National Capacity Variance/Generator Status: U.S. Environmental Protection Agency Guidance Addresses Hazardous Waste Pharmaceuticals Questions

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The United States Environmental Protection Agency ("EPA") addressed in a March 22nd letter questions it was asked regarding the application of the Resource Conservation and Recovery Act ("RCRA") to pharmaceutical hazardous waste.

The March 22nd letter was addressed to Anne M. Germain, P.E., BCEE, of the National Waste & Recycling Association ("NWRA") from EPA Office of Resource Conservation and Recovery Director Carolyn Hoskinson.

EPA states it was responding to two letters sent on behalf of the Healthcare Waste Institute ("HWI") asking it to issue:

- A National Capacity Variance for hazardous waste pharmaceuticals.
- Additional guidance for various scenarios associated with hazardous waste pharmaceuticals.

HWI is stated to have requested a National Capacity Variance for Hazardous Waste Pharmaceuticals for up to two years allowing restricted waste to be landfilled at RCRA Subtitle C facilities in compliance with minimum technological requirements of RCRA §3004(o). Section 3004(h)(2) was cited in support of the request.

EPA responds that it is unable to issue such a variance because Section 3004(h)(2) only allows the agency to establish an alternative effective date by rule as opposed to guidance. The agency also states that:

. . . in no case could the extension be granted longer than two years from the date the standard was promulgated, and Section 3004(h)(2) does not authorize the EPA to extend the effective dates of the standards at this late date. These variances provided temporary relief only from the effective date of the LDR standards, not from the standards themselves.

The remainder of the March 22nd guidance letter addresses HWI's questions related to:

- Generator Status/Very Small Quantity Generator ("VSQG") Waste Treatment Options.

Two scenarios are discussed, which include:

1. Asking for 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 § 206.10)

EPA agrees with this conclusion and provides an analysis.

2. Guidance is also requested pertaining to generators status change due to either Subpart P or episodic generation.

The request asks:

. . . 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 B and qualifies as VSQG.

EPA disagrees with this request and provides an analysis.

Second, EPA is requested:

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

EPA references its disagreement that a delay in waste services would qualify as either type of episodic event and provides an analysis.

Third, EPA is requested:

. . . to provide guidance allowing hazardous waste pharmaceuticals generated by a healthcare facility that experiences episodic hazardous waste generation of other hazardous waste resulting and then becoming a LQG or SQG (regardless of it 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.

EPA provides that if a healthcare facility meets five criteria (specified in the letter), 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 Combustor.

However, it disagrees with:

. . . respect to a healthcare facility that is a VSQG that has opted into Part 260 Subpart P for the management of its hazardous waste pharmaceuticals.

The rationale is that if a VSQS healthcare facility has opted into Subpart P, then the hazardous waste pharmaceuticals must go to hazardous waste treatment, storage, disposal, as opposed to Alternative Combustors.

A copy of the March 22nd letter can be downloaded here.