

Notes
EPA - NEWMOA Pharmaceutical Waste Management Webinar
July 10, 2012

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Summary of the Status of the Pharmaceutical Rule:

- EPA continues to work on the pharmaceutical waste rule
- Lots of negative comments from 2008 proposal - do not have tracking and notification requirements, which could have created problems
- Moving forward with re-proposal for health care facilities
- Anticipate new proposal March 2013, depending on Office of Management and Budget's review
- Trying to keep the parts of the UW 2008 proposal that the commenters liked, like streamlined onsite management under universal waste program
- Working to address lack of tracking and notification
- Looking to address health care specific issues, i.e. p-listed pharmaceutical residue left in pill containers makes container p-listed
- Looking to address Drug Enforcement Agency (DEA) controlled substances that are also hazardous waste – burdensome to have two agencies with regulatory oversight
- Looking to address sewer disposal issue, agency has concerns about pharmaceuticals in water sources; may address that w/in rule making
- Looking to address reverse distribution of pharmaceuticals – planning to approach in different more holistic way; state interpretations vary quite a bit; will try to clarify; EPA's current policy is in question - online memo #11606 discusses this and says because these returned pharmaceuticals are reused, recycled, and repurposed that they are not wastes at the health care facility; EPA cannot change this interpretation without providing for public notice and comment, which can be done through a rulemaking.

EPA Response to NEWMOA letter

Agency is working on a response to NEWMOA's letter and investigating their authority to address non-hazardous waste pharmaceuticals. They would like to hold a conference call with the states that signed on to the NEWMOA letter.

IG Report

Office of the Inspector General released a report on May 29, 2012 that was critical of EPA's listings for pharmaceutical waste. The report is currently available at www.epa.gov/oig. EPA has responded to the report. The IG has responded by asking for more information from EPA on the issues identified in the report. EPA has 90 days to respond to the IG and that formal response will be published on the same website where the report is located. EPA looking at listing issues to see what could potentially address the IG's recommendations.

DEA proposal to expand consumer disposal options for controlled substances

DEA's proposal is at OMB currently. OMB started its review on May 15th, and they have 90 days for their review. It's possible that the proposal will be published for public comment sometime in August or September. EPA submitted comments to DEA during the interagency review period which occurs while a rule is at OMB.

New EPA Project

- Developing wiki for the health care sector to share their own information about what pharmaceuticals can become hazardous waste; includes a searchable spreadsheet /table that lists the drugs name /brand name and the results of the waste determinations/characterizations that have been done
- The wiki will not house EPA information but rather be a platform where community members can share their information about which pharmaceuticals become HW
- Wiki is under internal review and should be up and running by the end of August
- Will be for health care providers and government officials; users can post information but have to join as a member, which requires registration; anyone will be able to view the wiki
- EPA is also updating its ORCR website (available at: <http://www.epa.gov/epawaste/hazard/generation/pharmaceuticals.htm>) and the Health Care Environmental Resource Center – a compliance assistance center for the health care sector, which is funded by the Compliance Office; will be posting the guidance on best management practices for managing pharmaceutical waste, which is the 10-step blueprint for healthcare facilities
- Contacts for more information - Lisa Lauer, Jessica Young, and Kristen Fitzgerald

Discussion, Questions & Answers

- Q: Can FDA drug approval include HW determination/guidance?
A: EPA is working with FDA on improving disposal instructions; FDA has flush list
- Q: What can we tell someone about disposal of Chlorhydrate waste, which is a hazardous waste and a controlled substance?
A: Can flush if meet certain exclusions, may not be ok with DEA or state. Other option is sending through DEA registered reverse distributor.
- Q: Are drugs used in long term health care facilities considered household hazardous waste (HHW)?
A: Last year NEWMOA conducted a survey on this question of its states. Will have to look up the results from discussion. Here are some basic responses from the phone:
 - CT – has not tackled these facilities
 - NH – dividing line is whether an in-house pharmacy prescribed the medication, in which case it would not be considered a HHW; otherwise would be a HHW
 - MA – same approach as NH
 - RI – looking at whether the facility has a nurse or other professional in charge; if so, wouldn't look at household exclusion
 - VT – have not addressed this question
- Clarification on NEWMOA letter from RI and VT - not necessarily asking for many additional listings; suggesting a rationale for treating pharmaceutical waste differently;

may be looking to allow other destruction of pharmaceutical waste; conditional exemption that would allow incineration at municipal waste incinerators

- Comment: ME DEP looking for flexibility in revised EPA rule
- Comment: CT noted that they are struggling with retail pharmacies and big box stores; returned unused nicotine gum makes many Target stores large quantity generators (LQGs)
- Response: this is an issue that is currently being handled differently by different states, needs federal clarification in rule
- Comment: a few years inspectors in NY visited big pharmacies - Walgreens, CVS, Eckerd's - and finding that there was no training on hazardous waste determinations or segregation of HW; more recently they seem to be improving significantly as a result of the inspections, but they are finding that the smaller pharmacies have no understanding of the rules
- Comment: big retailers were recently hit with enforcement case; generally all Walmarts are operated as SQGs and were one of the first big box store to get a hazardous waste program in place; now all the big box stores are trying to get programs in place
- Suggestion: Possible change listing of nicotine gum to U-listed so it doesn't bump up smaller generators to LQGs just because of nicotine gum
- Response: EPA's proposal will address this issue in a different way that doesn't involve the listings
- Discussion about epinephrine and its various forms and how that affects its listing; question about whether epi-pen waste would be p-listed; information on the MSDS makes this confusing