UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 10, 2023

OFFICE OF
LAND AND EMERGENCY
MANAGEMENT

Brad Bury
Director of Supply Chain Management
ProMedica Health System
300 North Summit St.
Toledo, Ohio, 43604

Mr. Bury,

Thank you for your letter of December 12, 2022. You cited the temporary backlog of containerized hazardous waste destined for incineration as the cause of recent challenges for healthcare facilities that need to ship hazardous waste off site. You stated that the options described in the August 10, 2021 EPA memo (RCRA Online No. 14939) are not feasible for the healthcare sector and requested that EPA take action to allow incineration of all hazardous waste pharmaceuticals at the types of incinerators listed in § 266.506(b)(3), which includes:

- Hazardous waste combustors
- Large or small municipal waste combustors
- Hospital, medical and infectious waste incinerators (HMWIs), and
- Commercial and industrial solid waste incinerators (CISWIs)

EPA recognizes that the backlog continues to some extent at commercial hazardous waste incinerators, and we have indicated on our website (www.epa.gov/hwgenerators) that the regulatory flexibilities in the August 10, 2021, memo can continue to be used. We have heard encouraging reports that the backlog has eased at some incinerators. We also encourage you to reach out to RCRA-permitted commercial storage facilities to see if that is an option you can use if you are still experiencing delays getting your hazardous waste off-site to incinerators in a timely manner.

EPA promulgated the conditional exemption in § 266.506(a)(1) to apply specifically to the few hazardous waste pharmaceuticals that are also DEA controlled substances in order to eliminate dual regulation. It is because of this specific conditional exemption that only these particular hazardous waste pharmaceuticals, and not all hazardous waste pharmaceuticals, are allowed to be destroyed or combusted at one of the listed types of combustors or incinerators in § 266.506(b)(3). EPA's basis for this conditional exemption which only applies to a handful of dually regulated hazardous waste pharmaceuticals s that are also DEA controlled substances, would not apply to all hazardous waste pharmaceuticals.

Therefore, except for the narrow conditional exemption, hazardous waste pharmaceuticals must be managed at a RCRA Subtitle C permitted treatment storage and disposal facility. However, there are existing options not mentioned in your letter that may help alleviate some of the issues your

facility is facing. Also included in this letter, is detailed explanation for how off-site consolidation of hazardous waste pharmaceuticals works under 40 CFR part 266 subpart P to ensure this practice, when utilized, is done correctly. Our hope is that a better understanding of these regulatory flexibilities will alleviate some of the accumulation and logistical challenges that some healthcare facilities are encountering related to the incinerator backlog.

In your letter, you indicate that many healthcare facilities have no associated LQG to which they may send their hazardous waste pharmaceuticals. To be clear, the VSQG-LQG consolidation provisions in § 262.14(a)(5)(viii) are similar, but not exactly the same as the subpart P consolidation provisions for healthcare facilities in § 266.504(b). Under subpart P, a healthcare facility that is a VSQG when counting all of its hazardous waste, including hazardous waste pharmaceuticals, may *send* its hazardous waste pharmaceuticals to another healthcare facility regardless of the generator category of the receiving healthcare facility, as long as the receiving facility is operating under subpart P with respect to its hazardous waste pharmaceuticals and is either:

1) under the control of the same person, or
2) supplies pharmaceuticals to the VSQG healthcare facility under a contractual or other documented business relationship.

In other words, the receiving healthcare facility does not have to be an LQG if they are operating under 40 CFR part 266 subpart P with respect to the management of their hazardous waste pharmaceuticals. To provide additional flexibility, VSQG healthcare facilities may also opt into subpart P, which would allow them to *receive* hazardous waste pharmaceuticals from other off-site healthcare facilities.

We note that the off-site consolidation regulations for VSQG healthcare facilities that send their hazardous waste pharmaceuticals to another healthcare facility are located in § 266.504(b). All of the provisions § 266.504 are optional and only pertain to VSQG healthcare facilities that are not operating under subpart P (i.e., have not opted into subpart P). VSQGs healthcare facilities that utilize any of the optional provisions in § 266.504 are not considered to be operating under 40 CFR part 262 subpart P. Alternatively, a VSQG healthcare facility that has opted into subpart P is subject to full regulation under subpart P and cannot use the optional provisions in subsection § 266.504.

We would also note that VSQGs that are not operating under subpart P (i.e., are subject to 40 CFR 262.14 hazardous waste VSQG regulations) do not have an accumulation time limit[1], and have the option of sending their hazardous wastes, including hazardous waste pharmaceuticals, to any of the relevant types of facilities listed in § 262.14(a)(5). While 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, HMWIs, and CISWIs. EPA recommends checking with any non-hazardous waste incinerator before sending a shipment of hazardous waste.

Healthcare facilities operating under subpart P have a maximum of one year to accumulate hazardous waste pharmaceuticals on site. Because of the one-year accumulation time limit, there is no regulatory mechanism to request or grant an extension beyond the one-year period. Because

[1] See §§ 262.14(a)(3) and 262.14(a)(4) for more information about the amount of hazardous waste that VSQGs can accumulate.

states are the primary implementers of the RCRA hazardous waste program in authorized states, we strongly encourage any healthcare facility that is experiencing or foresees difficulty complying with accumulation time limits for any reason, to contact their state environmental agency or EPA Region in states and territories that do not have authorized hazardous waste programs.

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

Sincerely,

JESSICA YOUNG
Digitally signed by JESSICA YOUNG
Date: 2023.03.10 16:04:59 -05'00'

Jessica Young, Chief
Recycling and Generator Branch
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cc: Anne Germain, Healthcare Waste Institute