

Call Notes: October, 2008 NEWMOA Conference Call State & EPA Regulatory & Policy Issues on Waste Pharmaceuticals

Bill Cass began the call with a roll call of states. All NEWMOA member states except for RI were represented on the call. Janet Bowen, Steve Yee, and Robin Biscaia of EPA Region 1/New England were also on the call. EPA regional staff and then individual member states took turns summarizing their state's policies concerning the management of waste pharmaceuticals.

USEPA Region 1/New England: Janet Bowen mentioned that EPA HQ is preparing a proposed universal waste rule for pharmaceuticals which is expected in or about December, 2008. She indicated that if she heard of a more precise schedule for the issuance of this proposed rule, she would inform the group. She further indicated that, on the water side, there have been a lot of activities involving pharmaceuticals. For example, there is an 8/12/08 proposed information request to be sent out to the health care industry. Janet indicated that she would email us a link for the Federal Register Notice. A draft questionnaire is included, she said. The public comment period on the proposal ends on 11/10/08. Through this process, EPA hopes to get information on one in seven health care facilities in the U.S. (about 3500 in total). The survey will be mandatory. Janet also indicated that she has a slide show on this information request. EPA is targeting a final rule for the survey by about April, 2009. There is also a web page on the EPA website with more information.

Robin Biscaia spoke next for Region 1/New England, indicating that she had received an inquiry from a hospital in ME asking how to dispose of nicotine, EpiPens, epinephrine, and nitroglycerin in ampoules, vials, and bottles. She indicated that a draft response is being prepared. At this point, they feel that EpiPens are syringe-like. They also feel that small containers would have to be managed as hazardous waste, although the empty container provision may apply. In formulating its response, EPA is working with ME DEP with respect to ME's policies on these issues.

Steve Simoes of VT indicated that VT is wondering whether some material might qualify as "manufactured articles" and therefore be exempt from RCRA.

Robin replied that EPA HQ does not necessarily agree with this approach. Rather, items such as these should be more appropriately considered a chemical formulation with a sole active ingredient. Region 1/New England would agree with HQ on this issue.

Steve Simoes cited guidance on nicotine (Nicoderm) patches and Nicorette gum. In particular with the latter, the wonder why if it's safe to eat it should be considered a hazardous waste.

Connecticut: Ross Bunnell described CT's policies on nitroglycerin, epinephrine, and nicotine. More specifically, CT does not consider used nitroglycerin patches to be P081 wastes because they have been used. Unused patches, as well as unused pills, and other forms of nitroglycerin, however, are considered P081 (CT has not yet adopted the EPA's changes to the mixture and

derived from rules concerning wastes listed only for reactivity being non-hazardous if they are not themselves reactive). With respect to epinephrine, CT is evaluating but has not thus far adopted the 10/15/20007 EPA policy concerning epi salts. As a result, all waste epi products in which epi is the sole active ingredient must be managed as P042 wastes in CT, except for partially-used syringes pursuant to the long-standing EPA HQ policy letter regarding these items. For nicotine, CT considers used patches and gum not to be P075 wastes since they have been used, whereas unused formulations are considered P075 wastes. CT is very interested in the prospect of universal waste designation for waste pharmaceuticals, since this would be a way to provide appropriate regulatory relief for health care providers, reverse distribution centers, etc., while at the same time ensuring that materials are adequately handled and disposed. CT will look at EPA's upcoming universal waste proposal, and is likely to adopt either the final EPA rule or its own version in the future. CT also has developed a fact sheet for individual consumers (forwarded to Bill Cass prior to the call and available on the DEP website), and is currently working on guidance for long-term health care facilities.

EPA Region 1/New England asked if CT has thought about visiting nurses. Ross answered that although CT was aware of this group and their unique issues, we had not conducted any specific outreach to them. A question was also raised as to how CT regulated IV bags. Ross replied that CT considers all such bags to be regulated as hazardous waste if the material in them meets a HW listing or characteristic.

Maine: Kevin Jenssen stated that at this point, ME's policies are still on the stringent side, although they have adopted the EPA letter regarding epi salts. Ann Pistell, from ME's solid waste program talked about ME's household pharmaceutical guidance (which also applies to long-term health care facilities). On the latter point, she explained ME's interpretation indicating that since the patient actually owns the medications in these facilities, they qualify as household hazardous waste (HHW) when disposed. However, ME's policy is that once HHW medications are aggregated at a collection point, they lose their HHW exemption and must be managed as HW. Since the collected medications include both hazardous and non-hazardous types, the aggregated material must all be handled as HW. ME also has a pilot mail-in collection program. They are pursuing legislation to eventually make this program permanent.

Bill More of NY asked where the mail-in materials were going. Ann replied that this material goes to ME's state DEA facility. Personnel here open the mailers, and catalog what has been received. She stated that if the program becomes permanent, they hope to skip this step and just ship all the collected material as combined HW/controlled substances for witnessed-destruction at a RCRA Part B incinerator.

Bill then asked if ME had gotten buy-in from DEA. Ann indicated that they had, and that DEA is working on changes to their regulations to allow reverse distributors to take controlled substances, so that it may be possible in the future to mail unwanted medications direct to reverse distributors.

NY asked about ME's policy of applying the HHW exemption to long-term health care facilities. In particular, does ME have any sort of criteria or cutoff that the facility has to meet in order to be eligible for this policy, or are all facilities eligible? Ann replied that there is no distinction in

the mail-in program, but sometimes in one-day collections. She further indicated that if a reg change comes along, they may review this policy, but that they don't think there's any distinction among the long-term health care facilities based on number of beds or anything like that.

Massachusetts: MA is working on adopting the EPA mixture and derived-from revisions soon. MA also agrees with EPA HQ's syringe and epi salt letters. They also have an interpretive letter indicating that nicotine patches and gum are not commercial chemical products because they are manufactured articles. MA is watching EPA's universal waste rule process and is interested in adopting it. There are also activities on MA DEP's water side, but a person from that program was not present to provide details.

New Hampshire: Bob Bishop indicated that NH had several recent inspections at hospitals during which they looked at patient care and pharmacy facilities. The patient care areas seemed to be pretty good, as a rule, and generally had color-coded boxes for segregating different wastes (e.g. P-listed, U-listed, Ingestible, Toxic). The pharmacies also seemed to be pretty good. Many hospitals in NH are now listed as Large Quantity Generators (LQGs). One issue NH has is reverse distributors: they want to determine if potentially hazardous pharmaceuticals can legitimately go to them, or if they must be managed as fully regulated as HW. Bob indicated that NH considers used nicotine products to be non-hazardous. Also, individual-dose blister packs that contained P-listed medications do not have to be triple-rinsed. NH plans on adopting the revisions to the mixture and derived-from rules soon. NH agrees with the EPA epi salt and used syringe memos. NH applies the EPA syringe policy to all syringes (not just EpiPens), but not to other delivery systems (e.g., IVs). NH has more details on their website, www.des.nh.gov. On the water side, NH is coming up with a policy on the disposal of unused medications. They have a white paper on use trends, disposal trends, BMPs, etc. that is used internally for now, but that they are still seeking external input prior to finalizing. They hope to finish this document in about two months. NH is also working on a collection program to allow long-term health care facilities to send good unused medications to other facilities that can use them. NH agrees with the earlier comments concerning DEA changing their regulations to make movement of controlled substances easier. NH is also studying plans to address the impacts of pharmaceuticals on the environment.

New Jersey: NJ began with a question for EPA: is the universal waste rule going to be for pharmaceuticals only, or for commercial chemical products in general? EPA replied that they were not sure. CT pointed out that the rule title as currently entered in the semiannual regulatory agenda includes pharmaceuticals only.

NJ has a subset of its rules for regulated medical wastes, which uses a cradle-to-grave tracking system much like that for HW. Some of this waste could include HW; some of it could qualify as RCRA-empty. NJ has seen some problems with proper classification of pharmaceuticals (handlers sometimes include some materials that are technically not regulated). The biggest problem that NJ has seen concerns out-of-date pharmaceuticals going to reverse distribution centers. NJ has rules coming out which will officially recognize these facilities (they have been unofficially recognized for some time now). NJ also favors universal waste regulations for waste pharmaceuticals. NJ has an approval process for universal waste facilities that would apply to

universal waste pharmaceutical facilities also. NJ agrees with EPA's epi salts letter. On the water side, NJ had a big effort to discourage drain disposal of medications. Unfortunately, this conflicted with DEA publicity which still encourages people to dispose to the drain. There has been a lot of attention on the part of NJ's water staff to the pharmaceutical issue.

NJ concluded by asking if anyone had any ideas for how to deal with DEA and their "down the drain" policies.

Steve Simoes of VT asked what NJ's upcoming rule change recognizing reverse distributors would look like. NJ replied that they intend to change their solid waste rules to add a definition of reverse distribution facilities. If they eventually adopt a universal waste rule for discarded pharmaceuticals, this may eliminate the need for this language, however.

New York: NY's policy on nicotine patches is that if they are used, they are not classified as hazardous waste, but if they are unused, they are considered hazardous. On the issue of nicotine gum, NY had written a letter to EPA seeking confirmation that nicotine gum and lozenges are not P075 because they contain more than one active ingredient, but they have not received a response to date. NY has adopted EPA's changes to the mixture and derived-from rule. NY plans to adopt EPA's epi salts policy in writing soon, with some reservations. NY has a "no flush" campaign for household pharmaceuticals. NY is struggling with how to deal with long-term health care facilities' issues. They are seeing lots of interest from towns for having collection events for household residents. NY regulates such collections, but in a simple way. They have a workgroup with the NY Department of Health to evaluate alternatives for the management of long-term health care facilities and hospitals.

Vermont: With respect to nitroglycerin, VT has adopted the EPA's revisions to the mixture and derived-from rules. VT is still wrestling with how to classify nicotine gum and patches, and has not yet set on a final policy. Historically, VT has classified patches as P-wastes (they have a facility that manufactures them, so it seemed inappropriate for the patches from this facility to be disposed of as non-hazardous waste). VT agrees with EPA's epi salt policy. VT was seeing a lot of their hospitals becoming LQGs due to epi, so they thought that this policy made sense. VT will look closely at EPA's proposed universal waste rule for pharmaceuticals, and think it is a good idea.

Additional Discussion: Bill More from NY had some questions for the group. First, has anyone looked into Thimerosal preservatives in vaccines (can include up to 1000 ppm mercury)? A particular problem is how to handle waste vaccines from doctors' offices. Also, how are states handling chloral hydrate (U034), which is both hazardous and a controlled substance? And how do states regulated chemotherapeutics (often administered via IV): U-waste? P-waste? What about Lindane, which NY often finds being used in penal facilities (a potential D- and U-waste). Also with respect to reverse distributors, can past-shelf-life materials go there?

Bill was advised to call Paul Counterman on the chloral hydrate issue. Ross Bunnell discussed the former EPA guidance on return centers which was based on the presumption that returned medications could potentially be reused; however, real-world experience has shown that none of the returned materials are reused, but are instead disposed of, voiding out the rationale for this

policy. This leaves return centers as potential TSDF storage facilities. However, the universal waste rule should help resolve this problem, making such facilities mere universal waste handlers.

Robin Biscaia asked about how states handle blister packs (no response).

Ross Bunnell asked if any states had inspected any of their CVS Pharmacies for pharmaceutical management issues (none had).

Bill Cass ended the call by noting that the next conference call would be held on Wednesday, 11/12/08 due to Veteran's Day.

- - End of Call - -