



State of Oregon Department of Environmental Quality

# Pharmaceutical Rule Definitions Correction

Hazardous Waste Federal Rule Alignment 2021

The purpose of this document is to provide corrections and clarifications to the Pharmaceutical Rule definitions section of the [Notice of Proposed Rulemaking and Draft Rules](#).

## Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine

[[84 FR 5816-5950](#) – Federal Rulemaking Feb. 22, 2019, effective Aug. 21, 2019]

### Definitions

- **Pharmaceutical** includes, but is not limited to: dietary supplements, prescription drugs, over-the-counter drugs, homeopathic drugs, compounded drugs, investigational new drugs, pharmaceuticals remaining in containers, personal protective equipment contaminated with pharmaceuticals, and clean-up material from spills of pharmaceuticals.
  - **Pharmaceutical** does not include dental amalgam, sharps or medical waste.
- **Healthcare Facility** includes, but is not limited to: military medical logistics facilities, hospitals, ambulatory surgical centers, health clinics, physicians' offices, optical and dental providers, chiropractors, some long-term care facilities, ambulance services, pharmacies, long-term care pharmacies, veterinary clinics and hospitals.
  - **Healthcare Facilities** do not include pharmaceutical manufacturers, reverse distributors or reverse logistics centers.
  - **Healthcare Facilities** do include long-term care facilities with nursing care and hospice facilities; **not** included in this definition are independent living communities, assisted living facilities and group homes.
    - **Long-term care facility** means a licensed entity providing assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility. This definition includes, but is not limited to, hospice facilities, nursing facilities, skilled nursing facilities, and the nursing and skilled nursing care portions of continuing care retirement communities.
    - **Long-term care facility** does not mean group homes, independent living communities, assisted living facilities, and the independent and assisted living portions of continuing care retirement communities. EPA has also determined intermediate care facilities are not long-term care facilities.
- **Potentially creditable hazardous waste pharmaceutical** means a prescription hazardous waste pharmaceutical that has a reasonable expectation of receiving

manufacturer credit and is 1) in original manufacturer packaging, 2) undispensed and 3) unexpired, or less than one year past its expiration date.

- **Noncreditable hazardous waste pharmaceutical** means a prescription hazardous waste pharmaceutical that does not have a reasonable expectation to be eligible for manufacturer credit or a nonprescription hazardous waste pharmaceutical that does not have a reasonable expectation to be legitimately used, reused or reclaimed.
- **Reverse distributors** are entities that receive and accumulate prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals from healthcare facilities, and evaluate them to determine if they are eligible for manufacturer credit. The reverse distributor must evaluate each potentially creditable hazardous waste pharmaceutical within 30 calendar days of receipt. Once the evaluation is complete, the material becomes known as an **evaluated hazardous waste pharmaceutical**.

**Additional resources:** [EPA FAQ](#)

#### **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](mailto:deqinfo@deq.state.or.us).