U.S. EPA Proposes Sector-Specific Rules for Hazardous Waste Pharmaceuticals

By Karlie Clemons Webb, Troutman Sanders

Under existing regulations, retail pharmacies, hospitals, and other healthcare facilities such as nursing homes are subject to the same U.S. Environmental Protection Agency (EPA) hazardous waste regulations as industrial facilities. Healthcare facilities have for years wrestled with challenges inherent in managing their hazardous waste streams, such as prescription and over-the-counter drugs, pursuant to applicable regulations, while also implementing a management program that is workable in a retail or healthcare setting. Pharmaceuticals, like vitamins or cough medicine, can be deemed waste if expired or unsalable, and can be deemed hazardous if toxic or flammable, for example. National retail pharmacies in particular have struggled with the myriad of deviations in state requirements, as some states have adopted regulations or guidance specific to hazardous waste pharmaceuticals, and others have not.

EPA has recognized the challenges faced by the healthcare sector in complying with Resource Conservation and Recovery Act (RCRA)[1] hazardous waste regulations. On September 25, 2015, EPA published in the Federal Register the proposed *Management Standards for Hazardous Waste Pharmaceuticals*,[2] which proposes healthcare sector-specific requirements for managing hazardous waste pharmaceuticals. While not a comprehensive analysis of the proposed rule, this article highlights several key points in the proposed rule and comments on potential impacts to healthcare facilities.

Rulemaking History

The proposed rule is not EPA's first time recognizing the challenges faced by healthcare facilities with respect to hazardous waste pharmaceuticals. In 2008, EPA proposed to add hazardous waste pharmaceuticals to the Universal Waste Rule as a means of streamlining the management process.[3] After many negative public comments, EPA formally rescinded the proposed rule in 2012. Since that time, the regulated community has provided significant feedback to EPA on issues related to managing hazardous waste pharmaceuticals, which aided EPA in drafting the proposed rule.

Specific to issues faced by retail pharmacies (and other retailers), on February 14, 2014, EPA published its Notice of Data Availability and Request for Comment (NODA),[4] which asked retailers to comment on various issues related to hazardous waste management. Retailers responded on various issues, including, for example, over-the-counter drugs. While EPA has not proposed a rule specific to the retail sector, the NODA confirmed that EPA was listening to retailers' concerns, including concerns related to over-the-counter drugs. It is unclear whether EPA will propose retail-specific hazardous waste regulations applicable to the broader universe of retail consumer products.

Applicability of Proposed Rule

Subpart P. The proposed rule would create a new subpart P under 40 C.F.R. Part 266, "Standards for the Management of Specific Hazardous Wastes and Specific Types of Hazardous Waste Management Facilities."[5] Except for Conditionally Exempt Small Quantity Generator (CESQG) healthcare facilities, *hazardous waste* pharmaceuticals generated by *healthcare facilities* would be solely managed under the new 40 C.F.R. Part 266 Subpart P, in lieu of 40 C.F.R. Part 262.[6] A healthcare facility is also given the option of electing to manage its solid waste pharmaceuticals as hazardous waste pharmaceuticals under Subpart P.[7] "Healthcare facility" is defined broadly in the proposed rule, to include, for example, hospitals, health clinics, pharmacies, and long-term care facilities.[8] "Pharmaceutical" is also defined broadly and would capture over-the-counter medications, including some nicotine-containing products, such as nicotine replacement therapy (NRT) products (gum, lozenges, and patches).[9]

Generator Status. Under the proposed Subpart P, a healthcare facility's hazardous waste pharmaceuticals would not count toward its generator status.[10] This would provide some relief to healthcare facilities, particularly retailers, which, under the current regulatory scheme, often do not maintain a consistent generator status, generally due to fluctuations in the amount of acute hazardous waste generated from month to month, resulting from expired or returned NRT products. Further, because hazardous waste pharmaceuticals, particularly NRT, would no longer count toward a healthcare facility's generator status under the proposed rule, the healthcare facility would likely experience a change in its generator status for its non-pharmaceutical hazardous waste as well.

CESQGs. Under the proposed rule, CESQGs would maintain the conditional exemption under 40 C.F.R. § 261.5.[11] Alternatively, a CESQG could choose to manage its hazardous waste pharmaceuticals pursuant to the proposed Subpart P.[12] EPA also proposes to revise the list of facilities[13] to which CESQGs may ship, to allow CESQGs to send hazardous waste pharmaceuticals to pharmaceutical reverse distributors. [14] Importantly, in determining whether a healthcare facility must manage its hazardous waste pharmaceuticals under the proposed

Subpart P or would remain a CESQG pursuant to 40 C.F.R. § 261.5, the healthcare facility would be required to count all hazardous waste it generates in a calendar month, including both pharmaceuticals and non-pharmaceuticals. Currently a retail pharmacy does not count hazardous waste pharmaceuticals sent to a reverse distributor toward the retailer's generator status. Under the proposed rule, hazardous waste pharmaceuticals sent for reverse distribution pursuant to the proposed rule would be counted toward the retailer's generator status when initially determining whether the retailer is a CESQG or subject to Subpart P.[15] Accordingly, although a particular retailer may currently be a CESQG without counting hazardous waste pharmaceuticals sent for reverse distribution, under the proposed approach, the retailer may no longer be a CESQG.[16]

DEA Regulated Hazardous Waste Pharmaceuticals.

EPA also proposes a conditional exemption for those hazardous waste pharmaceuticals that are also Drug Enforcement Administration (DEA) controlled substances. Currently, hazardous waste pharmaceuticals that are also DEA controlled substances are subject to both RCRA hazardous waste requirements and the Controlled Substances Act and DEA regulations. The proposal would exempt these hazardous waste pharmaceuticals from the RCRA regulatory requirements, provided the hazardous waste pharmaceuticals are managed in accordance with DEA regulations and ultimately incinerated at a permitted or interim status hazardous waste incinerator or a permitted municipal solid waste incinerator.[17]

Sewer Ban

EPA states that a primary goal in issuing the proposed rule is to restrict the currently acceptable practice of discharging hazardous waste pharmaceuticals to the sewer. The proposed rule would prohibit all healthcare facilities and pharmaceutical reverse distributors from discharging hazardous waste pharmaceuticals to a sewer that passes to a publicly owned treatment works.[18] Importantly, the proposed prohibition would apply to all healthcare facilities.[19] While CESQGs would be exempt from other portions of the proposed rule, as proposed, the sewer prohibition would equally apply to CESQGs.[20] EPA anticipates that the proposed prohibition would reduce the volume of hazardous waste pharmaceuticals discharged annually by approximately 6,400 tons, and save approximately $4.3 million annually in the cost of eliminated wastewater treatment.[21] The proposed rule would not restrict sewering of non-hazardous waste pharmaceuticals.

Reverse Distribution of Pharmaceuticals

Retail pharmacies rely heavily on the reverse distribution process to obtain monetary credit for expired, damaged, recalled, or discontinued pharmaceuticals. In short, a retailer sends pharmaceuticals to the reverse distributor, and the reverse distributor then determines whether a given pharmaceutical is eligible for manufacturer credit. While reverse distribution of pharmaceuticals is not currently addressed by statute or regulation, EPA has addressed reverse distribution through guidance and in the preamble to the 2008 Universal Pharmaceutical Waste rule.[22] Historically EPA's position has been that a pharmaceutical returned for credit through reverse distribution does not become a waste until a determination is made to discard the pharmaceutical.[23] Accordingly, EPA considered pharmaceuticals not to be a waste at the retail pharmacy because the credit determination has not yet been made. Several states have also addressed reverse distribution through guidance materials, most of which accepted EPA's position. A couple states, however, rejected EPA's position and instead concluded pharmaceuticals are a waste at the retail pharmacy, prior to being sent to the reverse distributor.[24] This inconsistency between states has presented challenges for national retail pharmacies that have established a consistent, national approach to reverse distribution of pharmaceuticals.

In the preamble to the proposed rule, EPA explicitly changes its position as to when a pharmaceutical becomes a waste:

> *EPA is proposing to reinterpret its position such that the decision to send a pharmaceutical to a reverse distributor is the point at which a decision has been made to discard the pharmaceutical. As a result, once the decision is made to send a hazardous waste pharmaceutical to a reverse distributor, it is a solid waste at the healthcare facility.*[25]

However, EPA then clarifies that although a waste at the healthcare facility, the proposal would allow "potentially creditable hazardous waste pharmaceuticals"[26] to be sent to a "pharmaceutical reverse distributor,"[27] which would then facilitate credit. Under the proposed rule, "potentially creditable hazardous waste pharmaceutical" would mean a hazardous waste pharmaceutical that has the potential to receive manufacturer's credit and is unused or un-administered and either unexpired or less than one year past expiration date. Non-creditable hazardous waste pharmaceuticals"[28] would not be eligible for reverse distribution. While potentially creditable hazardous waste pharmaceuticals and non-creditable hazardous waste pharmaceuticals would both be managed under the proposed Subpart P, different management requirements would apply.

EPA's proposed requirements specific to reverse distribution of pharmaceuticals is likely to be a retail pharmacy's biggest concern with the proposed rule. The proposed rule raises questions on whether all pharmaceuticals sent for reverse distribution will be considered a waste. Importantly, although the preamble does not clearly make this point, EPA clarified the following in an Oct. 13, 2015, webinar: "If a pharmaceutical product is redistributed for reuse or legitimately recycled, then it is not considered a solid waste or hazardous waste and is not covered by this proposed rule." However, a challenge inherent in sending

pharmaceuticals for reverse distribution is that a retail pharmacy is not likely to know the ultimate disposition of the pharmaceuticals. Accordingly, it may be difficult or impracticable for retailers to document how thousands upon thousands of pharmaceuticals sent for reverse distribution are ultimately reused or legitimately recycled.

Potentially Creditable Hazardous Waste Pharmaceuticals.

EPA did not propose onsite management standards for potentially creditable hazardous waste pharmaceuticals while at a healthcare facility, such as labeling and accumulation time limits.[29] EPA notes in the preamble that fewer management requirements are warranted for potentially creditable hazardous waste pharmaceuticals, as EPA believes potentially creditable hazardous waste has a lower risk of release.[30]

The proposed rule would require that the healthcare facility shipping potentially creditable pharmaceuticals to a pharmaceutical reverse distributor follow specific tracking requirements, including, for example, notifying the pharmaceutical reverse distributor of an upcoming shipment prior to shipping the pharmaceuticals and notifying the shipper and pharmaceutical reverse distributor of a discrepancy if the healthcare facility does not receive confirmation of delivery within seven calendar days of shipment.[31]

Non-Creditable Hazardous Waste Pharmaceuticals.

Where a healthcare facility knows a hazardous waste pharmaceutical would not be creditable, the healthcare facility would be required to manage the pharmaceutical as a non-creditable hazardous waste pharmaceutical, which the proposed rule would not allow to be sent to a pharmaceutical reverse distributor.

Non-creditable hazardous waste pharmaceuticals would be subject to more stringent management standards than those proposed for potentially creditable hazardous waste pharmaceuticals. For example, unlike potentially creditable hazardous waste pharmaceuticals, non-creditable hazardous waste pharmaceuticals must be labeled "Hazardous Waste Pharmaceuticals;"[32] may be accumulated onsite for no more than one year, unless an extension is otherwise granted;[33] must be shipped on a hazardous waste manifest,[34] except waste codes are not required on the manifest; and each shipment must be either shipped to an interim status or permitted treatment, storage, and disposal facility via a licensed hazardous waste transporter.[35] Importantly, although non-creditable hazardous waste pharmaceuticals would be subject to more stringent management standards, like potentially creditable hazardous waste pharmaceuticals, non-creditable hazardous waste pharmaceuticals would also not count toward the healthcare facility's generator status.[36]

Nicotine-Containing Products

Retail pharmacies often register as LQGs based solely on

the amount of acute hazardous waste generated as a result of expired or returned NRT. NRT and other nicotine-containing products, such as e-cigarettes, are classified as P075 listed acute hazardous waste when discarded. Historically there has been little opportunity to return NRT for manufacturer credit through the reverse distribution process. Accordingly, under current regulations, when a healthcare facility accumulates more than 2.2 pounds of expired or returned NRT or other nicotine-containing products, the healthcare facility is subject to LQG regulations.

In recent years, such as in response to the Feb. 14, 2014, NODA, retail pharmacies have urged EPA to reconsider its position on nicotine contained in nicotine-containing products. Although EPA did not propose language related to nicotine-containing products, EPA requested comment on two possible approaches: (1) exempting P075 listing for Food and Drug Administration (FDA)-approved, over-the-counter NRT products; and (2) exempting P075 for low-concentration nicotine-containing products.[37] EPA noted it is working with the FDA to obtain FDA's risk evaluation for NRT products, and EPA requests that the healthcare sector provide other data to support any future regulations EPA may adopt specific to nicotine-containing products.

While it remains to be seen whether and how EPA will address nicotine-containing products, as proposed, NRT is within the definition of "pharmaceutical." Under the proposed Subpart P, the weight of pharmaceuticals would not count toward the healthcare facility's generator status. Because retailers often only reach LQG status as a result of exceeding the acute hazardous waste threshold because of NRT, the proposed rule would reduce the likelihood that most retail pharmacies would become LQGs. Likewise, depending on the weight of non-pharmaceutical hazardous waste, which would count toward the healthcare facility's generator status, retailers currently registered as LQGs would likely become either SQGs or CESQGs.

Importantly, it is currently unclear whether e-cigarettes, which contain nicotine, and e-cigarette refill liquids would be a "pharmaceutical" under the proposed rule. If e-cigarettes were not a "pharmaceutical," they would not be subject to the proposed Subpart P and would thus count toward a facility's generator status, just as all NRT currently does under 40 C.F.R. § 262. EPA requested comment on whether e-cigarettes and e-cigarette refill liquids should be considered a pharmaceutical.[38]

U.S. EPA's Proposed Generator Improvements Rule

On Sept. 25, 2015, the same day EPA's proposed hazardous waste pharmaceuticals rule was published in the Federal Register, EPA's proposed *Hazardous Waste Generator Improvements* rule also was published in the Federal Register.[39] While the proposed pharmaceuticals rule would apply only to healthcare facilities, the proposed generator rule would apply to all hazardous waste generators, ranging from healthcare facilities to industrial facilities. Because of the proposed generator rule's broader scope and the uniqueness of managing hazardous waste pharmaceuticals, the proposed generator rule alone would present challenges beyond the existing compliance challenges faced by the healthcare facilities.

For example, the proposed generator rule would require SQGs and LQGs to maintain waste determination documentation for solid waste determined to be non-hazardous.[40] Currently a hazardous waste generator is required to document waste determinations for solid waste determined to be *hazardous* (but not non-hazardous). As retailers commented to EPA in response to the Feb. 14, 2014, NODA, this requirement is particularly challenging for retail pharmacies because a retailer is likely to have thousands of products in inventory at any given time, and is even more challenging for close-out retailers that do not maintain a consistent inventory. Further, manufacturers rarely provide ingredient-level information needed to make waste determinations. Heightening the documentation requirements to also include solid waste determined to be non-hazardous would further increase the burden on retail pharmacies.

In the proposed generator rule, EPA attempted to provide some flexibility to allow CESQGs[41] and SQGs to occasionally generate higher volumes of hazardous waste without having to change the facility's generator status.[42] As drafted, however, retail pharmacies likely would not qualify. Among other things, to qualify for an episodic event, there must only be one episodic event per year, unless otherwise approved by EPA; the generator must notify EPA at least 30 days prior to initiating a planned episodic event or within 24 hours after an unplanned episodic event, or as soon as possible depending on the circumstances; and the generator must ship the waste to a RCRA-designated disposal facility within 45 calendar days from the start of the episodic event.[43] A retail pharmacy is often unaware it generated LQG quantities until the waste vendor conducts a hazardous waste pickup. Accordingly, the facility would not have notified EPA of an upcoming episodic generation event, and the facility would likely be well past the 24-hour period for notifying of an unplanned event. The retail pharmacy may also be well past the required 45-day pickup timeframe, since a CESQG is not subject to accumulation time limits and an SQG may lawfully accumulate hazardous waste onsite for up to 180 days.[44]

EPA issued the proposed hazardous waste pharmaceuticals rule and proposed generator rule on the same day, and public comments to both rules are due to EPA on December 24, 2015. To the extent EPA also issues *final* rules simultaneously, many requirements in the proposed generator rule -- such as waste determination documentation, heightened labeling requirements, and a requirement to obtain confirmation from emergency responders that they will provide services -- may

not apply to many healthcare facilities, since many healthcare facilities would likely move down in generator category to a CESQG. However, because of the uncertainty surrounding whether and when EPA will issue each final rule, it remains to be seen to what extent certain challenging requirements in the proposed generator rule will affect retail pharmacies.

Conclusion

EPA appears to recognize many of the challenges faced by healthcare facilities in managing hazardous waste pharmaceuticals, and has made an effort to streamline applicable requirements. Healthcare facilities should carefully review EPA's proposed pharmaceuticals rule and consider commenting to EPA on issues concerning to operations. Healthcare facilities should also parse EPA's proposed generator rule, and consider how the proposed rule would affect healthcare facilities. Because we cannot be certain whether EPA will issue the final hazardous waste pharmaceuticals and generator improvements rule simultaneously, healthcare facilities should analyze each proposed rule with the assumption that the other will not be adopted and comment accordingly. Public comments for both proposals are due Dec. 24, 2015.

(Endnotes)

1 42 U.S.C. 6902 et seq. (1976).
2 80 Fed. Reg. 50,014 (Sept. 25, 2015).
3 Proposed Amendment to the Universal Waste Rule: Addition of Pharmaceuticals, 73 Fed. Reg. 73,520 (Dec. 2, 2008).
4 *Hazardous Waste Management and the Retail Sector: Providing and Seeking Information on Practices To Enhance Effectiveness to the Resource Conservation and Recovery Act Program*, 79 Fed. Reg. 8,926 (Feb. 14, 2014).
5 Proposed Rule 40 C.F.R. § 262.10 (m)-(n).
6 The proposed rule would only apply to *hazardous waste* pharmaceuticals generated by *healthcare facilities.* The proposed rule would not apply to non-healthcare facilities (except pharmaceutical reverse distributors) generating hazardous waste pharmaceuticals. The proposed rule also would not apply to healthcare facilities' non-pharmaceutical hazardous waste and non-hazardous waste pharmaceuticals.
7 80 Fed. Reg. 58,085.
8 "*Healthcare facility* means any person that (1) provides preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or (2) sells or dispenses over-the-counter or prescription pharmaceuticals. This definition includes, but is not limited to, hospitals, psychiatric hospitals, ambulatory surgical centers, health clinics, physicians' offices, optical and dental providers, chiropractors, long-term care facilities, ambulance services, coroners and medical examiners, pharmacies, long-term care pharmacies, mail-order pharmacies, retailers of over-the-counter medications; and veterinary clinics and hospitals." Proposed Rule 40 C.F.R. § 266.500.
9 "*Pharmaceutical* means any chemical or biological product that is intended for use in the diagnosis, cure, mitigation, care, treatment, or prevention of disease or injury of a human or other animal; or any chemical or biological product that is intended to affect the structure or function of the body of a human or other animal. This definition includes, but is not limited to: dietary supplements as defined by the Federal Food, Drug and Cosmetic Act, prescription drugs, over-the-counter drugs, residues of pharmaceuticals remaining in containers, personal protective equipment contaminated with pharmaceuticals, and clean-up material from spills of pharmaceuticals." Proposed Rule 40 C.F.R. § 266.500.
10 80 Fed. Reg. 58,050.
11 Proposed Rule 40 C.F.R. § 266.501(a).
12 Proposed Rule 40 C.F.R. § 266.501(b).
13 *See* 40 C.F.R. § 261.5.
14 Proposed Rule 40 C.F.R. § 266.504(a).
15 80 Fed. Reg. 58,068.
16 80 Fed. Reg. 58,068.
17 Proposed Rule 40 C.F.R. § 266.506.
18 Proposed Rule 40 C.F.R. § 266.505.
19 Proposed Rule 40 C.F.R. § 266.505.
20 Proposed Rule 40 C.F.R. § 266.505; 80 Fed. Reg. 58,046.
21 80 Fed. Reg. 58,064.
22 Amendment to the Universal Waste Rule: Addition of Pharmaceuticals, 73 Fed. Reg. at 73,525.
23 *See* Sylvia Lowrance to Mark J. Schulz on May 16, 1991 (RCRA Online # 11606); Alan Corson to Steven Wittner on May 13, 1981 (RCRA Online #11012).
24 For example, the New Mexico Environmental Department issued a May 14, 2014, *Fact Sheet For Hazardous Waste Pharmaceuticals*, which states that NMED "does not recognize the reverse distribution of expired hazardous waste pharmaceuticals," and that "[o]nce a product has expired it is considered a waste and must be disposed of in accordance with hazardous waste regulations."
25 Proposed Rule 266.502(i); 80 Fed. Reg. 58,043.
26 The term does not include "evaluated hazardous waste pharmaceuticals," residues of pharmaceuticals remaining in containers, contaminated personal protective equipment, and clean-up material from the spills of pharmaceuticals." Proposed Rule 40 C.F.R. § 266.500.
27 EPA proposes stringent standards applicable to pharmaceuticals reverse distributors, similar to current regulations applicable to LQGs, with added inventory and tracking requirements. *See* Proposed Rule 40 C.F.R. § 266.510. This article does not focus on the proposed requirements specific to pharmaceuticals reverse distributors.
28 "*Non-creditable hazardous waste pharmaceutical* means a hazardous waste pharmaceutical that is not expected to be eligible for manufacturer's credit." Proposed Rule 40 C.F.R. § 266.500.
29 *See* Proposed Rule 40 C.F.R. § 266.503.
30 80 Fed. Reg. 58,044.
31 Proposed Rule 40 C.F.R. § 266.509(a).
32 Proposed Rule 40 C.F.R. § 266.502(e).
33 Proposed Rule 40 C.F.R. § 266.502(f).
34 Proposed Rule 40 C.F.R. § 266.508.
35 Proposed Rule 40 C.F.R. § 266.508.
36 80 Fed. Reg. 58,040.
37 80 Fed. Reg. 58,072-58,073.
38 80 Fed. Reg. 58,073.
39 80 Fed. Reg. 57,918.
40 Proposed Generator Improvements Rule 40 CFR § 262.11 (e).
41 CESQGs are referred to as "Very Small Quantity Generators" under EPA's proposed generator rule. 80 Fed. Reg. 57,919.
42 Proposed Generator Improvements Rule 40 CFR § 262.232.
43 80 Fed. Reg. 57,973.
44 80 Fed. Reg. 57,923.