NEWMOA Hazardous Waste Conference Call
November 23, 2015

Topic: "Question and Answer" Session on EPA's Proposed Pharmaceutical Rule & Generator Improvement Rule

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 person); Mass DEP (4 people); NH DES (12 people); NJ DEP (2 people); NYS DEC (13 people); VT DEC (1 person); EPA HQ (6 people); EPA Region 1 (5 people); NEWMOA (1 person)

Introduction
The purpose of the call was for the NEWMOA states to have an opportunity to ask questions about the two proposed rules and to hear answers directly from EPA.

EPA Headquarters Introduction
Kristin Fitzgerald (EPA HQ) reminded the participants that this conference call would not constitute an official way to submit comments on either of the proposed rules. However, if the discussion moves in that direction, EPA will take note of the issues that are discussed. Beth Deabay (EPA Region 1) asked the participants to highlight both what we like and what we don't like about the proposed rules.

Q&A Concerning the Proposed Pharmaceutical Rule

Question 1: On page 58017 of the Pharmaceuticals proposal, EPA briefly describes a number of written clarifications and determinations for P- and U-listed pharmaceuticals they have issued over the years. Is EPA taking comments on those? Some appear to be in error, and this proposed rule would be a good opportunity to make needed corrections.

(ASIDE: It is noted that in EPA's September 25 companion 'Generator Improvements' proposal at page 57966 EPA 'requests comment on proposing to revoke [RO# 11317]' – 11317 addresses generator satellite accumulation areas -- so it seems appropriate that EPA would allow comments on RO documents relevant to the companion Pharmaceuticals proposal. We also note that on page 58021 of the Pharmaceutical proposal EPA writes it 'welcomes comments on all aspects of this proposed rule,' and possible errors in past pharmaceutical-related clarifications/ determinations can be very relevant to the proposal [particularly when the documents are specifically listed in the preamble discussion].)

EPA Response: Kristin Fitzgerald (EPA HQ) indicated that EPA will not be taking comment relating to existing hazardous waste listings, except for the ones specifically mentioned in the proposed rule pertaining to reverse distributors and in particular, the memos from the 1980s and 1990s regarding the role of reverse distributors and the point of generation.

Question 2: The definition of pharmaceuticals includes the residue remaining in containers, so what would be the "practice commonly employed" to remove that pharmaceutical from a pill bottle? Tapping? Rinsing? [References: 266.507(a)(1) and preamble discussion on p 58055]

EPA Response: Liz McCarthy (EPA Region 1) stated that this issue would be interpreted the same way as the wording in 40 CFR 261.7 regarding empty containers. She further explained that the idea was to avoid the need for health care facilities to engage in rinsing of containers to get the residues out of them, which is consistent with the proposed ban on sewering. EPA might add some clarifying language in the preamble on this subject.

Connecticut follow-up question: Has EPA had given any thought to its proposal to allow empty containers to be disposed of in the trash as it pertains to liquids, especially thick liquids (e.g., cough syrups) and powders, either of which might retain more residue than a bottle that contained pills or capsules?

Kristin Fitzgerald (EPA HQ) responded that the studies that EPA reviewed did include liquids. Although the studies showed that there were more residues in containers that formerly held liquids, this did not preclude safe disposal.

New York follow-up question: Are we taking out all of the "P" listings so that Warfarin bottles aren't regulated?

Kristin Fitzgerald (EPA HQ) stated that, no, EPA's intent was simply to release them from the requirement to triple-rinse the containers. In making its proposal to allow these containers to be disposed of in the trash, EPA noted that containers used to hold hazardous pharmaceuticals are much smaller than most other RCRA wastes.

Question 3: Why does EPA consider this proposed rule to be more stringent than the current federal standards?

EPA Response: Kristin Fitzgerald (EPA HQ) stated that the proposed Subpart P of Part 266 is intended to be a whole new program, and is more stringent than the existing federal standards,

especially with respect to the changes to the regulatory status of pharmaceutical wastes going to reverse distributors and the ban on sewering.

Questions 4, 5, and 6: Why does a manufacturer's credit need to play a role in whether a hazardous waste pharmaceutical can be shipped to a "pharmaceutical reverse distributor"?

How will states be able to determine whether a "healthcare facility" is only shipping "potentially creditable hazardous waste pharmaceuticals" to a "pharmaceutical reverse distributor"?

What are the consequences if a "healthcare facility" ships "non-creditable hazardous waste pharmaceuticals" to a "pharmaceutical reverse distributor"?

EPA Response: Beth Deabay (EPA Region 1) responded that this is the current industry model that the rule is based upon. If there is no potential for credit, the pharmaceutical waste should go directly to a TSDF. The only function of a reverse distributor is to assess credit. Kristin Fitzgerald (EPA HQ) agreed, and stated that some reverse distributors are currently going way beyond this model without TSDF permits. If a reverse distributor wants to continue operating this way, they would have to get a TSDF permit under the proposed rule.

New York follow-up question: How do we know if a hazardous pharmaceutical is potentially creditable if the rules for giving credit can change from week to week?

Kristin Fitzgerald (EPA HQ) replied that this is why the phrase "potentially" creditable is used.

New York followed up by asking if this means that it is OK for everything to go into the same box and be shipped to a reverse distributor. Kristin Fitzgerald (EPA HQ) replied that, no, the materials must be in their original containers, can't already have been paid for by a third party, etc., as described in the preamble. She also stated that originally EPA was of the impression that generic drugs were not creditable, but now they are hearing that they sometimes are (EPA is looking into this issue further). Samples, too, are considered not to be creditable.

New York asked are we going to expect hospitals to review their return sheets from reverse distributors to decide what to send and what not to send? Kristin Fitzgerald (EPA HQ) replied that, no, not necessarily.

New York followed up asking if a hospital could therefore send a particular drug for credit all the time even if they only got credit for it once. Kristin Fitzgerald (EPA HQ) indicated that New York should submit this as a comment on what they think any "bright lines" should be with respect to what is and what is not creditable.

New York indicated that they had seen EpiPens being returned to reverse distributors all the time even though no one ever got credit for them. Kristin Fitzgerald (EPA HQ) stated that EPA's intent here was to strike the right balance so that reverse distributors can carry out the industry model but not act like TSDFs.

New Jersey follow-up question: We understand the premise of the proposed rule, but if a state finds someone sending non-creditable pharmaceuticals, but we're not sure if they would want to enforce against the reverse distributor as a TSDF, since that is a high-priority violation. Beth Deabay (EPA Region 1) indicated that this will be addressed in EPA's answers to questions 5 and 6. There's a provision in the proposed rule regarding unauthorized hazardous pharmaceuticals that required reverse distributors to report if they receive hazardous waste rather than potentially-creditable pharmaceuticals. The reveres distributor then becomes responsible for disposing of the unauthorized material. EPA expects that this will create a cost incentive on health care facilities not to send unauthorized materials to reveres distributors (i.e., to avoid additional charges passed down to them by the reverse distributors).

New York follow-up question: Has EPA gone to any reverse distributors to see what kinds of materials they receive and what they do with them? NYS DEC has visited homes for the disabled and found that they throw everything into a box and send it to a reverse distributor. Less than five percent of what they are sending in these boxes is creditable. Kristin Fitzgerald (EPA HQ) replied that, yes, EPA has spoken to reverse distributors. She also noted that practices may vary from one reverse distributor to the next. A lot of the reverse distributors don't really want the unauthorized materials and waste, and reverse distributors like the one NY described aren't going to be able to operate like that anymore. New York added that some reverse distributors receive materials that the manufacturer instructs the reverse distributor to dispose of locally.

Question 7: Why are states being required to determine whether all "healthcare facilities" have notified pursuant to this proposed rule? By what means are states supposed to determine whether all "healthcare facilities" have notified?

EPA Response: Kristin Fitzgerald (EPA HQ) stated that reverse distributors will be required to notify EPA and get an EPA ID Number as Subpart P healthcare facilities rather than as generators under Part 262.

NEWMOA follow-up question: How will the state programs know if all of them have notified? Kristin Fitzgerald (EPA HQ) stated that most of the healthcare facilities should be generators rather than reverse distributors. States can go into RCRAInfo and search using key words like "health" or "hospital" to find them and determine if they have re-notified.

Question 8: How are recalled pharmaceuticals required to be managed?

EPA Response: Liz McCarthy (EPA Region 1) added that page 58062 of the proposed rule has a description of this issue. The rule will have a provision that allows extra time to process recalls, if needed. She also noted that some reverse distributors specialize in recalls.

Question 9: EPA is proposing to prohibit the flushing/sewering of hazardous waste pharmaceuticals. Why isn't the proposed sewer ban being extended to healthcare facilities connected to a septic system or privately-owned treatment system?

EPA Response: Kristin Fitzgerald (EPA HQ) responded that EPA can only regulate discharges to the sewer, not to septic. However, states can be more stringent in this respect.

Question 10: Can generic drugs be shipped to a reverse distributor?

EPA Response: Kristin Fitzgerald (EPA HQ) indicated that, based on conversations with reverse distributors and a survey that EPA did, they heard that generics are not creditable. Lately, however, EPA has been hearing that some generics may be creditable.

Connecticut follow-up question: Is there any rhyme or reason as to which generics get credit? How about Coumadin and Warfarin? They are usually sold as generics, and they are a major portion of the hazardous pharmaceuticals. Do they get credit? Kristin Fitzgerald (EPA HQ) responded that she is not sure. In addition, she was frankly surprised that any generics would get credit because of the small margins that generic manufacturers operate under.

Connecticut followed up stating that is very important that EPA be very clear on this issue, since generics are a big part of the hazardous pharmaceutical universe.

Question 11: Is a Ziploc-type plastic bag considered a container under the proposed rule?

EPA Response: Liz McCarthy (EPA HQ) stated that if a Ziploc bag is a "unit dose container" then it could be classified as a container under the proposed rule. But, if it is used as a secondary containment container, it would not be classified as a container. Kristin Fitzgerald (EPA HQ) added that the preamble discusses putting things in Ziplocs in a larger outer container. This is listed as a best management practice in the preamble for creditable pharmaceuticals.

Connecticut follow-up question: The real question here is that, when it comes to complying with the requirements for containers in the proposed rule, what is considered to be the "container?" An outer container consisting of a cardboard box, or each of the several Ziploc bags in the cardboard box, or the pill bottle inside the Ziploc? Which one of these has to be marked "hazardous pharmaceutical" for example? Kristen Fitzgerald (EPA HQ) replied that she felt that it would probably be the outer container (e.g., the cardboard box in the example given).

Question 12: Can EPA provide a copy of the list of hazardous waste pharmaceuticals that allegedly can be found in the full Regulatory Impact Analysis for the proposed rule to those states that request it?

EPA Response: Kristen Fitzgerald (EPA HQ) indicated that this information may be found on page 46 of the Economic Impact Analysis. The list in the preamble is very brief. However, the actual list of drugs is much longer (especially those that are characteristically hazardous for ignitability).

New Jersey follow-up question: What about the Pharm waste Wiki? Can EPA use the information there? Kristen Fitzgerald (EPA HQ) replied that no, they can't because it's a user-generated system. However, EPA did use a list that Colorado DPHE had developed. Other states have similar lists, too.

Additional Question from New Hampshire: What is the status of e-cig liquids?

EPA Response: Kristin Fitzgerald (EPA HQ) stated that EPA solicits comment on e-cig liquids in the proposed rule preamble. New Hampshire asked if this meant that the local vape shop would be a health care facility. EPA responded that if EPA considers nicotine to be a pharmaceutical, then yes it would. She noted that EPA specifically asked for comment on this issue, and noted that if they are not classified as pharmaceuticals, then the local vape shop could be subject to full regulation under RCRA. However, most of the disposal would be done by the customer, not the vape shop, so this may not be much of an issue.

Additional Question from Connecticut: Is there any requirement for closure?

EPA Response: Kristin Fitzgerald (EPA HQ) said yes, there is. See proposed section 266.510(a)(7) and page 58089 of the preamble. Connecticut asked if there was any closure requirements for healthcare facilities that are generators. Kristin Fitzgerald (EPA HQ) replied that the requirement applied to reverse distributors only. Facilities that are generators would still have to do generator closure with respect to the storage of their other (non-pharmaceutical) hazardous wastes, however.

Additional Question from Connecticut: Under the proposed rule, reverse distributors would be receiving hazardous pharmaceuticals, from, for example, SQGs and LQGs without a permit, provided they comply with the conditions of the proposed rule. The language of the proposed rule does not include revisions to 40 CFR 264.1, 265.1, and 270.1 to include exemptions from the requirement to obtain a TSDF permit for these reverse distributors, which is done, for example in the case of universal waste handlers receiving hazardous waste from other universal waste handlers. Was this an oversight on EPA's part, or is there something I missed here?

EPA Response: That was an oversight on our part. It would be good if you could submit a comment to that effect.

Part 2: Q&A Concerning the Generator Improvements Proposed Rule

Question 1: On page 58006, section 262.250 states that Part 262's Subpart M applies to an LQG's site (1) where hazardous waste is accumulated under 262.17 or (2) where it is generated. Would Subpart M apply in cases where a hazardous waste stream exits a production unit and is immediately drained into a satellite accumulation container? (Satellite accumulation containers will be regulated under 262.15 and not under 262.17.) An example would be a jug receiving waste draining directly from an HPLC chromatograph instrument.

EPA Response: Jim O'Leary (EPA HQ) said, no, EPA is not proposing to make any changes in this area. EPA's satellite accumulation FAQ document mentions personnel training is not required for SAAs. A hazardous waste determination needs to be made at the point of generation, but ironically, that person may need to be trained.

New York follow-up question: Is Subpart M applicable at the point of generation i.e., Section 262.250? EPA responded that they had not thought of that particular situation. Jim O'Leary

(EPA HQ) suggested that New York include that issue in their comment letter. The jug getting waste from an HPLC machine would be a satellite container, however.

Additional Comment: Jim O'Leary (EPA HQ) said that would be better if the waste went to an LQG than a municipal solid waste landfill, and would increase options for recycling. It is possible that a facility could become a quasi-TSDF under the proposed provision. However, they would only have 90 days to manage the waste. EPA is aware that this provision could result in facilities storing very large amounts of waste, but LQGs are not limited in the amount of waste they are allowed to store. EPA had also considered that if a state had a situation with a very large facility like this, they could pull the program and not allow them.

New York follow-up question: What's the status of the aggregation facility? What do they become? Jim O'Leary (EPA HQ) replied that they would have to be an LQG to start with.

Connecticut follow-up question: Has EPA given any thought to an accumulation limit for these LQGs? Jim O'Leary (EPA HQ) replied that they had considered such a limit, but decided against it. LQGs currently have no accumulation limit, so they didn't see any reason to set a limit for LQGs accepting waste from CESQGs. However, states were encouraged to send comments if they have any on this issue.

New York follow-up question: Is there anything built in to the proposed rule that would allow states to verify that the generators sending waste to LQGs in their state are truly CESQGs? Jim O'Leary (EPA HQ) replied that any LQG wanting to accept CESQG waste would have to submit a notification listing all of the CESQGs they are getting waste from. States could coordinate pursuant to these notifications to confirm the identity and generator status of the CESQGs.

Maine follow-up question: Are there any paperwork requirements for self-transportation of CESQG waste to LQG sites? Jim O'Leary (EPA HQ) replied that the only requirements would be labeling and the applicable federal DOT requirements.

New York follow-up question: What is considered "self-transport" with big companies? Would Walmart have to have trucks for each store or nationwide transporters? Jim O'Leary (EPA HQ) replied that is could be any of the above. The proposed rule has no requirements for "self-transport," per se. The actual transport of the CESQG waste doesn't have to be by the same entity. Kristen Fitzgerald (EPA HQ) added that EPA thought of this provision as being self-limiting by the economics of the situation. It's not practicable to move CESQG wastes all over the country.

Additional Comment: Jim O'Leary (EPA HQ) commented that, setting aside the self-transportation issue, whether the waste is self-transported or transported by a third party, could they pick up the maximum of 2200 pounds that a CESQG could have on-site at any one time all at once? The answer is yes, they could. The LQG is going to want some control of the situation, too. Things will be company-specific and vary from one entity to the next.

Additional Comment: Jim O'Leary (EPA HQ) stated that the TSDF will have to report in on their biennial report.

Additional Comment: Jim O'Leary (EPA HQ) stated that there is no definition of "property line" in RCRA. EPA staff have checked and found that the common definition is a boundary line between one property and another.

New Hampshire follow-up question: What about the example of a strip mall, which may have multiple tenants in the same property, all rented separately – is the property line the line between the rented properties or the owned property? Jim O'Leary (EPA HQ) replied that the site ID would help define this. This provision only applies to LQGs, so it is not likely to happen often in strip malls. However, a difficult issue that EPA has encountered is multi-story buildings. That is, should the 50 foot buffer be vertical as well?

Connecticut follow-up question: Has EPA considered checking with NFPA to see how they interpret this issue? The 50-foot setback requirement stems from NFPA codes, so they may have addressed many of these issues before. Jim O'Leary (EPA HQ) agreed that this might yield some good information. Also the waiver procedure will consider these kinds of things. Have any of the states issued variances?

Connecticut: No. Have been pretty strict on this issue. CT actually made one Safety-Kleen facility paint a line on the floor of their building to ensure compliance with the buffer zone requirement.

New Hampshire: Issued one variance a number of years ago.

EPA HQ follow-up comment: Jim O'Leary (EPA HQ) asked if notification is a possibility, instead of just recordkeeping. He advised the states to consider it and provide comment.

New York follow-up question: Can states get guidance on these variances? NY has an auto body shop that is on a 50 foot by 150 foot lot. They have no place to store their waste that would comply with the 50 foot buffer rule.

Connecticut: We've all been talking about reaching out to the fire department for guidance on the 50 foot buffer zone requirement. However, you actually want to talk to the Fire Marshal, not the fire department. The fire department is responsible for putting out fires. The Fire Marshal is responsible for making interpretations of the fire code and issuing certificates of occupancy for buildings.

Additional Question from New York: Under the proposed episodic generator rules, CESQGs must submit EPA Form 8700-12. Why is there no specific timeframe for unanticipated events – for example, "as soon as possible?"

EPA Response: Jim O'Leary (EPA HQ) replied that EPA had a hard time thinking of a reasonable time frame because there are all kinds of situations that could occur. You could have a Hurricane Sandy type of event where utilities and services are out for an extended period of time. If people would like to propose a timeframe, include it in their comments.