NEWMOA Hazardous Waste Conference Call
May 13, 2014

Topic: Managing Pharmaceutical Waste

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Participants: CT DEEP (10 people); ME DEP (2 people); Mass DEP (8 people); NH DES (7 people); NJ DEP (1 person); NYS DEC (14 people); RI DEM (1 person) VT DEC (4 people); EPA Region 1 (1 person); EPA Region 2 (1 person); EPA HQs (1 person); NEWMOA (1 person)

Call leader: NYS DEC

<u>Summary of NYS DEC Review of the Issues</u>
NYS DEC presented a proposal for a promising new approach to the pharmaceutical waste problem, and then asked others for comments or other possible approaches they think might work better. Basically, the approach New York would like to propose is what could be called a "super Universal Waste Rule (UWR)" proposal, since it would regulate both hazardous and non-hazardous waste pharmaceuticals, and allow reverse distributors to be receiving the material as "destination facilities". This would be done by changing not only Part 273 *but also EPA's subtitle D regulations that are applicable to non-hazardous wastes.* Reviewing the existing RCRA-subtitle D provisions, it does not appear that EPA currently has enough authority to regulate non-hazardous pharmaceuticals without a statutory change, even when done indirectly through the states. DEC thought it was best to *not* limit the choice of new approaches for regulating pharmaceuticals to just those not requiring statutory changes. Sometimes having minor statutory changes be necessary is ultimately a faster way of getting a new regulation in place than trying to accomplish the change through only regulatory channels.

DEC compared this approach of a "super UWR" with NEWMOA's February 12, 2012 letter to EPA-HQs on the topic, and there are some areas where the two overlap. For example, the 2012 NEWMOA letter said that the "issues cannot be adequately addressed through a rule that applies only to the handful of pharmaceutical wastes that are currently RCRA-regulated," and that "RCRA Subtitle C only addresses the 'tip of the iceberg'." Our suggested approach addresses this shortcoming by placing a counterpart to the UWR in the regulations for non-hazardous waste pharmaceuticals. The February 2012 NEWMOA letter also suggested that the "existing reverse distribution system be utilized as an integral part" of the solution, which is what our proposal does, albeit for both the hazardous and non-hazardous pieces. The use of reverse distributors (RD) is especially appealing because most waste pharmaceutical generators *already* utilize the services of a RD for their Drug Enforcement Administration (DEA)-controlled substances, and that makes it simpler and probably more cost effective: The generators/collectors can just ship everything to the RD regardless of whether it is "creditable" or not. And because Universal Wastes (UWs) are not counted in making quantity determinations, EPA would no longer have nearly as many corner pharmacies being bumped up into meeting full LQG requirements.

The DEA has bought into the use if reverse distributors in their regulations, and is now "doubled-down" on allowing reverse distribution in their December 21, 2012 proposal implementing the 2010 Drug Disposal Act. This DEA proposal has added security and recordkeeping requirements, which gives an added level of comfort that DEA-registered reverse distributors would have the capability to properly manage hazardous and non-hazardous wastes. Potentially EPA could include compliance with DEA requirements as a precondition for the receipt of the returned hazardous and non-hazardous pharmaceuticals*, including those that were not controlled substances*, basically "piggy-backing" DEA's requirements.

There are many details that would need to be worked out, particularly the specific management requirements that the universal waste must meet at both the "handlers" and the destination facilities. DEC intentionally looked at the bigger picture, rather than getting too deeply into the weeds and run the risk of bogging down on the details, such as:

- Whether the reverse distributors should be required to comply with the ordinary *generator* requirements once they receive the pharmaceuticals, or
- Whether RDs should be allowed to accept only pharmaceuticals in *their original packaging*.

During the call, participants discussed several questions:

- Conceptually, how would you suggest that EPA might better regulate pharmaceutical wastes?

- Do you think that such regulations should allow the use of reverse distributors?

- Where do you think EPA should go with the issue of pharmaceutical waste management?

CT DEEP: Agency is pursuing a rulemaking based on the Universal Waste Rule (UWR) for waste pharmaceuticals. They think that the traditional RCRA rules do not fit well with the retail sector. There has been an explosion in the universe of retailers notifying as LQGs and SQGs. DEEP stated that they agreed with some aspects of NYS DEC's proposal. However, they do not

believe that the management of non-hazardous pharmaceuticals need to be part of the rule. They agree that reverse distribution should be part of the rule. They are considering adding chemotherapy drugs to their Universal Waste rule. They believe that the point of generation is the facility regardless of whether they receive credit from the reverse distributor (RD) for the materials. They would like to see training for small quantity handlers the same as large quantity handlers and to have beefed up security.

They are working with stakeholders on their proposal to obtain input on what should be included in the proposed rule. They have set a May 31st deadline for this stakeholder process. The stakeholders include the hospital association, pharmacists, Department of Consumer Protection, Department of Public Health, pharmaceutical industry, retailers, attorneys, transporters, veterinarians, and others. After that time, they will work on drafting the rule. They are documenting their process on their website.

ME DEP: Expressed reservations about brining non-hazardous pharmaceuticals into the UWR. They have not discussed the issue internally. They are not doing a rulemaking on this and are awaiting EPA's proposal.

MassDEP: Echoed the position expressed by ME DEP; no internal discussions. They are following EPA's efforts and listening and learning. They believe it is a good idea for the Drug Enforcement Agency (DEA) to register RDs. They are interested in identifying adequate destruction methods that avoid discharge to groundwater or land contamination. They are interested in learning more about available treatment technologies. Their overall goal is to keep the materials out of groundwater and landfills. They would like to see a proposal that would make it easier for all stakeholders to follow and that achieves environmental and public health benefits. They are concerned about e-cigarettes and the nicotine liquid in the refillable jars. They contain more nicotine than the patch and can be thrown out.

NH DES: They are waiting for EPA's proposal to see what direction the Agency takes. They have not had any internal discussions to date. They are enforcing the current rules and actively doing inspections of pharmacies and hospitals. They do not have any RDs in the State. They are interested in how to inspect them. DEA oversight of the RDs is good. RDs are an important aspect of the pharmaceutical system and an important part of the future EPA rule.

NJ DEP: They are also waiting for EPA's proposal. They have inspected sites with hazardous waste pharmaceuticals and treat them like other generators. They currently have a no flush rule; cannot flush pharmaceuticals in the sewer, septic, or sink. The technology for accumulating the material is in its infancy. They are working on take back solutions for communities; placement of drop off boxes to collect materials in all of the counties. The boxes are located in police stations and county sheriff's offices. They have a webpage that lists all of the sites. The State Health and Senior Services Department is working on a policy internally on how to address accumulation.

NJ's no flush rule are within the State's health laws. RCRA and water can enforce it. It was part of a statute signed by Governor Corzine.

The group discussed the status of RCRA's household waste exclusion in terms of its impacts on the collection of waste pharmaceuticals for RD. The group also discussed the manifesting of P2-listed wastes, including warfarin and Coumadin. NY noted that the household waste exclusion does not exclude the waste from being a solid waste, and so if solid wastes were made subject to the Universal Waste Rule a pharmaceutical, such as warfarin, from a household would be subject to the UWR even though it enjoys the RCRA C household waste exclusion.

RI DEM: Recently finished changing its RCRA regulations. They added a category of chemo drug wastes, particularly those that are toxic and mutagenic. They think the EPA listings and rules have not kept pace with the developments in the industry. They exempted HHW pharmaceuticals collected by police departments. Hazardous waste and controlled substances are complex when regulated. They are focused on the big picture – RCR was designed to address industrial settings and does not make sense for waste pharmaceuticals generated by households. They are under pressure in RI to try to regulate chemo-therapy drugs discharged in human waste.

VT DEC: Agency agrees with the position outlined in NEWMOA's letter to EPA and ASTSWMO's letter to EPA. This position is that pharmaceuticals ought to be regulated as a category. Any new approach needs to easy to comply with. RCRA regulations do not fit well with this challenge and sector. The RCRA C portion only covers about five percent of the waste materials. The RCRA C listing process can be cumbersome. They want to see pharmaceuticals directed to high temperature combustion so they are thoroughly destroyed. There are no RDs in Vermont. They would like to see an extended producer responsibility (EPR) approach to the management of the materials at end of life to address the HHW component. They have started an internal working group within DEC that includes representatives of wastewater and solid and hazardous waste programs, water programs, ecologists, health officials, and others. They are working at the state level to address all sources. They are focusing on addressing all drugs – prescription, over-the-counter, and illegal drugs. Keep them from being flushed and out of the waste stream and dealing with concerns about the environment and drug abuse.

EPA Headquarters

EPA and DEA are talking about the DEA rule and the EPA rule that is under development. There are no major conflicts between the agencies in terms of their points of view. EPA's rulemaking effort has been slowed down recently. They are trying to address a number of aspects to the program in the proposed rule to address many aspects of the issue. They are close to finalizing a proposal and the hope is that the EPA workgroup will reach closure on the draft in June. At that point, it will go to OMB for a 90-day review. EPA hopes to have a version asking for public comment for publication in the *Federal Register* by the end of the calendar year. Commenters are urged to discuss what they agree with and disagree with in the proposal.

EPA's 2008 Universal Waste proposal received a considerable amount of negative comments. The new proposal will build on the Universal Waste proposal, particularly what people liked, and address the gaps. It will address reverse distributors. It will not address materials that are not hazardous wastes. It will address the container issue, particularly vials.

The EPA Office of Research and Development (ORD) has been conducting studies on pharmaceutical containers and the results should be out of the QA/QC process soon.

The Inspector General (IG) Report of a few years ago focused on how out-of-date the HW listings for pharmaceuticals is. The proposed Rule will talk about the listings. They will be seeking comments on the process for listings and the toxicological data to do listings. EPA believes it would need a statutory change to address the large universe of non-hazardous pharmaceuticals.

They have been coordinating with the DEA and commented on the DEA rule during the OMB process. DEA is coordinating with EPA on its rule and there is a good working relationship. DEA's proposal does not allow flushing as a means of destruction. The DEA Rule is under review at OMB and will hopefully be out as final soon.

The RD issues have been challenging. The new proposal will address some of the issues in past EPA policies. In particular, past memos discussed reuse or redistribution, but EPA is now aware that is not occurring. The new proposal will examine RD in this new context. They do not want to scare RDs out of business.

CVS has told EPA that RD is involves $1 billion in returns for them. They are trying to develop a middle approach to addressing them.

CT DEEP: They are working on a Universal Waste Plus approach. They are considering permitting RDs but not regulating them as a Treatment, Storage, and Disposal Facility (TSDF).

NYS DEC: There has been some enforcement of facilities on Long Island. They have storage areas with satellite accumulation taking boxes of loose pills with no idea what's in them. One RD has gotten a storage permit. Some RDs are taking back medical waste, such as unused medical sharps, which is medical waste in NY.

How will these proposals address recalls? CT is considering allowing a petition process for unforeseen situations to allow for extended accumulation times.

There are some proposals in the NY State legislature for an extended producer responsibility (EPR) approach to pharmaceutical waste management.

There is concern about the management of e-cigarette waste, particularly the bottle of nicotine, which is a P-listed waste. These bottles are large and colorful, often flavored. Reported poisonings to Poison Control Centers from these are way up.