NEWMOA Hazardous Waste Conference Call
December 9, 2014

Topic: Addressing P and U-listed waste pharmaceuticals while waiting for the final EPA rule: inconsistencies in interpretation among the large pharmacy chains

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Participants: CT DEEP (9 people); Mass DEP (3 people); NH DES (4 people); NJ DEP (5 people); NYS DEC (12 people); RI DEM (2 people); EPA Region 1 (4 people); EPA HQs (2 people); NEWMOA (1 person)

Call leader: New York State DEC

Note-taker: Terri Goldberg, NEWMOA with assistance

Background Provided by NYS DEC

Large pharmacy chains classify their waste pharmaceuticals whichever way EPA and the state agencies require them to be classified since they want to avoid being cited. About the only time NY hears of differing P- and U-listing interpretations from the pharmacies is when the pharmacy has already been cited for a violation and they are responding to the citation.

DEC feels that EPA has done a good job in getting the word out of when pharmaceutical wastes meet the P- and U-listings (e.g., see http://www.epa.gov/waste/hazard/generation/pharmaceuticals.htm). The call focused on why there are differences in how the major pharmacies classify their pharmaceutical wastes relative to EPA's classification. The reasons fall into two basic categories:
(1) The states where they operate have differing interpretations

To avoid having a patchwork of requirements, large chains will often go with the most stringent state's interpretation in their operating area (or at least regionally if they're a national chain).

This has the advantage of greatly simplifying such things as the chain's training requirements, which they might conclude would otherwise be an administrative nightmare.

(2) Non-governmental guidance advises a classification more stringent than the government agencies' classifications

There are publications recommending certain types of pharmaceutical waste be classified as P- or U-listed that are more stringent than what EPA or the states require, and the pharmacy chain sometimes elect to go with that more stringent classification. A good example is the well-respected "10-Step Blueprint" document (found at: www.hercenter.org/hazmat/tenstepblueprint.pdf) recommending that even *used* nicotine patches be classified as P075 (p. 16). (A large pharmacy might generate used patches at their in-store clinics.)

In 2010 EPA published a proposed "Best Management Practices for Unused Pharmaceuticals at Health Care Facilities" document (see 9/8/10 *Federal Register* announcement) and that document specifically quoted from the 10-Step Blueprint document as well as listing it as a resource, so there is some overlap taking place between these two categories that can muddy the waters for the regulated community.

A variant of category 2 is where the pharmacy chain concludes they are getting sufficient mixed signals that they evaluate their P- and U-classifications independently either with their own in-house staff or with consultants and draw their own conclusions. But, as suggested above, they are largely constrained by the overseeing governmental agencies' interpretations because of the governmental agencies' ability to cite the pharmacies for violations if their P- & U-classifications are less stringent.

A letter recently surfaced that illustrates many of these points. It is a 2014 letter by Wisconsin DNR that was distributed last week through EPA's RCRA Interpretation Network (RIN) (the document, "Veolia ES Technical Solutions ecigarettes.pdf" was sent out via email by NYS DEC prior to the call). Although it technically does not address a pharmaceutical but rather e-cigarettes and the unused nicotine solution container inside, the classification issues are essentially the same as for nicotine-containing pharmaceuticals. Wisconsin's letter is useful for the purposes of the discussion because it relies heavily on EPA guidance by which RCRA-authorized states must abide by (at a minimum).

The incoming letter to which Wisconsin is replying is not available, but it is clear there was some significant pushback by the treatment, storage, and disposal facility (TSDF) (as opposed to the retailer), who presented some arguments about nicotine not being the sole active ingredient, and the state refutes those arguments by basically overstating what various EPA guidance have said. EPA guidance does not say "primary active ingredient", it refers to "sole active ingredient". In a 1986 *Federal Register* (2/13/86 FR 5472), EPA proposed to have the P-listings apply to mixtures of ingredients, stating "until now, only products in which a listed chemical was the sole active ingredient were regulated." That proposal was never promulgated, so the P-listings continue to require that the chemical be the sole active ingredient.

Another argument is that flavorings and sweeteners in e-cigarette nicotine formulations are not active. In 2010 when EPA was in the process of dropping the sweetener Saccharin from being U202, it said in the *Federal Reg*ister that "the U202 listing is narrow and does not apply to… discarded products that contain saccharin as a sweetening agent." (4/22/10 FR P 20947) In other words, in 2010 EPA regarded a sweetener as an active ingredient, and so to be consistent one has to conclude that when nicotine is combined with a sweetener to form a product, it no longer has a sole active ingredient and the P075 listing cannot apply to the discarded product. Later in the letter, WI DNR goes the other way and ignores the fact that a waste-manufactured product having P-listed material inside must be managed as a P-listed hazardous waste.

Among other things, this letter illustrates how there is a patchwork of requirements that large retail chain pharmacies have to try to negotiate and reconcile when classifying their pharmaceuticals.

<u>EPA Headquarters (HQs) Response to Introduction</u>
Participants in the call from EPA HQs noted that they agree with some aspects of the WI letter and disagree with others. They noted that EPA needs to review the regulations and develop answers with respect to e-cigarettes, e-nicotine, and e-liquids. It's not clear what EPA will say about these materials. They are considering the view that nicotine and liquids are the sole active ingredient, but this is not yet official. They would like to see nicotine sent for reclamation not included in the P075 listing. EPA has issued some letters that focus on the P-listings. They have noted that salts are not on the P list. They have taken nitroglycerin pills off the list. The P-list has been gradually chipped away, and some states are not following EPA's letters. The Ten Step Blueprint noted in the call introduction focuses on chemotherapy drugs. EPA refers people to the document and recommends that they follow it.

<u>Connecticut</u>
DEEP is working on a proposal to regulate pharmaceutical waste under the Universal Waste (UW) Rule. P and U-listed pharmaceutical wastes that are generated at a pharmacy are hazardous and should be managed as UW. CT has not adopted the federal mixtures and derived-from rule revisions. So in CT nitroglycerin is still P081. DEEP does not agree with EPA's memo regarding epinephrine salts. They have examined the toxicity of salts and found that they are sometimes the same or more toxic that the other forms. Salts are sometimes more amenable to absorption. They have a question about phentermine and phentermine salts and think they may be similar to epinephrine.

CT considers nicotine patches to be P075 waste. They think the sole active ingredient is nicotine. They do not think the saccharin argument applies, since it is a sweetener.

When the P and U-listed wastes come off the shelf, expired or not, they consider then to be non-dispensable and a waste.

They do not view reverse distribution as a reason to exempt pharmaceuticals from designation as hazardous waste (HW) if they are P and U-listed. Whether or not the pharmacy gets credit from the reverse distributor (RD), they consider the material a waste.

DEEP's inspectors have not encountered any situations where a manufactured article, like an e-cigarette, is being disposed of.

Massachusetts
They follow EPA's interpretations and are working on the issues. They currently regulate the collection of pharmaceuticals and drugs at police stations and collection centers. The sites must submit a waiver to the household hazardous waste (HHW) rules. Normally, facilities that sponsor HHW days or events or set up a permanent center must get a permit. The kiosks at the policy stations must have a waiver from the HHW permit requirement.

New Hampshire
DES is aligned with EPA on the P and U-listed wastes, particularly the epinephrine (not including the salts), nitroglycerin (not HW and not reactive), and phentermine salts. The Agency has been contacted by companies that are marketing drug disposal units to pharmacies and hospitals. These products appear to be in response to the recent Drug Enforcement Agency (DEA) Rule requiring that the drugs be rendered non-retrievable. They have heard about three different products, including Cactus Smart Sync, Drug Disposal, and Med Safe. The manufacturers want all of the pharmaceuticals to be managed in these units, but there is a problem with putting P and U-listed wastes in these units. NH will not extend HHW exemption to pharmaceutical waste generators. NH is skeptical of the claims by the manufacturers of the units because there is little research to support them, and the units are proprietary black boxes – "trust us the materials are not retrievable."

NH's RD policy follows EPA's policy. DES has done some inspections of hospitals (no pharmacies). They want to make sure the material is being managed properly through RD, like a product, as if it has value. They are struggling with the issues and waiting to see the EPA proposal. NH indicated that it considered warfarin pill bubble-packs to be delivery devices and not containers, and therefore are not P001, citing EPA's syringe memo [editor's note: Likely RO# 14788]

EPA HQs is interested in engaging the DEA on the "non-retrievable disposal" units and to come out with a joint policy.

New Jersey
DEP follows the federal rules and are awaiting EPA's interpretations. They have many pharmacies that have notified as large quantity generators (LQGs) that never were before due to nicotine waste materials. They would like to see this situation changed.

Commentary
Mass DEP does not regulate blister packs and single serving cups with Coumadin or warfarin as HW. NH DES focuses on the delivery devices and not the containers. They consider them pre-loaded delivery devices. Multi-dose containers are considered to be different because there is likely to be more residue as pills knock into one another. Nicotine used patches and gums are not P-listed in NH and CT.

New York

DEC has a problem with EPA's used syringe interpretation for epinephrine. The syringe is used when partially administered but the remaining contents are not used. RCRA online includes the "Sure-Way memo", which talks about P or U-listed drugs in syringes.

Connecticut
DEEP does not consider returned credit from an RD to be an indicator that the product was not discarded. All drugs removed from shelves for any reason and sent to a RD facility is a waste even if there is the potential for credit. The value placed on the material is not an indicator that the material is not a waste.

New York
DEC is leaning in another direction. They think the material can go to RD regardless of whether credit is given. NY follows the 1981 EPA guidance on RDs (See RO# 11092).

Rhode Island
DEM adopted regulations in 2014. They picked up the EPA rule changes and definitions for epinephrine and phentermine. They have not encountered the syringe issue.

DEM has conducted inspections at retail pharmacies and uncovered many issues. They have found a patchwork of compliance and interpretations. CVS was generally found to be in compliance and knowledgeable. Walgreens and Rite Aid claimed at first that they have no HW. DEM has asked for information on RD. They have found that credit is provided much of the time and most of the material goes to incineration. They have found that less than five percent of the pharmaceuticals sent to RD are P and U-listed HW. RD is acceptable in RI if they can document credit and if they can tie the material to a specific shipment.

At Rite Aid they found lots of material spilled and not handled properly for RD. Dropped pills are HW. They have not encountered the syringe issue. They are leaning toward considering the unused material as P-listed.

Connecticut
In CT's enforcement settlement with CVS, in order to settle the case DEEP allowed them to use RD as long as there was an expectation of credit. True waste-like material cannot go to RDs. Need to be managed under full RCRA rules. For new inspections after the CVS case, DEEP applies full RCRA regulations unless the facility has signed a consent order requiring best management practices (if they want to follow similar logistics as CVS).

EPA HQs
The draft EPA pharmaceutical rule is in final internal review by EPA management. EPA plans to send it to the Office of Management and Budget (OMB) for their review early in 2015. They hope to publish the proposal in June.

DEA held a webinar to explain their rule. EPA HQs will share a link with NEWMOA to the hour long training by DEA and a contact at DEA.