

DOWN THE DRAIN: EPA’S “SEWERING PROHIBITION” IS RIGHT AROUND THE CORNER

Healthcare facilities of all types and sizes – from large hospitals in heavily-populated metropolitan areas to small, rural urgent care clinics – should have **August 21st** circled on their calendars. That is because EPA’s “sewering prohibition” goes into effect on this date. The sewerage prohibition will prohibit pharmaceuticals that meet the regulatory definition of “hazardous waste” from being flushed down the drain.¹ This prohibition is part of a broader pharmaceutical hazardous waste management rule recently promulgated by EPA.² Unlike the sewerage prohibition, however, most of the other provisions of the Subpart P Rule will not go into effect until states delegated with authority to implement EPA’s RCRA hazardous waste management regulations promulgate their own regulations to implement these new requirements.

The sewerage prohibition only prohibits the sewerage of pharmaceutical hazardous wastes.³ Examples of pharmaceutical hazardous wastes include: nicotine⁴, warfarin – a blood-thinning agent, and certain chemotherapeutic agents such as mitomycin C. While most of the other provisions of the Subpart P Rule will generally not apply to “very small quantity generators” (VSQGs)⁵, the sewerage prohibition applies to *all healthcare facilities*. The definition of “healthcare facility” under the Subpart P Rule includes hospitals, long-term care facilities, physician’s offices, eye care centers, dental offices, and urgent care clinics.


¹ 84 Fed. Reg. 5,816, 5,892 - 5,896 (Feb. 22, 2019). Discarded pharmaceuticals that meet the regulatory definition of “hazardous waste” are referred to herein as “pharmaceutical hazardous wastes.”

² 84 Fed. Reg. 5,816. EPA’s existing hazardous waste management regulations already apply to pharmaceutical hazardous wastes. Other than the sewerage prohibition, most of these new rules amend, clarify, and in some respects restructure the hazardous waste management compliance regime for healthcare facilities and certain other types of facilities in the healthcare industry, including reverse distributors. The new rule is codified at 40 C.F.R., part 266, subpart P, and thus is referred to herein as the “Subpart P Rule.”

³ EPA opines in the preamble to the Subpart P Rule that pharmaceuticals of any kind should not be flushed down the drain (except in very limited circumstances). 84 Fed. Reg. 5,895.

⁴ Although beyond the scope of this article, the Subpart P Rule includes several amendments to the hazardous waste listing for nicotine. See Fed. Reg. 5,822 - 5,827.

⁵ Under EPA’s hazardous waste management regulations, a “very small quantity generator” (or VSQG) includes anyone who generates less than 100 kg of non-acute hazardous waste or less than 1 kg of acute hazardous waste in a calendar month. 40 C.F.R. § 262.13. The determination of whether a facility is a VSQG for purposes of the Subpart P Rule can be somewhat complex, and beyond the scope of this article. It requires, among other things, separate analyses of a facility’s pharmaceutical hazardous waste generation, and total hazardous waste generation (including pharmaceutical hazardous waste). 84 Fed. Reg. 5,889 - 5,892. If a healthcare facility has any questions about its generator status for purposes of the Subpart P Rule, it should consider consulting legal counsel and environmental consulting professionals with expertise in this area.



The consequences for failure to comply with the upcoming sewerage prohibition can be severe. EPA's maximum statutory penalty authority under RCRA is now nearly \$100,000 per day for each violation. Some healthcare facilities have already felt the sting of such penalties under existing hazardous management regulations that cover pharmaceutical hazardous wastes. To take just one example, a hospital in Wisconsin was assessed a penalty of \$360,000 for, among other things, improperly disposing of pharmaceutical hazardous wastes.⁶

So, what then should healthcare facilities be doing now to ensure compliance with the sewerage prohibition when it goes into effect?


First, it is important to remember that in certain circumstances, the sewerage of pharmaceuticals may already be prohibited. Existing federal regulations prohibit certain types of flammable, reactive, and corrosive materials from being seweraged. Sewerage of pharmaceutical hazardous wastes may also be prohibited by state and local laws, regulations, and ordinances. And, even where no such specific laws, regulations, and ordinances exist, dischargers to publicly-owned treatment works (POTWs) may be prohibited from sewerage pharmaceutical wastes under existing pre-treatment permits. These prohibitions may include pharmaceuticals that are not considered as hazardous wastes when discarded. It is important for healthcare facilities to understand the full scope of their compliance obligations, not only under federal laws and regulations, but also under state and local laws, regulations, and ordinances.

Second, healthcare facilities may want to consider instituting policies and procedures that mostly prohibit the sewerage of *any* pharmaceutical wastes. According to EPA, the better practice in all but the most exceptional of circumstances is to refrain from pouring pharmaceuticals of any kind down the drain. Instituting such policies and procedures is a simple and straightforward way of ensuring compliance with the upcoming prohibition against the sewerage of pharmaceutical hazardous wastes.

Third, healthcare facilities should consider updating their existing compliance management systems by incorporating policies and procedures addressing the compliance obligations associated with the sewerage prohibition and the other provisions of the Subpart P Rule. These compliance management systems are likely to vary in size, scope, and complexity depending on the size and type of the healthcare facilities in question. Regardless of size or type of healthcare facility though, incorporating such policies and procedures can help facilitate compliance with these new provisions, and thus minimize exposure to governmental agency enforcement actions.

Finally, if they are not already doing so, healthcare facilities should consider engaging healthcare facility waste management service providers to assist with the implementation of the sewerage prohibition and other activities associated with the Subpart P Rule. Many healthcare

⁶ <https://www.doj.state.wi.us/news-releases/ag-kaul-announces-judgment-requiring-milwaukee-county-health-care-provider-froedtert>.



facilities already outsource activities associated with the management of infectious and medical wastes, non-pharmaceutical hazardous wastes, and other wastes to these service providers. Most of these service providers also offer pharmaceutical hazardous waste management services.

Healthcare facilities that outsource these activities should keep in mind that they will still be held accountable by federal, state, and local regulatory agencies for noncompliance. Thus, any healthcare facility engaging a waste management services provider should have a clear understanding of the contractual terms and conditions associated with the services to be provided. The respective roles of the facility and the service provider should be delineated as clearly as possible. The facility should take care to provide the service provider with complete and accurate information regarding its activities, including the wastes it generates (or may potentially generate), and how it currently manages such wastes. The healthcare facility should negotiate for the best and most appropriate terms it can achieve with respect to price, indemnities and allocation of liability, insurance requirements, and other key terms and conditions. The terms and conditions that can be achieved will likely depend upon a variety of market-based circumstances. Thus, in order to get the best terms and conditions that the marketplace can offer, the healthcare facility may want to consider implementing a competitive bidding process to select a qualified, suitable, and cost-effective services provider.

Finally, and perhaps most importantly, since the healthcare facility is accountable for noncompliance, the facility should continue to maintain oversight over all its waste management activities, even those activities that have been outsourced to a healthcare facility waste management services provider.

Healthcare facilities with questions about the sewerage prohibition or any of the other provisions in the Subpart P Rule should consider consulting with legal counsel. Daniel J. Brown, attorney and sole member of Daniel J. Brown, L.L.C., has over 25 years of experience with hazardous waste management compliance management as an attorney in private and in-house practice, and as an environmental engineer.

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