

**Notes for the July 25, 2011 NEWMOA HW Program Webinar on
The Management of Waste Pharmaceuticals
Draft: September 15, 2011**

Notes drafted by CT DEEP with edits by Jennifer Griffith, NEWMOA (Note: Connecticut joined the webinar late due to technical difficulties.)

Lisa Lauer, EPA HQ (slides are available in the Members-only area on the NEWMOA website: www.newmoa.org/hazardouswaste):

EPA will not be finalizing the proposed amendment to add pharmaceuticals to the Universal Waste Rule (“UWR”) public noticed in the Federal Register on December 2, 2008. EPA is considering other regulatory options for the proper management and disposal of hazardous pharmaceutical waste in part as a result of comments received expressing concern over the lack of notification and tracking requirements for facilities handling and transporting such wastes.

EPA understands that reverse distribution became popular as a drug manufacturer marketing incentive. EPA recognizes that the 1991 interpretive letter may be no longer accurate because few pharmaceuticals sent to a reverse distributor are recycled today. However, EPA cannot change their interpretation without a future rulemaking.

EPA is evaluating if the reverse distribution system can be adapted to fit into RCRA - the point of generation would be the health care facility, pharmacy, and so on, and reverse distributors would have to obtain a RCRA Part B permit for the storage of hazardous waste. EPA is also evaluating whether RCRA can be adapted to fit into the reverse distribution system - create a new part in RCRA that recognizes the uniqueness of the reverse distribution system that would be sector-based for health care and retail settings (not pharmaceutical manufacturing waste) - similar to what was promulgated for academic laboratories.

EPA anticipates that it will take 1 1/2 to 2 years to propose a new rule.

Questions, Comments and Discussion on Lisa’s Presentation:

NY stated that large drug store chains “do not have a clue” as to how to manage hazardous waste before a hazardous waste compliance inspection. Chain pharmacies repeatedly send non-creditable pharmaceuticals to reverse distributors.

EPA responded that there must be a reasonable expectation for credit in order for the pharmaceutical to be sent to a reverse distributor.

NJ commented that EPA needs to define “health care facility” – for example, does it include senior-living communities where residents have their own units and do their own shopping, including pharmaceutical purchases – but the cumulative impact of pharmaceutical disposal might be significant?

RI noted that at long-term health care facilities, they consider drugs that belong to individual patients to be household hazardous waste. But what about drugs provided by a provider in the facility?

NY pointed out that most long-term health care facilities do not have a pharmacy and so cannot send waste pharmaceuticals to a reverse distributor. In addition, such facilities handle a lot of controlled substances.

CT commented that some reverse distributors do not accept controlled substances. Ross Bunnell offered to send out a list of current reverse distributors.

EPA noted they are coordinating with EPA's Office of Water and the DEA to coordinate their guidance on BMPs for managing waste pharmaceuticals.

NY stated that there are six controlled substances that are also a hazardous waste. Three are listed and three are characteristic hazardous wastes.

EPA is planning to develop a Wikipage for management of pharmaceuticals that are hazardous and hopes to have it completed within the next two months.

Mark Dennen, RI DEM (slides are available in the Members-only archive on the NEWMOA website: www.newmoa.org/hazardouswaste):

The Rhode Island Department of Environmental Management held a hazardous waste pharmaceutical stakeholder discussion group on May 18, 2011. Suggestions included drafting a UWR for pharmaceuticals, changing the state's definition of hazardous waste, allowing medical waste transporters to haul waste pharmaceuticals, and exploring producer responsibility laws and rules.

Regarding EPA's proposed modification to the UWR - RI had concerns over security and felt that EPA should define alternative health care facilities. RI DEM drafted a UWR for pharmaceuticals, but later withdrew it. They want to see what EPA proposes before proceeding.

Other items noted: In RI all generators must ship off waste within 90 days. RI DEM is now considering classifying certain items (e.g., chemotherapy drugs) as a state hazardous waste. There could be a bill in the RI legislature this year regarding the management of sharps and pharmaceuticals.

Robert Bishop, NH DES lead a round table discussion on questions sent out previously:

1. Is any state considering adding pharmaceutical waste as a universal waste? If so, under what conditions and what is your estimated timeline?

New Hampshire – No.

New Jersey – No.

New York – No.

Rhode Island – State was, but now leaning toward "No".

Vermont – No, but they were considering.

Connecticut – During the call the response was “No”. However, CT is now reconsidering adding pharmaceutical waste as a universal waste, but does not have an estimated timeline.

Maine – No.

Massachusetts – No.

[Most states are waiting to see what EPA proposes.]

2. What are your state’s policies (if any) regarding the management of residential unwanted or unusable pharmaceuticals?

New Hampshire – Don’t keep unwanted/unneeded medications at home. Do not flush them down the drain. Dispose of pharmaceuticals in the trash after being disguised, or at a drug collection event. Pharmaceuticals collected at events are fully regulated, so they issue waivers.

New Jersey – Policies similar to New Hampshire. Incineration is the preferred method of disposal for pharmaceuticals collected – what are the air impacts?

New York – The preferred option is to dispose of them at a collection event first. Law enforcement officials are present at collection events, and collected material must be incinerated – 35,000 pounds was collected in 2010. Don’t flush unwanted drugs down the drain. If necessary, dispose in the trash after disguising.

Rhode Island – Dispose in the trash; however, the Rhode Island Resource Recovery Corporation (RIRRC) which manages virtually all MSW in RI does not knowingly accept pharmaceuticals.

Vermont – Bring to police station where they are kept until DEA sponsored collection event is held.

Connecticut – Policies similar to NH. Disguise and dispose in the trash. Collection events require general permit. All collected material sent to a CT incinerator.

Maine – Has mail-back program. They also have drop boxes at police stations and sheriff offices where they are kept until the next DEA sponsored collection event. Do not recommend disposing in trash. Landfill leachate has shown the presence of pharmaceuticals. Maine will be conducting a composting study next – should have results in January for small scale pilot, and in March for a larger scale pilot.

Massachusetts – Do not flush pharmaceuticals down the drain. The state does not discourage solid waste disposal. DEA sponsored collection events were successful. They have issued permits for waste pharmaceutical kiosks at some police stations.

[States are wondering what will happen if DEA collections end?]

3. What are your state’s policies (if any) regarding the management of non-residential unwanted or unusable pharmaceuticals?

New Hampshire – Require a hazardous waste determination be performed if the pharmaceutical is not being sent to a reverse distributor.

New Jersey – Same as New Hampshire.

New York – Same as New Hampshire.

Rhode Island - Same as New Hampshire.

Vermont - Same as New Hampshire.

Connecticut – Similar to New Hampshire, except that hospitals must determine if a non-dispensable pharmaceutical is a hazardous waste, and manage it as such whether or not a reverse distributor is used. Hospitals’ overall return credits from reverse distributors do not seem to have been adversely affected by this practice. Connecticut has some ideas concerning long-term health care facilities, but nothing in writing. There doesn’t appear to be a lot of hazardous pharmaceuticals at long-term health care facilities. The state is currently pursuing a formal enforcement action against a retail pharmacy chain.

Maine - Same as New Hampshire.

Massachusetts - Same as New Hampshire.

4. If non-residential pharmaceuticals conform to a hazardous waste characteristic or listing, do you require that they be managed as hazardous waste?

New Hampshire – Yes.

New Jersey – Yes.

New York – Yes.

Rhode Island – Yes.

Vermont – Yes.

Connecticut – Yes, if from a hospital.

Maine – Yes.

Massachusetts – Yes.

5. What do you consider to be the point of generation for unusable pharmaceuticals? At the pharmacy or health care facility at which it is determined that the pharmaceutical is no longer usable or needed, or somewhere further down the line?

New Hampshire – According to the January 22, 1999 New Hampshire Department of Environmental Services (“DES”) policy letter, the point of generation is at the pharmacy or health care facility unless the generator definitely knows that the pharmaceuticals being sent to a reverse distributor will be used or reused.

New Jersey – At a reverse distributor, unless facility is not using one.

New York – At the reverse distributor.

Rhode Island – At the source.

Vermont – At a reverse distributor, unless the pharmaceutical is not being sent there.

Connecticut – At the source for hospitals. They are still looking at retail pharmacies.

Maine – At the source.

Massachusetts – At the pharmacy, unless going to a reverse distributor.

6. Do you have any specific policies relating to the management of unusable/unwanted pharmaceuticals at retail pharmacies (CVS, Walgreens, Rite Aid, etc.).

New Hampshire – No.

New Jersey – No.

New York – No.

Rhode Island – No.

Vermont – No.

Connecticut – No. Has an enforcement case against a major chain pharmacy

Maine – No.

Massachusetts – No.

7. Do your policies differentiate in any way between different types of health care facilities (i.e., hospitals vs. long-term health facilities vs. retail pharmacies)?

New Hampshire – No, except at residential facilities when the pharmaceutical is patient-generated when it is considered a household hazardous waste.

New Jersey – Similar to NH.

New York – No written policy. Have done outreach to over 1,000 long-term health care facilities because most are not eligible for reverse distribution (do not have a pharmacy). For other facilities, reverse distribution should be the first option.

Rhode Island – No.

Vermont – No.

Connecticut – Policy for hospitals only.

Maine – Similar to New Hampshire.

Massachusetts – Similar to New Hampshire.

8. Have any of you had enforcement of any kind with any retail pharmacies in your state? If so, please briefly summarize the nature of the violations and the resolution of the case.

New Hampshire – No.

New Jersey – Two administrative consent orders in the works – large retail chain for nicotine gum and large pharmacy chain for photographic processing waste.

New York – No, although there is currently some discussions about possible enforcement. One retail pharmacy chain has been found to have “no clue” and another was found to have manifesting violations.

Rhode Island – NOV to one retail pharmacy store for violation associated with photographic processing waste.

Vermont – No.

Connecticut – NOVs have been issued to a large retail pharmacy chain for mismanagement of photographic processing waste. Additional NOVs have been issued to the same retail pharmacy chain for mismanagement of pharmaceutical waste, consumer products, recyclables, and generator closure. Draft consent orders for eight stores and for corporate are being negotiated.

Maine – Informal enforcement for photographic processing waste.

Massachusetts – No, have not investigated.

9. Reverse Distribution:
 - a. How do states implement EPA’s allowance for reverse distribution systems for unneeded pharmaceuticals?

New Hampshire – NH DES issued a “Reasonable expectation” policy (NH DES) on January 22, 1999 stating that a generator needs to have a reasonable expectation and be able to document that any expired pharmaceutical sent to a reverse distributor will be recycled by being used or reused, but have not explicitly asked pharmacies for this documentation.

New Jersey – Similar to NH, but no written policy.

New York – Similar to NH, but no written policy. Allows pharmacies to use reverse distribution and it’s the reverse distributor that makes the waste determination.

Rhode Island – Unsure.

Vermont – Similar to NH, but no written policy - allows reverse distribution.

Connecticut – No written policy, except as discussed above, hospitals cannot reverse distribute those that are hazardous. Chain pharmacy has claimed that they would incur a large monetary loss if they could no longer send hazardous pharmaceuticals to a reverse distributor.

Maine - Does not allow reverse distribution for hazardous waste pharmaceuticals unless they are unopened, unused and not expired.

Massachusetts – Similar to NH, NJ, NY and VT.

[Most states follow EPA policy from 1991.]

- b. Do you have any specific policies relating to the use of pharmaceutical return centers?

New Hampshire – No.

New Jersey – No.

New York – No.

Rhode Island – No.

Vermont – No.

Connecticut – Expects the reverse distributor to have a permit to take hazardous waste pharmaceuticals.

Maine – No.

Massachusetts – No.

- c. Has anyone asked for documentation to find a pattern of disposal fees being assessed in addition to or instead of a “credit” every time a generator is sending drug “x” through reverse distribution?

New Hampshire – No.

New Jersey – No.

New York – Have seen lack of credit for certain drugs and no charges for disposal.

Vermont – No.

Connecticut – No.

Maine – Asked for documentation as to how reverse distribution system works.

Massachusetts – No.

10. Warfarin (P001) – How do other states regulate or interpret “packaging” that once held a Coumadin pill? Can the container be managed as a solid waste? Containers include

foil/blister packs, and paper/plastic cups to administer individual doses. How about if the tablet is still in the container?

New Hampshire – Dispensing device is not considered a container – along the lines of EPA's interpretation for syringes. However, an unused tablet inside a blister pack would be considered a hazardous waste.

New York – Empty blister pack and cup are considered subject to empty container requirements.

Connecticut – Still working on issue.

[The call was long and many states had to leave before this discussion.]

Ross Bunnell of Connecticut had asked many of these questions via e-mail and received some responses - he would forward those responses to Jennifer Griffith at NEWMOA. He asked that those who responded let Ross or Jennifer know if it was OK to share their responses with the other states. If so, they will be posted in the Members-only area of the NEWMOA website: www.newmoa.org/hazardouswaste.