthorized facility. \$205,000 penalty in 2013.

Cheshire Medical Center – 2013 inspection. Failed to identify certain pharmaceuticals prior to 2010 as hazardous waste and shipped to unauthorized facility (i.e., infectious waste facility, sewer, solid waste). \$200,000 penalty.

Connecticut

- Has a very large outreach program (e.g., web information, training, involvement with professional organizations, guidance documents, information letters)
- Performed inspections at various facilities
- Issued notices of violation (NOVs) and enforcement actions with penalty
- Proposing U-waste type regulations for these generators

Maine

- Has been working with the hospitals to assist them with compliance
- Attend annual hospital organization meetings
- Performed 32 compliance inspections in last 7 years
- They have just started inspecting the retail sector
- 5 – 10 percent of pharmacies are LQGs
- Treat these generators like all other generators
- Have had enforcement actions with penalty

Massachusetts

- Have had an outreach program since 2006
- Performing multi-media inspections at hospitals
- Participate in roundtable discussions and conferences
- Have been doing inspections at retail establishments
- Acute care hospitals seem to be in good shape
- Retail establishments have many issues
- Issued NOVs and enforcement actions with penalty

New Jersey

- Has performed compliance assistance visits and seminars
- State has own Regulated Medical Waste (RMW) rules that cover all RMW generators no matter what size (i.e., hospitals, doctors, dentists, and tattoo parlors)
- A facility that generates RMW (at any quantity) must register
- Many of these facilities are also SQGs or LQGs
- Have inspected generators at all levels from dentists to large hospitals
- Issued NOVs and enforcement actions with penalty
- Treat these generators like all other generators

New York

- Currently has moratorium on inspecting pharmacies

- Preparing new environmental audit program for this sector
- Have not yet performed inspections of these facilities
- Enforce “Subpart C” regulations in NY
- Have a drop box initiative for dropping off expired pharmaceuticals

Rhode Island

- Has been working with the hospitals to assist them with compliance
- Has an outreach program
- Issued NOVs and enforcement actions with penalty

Vermont

- Presented at annual hospital organization meeting in 2013
- Performed outreach at solid waste facilities
- Informational letters have been issued to generators
- On line training available to SQGs
- Relatively small universe
- Have been doing inspections
- Issued NOVs and enforcement actions with penalty