State of Oregon Department of Environmental Quality

Draft Fiscal Impact Statement

Hazardous Waste Pharmaceutical and Nicotine Listed Rule

Hazardous Waste Federal Rules Alignment 2021 Rulemaking
Advisory Committee Meeting #2

Introduction

DEQ proposes adopting the federal Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine. These amendments are in response to the U.S. Environmental Protection Agency (EPA) rules issued under the Resource Conservation Recovery Act (RCRA) and were published in the Federal Register on Feb. 22, 2019. These amendments add specifically tailored rules for the management of hazardous waste pharmaceuticals by healthcare facilities and reverse distributors. The federal rule also revises the P075 listing for nicotine under the hazardous waste regulations. P-listed pharmaceutical waste is acutely hazardous and includes drugs such as warfarin and nicotine patches.

Currently, healthcare facilities and reverse distributors operate under Title 40, Code of Federal Regulations Part 262 requirements applicable to all generators of hazardous waste. EPA authorizes DEQ to implement the RCRA Hazardous Waste Program in Oregon. EPA's rule is less stringent than the current DEQ rules regulating hazardous waste pharmaceuticals (HW Pharms), except for the ban on sewering highlighted below, which is more stringent.

Some pharmaceuticals are regulated as hazardous waste under RCRA when discarded. If Oregon adopts the federal rules, healthcare facilities, both human and animal, and reverse distributors will also be able to manage their hazardous waste pharmaceuticals under this new set of sector-specific standards in lieu of existing hazardous waste generator regulations. The new regulations also prohibit disposal of hazardous waste pharmaceuticals down the drain and eliminates the dual regulation of RCRA hazardous waste pharmaceuticals also subject to the Drug Enforcement Administration (DEA) controlled substance requirements.

The proposed rule amendments also maintain the household hazardous waste exemption for pharmaceuticals collected by takeback programs and events while ensuring their proper disposal. The proposed rules also adopt EPA's prior policy on the regulatory status of nonprescription pharmaceuticals going through reverse logistics. Furthermore, the proposed rules exclude certain U.S. Food and Drug Administration (FDA) approved over-the-counter (OTC) nicotine replacement therapies (NRTs) from regulation as hazardous waste. Finally, the proposed rules provide a new definition of RCRA-empty pharmaceutical containers better tailored for the low level of residues in most empty containers of hazardous waste pharmaceuticals.

Fee Analysis

This rulemaking does not involve fees.

Statement of fiscal and economic impact

Fiscal and Economic Impact

In this analysis, DEQ assumes the fiscal and economic impacts identified in federal rulemaking are accurate estimates for Oregon businesses. EPA's estimates, presented below, are based on the known population of entities regulated by EPA's rules. If state adopted, DEQ anticipates the proposed rules will generate cost savings for businesses defined as healthcare facilities and reverse distributors.

Additionally, the ban on sewering of hazardous waste pharmaceuticals will generate cost savings for municipalities and service districts managing municipal wastewater. However, as noted below, DEQ's Hazardous Waste Program anticipates a loss in activity and generation fees representing approximately 1.80% of total fees invoiced.

Statement of Cost of Compliance

State agencies

DEQ

DEQ's Hazardous Waste Program will experience a decrease in revenue for overseeing hazardous waste management in Oregon with the state adoption of these proposed rules.

Under the proposed rules, healthcare facilities will determine their generator category, such as Large Quantity Generator (LQG) or Small Quantity Generator (SQG), by factoring both their hazardous waste pharmaceutical and nonpharmaceutical hazardous waste weight. After making this determination, healthcare facilities that are small quantity generators and large quantity generators must comply with Part 266 Subpart P for the management of their hazardous waste pharmaceuticals. However, once under Subpart P of EPA's 2019 rule, healthcare facilities do not need to count their hazardous waste pharmaceuticals for their generator category. Given this option, EPA's regulatory impact analysis anticipates many healthcare facilities will change generator category to either a SQG or Very Small Quantity Generator (VSQG). Additionally, as detailed below, the revision of the P075 nicotine listing will also provide an opportunity for healthcare facilities to reduce their generator category. DEQ believes these changes are likely to reduce revenue for DEQ's oversight of hazardous waste management in Oregon.

In response to comments EPA received from retail associations during rule development, the 2019 rule removes low-concentration, FDA-approved, OTC replacement products such as lozenges, gums, and patches from the acute hazardous waste P075 classification. With this P075 classification revision, OTC nicotine replacement products become solid waste rather than hazardous waste. As a result, healthcare facilities - particularly pharmaceutical retailers - will likely be able to reduce their generator status to SQG or, possibly, VSQG, currently in Oregon known as Conditionally Exempt Generator (CEG).

With healthcare facilities able to potentially reduce the reporting costs and generator fees, DEQ's Hazardous Waste Program will experience a decrease in revenue for overseeing management of these wastes in Oregon. For this fiscal impact analysis, DEQ analyzed annual reports data from 2017 through 2019 from DEQ's HazWaste.net database. DEQ's analysis included generators reporting waste streams with descriptions of medicine and medical, pharmaceuticals, nicotine, Warfarin, or

waste codes P075 and P001, as these generators are likely to meet the regulatory definition of healthcare facilities. Additionally, DEQ's fiscal impact analysis did not consider generators reporting one-time events, such as for "medicine cabinet" cleanouts. DEQ determined that removing HW Pharms from the waste stream calculation would lower a generator's category, resulting in lower costs.

DEQ presents these fiscal impact estimates to its Hazardous Waste Program resulting from the state adoption of these proposed rules. The P075 revision will reduce SQG and LQG annual verification fees between $8,500 and $14,200 due to large retail pharmacies dropping their status from LQG to SQG or VSQG. For example, one national over-the-counter retail pharmacy reported all of their facilities as SQGs due to small amounts of HW Pharms waste as well as non-pharmaceutical hazardous waste. Although another retailer reported all stores as SQGs, these stores may no longer need to report as such under this rule and, therefore, operate as VSQGs. This example shows how healthcare facilities could adjust management of HW Pharms to help minimize their waste management costs.

With HW Pharms no longer counting toward generator status under these proposed rules, DEQ also anticipates several hospitals and medical centers would move from LQG status to VSQG status, depending on the amount of HW Pharms generated. DEQ estimates this shift would result in a loss of activity fees of approximately $14,330 from hospital and medical pharmacies. Additionally, using DEQ's 2019 HazWaste.net reporting data, DEQ estimates an approximately $10,000 loss in revenue from generation fees.

Given the above estimates, DEQ anticipates a total loss in activity and generation fees of approximately $38,500. This represents about 1.80% of the total amount of invoice fees in 2019, which was $2,147,000.

Local governments

DEQ's analysis of the fiscal impact for local governments relied on EPA's 2019 regulatory impact analysis. Unlike the other provisions of the 2019 rule, the sewering ban applies to all levels of generators, including VSQGs. EPA estimates the sewering prohibition will help eliminate the need for future wastewater treatment for pharmaceuticals in wastewater, reducing future treatment costs. In our review of the literature, some pharmaceuticals in wastewater are discharged into receiving water, indicating current wastewater treatment systems cannot remove these particular pollutants in wastewater prior to discharge.

In a study commissioned by International Joint Commission of U.S. and Canadian officials studying the Great Lakes, sewered hazardous waste pharmaceuticals are often untreated by municipal wastewater treatment plants. The Commission's review identified national studies detecting pollutants, such as pharmaceuticals, pesticides, consumer products, and industrial chemicals, in 80 percent of streams sampled. Additionally, in a statewide water quality toxics assessment, DEQ detected at least one specific pharmaceutical in 31 percent of the streams studied. This pharmaceutical was the common antibiotic sulfamethoxazole. In its regulatory impact analysis, EPA anticipates preventing 6,400 tons of hazardous waste pharmaceuticals from reaching waterways by the adoption of this rule nationally. EPA estimates the savings from this sewering ban in its 2019 rule to be $4.3 million annually for municipalities and service districts managing municipal wastewater.

Public

As discussed in the sections below, the proposed rules present several opportunities for healthcare facilities to reduce their hazardous waste management costs. These potential cost savings may translate into lower costs to consumers of pharmaceuticals dispensed at healthcare facilities.

Large businesses - businesses with more than 50 employees

DEQ believes the fiscal impacts for large businesses will be identical to the impacts for small businesses as defined under the Small Business section below.

Small businesses – businesses with 50 or fewer employees

a. Estimated number of small businesses and types of businesses and industries with small businesses subject to proposed rule.

The number of small businesses in Oregon affected by the proposed rules is estimated in the table below. This information is from 2019 data.

Oregon Small Businesses Affected by Rules		
Business Classes Affected by Rule	**North American Industry Classification System (NAICS) Code**	**Number of Small Businesses**
Pharmacies	44611	421*
Vet Clinics	54194	545
Physician Offices	6211	2078
Dentist Offices	6212	1891
Other Health Practitioners	6213	743
Outpatient Care Centers	6214	174
Other Ambulatory Healthcare Services	6219	34
Hospitals	622	28
Nursing Care Facilities	6231	56
Continuing Care Retirement Communities	623311	1364
Medical Examiners & Coroners' Offices	Subset of 92219	5**
Reverse Distributors	Various NAICS	Unknown

* This estimate includes pharmacy departments meeting the definition of a small business but are part of a large business with an institutional support system characteristic of large businesses.
**This is the number of municipal listing in this class that are likely to have a coroner's office.

b. Projected reporting, recordkeeping and other administrative activities, including costs of professional services, required for small businesses to comply with the proposed rule.

In the federal regulatory impact analysis, EPA estimates the rule to impact approximately 144,228 small businesses nationwide based on the thresholds from the Small Business Administration (SBA) in the 2007 economic analysis of census data. EPA estimates the highest cost impact to small entities will be 0.013% of revenues at healthcare facilities, and 0.002% of revenues at hospitals. EPA did not obtain revenue fiscal impact data on reverse distributors as they are identified by a variety of industrial codes. However, EPA estimates the cost impact to small entity, pharmaceutical reverse distributors at $5,300 and does not anticipate the rule will cause significant hardship.

In DEQ's fiscal analysis of both small and large businesses, DEQ considered how the changes in management standards and P075 listing changes may affect hazardous waste management costs. DEQ believes these changes provide a number of additional opportunities to reduce hazardous waste management costs as discussed in the sections below for small and large businesses.

c. Projected equipment, supplies, labor and increased administration required for small businesses to comply with the proposed rule.

For healthcare facilities, the premise for EPA's adoption of the 2019 HW Pharms Rule is based in part upon the wide variety of small quantity pharmaceutical waste streams generated by healthcare facilities and reverse distributors. Under current Oregon adopted-federal rules, this fact increases the cost of hazardous waste management and disposal for generators and increases costs for reverse distributors who provide credit for pharmaceuticals. The occurrence of P-listed, i.e., acute, hazardous waste pharmaceuticals often pushes healthcare facilities into the large quantity generator category and the increased requirements associated with this category. The LQG regulatory requirements increase management costs of HW Pharms for healthcare facilities. Moreover, employees working in healthcare facilities often lack the training and, therefore, the knowledge, to perform hazardous waste determinations. As a result, this creates inconsistent compliance with regulations and increased management cost due to noncompliance with hazardous waste rules.

To address these concerns, EPA's 2019 rule allows certain generators meeting the definition of a healthcare facility to streamline requirements and to simplify their management approach. In adopting EPA's 2019 rule, DEQ believes that the streamlining of requirements targeted at pharmaceuticals and the simplification of the management of HW Pharms will ultimately lower waste management costs for healthcare facilities. The proposed rule also provides generators and reverse distributors more flexibility in managing hazardous waste pharmaceuticals. The simplification, streamlining, and greater flexibility provides generators and reverse distributors an opportunity to develop more cost-effective management strategies. As discussed below, the reduction in management standards in the rule capitalizes on HW Pharms destined for a reverse distributor having value, such as potentially creditable hazardous waste pharmaceuticals. This value will help ensure healthcare facilities and reverse distributors provide proper container management for potentially creditable HW Pharms.

To refine risk management through this rule, the 2019 rule defines two types of HW Pharms. The rule distinguishes HW Pharms as either potentially creditable HW Pharms or non-creditable HW Pharms. Using this distinction, the rule adjusts management requirements based on the hazardous waste pharmaceutical type. Reverse distributors associated with pharmaceutical manufacturers provide credit for unused pharmaceuticals. This credit provides healthcare facilities the incentive to carefully manage creditable HW Pharms to recoup this value from this waste stream when destined to a reverse distributor.

The list below highlights specifically how the 2019 HW Pharm Rule minimizes the costs to generators meeting the definition of healthcare facility and reverse distributor.

Example Cost Saving Opportunities for All Healthcare Facilities:

- Once a healthcare facility determines its generator status for all its hazardous wastes, such as HW Pharms and non-HW Pharms, the facility is subject to Subpart P if a SQG or LQG after making this determination. Once under Subpart P, the facility no longer has to count HW Pharms since the proposed rule lacks generator category distinctions. This allows generators to potentially reduce waste management costs by lowering generator status as discussed above.
- VSQGs will have flexibility to pursue one of the following three paths to optimize hazardous waste pharmaceuticals management: (1) under Part 262 rules for VSQGs; (2) under Part 266.504(a) and (b) allowing a VSQGs to send HW Pharms to an off-site healthcare facility under the control of the same person; or, (3) under Subpart P provisions of 266.501(b) and (d) concerning management standards for non-creditable and creditable HW Pharms. This flexibility provides an opportunity to select the most cost-effective pathway forward.
- LQG-level training is not required to manage hazardous waste pharmaceuticals, and generators can use facility-specific training similar to SQGs and small quantity universal waste handlers.
- The P075 listing is revised to eliminate low risk, over-the-counter nicotine replacement therapy products, such as gums, lozenges, and patches. The facilities can now discard the products. This reduces management costs, reporting costs and, potentially, generator fees.
- Healthcare facilities must perform hazardous waste determinations on pharmaceutical waste. If comingling non-hazardous waste pharmaceuticals with the noncreditable HW Pharms and properly managing under Subpart P, then facilities do not have to retain hazardous waste determination documents.
- "RCRA-empty" for pharmaceutical containers is defined in Subpart P for all pharmaceuticals. This additional "RCRA-empty" definition differs from the current definition in Part 261. This distinction makes it easier for all generators to dispose of containers with residues of HW Pharms as non-hazardous waste.
- A conditional exemption is provided for Drug Enforcement Agency-controlled substances allowing all generators to streamline compliance with hazardous waste management and DEA-controlled substance requirements.

Example Cost Saving Opportunities for Managing Potentially Creditable Hazardous Waste Pharmaceuticals:

- A VSQG can ship potentially creditable hazardous waste pharmaceuticals to a reverse distributor under the optional provisions of Subpart P without opting in and following all the Subpart P standards, which can increase hazardous waste management costs.
- There are no accumulation time limits, container labeling, or container management standards for healthcare facilities managing potentially creditable HW Pharms. This eliminates the potential for violating these requirements.
- Healthcare facilities do not have to use uniform hazardous waste manifests and land disposal restriction forms when shipping potentially creditable HW Pharms thus reducing management cost and potential penalties for noncompliance with these requirements.
- Healthcare facilities and large quantity generators can accept potentially creditable HW Pharms from an offsite VSQG under the control of the same "person" if specific standards in Part 266 for healthcare facilities are followed or, if an LQG, consolidation standards in Part 262 are followed. Relying on the capacity and expertise available at a larger facility could potentially reduce costs for the VSQG.
- To avoid duplicative inventory management requirements, reverse distributors may follow, for example, State Board of Pharmacy inventory requirements to meet Subpart P inventory requirements. Avoiding duplicative requirements presents potential cost savings.

- Reverse distributors have flexibility with the allowance of 30 days to evaluate potentially creditable hazardous waste pharmaceuticals and, once evaluated, have an accumulation time limit of 180 days. These accumulation time limits can be more flexible than requirements in Part 262 and may provide cost savings.
- A performance-based container storage standard is provided for a reverse distributor's accumulation areas for more flexibility or, to avoid duplicative requirements, the reverse distributor may manage storage area security requirements following, for example, those established by the State Board of Pharmacy.

Example Cost Saving Opportunities for Managing Noncreditable Hazardous Waste Pharmaceuticals:

- Central accumulation areas and satellite accumulation areas are not required for healthcare facilities managing non-creditable hazardous waste pharmaceuticals, thus simplifying requirements and, presumably, decreasing the potential violations.
- Healthcare facilities may choose to manage their nonhazardous waste pharmaceuticals as non-creditable hazardous waste pharmaceuticals to streamline their waste management approach for cost savings.
- Noncreditable hazardous waste pharmaceuticals at a healthcare facility can be accumulated for up to a year to economize shipping costs. This flexibility in management standards may generate cost savings.
- Although a uniform hazardous waste manifest form is required, healthcare facilities and reverse distributors are allowed to use the word "Pharms" or "Pharmaceuticals" in the waste code block of the manifest, thereby simplifying this step and avoiding omissions of specific waste codes leading to violations and associated penalties.
- Land Disposal Restrictions paperwork is required when shipping to a Transfer Storage and Disposal Facility. However, to simplify compliance, the proposed rule does not require waste codes on this manifest and allows a generic treatment standard, such as combustion, except for HW Pharms subject to the dilution prohibition.
- Container management standards for non-creditable hazardous waste pharmaceuticals are similar to those for a SQG under Part 262 thus simplifying the management of hazardous waste pharmaceuticals by avoiding prescriptive standards and relying on performance-based standards, such as ensuring a container is secure. Although necessary at times to protect human health and the environment, performance based standards provide an opportunity to develop a compliance better tailored to an entity's operations.
- Healthcare facilities and large quantity generators are allowed to accept non-creditable HW Pharms from an offsite VSQG under the control of the same person if specific standards in Part 266 for healthcare facilities are followed, or if an LQG, consolidation standards in Part 262 are followed. Relying on the capacity and expertise available at a larger facility could potentially reduce costs for the VSQG.
- Noncreditable HW Pharms do not have to be included in annual reporting, thus reducing accounting costs for generators subject to reporting requirements.

d. Describe how DEQ involved small businesses in developing this proposed rule.

DEQ included small business representatives on the rulemaking advisory committee that will help advised DEQ on the potential cost of compliance for small businesses. DEQ will also provide rulemaking notice to all manufacturers registered with Oregon DEQ as a small and large quantity generator. These generator groups include small businesses.

Documents relied on for fiscal and economic impact

Document title	Document location
80 Federal Register 58014, Sept. 25, 2015	Link EPA Final Rule: https://www.federalregister.gov/documents/2015/11/05/2015-28100/management-standards-for-hazardous-waste-pharmaceuticals
Summary of Regulatory Impact Analysis, Preamble Outline XI. 80 Federal Register 58014 (Sept. 25, 2015)	Link EPA Fiscal Impact Analysis: https://www.regulations.gov/document?D=EPA-HQ-RCRA-2007-0932-0150
Only Half of Drugs Removed by Sewage Treatment. Environmental Health News (Nov. 22, 2013)	https://www.scientificamerican.com/article/only-half-of-drugs-removed-by-sewage-treatment/
Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams. Environmental Science & Technology (1999-2000)	Kolpin, D.W., Furlong, E.T., Meyer, M.T., Thurman, E.M., Zaugg, S.D., Barber, L.B., Buxton, H.T., 2002. Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams, 1999-2000: A National Reconnaissance. Environmental Science & Technology; v. 36, pp. 1202-1211 https://pubs.acs.org/doi/10.1021/es011055j
A National Reconnaissance for Pharmaceuticals and Other Organic Wastewater Contaminants in the United States – II: Untreated Drinking Water Sources. Science of the Total Environment (2008)	Facazio, M.J., Kolpin, D.W., Barnes, K.K., Furlong, E.T., Meyer, M.T., Zaugg, S.D., Barber, L.B., Thurman, M.E., 2008. A National Reconnaissance for Pharmaceuticals and Other Organic Wastewater Contaminants in the United States – II: Untreated Drinking Water Sources. Science of the Total Environment; 402, pp. 201 – 216 https://pubmed.ncbi.nlm.nih.gov/18433838/
Statewide Water Quality Toxics Assessment Report. DEQ (April 2015)	https://www.oregon.gov/deq/FilterDocs/WQToxicsAssessmentReport.pdf

Advisory committee fiscal review

DEQ appointed an advisory committee for this rulemaking.

As ORS 183.33 requires, DEQ will ask for the committee's recommendations on:

- Whether the proposed rules would have a fiscal impact,
- The extent of the impact, and
- Whether the proposed rules would have a significant adverse impact on small businesses; if so, then how DEQ can comply with ORS 183.540 reduce that impact.

The committee will review the draft fiscal and economic impact statement and document its recommendations in the final approved meeting summary in July 2021.

The committee will determine if the proposed rules would or would not have a significant adverse impact on small businesses in Oregon.

ORS 183.333 and 183.540 require the committee to consider how DEQ could reduce the rules' fiscal impact on small business by:

- Establishing differing compliance or reporting requirements or time tables for small business;
- Clarifying, consolidating or simplifying the compliance and reporting requirements under the rule for small business;
- Utilizing objective criteria for standards;
- Exempting small businesses from any or all requirements of the rule; or
- Otherwise establishing less intrusive or less costly alternatives applicable to small business.

Housing cost

As ORS 183.534 requires, DEQ evaluated whether the proposed rules would have an effect on the development cost of a 6,000-square-foot parcel and construction of a 1,200-square-foot detached, single-family dwelling on that parcel.

DEQ determined the proposed rules would have no effect on the development costs because these rules do not affect the development of housing and associated infrastructure to support this housing. Rather, these rules are designed to regulate the management of hazardous waste pharmaceuticals at healthcare facilities and reverse distributors. Moreover, DEQ anticipates that the proposed management standards in these rules will reduce operational costs at healthcare facilities when compared with existing requirements for hazardous waste pharmaceuticals. Healthcare facilities provide needed services for housing developments; therefore, these rules will help support a favorable regulatory environment for commercial services that households need.

Consequently, these rules will not influence directly or indirectly decisions regarding the development of housing.

Alternative formats

DEQ can provide documents in an alternate format or in a language other than English upon request. Call DEQ at 800-452-4011 or email deqinfo@deq.state.or.us.