



## EPA attempts to stop pharmaceuticals from going down the drain

By Alison Torbitt and Dana Stanton

Nationwide, 80% of lakes, rivers and streams now contain low levels of pharmaceuticals. Chronic exposure to low levels of medications in the environment, even expired medications, harms the fertility of fish and other aquatic animals. Most current municipal wastewater treatment technology cannot intercept drugs when they enter the wastewater stream. For these reasons, the EPA has finalized a new rule prohibiting health-care facilities from flushing hazardous waste pharmaceuticals down the drain.

EPA's rule, 40 CFR Part 266, Subpart P, entitled, "Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine," will prevent the flushing of 1,644 to 2,300 tons of hazardous waste pharmaceuticals annually by banning the disposal of hazardous waste pharmaceuticals down the sink or toilet.

In addition, health-care facilities will be allowed to manage hazardous waste pharmaceuticals under the Subpart P regulations—which are tailored to the needs of the health-care industry—rather than comply with the general Resource and Conservation Recovery Act (RCRA) requirements—which are a poor fit for many health-care facilities. The full text of the rule is available [here](#).

Health-care facilities and reverse distributors that generate and manage hazardous waste pharmaceuticals will be subject to Subpart P. "Health-care facility" is broadly defined to include hospitals, health clinics, physician's offices, long-term care facilities, optical and dental providers, ambulatory services, veterinary clinics and hospitals and pharmacies. "Reverse distributors" are entities that help health-care facilities calculate and receive credit from pharmaceutical manufacturers when health-care facilities have unused pharmaceuticals they no longer need. The rule does not apply to pharmaceutical manufacturers (unless they act as reverse distributors), production facilities or other generators of hazardous waste pharmaceuticals.

EPA's definition of "pharmaceutical" includes prescription and over-the-counter drugs, dietary supplements, homeopathic drugs, pharmaceuticals remaining in non-empty containers and clean-up material from spills of pharmaceuticals. In contrast, dental amalgam, sharps and medical waste are not considered "pharmaceuticals."

Not all pharmaceuticals will constitute “hazardous waste pharmaceuticals.” A pharmaceutical is considered a “hazardous waste” if it is a “solid waste” (for example, it is discarded or abandoned), and (i) it exhibits one or more hazardous characteristics (ignitability, corrosivity, reactivity and toxicity), or (ii) is listed by EPA as a hazardous waste at 40 CFR § 261.33.

Importantly, pharmaceuticals are not considered “solid waste” if they can be legitimately used or re-used (for example, lawfully donated or redistributed for their intended purpose), or reclaimed.

Health-care facilities will be required to manage their hazardous waste pharmaceuticals in accordance with Subpart P (40 CFR § 266.500 et seq.), instead of the standard, more complicated RCRA regulations under 40 CFR Part 262. Under the new paradigm, a health-care facility will not be considered a large quantity generator (with all the attendant, onerous requirements), simply by generating more than one (1) kilogram of acutely hazardous waste pharmaceuticals per month. Health-care facilities will not be subject to satellite accumulation area regulations, which are a poor fit for health-care facilities, and will be able to accumulate hazardous waste pharmaceuticals on site without a RCRA permit for up to 365 days. Finally, health-care facilities will not need to specify hazardous waste codes on manifests. Health-care facilities will need to comply with basic training requirements for personnel.

In addition, under the new rule, over-the-counter nicotine replacement therapies, such as nicotine patches, gums and lozenges, will no longer be considered hazardous waste when discarded. Therefore, these wastes may be discarded as non-hazardous waste. This will result in cost savings with respect to managing nicotine wastes.

The prohibition on sewer disposal automatically takes effect in all states and territories on August 21, 2019. Subpart P goes into effect in Iowa and Alaska on August 21, 2019, and will go into effect for the remainder of the states when adopted by each state—all are required to adopt Subpart P by July 1, 2021 (or July 1, 2022, if a statutory amendment is required). Since it is less stringent than the current regulation, the nicotine waste aspect of the rule is not required to be adopted by the states, and health-care facilities cannot use the nicotine waste exemption unless or until it is adopted by their state.

For more information on the content of this alert, please contact your Nixon Peabody attorney or:

- Alison Torbitt, 415-984-5008, [atorbitt@nixonpeabody.com](mailto:atorbitt@nixonpeabody.com)
- Dana Stanton, 518-427-2735, [dstanton@nixonpeabody.com](mailto:dstanton@nixonpeabody.com)