OFFICE OF RESOURCE CONSERVATION AND RECOVERY
WASHINGTON, D.C. 20460

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Dear Anne Germain:

Thank you for your two letters from December 4, 2023, on behalf of the Healthcare Waste Institute, asking for U.S. Environmental Protection Agency to issue a national capacity variance and for the EPA to issue additional guidance for various scenarios you posed related to RCRA generator status and treatment options available to generators. Although they were separate letters, we will respond to both in this response.

HWI's Request for National Capacity Variance

Your first letter states, "RCRA § 3004(h)(2) provides a mechanism for EPA to provide a national capacity variance for up to two years allowing restricted waste to be landfilled at Subtitle C hazardous waste landfills that are in compliance with the minimum technological requirements of RCRA §3004(o)." It then requests, "EPA to provide guidance allowing for land disposal of restricted non-creditable hazardous waste pharmaceuticals under this variance."

The EPA is unable to issue a national capacity variance. Section 3004(h)(2) references a national capacity variance available to extend the effective date of land disposal restrictions at the time of promulgation. This variance allowed the EPA to establish an alternative effective date – by rule, not through guidance – when there was not sufficient Best Demonstrated Available Technology capacity available to treat the wastes. However, in no case could the extension be granted longer than 2 years from the date the standard was promulgated, and section 3004(h)(2) does not authorize the EPA to extend the effective dates of standards at this late date. These variances provided temporary relief only from the *effective date* of the LDR standards, not from the standards themselves.

HWI's Request for Guidance on Generator Status and on Very Small Quantity Generators Waste Treatment Options

Your second letter requests "guidance on generator status and on VSQG waste treatment options," specifying two sets of scenarios for which the EPA should provide additional guidance.

1. First set of scenarios

The first set of scenarios for which HWI requests guidance relate to VSQGs and households.

HWI first asks "EPA to provide guidance confirming that the disposal of hazardous waste pharmaceuticals generated by all VSQG healthcare waste generators complying with 40 CFR § 262.14 and all pharmaceuticals generated by exempt entities (e.g., households, hotels) are not required to be managed as hazardous waste pharmaceuticals at RCRA designated facilities (as defined in 40 CFR § 260.10)."

The EPA agrees and confirms. As discussed in our March 10, 2023, response to ProMedica (RO #14959), VSQGs operating under 40 CFR § 262.14, including VSQG healthcare facilities that are not operating under Subpart P, have the option of sending their hazardous wastes, including hazardous waste pharmaceuticals, to any of the relevant types of facilities listed in 40 CFR 262.14(a)(5). While the EPA recommends that VSQGs that are not operating under Subpart P send their hazardous waste, including all pharmaceutical waste, to a hazardous waste incinerator, sending them to other destination facilities is allowed, including municipal waste combustors; hospital, medical and infectious waste incinerators (HMWIs); and commercial and solid waste incinerators (CISWIs). The EPA recommends checking with any nonhazardous waste incinerator before sending any shipments of hazardous waste.

The EPA also agrees that wastes generated at residences, including pharmaceutical wastes, are household wastes that are not regulated by the RCRA hazardous waste regulations (see 40 CFR 261.4(b)(1)). However, if the household pharmaceuticals are collected in certain situations they may be subject to the conditional exemption in 40 CFR 266.506(a)(2), such as when they are collected by a healthcare facility that is an authorized collector (as defined by the Drug Enforcement Administration) in a collection receptacle (a.k.a., a kiosk).

Since you mentioned hotels in your question, we will note that the term "household waste" as used in 40 CFR 261.4(b)(1) includes waste from hotels and motels. Note that in previous guidances (RO #12624 and #13736), the EPA has indicated that "normal household waste" generated at a hotel would be exempt as household waste. On the other hand, dry-cleaning and vehicle fleet or equipment maintenance are not routine household operations; wastes resulting from such activities at hotels and motels, if hazardous, are subject to RCRA hazardous waste regulations.

Second, you ask that "EPA issue explanatory guidance confirming, as stated in 40 CFR § 266.501(a), that healthcare facilities that qualify as a VSQG following § 262.14, and elect to opt into Subpart P, are allowed to dispose of hazardous waste pharmaceuticals in Alternative Combustors." HWI uses the term "Alternative Combustors" to refer to the four types of non-hazardous waste combustors that are

identified in the conditional exemption in 40 CFR 266.506(a)(1) for the few pharmaceuticals that are both a RCRA hazardous waste and also a DEA controlled substance (i.e., see 40 CFR 266.506(b)(3) for full definitions of the four types of non-hazardous waste combustors: large municipal waste combustor; small municipal waste combustor; hospital, medical and infectious waste incinerator; and commercial and industrial solid waste incinerator).

The EPA disagrees. A healthcare facility that is a VSQG that opts into using Subpart P with respect to its hazardous waste pharmaceuticals is subject to Subpart P in lieu of 40 CFR 262.14. All healthcare facilities operating under Subpart P, including VSQGs that opt into using Subpart P, must dispose of their hazardous waste pharmaceuticals at hazardous waste treatment, storage, and disposal facilities, and not at "Alternative Combustors." Note that if a healthcare facility that is a VSQG has opted into using Subpart P, then it may subsequently choose to opt out of Subpart P, as described in 40 CFR 266.501(a)(2).

2. Second set of scenarios

The second set of scenarios for which HWI requests guidance pertains to generator status change due to either Subpart P or episodic generation.

First, HWI requests "EPA to provide guidance allowing hazardous waste pharmaceuticals generated while a LQG or SQG to be managed consistent with the VSQG requirements at Alternative Combustors when the healthcare facility opts into Subpart P and qualifies as VSQG."

The EPA disagrees. A healthcare facility is *required* to operate under Subpart P for managing its hazardous waste pharmaceuticals if it generates above VSQG amounts of hazardous waste. A healthcare facility must count all of its hazardous waste—including its hazardous waste pharmaceuticals—when it determines whether it is subject to Subpart P. All healthcare facilities operating under Subpart P, including VSQGs that opt into using Subpart P, must dispose of their hazardous waste pharmaceuticals at hazardous waste treatment, storage, and disposal facilities, not at Alternative Combustors.

That said, once a healthcare facility is managing its hazardous waste pharmaceuticals under Subpart P, then it no longer needs to count the hazardous waste pharmaceuticals in determining its generator category for its non-pharmaceutical hazardous waste. As a result, it may be possible in some cases for a healthcare facility to drop down in generator category with respect to its *non-pharmaceutical waste*. But it must be emphasized that this is only possible if the hazardous waste pharmaceuticals are managed under Subpart P and sent to hazardous waste treatment, storage, and disposal. If a healthcare facility that is operating under Subpart P drops down in generator category to become a VSQG with respect to its non-pharmaceutical hazardous waste, then it may use the Alternative Combustors—but only for that VSQG non-pharmaceutical hazardous waste.

Second, HWI requests "EPA to provide guidance allowing the disposal of hazardous pharmaceuticals in Alternative Combustors from VSQG healthcare facility generators, not opting into Subpart P, that experience episodic generation of hazardous pharmaceuticals or delays in waste services that result in accumulation of hazardous pharmaceuticals that cause the facility to exceed VSQG volume accumulation limits and become a SQG or LQG."

The EPA defines an episodic event as "an activity or activities, either planned or unplanned, that does not normally occur during generator operations, resulting in an increase in the generation of hazardous wastes that exceeds the calendar month quantity limits for the generator's usual category" (see 40 CFR 262.231). The EPA has defined two types of episodic events: planned and unplanned, which are defined in the regulations of part 262 Subpart L:

- **A planned episodic event** means "an episodic event that the generator planned and prepared for, including regular maintenance, tank cleanouts, short-term projects, and removal of excess chemical inventory."
- **An unplanned episodic** event means "an episodic event that the generator did not plan or reasonably did not expect to occur, including production process upsets, product recalls, accidental spills, or "acts of nature," such as tornado, hurricane, or flood."

The EPA disagrees that a delay in waste services would qualify as either type of episodic event. Further, while the episodic generator regulations in 40 CFR part 262 Subpart L are intended to provide some regulatory relief to VSQG or SQG generators that infrequently bump up to a higher generator category (SQG or LQG), the relief is conditioned, among other things, upon the fact that the hazardous waste is ultimately managed at hazardous waste treatment, storage, and disposal facilities.

Nevertheless, if a healthcare facility that is normally a VSQG and *has not opted into Subpart P* did have an event that qualifies as a planned or unplanned episodic event (e.g., a recall), then:

- The hazardous waste (whether it is pharmaceuticals or non-pharmaceuticals) from the episodic event must follow the conditions in 40 CFR 262.232(a), including, but not limited to, removing it within 60 days of the start of the episodic event and managing it at a hazardous waste treatment storage or disposal facility.
- However, the routinely generated VSQG hazardous waste pharmaceuticals may be sent to an Alternative Combustor.

As explained in the preamble to the Generator Improvements Final Rule (see page 85785):

> However, the condition to manifest the hazardous waste and send it off site to a RCRA-designated facility only applies to the hazardous waste generated as a result of the episodic event. The condition does not apply to other hazardous waste generated at the same time as, but separately from, the episodic event. However, if the VSQG desires to ship all hazardous waste generated and accumulated on site to a RCRA-designated facility at once, for economic or logistical reasons, then it can be sent off site together. This applies whether the hazardous waste was generated as a result of the episodic event, independent of the episodic event, or prior to the event.

In addition, the EPA addressed the intersection of Subpart P and the episodic generator regulations in 40 CFR part 262 Subpart L on page 5935 of the preamble to the Hazardous Waste Pharmaceutical final rule:

A healthcare facility that is a VSQG for both hazardous waste pharmaceuticals and nonpharmaceutical hazardous waste can use the episodic generation provision of part 262 Subpart L for all of its hazardous waste, including its hazardous waste pharmaceuticals. If a healthcare facility is generally operating under § 262.14 as a VSQG, but has an episodic event, it would be far less burdensome to comply with part 262 Subpart L than to come into compliance with all the provisions of part 266 Subpart P for the short duration of the episodic event. For example, if a VSQG healthcare facility is directed to dispose of recalled pharmaceuticals, it could use the episodic generator provisions of part 262 Subpart L to avoid an increase in hazardous waste generator category.

However, if a healthcare facility that is a VSQG generates hazardous waste in excess of the allowable amounts as a VSQG, and it chooses not to use the episodic generator provisions in part 262 Subpart L, it would become subject to part 266 Subpart P for its hazardous waste pharmaceuticals.

Finally, HWI requests "EPA to provide guidance allowing hazardous waste pharmaceuticals generated by a healthcare facility that experiences episodic hazardous waste generation of other hazardous waste resulting in them becoming a LQG or SQG (regardless of if they opted into Subpart P) to continue to be managed following the VSQG requirements at Alternative Combustors while other hazardous wastes are managed at permitted hazardous waste facilities."

The EPA agrees that when a healthcare facility:

1. is a VSQG when counting all of its hazardous waste, and
2. has NOT opted into Subpart P for the management of its hazardous waste pharmaceuticals, and
3. is operating under 40 CFR 262.14 for all of its hazardous waste, and
4. has an episodic event for non-pharmaceutical hazardous waste, and
5. chooses to follow the part 262 Subpart L provisions with respect to the episodically generated non-pharmaceutical hazardous waste, including manifesting and sending to a designated facility,

then the healthcare facility can continue to manage its hazardous waste pharmaceuticals under 40 CFR 262.14 and send the hazardous waste pharmaceuticals to Alternative Combustors.

The EPA disagrees, however, with HWI's view with respect to a healthcare facility that is a VSQG that has opted into part 266 Subpart P for the management of its hazardous waste pharmaceuticals. EPA's view is that if a VSQG healthcare facility has opted into Subpart P, then the hazardous waste pharmaceuticals must go to hazardous waste treatment, storage, and disposal, not Alternative Combustors. This is true regardless of whether the healthcare has an episodic event for its non-pharmaceutical hazardous waste.

Please note that under RCRA, state regulations can be more stringent and/or broader in scope than the federal program, which is another reason we recommend checking with the appropriate regulatory authority.

Thank you again for your continued collaboration with the EPA as we strive to address challenges for waste generators, particularly for healthcare facilities accumulating containerized hazardous waste pharmaceuticals. I look forward to our ongoing dialogue.

If you have any questions concerning this response, please contact Kristin Fitzgerald of my staff at Fitzgerald.Kristin@epa.gov.

Sincerely,

CHoskinson

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Carolyn Hoskinson
Director