

From: Bishop, Robert B [Robert.Bishop@des.nh.gov]
Sent: Tuesday, June 14, 2011 11:50 AM
To: Bunnell, Ross
Subject: RE: Question
Attachments: NH Reverse Distribution of Pharmaceuticals.pdf

Ross,

I'm sorry for the delayed response to your email, I hope the information is still useful. My answers are in black.

Bob

- 1.) What are your state's policies (if any) regarding the management of non-residential unwanted or unusable pharmaceuticals?
If the pharmaceuticals are "solid waste" we expect a hazardous waste determination to be made on those wastes. We have a written policy (see attached) on the reverse distribution of pharmaceuticals; essentially the policy does **not** consider pharmaceuticals headed for reverse distribution to be solid wastes provided there is a reasonable expectation that the pharmaceuticals will be used.
We have not pushed on the "reasonable expectation" requirement up to this point. Our inspector interactions on reverse distribution have only been in hospital pharmacies. Provided the pharmaceuticals were being managed as a product and a qualified individual (pharmacist) was distinguishing between products for reverse distribution and waste pharmaceuticals we have not pressed the issue.
We have inspected 8 hospitals over the last 4 years, most had a waste pharmaceutical and reverse distribution programs in place. One did not have a waste pharmaceutical program and I am currently working on a penalty negotiation with that hospital.
- 2.) If non-residential pharmaceuticals conform to a hazardous waste characteristic or listing, do you require that they be managed as hazardous waste? If they are solid wastes (i.e., no reasonable expectation of use) we require them to be managed as hazardous waste.
- 3.) What do you consider to be the point of generation? 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? At the pharmacy or health care facility
- 4.) Do you have any specific policies relating to the use of pharmaceutical return centers? No, expect attached letter
- 5.) Do you have any specific policies relating to the management of unusable/unwanted pharmaceuticals at retail pharmacies (e.g., CVS, Walgreens, Rite Aid, etc.)? No
- 6.) Do your policies differentiate in any way between different types of health care facilities (i.e., hospitals vs. long-term health care facilities vs. retail pharmacies)? No, except for some hospice or long-term care facilities the pharmaceuticals may be considered household waste depending on if they originated from the facility or the patient.
- 7.) Have any of you had enforcement of any kind with any retail chain pharmacies in your state? (If so, please briefly summarize the nature of the violations and the resolution of the case.) No
- 8.) Do you have any written guidance that you can forward me relating to this topic?

Robert Bishop
Enforcement Manager
Hazardous Waste Management Bureau
New Hampshire Department of Environmental Services
29 Hazen Dr., PO Box 95
Concord, NH 03302
(603) 271-2383

-----Original Message-----

From: Bunnell, Ross [<mailto:Ross.Bunnell@ct.gov>]

Sent: Tuesday, May 10, 2011 10:12 AM

To: 'Jennifer Griffith'; 'Bret Reburn, NJ'; 'Brett Putnam, NYS'; 'Carole Cifrino, ME'; 'Ed Vigneault, ME'; 'Gary Gulka, VT'; 'George Desch, VT'; 'James Paterson (MA)'; Duclos, John; 'Judy Mirro, VT'; Sullivan, Kevin T.; 'Lynn Metcalf, VT'; 'Marc Roy, VT'; 'Mark Dennen, RI'; 'Mike Hastry, NJ'; Wimsatt, Mike; 'Richard Kaselis, ME'; Bishop, Robert B; Isner, Robert; 'Ron Gagnon, RI'; 'Russ Brauksieck (NYS)'; Johnson, Sara; 'Scott Whittier, ME'; 'Sean Carney (RI)'; 'Stacy Ladner, ME'; 'Steve Simoes, VT'; 'Steven DeGabriele (MA DEP)'; Leedberg, Tod; 'Tom Killeen, NYS'; Metzner, Tom; Bonner, Wendy; 'William Sirull, MA'; 'Yan Li, RI'

Cc: DiNoia, Michele; Ploch, Peter; Sullivan, Kevin T.; Applefield, Dean

Subject: Question

Dear NEWMOA HW Conference Call contacts:

I am emailing you all in the hopes that I can quickly collect some information about how other NEWMOA states handle a particular HW compliance issue that we are dealing with at the present time.

The issue has to do with the management of old (past shelf-life), recalled, damaged, unneeded, or discarded pharmaceuticals at health care facilities, and in particular retail pharmacies. I know we had a conference call on the management of pharmaceuticals back in October of 2008, but I suspect that some of you may have changed or refined your policies since then.

Here are my specific questions:

- 9.) What are your state's policies (if any) regarding the management of non-residential unwanted or unusable pharmaceuticals?
- 10.) If non-residential pharmaceuticals conform to a hazardous waste characteristic or listing, do you require that they be managed as hazardous waste?
- 11.) What do you consider to be the point of generation? 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?
- 12.) Do you have any specific policies relating to the use of pharmaceutical return centers?
- 13.) Do you have any specific policies relating to the management of unusable/unwanted pharmaceuticals at retail pharmacies (e.g., CVS, Walgreens, Rite Aid, etc.)?
- 14.) Do your policies differentiate in any way between different types of health care facilities (i.e., hospitals vs. long-term health care facilities vs. retail pharmacies)?
- 15.) Have any of you had enforcement of any kind with any retail chain pharmacies in your state? (If so, please briefly summarize the nature of the violations and the resolution of the case.)
- 16.) Do you have any written guidance that you can forward me relating to this topic?

Thanks in advance for any and all information you can provide.

--Ross Bunnell, Sanitary Engineer 3
CT Department of Environmental Protection (DEP)
Bureau of Materials Management and Compliance Assurance
Waste Engineering & Enforcement Division
Tel. 860.424.3274
Fax 860.424.4059
ross.bunnell@ct.gov