

Pharmaceutical Waste Rule Impact in Utah

The Division has received many questions regarding the Pharmaceutical Waste Rule that was finalized by the Environmental Protection Agency (EPA) in February of 2019.

The goals of this rule were to:

1. create regulations that are a better fit for the healthcare sector,
2. eliminate the intentional sewerage of hazardous waste pharmaceuticals,
3. reduce overlapping regulations,
4. provide regulatory clarity and national consistency on how Resource Conservation and Recovery Act (RCRA) applies to reverse distribution and reverse logistics and provide regulatory relief to healthcare facilities.

This final rule adds regulations for the management of hazardous waste pharmaceuticals by healthcare facilities and reverse distributors. Healthcare facilities (for both humans and animals) and reverse distributors will manage their hazardous waste pharmaceuticals under this new set of sector-specific standards in lieu of the existing hazardous waste generator regulations.

The new regulations prohibit the disposal of hazardous waste pharmaceuticals down the drain (sewerage) and eliminate the dual regulation of RCRA hazardous waste pharmaceuticals that are also Drug Enforcement Administration (DEA) controlled substances. The new rules also maintain the household hazardous waste exemption for pharmaceuticals collected during pharmaceutical takeback programs and events, while ensuring their proper disposal. Additionally, certain U.S. Food and Drug Administration (FDA) approved over-the-counter (OTC) nicotine replacement therapies (NRTs) are excluded from regulation as hazardous waste.

The question most often asked is, **“Will Utah be adopting the Pharmaceutical Waste Rule?”** The answer is **YES** and here is the timeline for adoption:

1. The prohibition on sewerage of hazardous waste pharmaceuticals was promulgated under authority of the Hazardous and Solid Waste Amendments (HSWA) and as such became effective in ALL 50 states, including Utah, six months after publication making it effective as of August 21, 2019.
2. The amendment to the nicotine listing is considered LESS stringent than existing regulations and therefore authorized states like Utah are NOT required to adopt the amendment. The State of Utah plans to adopt the amendment in the spring of 2020.
3. Subpart P which contains the new regulations for the management of hazardous waste pharmaceuticals by healthcare facilities and reverse distributors will not become effective in Utah until adopted. As an authorized state, Utah has until July 1, 2021 to adopt Subpart P. The State of Utah plans to adopt the rule in the spring of 2020.