

**NEWMOA Hazardous Waste Conference Call  
January 24, 2017**

**Topic: Addressing Controlled Substances that are also RCRA Waste at Pharmacies and Health Care Facilities – How to Satisfy the DEA and RCRA Requirements**

**Disclaimer:** NEWMOA organizes regular 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:** CT DEEP (4 people); ME DEP (2 people); Mass DEP (2 people); NH DES (2 people); NJ DEP (2 people); NYS DEC (10 people); RI (2 people); VT DEC (2 people); EPA HQ (3 person); EPA Region 1 (1 person); NEWMOA (1 person)

Call leader: RI DEM

Note-taker: NH DES

Rhode Island kicked off the call by referring to the comment letter on the proposed Pharmaceutical Rule, specifically the need to interface better with the Drug Enforcement Agency (DEA) for pharmaceuticals that are both RCRA hazardous waste (regulated by EPA) and controlled substances (regulated by the Drug Enforcement Administration). The proposed rule needs to address this.

Under DEA requirements, the disposal of controlled substance waste needs to ensure there is no reclamation or recovery of the controlled substance (i.e., that the controlled substance is non-retrievable). A number of companies have claimed that they have units that can do this. It is unclear how DEA looks at these units.

See EPA's "10 Step Blueprint for Healthcare Facilities in the United States revised August 2008" for information on the regulation of pharmaceuticals, including controlled substances, and how to comply under the current regulations.

**Question 1: What are the RCRA hazardous wastes that are also controlled substances?**

EPA HQs offered that there are only six pharmaceuticals (with only one being listed and five being characteristic) that meet the criteria:

- Chloral hydrate (U034)
- Fentanyl spray (D001)
- Phenobarbital (D001)
- Somatropin (D024)
- Testosterone – injectable and gel – (D001)
- Valium (D001)

CT - has a list that includes Paraldehyde (U182) – apparently not commonly used – and Phentermine (P046): CT DEEP is leaning towards taking the same position on this material as it has for epinephrine. Namely, inclined to consider the P046 listing to apply to both the “base” phentermine and its salts.

NY - Testosterone gel is ignitable, but it was discussed whether it was a liquid.

EPA HQs offered that all injectables would be diluted in syringe so may not be ignitable when wasted.

RI – regulates chemotherapy agents that are toxic as “state only” hazardous waste.

**Question 2: Has your state any compliance or enforcement experience with this waste stream, including drug disposal units such as Cactus Smart Sinks?**

CT – Pharmacies are already managing non-waste controlled substances. If hazardous controlled substances are discarded (e.g., past expiration date, recalled, no longer needed, returns, etc.), they can be managed in containers in the pharmacy area in compliance with HW and controlled substance requirements. They would also need to be sent to a facility that is both a RCRA facility and a DEA registrant. However, DEEP is not confident that all pharmacies are operating in this way.

Here’s a successful approach that some hospitals in CT have used:

- On the dispensing end, they were using Pyxis Med Stations to distribute controlled substances and other meds. This was helpful because it minimized the amount of medications dispensed, and consequently the amount of excess medications to be wasted. In particular, this system almost totally eliminates pill/capsule/caplet waste.
- Controlled substances and other waste meds were put into designated color-coded collection containers on the floor. The containers for the collection of controlled substances were regularly removed and placed either in a secure (locked) location in the hospital pharmacy, or to a separate, locked room, where they were transferred into larger containers. These were then picked up by a waste hauler (e.g., Stericycle) for shipment to a witnessed destruction facility that is a DEA registrant.

- The hospital got a witnessed destruction report back from the hauler, to document for their records that the controlled substances were destroyed in accordance with DEA requirements.
- The hospitals also kept records of the amount of materials collected and shipped for destruction to complete the documentation cycle.

DEEP has not had much involvement with long-term health care facilities (LTCF). What involvement they have had has been mostly a modest amount of outreach. They believe LTCFs are less likely to generate hazardous pharmaceuticals in general, but are more likely than hospitals or pharmacies to be mismanaging the hazardous pharmaceuticals that they do have.

CT DEEP has encountered cactus sinks in at least one acute care facility in CT. It appears to function by absorbing or solidifying controlled substances and by the addition of a denaturant, emetic, or bittering agent to discourage consumption. It may also destroy some pharmaceuticals (e.g., by oxidation), but this is not clear. There is some information available in the patent application, but it does not identify the reagents or clearly describe how they work. The activity of adding absorbent material to a hazardous waste or adding a hazardous waste to an absorbent material would be exempt from HW treatment requirements under 40 CFR 264.1(g)(10), 265.1(c)(13), & 270.1(c)(2)(vii).

CT is still looking at the status of these devices and the spent cartridges that are removed from them. In particular, they have one facility that insists that the unit achieves the DEA standard of “non-retrievable.” CT is not yet convinced that this is the case, however. Barring further information on the controlled substance front, and as long as there is no “treatment” other than absorption going on, their position would probably be as follows:

- If a listed hazardous controlled substance is disposed of in one of these units, the unit would be a satellite container.
- The spent cartridge would have to be managed as a listed hazardous waste and a controlled substance when removed from the unit.
- If a liquid ignitable (D001) controlled substance is disposed of in the device, it would no longer be a liquid and the ignitability characteristic would no longer apply (i.e., the waste would no longer be hazardous). However, the cartridge would have to be managed as a state-regulated chemical waste and a controlled substance.

CT’s controlled substance laws does not allow collection receptacles at pharmacies, etc. These regulations are implemented by the CT Department of Consumer Protection (DCP) Drug Control Unit, and they have only allowed collection receptacles at 72 State and local police stations in CT. 23,651 pounds were collected via these drop boxes in 2015. There have also been many one-day collections, including the annual DEA collections, although DCP requires that law enforcement be present.

RI – has told hospitals they are required to ship the Cactus Smart sink as both a hazardous waste and controlled substance when the unit contains both.

ME – encountered two Cactus Smart Sinks: one at MDI Hospital and one in a correctional facility, and both only handled non-hazardous and non-DEA controlled substances so the unit upon disposal was non-hazardous. If the unit was to treat a hazardous waste, it would be subject to a permit.

MA., NH, and VT – have not seen Cactus Smart Sinks on inspections.

NJ – have not seen Cactus Smart Sinks in use although hospitals have asked about them. Safety-Kleen is coming out with a similar unit for their own customers.

NY – Safety-Kleen wants to update their permits to allow the use of Cactus Smart Sinks as claim that they render the controlled substances non-recoverable under DEA regulations.

Question if Big Box Stores can relinquish pharmaceuticals to Safety-Kleen, and EPA HQs offered that they can only if Safety-Kleen is a DEA registrant.

EPA HQs – Kristin followed up with NEWMOA after the call to report that “DEA confirmed that the Cactus Smart Sink does NOT meet the non-retrievable standard for the destruction of DEA controlled substances”.