

Notes

NEWMOA Hazardous Waste Conference Call

February 26, 2013

Topic: Roles of DEA, States & EPA in Management of Pharmaceutical Waste; Training Pharmacists in Proper HW Waste Handling

Disclaimer

NEWMOA organizes regular hazardous waste monthly conference calls or webinars so its members, EPA Headquarters, and EPA Regions 1 and 2 can share information and discuss issues associated with the implementation of the Resource Conservation and Recovery Act (RCRA), compliance assistance, enforcement, and other topics. Members of the group prepare draft notes of the calls for use by those members that were unable to participate and for future reference by the participants. These notes are intended to capture general information and comments provided by the participants and are not a transcript of the call. NEWMOA provides the participants on the calls with an opportunity to review drafts of the notes prior to posting them on the members' only area of the hazardous waste page on the NEWMOA website. NEWMOA staff makes all recommended corrections to the notes prior to posting.

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

Participants: CT DEEP (15 people); Maine DEP (4 people); MassDEP (5 people); NH DES (9 people); NJ DEP (2 people); NYS DEC (16 people); RI DEM (1 person); VT DEC (4 person); EPA Region 1 (4 people); EPA Headquarters (2 people); and NEWMOA (1 person).

Draft notes prepared by NYSDEC with help from NEWMOA.

Terri Goldberg opened the conference call with some general "housekeeping" items. She announced that the next call will be held on March 12th. The topic is "CRT Glass Processing: Incorporating the Requirements and Addressing Exclusions." Maine had volunteered to be the lead state with New Hampshire as a backup. Someone from Maine will get back to Terri with a decision on their involvement. Rhode Island is the note-taker.

Terri also gave a summary of the results of the NEWMOA note-taking survey. The survey showed a strong interest in continuing documentation and note-taking for the conference calls. Respondents indicated that they use the posted notes in the private section and consider them to be a useful resource. There is some interest in taping the calls to verify information in the minutes. However, there are some strong objections to taping. Massachusetts commented that on advice from general counsel, they might no longer be able to participate if the calls were taped. There was no strong desire to transcribe the tapes, and Terri noted that this would take

significant time and resources that are not currently available at NEWMOA. The decision is for NEWMOA to continue with the current note-taking system.

Pharmaceutical Waste Management

Connecticut was the lead state for the conference call. They supplied the following agenda items:

- Describe and summarize CT's recent large enforcement settlement with CVS (which included, in large part, pharmaceutical waste management issues).
- Where CT is headed in terms of pharmaceutical waste management (i.e., state-only Universal Waste Rule).
- CT's position on pharmaceuticals sent to reverse distribution facilities (i.e., return centers).
- Recent Large Quantity Generator (LQG) notifications by large retail pharmacy chains (e.g., CVS, Target, and Rite-Aid).
- Review of proposed Drug Enforcement Agency (DEA) regulations.
- Interface with DEA on controlled substances.
- Proposed bill in CT regarding disposal of pharmaceuticals.
- CT outreach efforts to pharmacists.

Connecticut

Michele DiNoia of Connecticut DEEP discussed the first three items. She is the lead engineer for a CVS enforcement case that was issued in January 2013. She reviewed the history of the case. In 2005, Connecticut did an inspection at a CVS store located in Southbury, CT to determine whether they were in compliance with hazardous waste regulations regarding spent photo processing waste. At that time, CVS sent spent solutions offsite for recycling. The inspectors found that they were out of compliance with many facets of RCRA. A Notice of Violation (NOV) was issued in August, 2005. There was a lot of discussion between DEEP and CVS/Kodak as a result of the NOV. CVS did not think they needed to comply because of the precious metal exemption in 40 CFR 266.70. Connecticut DEEP disagreed with their position because the silver value did not provide a net financial return to the generator (i.e., CVS).

In 2007, DEEP conducted inspections of CVS store locations in Clinton and Coventry. Those CVS's were managing spent photo waste as hazardous waste due to silver. However, other RCRA regulations were not being met. In April, 2007 DEEP sent NOV's to those locations. The next year, DEEP actively attempted to get CVS into compliance. CVS did not correct the violations in the NOV's. In late 2008, additional and repeat inspections were conducted at seven stores in Connecticut. During those inspections, DEEP examined how the CVS stores were managing spent photographic processing chemicals, waste pharmaceuticals, Universal Wastes, recyclables, and non-saleable consumer products. The inspectors found that there was a systematic misunderstanding of the applicability of the Connecticut RCRA regulations at all of the stores. In June 2009, NOV's were issued to all seven stores. Violations included failure to make hazardous waste determinations, manifesting and Land Disposal Restrictions (LDR) notification violations, violations associated with the inspections of hazardous waste container storage areas and safety and emergency equipment, and failure to comply with inspection logs requirements. There was no training for RCRA. Other violations included having no emergency coordinator, aisle space violations, emergency response information not posted, satellite accumulation area (SAA) containers open, no markings on SAA containers, and no impervious

base or secondary containment in the hazardous waste container storage area. Numerous storage areas had been moved from outside to inside of buildings without closure, offering hazardous waste to unpermitted transporters, and offering to transporters and facilities with no EPA ID number. There was a systematic lack of compliance with universal waste regulations for e-waste and lamps. They were also not complying with Connecticut recycling laws.

In 2010, DEEP started drafting consent orders for the seven individual store locations and for the corporation. The initial calculated penalty and economic benefit was \$2-3 million. There were a number of challenges during the negotiations, most significantly, CVS wanted to correct all of the violations before signing the consent orders, but Connecticut wanted agreement on consent order language first. In the spring of 2012, DEEP and CVS began having weekly conference calls. In October 2012, an agreement was reached. The individual store consent orders require a return to compliance and submission of a future compliance plan. The corporate consent order includes:

- a \$300,000 cash penalty plus a \$500,000 SEP,
- a requirement for closure of about 12 hazardous waste container storage areas,
- implementation of pharmaceutical waste best management practices (BMPs) at all stores (145) across Connecticut, and
- development of a statewide environmental management systems (EMS). CVS considers this a pilot, and they hope to roll out the EMS to all CVS stores across the U.S. (approximately 7500 stores nationally).

Finally, there will be 20 unannounced compliance audits for hazardous waste and recyclables.

BMPs for pharmaceuticals include:

- Waste pharmaceuticals may only be sent to reverse distributors that are licensed by the CT Department of Consumer Protection, registered with the DEA, and have an EPA identification number;
- All other waste pharmaceuticals not going to reverse distributors must be managed as hazardous waste, including pills that have been dropped on the floor;
- All stores must have an EPA ID number;
- Once a credit has been determined for all waste pharmaceuticals, all will be destroyed by incineration at a hazardous waste treatment facility or municipal incinerator;
- While on site, segregated from all other wastes, labeled to show non-dispensable pharmaceutical, and stored in structurally sound closed containers;
- shipping documentation from each CVS store to reverse distributor to include name of pharmaceutical, and quantity;
- Documentation to show that they were received;
- Reconciliation of shipping records;
- Maintain documentation for three years or until consent order has been noted in compliance, whichever is later;
- Notify Connecticut of change in pharmaceutical reverse distributor used;
- All other non-dispensable pharmaceuticals managed as hazardous waste;
- All pills dropped on the floor managed as p-listed waste.

Connecticut DEEP hopes to do inspections at other pharmacy chains in Connecticut. Three Target Stores have been inspected. They are better than CVS but not satisfactory. They have done some pharmaceutical take backs.

Connecticut DEEP plans to propose a Universal Waste Rule for pharmaceuticals in Connecticut, with “enhanced BMPs”, and they will publish the rule and the BMPs.

Connecticut DEEP held the CVS’s to SQG requirements during the enforcement process, but since that time they have re-notified as LQGs at about 40 CVS’s. That number is expected to go up.

Under the consent agreement, CVS does not have to manage pharmaceuticals sent to reverse distribution for credit as hazardous waste, but if CVS finds that they are not receiving credit for particular pharmaceuticals, they will have to manage them as hazardous waste. In Connecticut’s experience, the majority of waste pharmaceuticals are going to reverse distributors.

Connecticut agreed to provide NEWMOA with a copy of the corporate and a store-specific ACOP, which details the violations so that Terri can share with the other states.

A participant asked about what happened with the photo waste. DEEP found that 13 stores did not have connections to a sanitary sewer system so are managing photo waste as hazardous waste at these locations. They are now in compliance. Remaining stores have registered for Connecticut general permits for photo processing and must meet effluent limits for silver before discharge. None of the stores are managing photo processing waste under the precious metal exemption. All of the older stores still have wet photo processes. The new big-box stores are going digital.

New Jersey reported that they have inspected CVS, Target, and Walmart stores and found similar violations. CVS is putting together something corporate-wide. New Jersey is in the process of issuing order; there are quite a few stores. New Jersey DEP will share their orders once they are issued.

NYSDEC has inspected nine CVS stores over a two-year period. The stores went from uniformed and out-of-compliance to starting to come into compliance for pharmaceuticals, and are going digital only for photo-processing waste. They are coming into compliance for non-saleable commercial waste. New York agreed to look into sharing the documentation of their inspections with others and will let Terri know what they can share.

CVS has substantially upgraded their scan guns. After scanning a non-saleable consumer product, the CVS employee can tell if an item can be salvaged, whether it is a hazardous waste, Connecticut regulated waste or can be disposed in the trash. [Note: Connecticut has a special waste category called, “Connecticut regulated waste” with specific requirements, including licensed transporter requirements if sent within Connecticut to a licensed Connecticut facility. This segregated waste is kept out of the municipal waste stream.]

Where is Connecticut headed?

State-only Universal Waste Rule that will encompass the corporate consent order BMPs in addition to adding more stringent requirements. When/if adopted, CVS will have to come into compliance with those more stringent BMP requirements.

A participant asked whether non-hazardous wastes will be included in the rule. DEEP will require hazardous waste pharmaceuticals to comply with the universal waste rule. They may include chemotherapy drugs and OSHA/NIOSH-recognized drugs as well. Some Connecticut-regulated wastes and non-RCRA hazardous may be pulled into Universal Waste Rule because of concerns (statutory authority in CT statute 22a-454 - described as “RCRA lite”).

A participant asked about how they can pull in non-RCRA waste. Connecticut responded that they have statutory authority that allows them to do so.

Rhode Island reported that they also plan to make chemotherapy wastes state-only hazardous wastes. Some state-only definitions are currently difficult to use for pharmaceutical wastes.

A participant asked about whether the Connecticut Universal Waste Rule will change the standards for P and U- listed waste pharmaceuticals. Connecticut explained that the universal waste rule allows standards that are less than full RCRA. The CT Universal Waste Rule will allow stores to not have to operate as LQG’s. However, Connecticut plans to write regulations that go farther than what EPA previously proposed. Pharmaceutical waste would be regulated from point of generation, not point of receipt at reverse distributor. Standards would include container management and tracking requirements.

Connecticut is hoping to have an internal draft of their Rule sometime this summer and do early public outreach.

Rhode Island commented that they list silver fixer in the Rhode Island Universal Waste regulations.

A participant asked about how the various issues with these requirements started. EPA issued a 1991 letter signed by Sylvia Lowrance (5/16/91; RCRA Online #11606). CVS brought this up at the first meeting with CT DEEP. At the time the letter was issued, EPA thought there was a viable option for reuse/reclaim. Now it is known that pharmaceuticals are not reused or recycled in any way, but mostly destroyed by incineration. In the second page of the EPA letter, it stated that EPA did not intend for reverse distributors to relieve generators of making hazardous waste determinations. In its conversations with CT DEEP, CVS kept saying that the reverse distributor was the generator, but the Agency disagreed with that position and referenced the entire EPA letter.

In their letter, EPA also said a reverse distributor could not be used as a waste disposal facility without applicable regulatory control. DEEP warned that CVS might be trying this rationale in other states. In order to settle the CVS case, Connecticut allowed CVS to continue sending hazardous waste pharmaceuticals to reverse distributors as long as they receive credit. Otherwise, they must be managed as hazardous waste. However, all other facilities in Connecticut are

required to manage hazardous waste pharmaceuticals from the point of generation. Connecticut will clarify the point of generation in their Universal Waste Rule.

EPA-HQs participants noted that the 5/16/91 letter is based on a fallacy, but that EPA is no longer allowed to change their interpretation without a rulemaking, adding that they used to be able to do so. The 5/16/91 letter will be addressed in their upcoming healthcare rulemaking, which will take at least a year to propose.

A participant asked whether the credit requirement could be sidestepped by having the initial cost of pharmaceutical to the drugstore be higher, and the 'credit' be a refund of the higher cost. EPA HQ answered that they are not at liberty to say what their rule will be saying. This issue will be addressed.

A participant asked about the number of places that look at the credit reports. These can fluctuate from month-to-month. These reports usually go through the billing office, not through hazardous waste staff.

Connecticut looked closely at return information from Yale and another hospital. The material confirmed that different companies have very different return policies. The number of drugs that are RCRA hazardous waste that get credit is fairly small. Generics and off-patents usually do not get credit. On-patent pharmaceuticals get most of credits, and most are non-hazardous. Most of the hazardous waste pharmaceuticals are not eligible for credit, from what they have seen so far, and so the concern about bogus credit is diminished.

In Connecticut, there have been recent LQG notifications as a result of the awareness around the CVS case. There have been 40 so far from CVS re-notifying from SQG to LQG. For 20 CT Target stores it is due to nicotine. Rite Aid has been notifying mostly due to p-listed wastes – Connecticut is seeing these on manifests. There has been a spike in the LQG universe. Also a number of Walmart notifications have come in, but Connecticut is not sure where Walmart and Costco are in terms of compliance. The long-term strategy, at least for now, is to have the universal waste rule available, which would take the burden off of the LQG universe.

A participant asked whether any p-listed wastes really stand out. Connecticut sees nicotine and warfarin from pharmacies; hospitals have epinephrine (Connecticut includes epinephrine salts as P-listed, but concurs with EPA on partially used syringes).

CVS has substantially upgraded its scan guns so it can tell if items can be salvaged, whether it is a Connecticut hazardous waste or other, and where it can go.

Connecticut has not yet discussed with EPA their inspection commitments.

Rhode Island has had a lot of notifiers as LQGs indicate current status as SQGs. Rite Aid pretty much got it right – manifest as LQGs.

In Massachusetts, 29 Targets and about 40 CVSs have re-notified as LQGs.

New Jersey has a lot of the stores sending LQG site ID forms – Targets, Wal-Mart's, Walgreens.

New York has a lot of CVS's as LQGs, mostly because of nicotine patches and warfarin.

In New York, Walgreens is the only one that at least one inspection has found to be in compliance. Most are using reverse distributors.

Drug Enforcement Agency (DEA) Proposal

CT DEEP has reviewed the DEA proposal for disposal of controlled substances. It includes three options – mail-back programs (in mailers or small packages), collection receptacles, and take-back events.

25-30 police stations in Connecticut have been involved in a pilot program with collection receptacles. Connecticut had a lot of comments about the long-term care option, under which registered retail pharmacies could set up collection receptacles at long-term care facilities - will pharmacies want to do this? Law enforcement presence at take-back events may restrict availability.

Comingling of controlled and non-controlled substances would be allowed, but all comingled items would have to be managed as a controlled substance.

Concerns about tracking – how to judge performance.

DEA's standard for destruction is performance-based. DEA has said flushing or mixing with coffee grounds does not meet non-retrievable standard for collected wastes. Connecticut might be looking for a state exemption. There are questions about the overlap with hazardous waste requirements.

Rhode Island has made the distinction between personal trash or collection site because criminals would know that it is at the collection site but would not know that it is in household trash.

New York has submitted comments on the draft DEA rule and will share with the group. Terri will share the Product Stewardship Institute comments.

Colorado also submitted comments – contact is William Gonzales.

EPA HQs commented when the DEA Draft rule was at OMB.

Connecticut commented that the standard practice for witness destruction has been by drain disposal, and they are trying to push them away from this. The drug control unit has authority to enforce Connecticut controlled substances laws. The director of CT's Drug Control Unit has indicated that the DEA will not acknowledge any other practices. An alternative at hospitals is a lockbox system, which is then transferred to a central location for pickup by a licensed hauler to a DEA-registered site. This is not technically in compliance with DEA, so they are continuing to struggle with this issue. Some hospitals are not comfortable with this. The State is considering

possibly allowing drain disposal through a wastewater permit to control amounts going down the drain for those facilities that do not want to do the lock-box.

Vermont commented that proposed rule does not mean non-retrievable.

The participants discussed waste drainage issues and those solely limited to drain disposal from collections. Connecticut did not submit comments but will pursue this issue of drain disposal.

In New York, flushing is allowed by the State Department of Health. They are concerned about long-term care locations and need more options because if there are not more options, flushing will continue to be prevalent. New York has only approved two options - flushing or law enforcement collection.

In Rhode Island flushing is still an option but they will consider others. What about a box with chemical destruction? And at the work station so much easier for witnesses.

The framework would allow DEA to approve other methods.

Some participants have heard that other than controlled substances are also being flushed. New York sent letters regarding BMPs that they should not be flushing non-controlled substances, but have heard that it has been a problem in the past.

Connecticut mentioned an issue when wastewater got caught up in a grinder. When a plug was cleared, a slug of wastewater went to wastewater treatment plant, and the pharmaceuticals behind the slug killed the bugs.

There is a pharmaceutical waste bill introduced in Connecticut, and they will share a copy of it.

One of participants asked about what outreach had been done for pharmacists. Connecticut supports a Hospital Environmental Roundtable. Charlotte Smith came and spoke a number of years ago to that group. Hartford Hospital has also spoken to that group. One great vehicle for education is continuing education programs for pharmacists, called "pharm-ed" - URL is <http://ahrevents.com/>. They hold events in many locations.