



NORTHEAST WASTE MANAGEMENT OFFICIALS' ASSOCIATION

December 22, 2015
OSWER Docket, EPA Docket
Center, Mail Code 28221T
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460
Attention: Docket ID No. EPA-HQ-RCRA-2007-0932

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Dear Sir or Madam:

The Northeast Waste Management Officials' Association (NEWMOA) appreciates the opportunity to comment on the "Management Standards for Hazardous Waste Pharmaceuticals; Proposed Rules," as published in the *Federal Register* (September 25, 2015). The comments outlined below represent a consensus of NEWMOA's members. Many of the member states plan to submit additional comments.

The proposed revisions are intended to facilitate compliance of healthcare facilities with RCRA Subtitle C and to clarify the regulation of the reverse distribution mechanism. In general, NEWMOA is supportive of the proposed rule and offers the following comments.

1. SECTION IV.B. (page 58020, column 3) – Background / Rationale and Goals

EPA states that, "This new proposed rulemaking will pertain to those waste pharmaceuticals that meet the current definition of a RCRA hazardous waste *and* are generated by healthcare-related facilities and managed by pharmaceutical reverse distributors, as defined by this proposal." This preamble language suggests that in order for waste pharmaceuticals to qualify for management under the proposed rulemaking, they must be managed by a pharmaceutical reverse distributor. NEWMOA requests that EPA clarify that this is not EPA's intent and that healthcare facilities are allowed to manage non-creditable hazardous waste (HW) pharmaceuticals under the proposed rulemaking without their needing to be sent to a reverse distributor provided they are instead sent directly to a Treatment, Storage and Disposal Facility (TSDF).

2. SECTION V.A. (page 58021) – Definitions of Proposed Terms

While we generally agree that the broad scope of waste materials included under EPA's definition of "pharmaceutical" is appropriate, we are concerned that it could be misinterpreted to mean that it is EPA's intent to expand the scope of waste materials subject to regulation under RCRA subtitle C. As such, we suggest that EPA provide some additional clarification that this is not the Agency's intent.

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In response to EPA's request for comment on the definition of "pharmaceutical," the inclusion of personal protective equipment (PPE) contaminated with pharmaceuticals is not clear. The current language could be interpreted by people not familiar with the details of the mixture and contained-in rules to include gloves used to pick up a pill, which NEWMOA does not believe is appropriate. Since this rule will apply to retail pharmacies that do not typically have that expertise, we believe that this portion of the definition should be clarified to exclude PPE that may have come into contact with HW pharmaceuticals (HWPs), but which have no (or de minimis amounts of) residue on them.

EPA requests comments on the definitions of "non-creditable hazardous waste pharmaceutical" and "potentially creditable hazardous waste pharmaceutical." We are concerned that the distinction between "potentially creditable" and "non-creditable" is practically unenforceable. In this rule, EPA provided examples of instances where "it is well known that a pharmaceutical will not be creditable," including:

- If the pharmaceutical has been removed from the original container and re-packaged for dispensing purposes;
- If an attempt was made to administer a pharmaceutical, but the patient refused to take it;
- If the hazardous waste pharmaceutical was generated during patient care;
- If the pharmacy receives a return of a dispensed pharmaceutical for which they had already received compensation by a third-party payer; or
- If the pharmaceutical is more than one year past its expiration date.

It has also been suggested that generic pharmaceuticals could be considered non-creditable. If a pharmaceutical manufacturer were to nonetheless explicitly offer credit for HWPs in some of these circumstances (e.g., for generic pharmaceuticals or pharmaceuticals more than a year past expiration), would EPA oppose having them become potentially creditable? For inspectors to know whether most of the above conditions are met, they would have to know the actions, and sometimes the intent, of healthcare workers, which could not be known by an inspector. NEWMOA asks that EPA expand on what RCRA inspectors should look for and the types of evidence health care facilities should produce to show that HWPs slated to be sent to a RD are potentially creditable.

NEWMOA supports EPA's proposed definition of "healthcare facility" in Section V.A.9. page 58024, but we think it should also include school nurse's offices and infirmaries. In addition, in the preamble EPA states, "The proposed definition of 'healthcare facility' does not apply to pharmaceutical manufacturers and their representatives, wholesalers, or any other entity that is involved in the manufacturing, processing or wholesale distribution of over-the-counter or prescription pharmaceuticals, unless they meet the definition of a 'reverse distributor'." EPA should include this language within the 40 CFR 262.500 definition of "healthcare facility." In addition, NEWMOA requests that EPA define the term "forward distributor."

3. SECTION V.B.1.c. (page 58027, column 2) – Scope of Proposed Rule / Conditionally Exempt Small Quantity Generators

EPA requested comment "...on whether the proposed healthcare facility standards, in addition to the sewer ban, should apply to Conditionally Exempt Small Quantity Generator (CESQG) healthcare facilities." NEWMOA supports the proposal as it applies to CESQGs and strongly supports the applicability of the sewer ban to CESQGs.

4. SECTION V.C. (page 58030) – Proposed Standards for Healthcare Facilities that Manage Non-creditable Hazardous Waste Pharmaceuticals

Notification Requirements (Section V.C.1., page 58031, column 2)

It is likely that if a healthcare facility is managing non-creditable hazardous waste pharmaceuticals, they are also generating potentially creditable hazardous waste pharmaceuticals. EPA appears to indicate that this notification can occur either via the RCRA Subtitle C Site Identification Form, or biennial reports. NEWMOA’s members wish to confirm that the notification must be made via the RCRA Subtitle C Site Identification Form, but that its submittal via the biennial report is also permissible. We recommend that initial notification be made by using an 8700-12 form (modified to include subpart P).

Processing the proposed notifications will place a burden on authorized states, particularly in light of dwindling state program resources. The preamble states (page 58031, column 3) that “...healthcare facilities are required to notify within 60 days of this new subpart becoming effective, or within 60 days of becoming subject to this new subpart.” NEWMOA’s members believe that inputting notifications, tracking and verifying compliance, and enforcing this notification requirement will be overly burdensome on state programs. As such, additional federal resources for state programs are warranted.

Making a Hazardous Waste Determination (Section V.C.3., page 58032, column 3)

EPA states that, “However, healthcare facilities may choose to manage all of their pharmaceutical waste as hazardous waste, and thus, if a healthcare facility chooses this approach, they would not need to make individual hazardous waste determinations, but would have made a generic decision that all of their waste pharmaceuticals are hazardous and managed them as hazardous waste pharmaceuticals in accordance with the proposed requirements of 40 CFR part 266, subpart P.”

NEWMOA applauds EPA for specifying this approach within the proposed rule. By having the option to not make hazardous waste determinations (a daunting task for facilities not well versed in RCRA) on waste pharmaceuticals, many healthcare facilities will likely be encouraged to manage all of their pharmaceutical waste in an environmentally protective manner (i.e., as hazardous waste pharmaceuticals).

Container Standards (Section V.C.5., page 58033, columns 2 and 3)

EPA states that, “Furthermore, the Agency is proposing to require that incompatible wastes not be placed in the same container unless... [five specified conditions are met].”

NEWMOA believes that the specified conditions are subjective (i.e., due to language like “*extreme* heat or pressure,” “*uncontrolled* toxic mists,” and “*uncontrollable* flammable fumes or gases”), and we feel that the traditional prohibition on incompatible wastes in the same container should be applied.

Shipments Off-Site (Section V.C.9., [also found in EPA’s Section V.F.] page 58039/column 3)

EPA is proposing that RCRA hazardous waste codes do not need to be listed on manifests. NEWMOA recommends that EPA create a single hazardous waste code for “non-creditable hazardous waste pharmaceuticals” that may be used by healthcare facilities when shipping such wastes off-site. It should be noted that the absence of a hazardous waste code on manifests may

create problems for state hazardous waste manifest tracking and tax assessment systems. If section 13 (i.e., Waste Codes) is a required field on the e-manifest, this may pose a problem.

Healthcare Facilities that Accept Hazardous Waste Pharmaceuticals from Off-Site Conditionally Exempt Small Quantity Generators (Section V.C.15., page 58042, column 2)
EPA states that, it “is proposing to allow healthcare facilities that are CESQGs operating under this subpart to send their hazardous waste pharmaceuticals to an off-site healthcare facility, without a hazardous waste manifest, provided four conditions are met. First, the receiving healthcare facility must be *contracted* (emphasis added) to supply pharmaceutical products to the CESQG... and the receiving healthcare facility must both be under the control of the same person...”

While NEWMOA agrees that it is important that both the sending CESQG and receiving healthcare facility be under the control of the same person, we do not understand the logic of requiring the receiving healthcare facility be “contracted” to supply pharmaceutical products to the CESQG. EPA should consider specifying a “business relationship” rather than a “contract.”

5. SECTION V.D.3. (page 58044) – Accumulation Time, Container Management, and Labeling for Potentially Creditable Hazardous Waste Pharmaceuticals at Healthcare Facilities

We applaud EPA for proposing the concept that once a decision has been made to send a pharmaceutical to a reverse distributor the pharmaceutical has been discarded by the generator. We are concerned about EPA’s proposal to not require labeling of the hazardous pharmaceutical waste. While we understand the concern about diversion, unlabeled waste is easily forgotten and ends up stored in unsecured locations where it is even more subject to diversion or improper disposal.

In column 2, EPA states that, “Therefore, because of the lower risk these pharmaceuticals pose, EPA is not proposing specific management standards for healthcare facilities that accumulate containers of potentially creditable hazardous waste pharmaceuticals.” In column 3 EPA states: “EPA also is proposing not to require specific labeling standards for containers holding potentially creditable hazardous waste pharmaceuticals, while they accumulate on-site.” To help facilitate compliance monitoring by EPA and authorized state programs, NEWMOA recommends that potentially creditable hazardous waste pharmaceuticals should be accumulated in a designated location and that either the designated location be identified with signage or the containers holding potentially creditable hazardous waste pharmaceuticals be marked/labeled.

6. SECTION V.E. (page 58044) – Proposed Novel Prohibitions, Exemptions, and Other Unique Management Requirements

Banning sewerage of hazardous waste pharmaceuticals (Section V.E.1.e., page 58046, column 1 and page 58047, column 1)

We strongly support the ban on sewer disposal of pharmaceuticals for all generators. This will serve to change the standard practice for pharmaceuticals at healthcare facilities and reinforce other messages sent to CESQG’s and homeowners.

EPA states that, “Finally, we would note that although the sewer ban is limited to pharmaceuticals that are RCRA hazardous wastes, EPA strongly recommends as a best management practice to not sewer any waste pharmaceutical, except when sewerage is specifically directed by FDA guidance.”

NEWMOA notes that by specifying an approach that allows healthcare facilities to manage all of their non-creditable pharmaceutical waste (i.e., both hazardous and non-hazardous) as hazardous waste and to not require healthcare facilities to make individual hazardous waste determinations if they choose this approach, it is likely that those facilities will not sewer their non-hazardous pharmaceuticals. If EPA eventually chooses to regulate all pharmaceutical waste as a category (as proposed in NEWMOA’s February 21, 2012 letter - www.newmoa.org/publications/letters/FinalPharmaceuticalLetteronLetterhead2-21-12.pdf and ASTSWMO’s Position Paper titled, “A New Regulatory Approach to Pharmaceutical Waste Management” - www.astswmo.org/Files/Policies_and_Publications/Hazardous_Waste/2013-04-Pharmaceutical_Waste_Position_Paper-Board_Approved.pdf), EPA could then ban the sewerage of all pharmaceutical wastes.

Exemption of HW Pharmaceuticals that are Controlled Substances (Section V.E.2., page 58047, column 2).

We strongly support the concept of exempting controlled substances from RCRA as dual regulations create too complex a network of regulatory issues. This would also complement the approach some of NEWMOA’s members use for household pharmaceutical collection.

Household Hazardous Waste Collected in DEA Authorized Collection Receptacles (Section V.E.2.b., page 58050, column 1)

NEWMOA agrees with the goal of ensuring that household waste pharmaceuticals collected in DEA-authorized collection receptacles are sent for combustion.

Management of Residuals in Pharmaceutical Containers (Section V.E.3., page 58051, column 2)

We agree with the proposal to conditionally exempt empty containers that once held hazardous waste pharmaceuticals.

7. SECTION V(F) – What are the Proposed Standards for Shipping Hazardous Waste Pharmaceuticals?

Recordkeeping for Shipments of Potentially Creditable Hazardous Waste Pharmaceuticals (Section V.F.2.c., page 58059, column 2)

EPA states that, “The Agency seeks comment on whether additional recordkeeping is necessary to document the cases when the pharmaceutical reverse distributor does not receive a shipment of potentially creditable pharmaceuticals within 7 calendar days and the steps (that) must be taken to locate the shipment.”

NEWMOA believes that such records must be maintained in order for EPA and authorized state programs to adequately evaluate compliance with the proposed shipping standards. NEWMOA recommends that there should be a requirement that all records for tracking shipments must be readily available at the time of a compliance inspection of a healthcare facility.

8. SECTION V.G.3. b. (page 58064, column 3) – Additional Standards for Pharmaceutical Reverse Distributors Managing Potentially Creditable Hazardous Waste Pharmaceuticals Destined for Another Pharmaceutical Reverse Distributor

EPA states that, "...the Agency believes a reasonable limit is three transfers of potentially creditable hazardous waste pharmaceuticals before the pharmaceutical hazardous waste is ultimately transported to a TSDF." NEWMOA would like EPA to clarify how states will be able to enforce this rule for interstate shipments.

9. SECTION VII (page 58071, columns 1 and 2) – Request for Comment on EPA’s Efforts to Identify Additional Pharmaceutical Hazardous Wastes

We agree with the recommendations of the Office of Inspector General (OIG) in their May 25, 2012 Report and strongly encourage EPA to work with other agencies to identify and review existing pharmaceuticals to determine whether they qualify for regulation as hazardous waste pharmaceuticals under subpart P, and establish a process to review new pharmaceuticals as they are introduced to determine whether they qualify for regulation as hazardous waste. We agree that the current universe of pharmaceuticals that are regulated under RCRA is out-of-date given the amount of pharmaceuticals that have been created in the last 35 years.

Given the enormity of the task, we suggest that EPA could take a number of alternate approaches including:

- Adopting the “NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings,” or
- Adopting criteria by which generators can determine if a pharmaceutical is hazardous (potentially reviewing and modifying the criteria used by NIOSH).

In addition to identifying pharmaceuticals that are most toxic to humans, we would encourage that future regulations consider those pharmaceuticals that have the greatest potential to impact the environment (e.g., antihistamines and endocrine disruptors).

EPA states (page 58071, columns 1 and 2) that, “For example, should EPA develop and promulgate new criteria specific to discarded pharmaceuticals that would allow it to establish a single hazardous waste listing for all discarded pharmaceuticals that meet the new criteria?”

This approach was recommended in NEWMOA’s February 21, 2012 letter and ASTSWMO’s Position Paper mentioned above, and NEWMOA continues to support this approach.

10. SECTION VIII.D. and E. (pages 58072 and 58073) – E-cigarettes and Nicotine-containing E-liquids

Request for Comment on EPA’s Efforts to Amend the Acute Hazardous Waste Listing for Nicotine and Salts (Two Possible Approaches for Amending the P075 Listing)

We recommend continued regulation of e-cigarettes and nicotine-containing e-liquids as the safety of these products is less widely accepted because they are neither pharmaceuticals nor supplements.

In summary, NEWMOA is generally supportive of EPA’s proposed rule and offers its comments to help improve upon the proposal.

NEWMOA is a nonprofit, nonpartisan interstate association that has a membership composed of the hazardous waste, solid waste, waste site cleanup, and pollution prevention program directors for the environmental agencies in Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, and Vermont. NEWMOA was established by the Governors of the New England states as an official regional organization to coordinate interstate hazardous and solid waste, pollution prevention, and waste site cleanup activities, and was formally recognized by the U.S. Environmental Protection Agency (EPA) in 1986. NEWMOA's mission is to develop, lead, and sustain an effective partnership of states that helps achieve a clean, healthy, and sustainable environment by exploring, developing, promoting, and implementing environmentally sound solutions for:

- Reducing materials use and preventing pollution and waste,
- Properly reusing and recycling discarded materials that have value,
- Safely managing solid and hazardous wastes, and
- Remediating contaminated sites.

The group fulfills this mission by providing a variety of support services that:

- Facilitate communication and cooperation among member states, between the states and the U.S. EPA, and between the states and other stakeholders;
- Provide research on and evaluation of emerging issues, best practices, and data to help state programs maximize efficiency and effectiveness; and
- Facilitate development of regional approaches to solving critical environmental problems.

Thank you for the opportunity to comment on the proposed rule. We look forward to EPA's final decision on this important rulemaking. Please contact Terri Goldberg, NEWMOA at (617) 367-8558 x302, tgoldberg@newmoa.org if you have any questions about these comments.

Sincerely,



Michael Wimsatt
New Hampshire Department of Environmental Services
NEWMOA 2016 Hazardous Waste Program Chair

cc: NEWMOA Board of Directors
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