

Guidance for Hazardous Waste Pharmaceuticals (HWP) Generators

What are Hazardous Waste Pharmaceuticals (HWP)? (R315-266-500)

HWP means a pharmaceutical that is a solid waste, as defined in R315-261-2 and exhibits one or more characteristics identified in R315-261-20 through R315-261-24 OR is listed in R315-261-30 through R315261-35.

- A pharmaceutical is <u>not</u> a solid waste as defined in R315-262-2, and therefore not a HWP, if it is legitimately used/reused
 - For example: lawfully **donated** for its intended purpose, or reclaimed
- An over-the-counter pharmaceutical, dietary supplement, or homeopathic drug is <u>not</u> a solid waste as defined in R315-261-2, and therefore not a HWP, if it has a reasonable expectation of being legitimately used/reused
 - For example: lawfully **redistributed** for its intended purpose or reclaimed

Who Does this Apply to? (R315-266-501)

- Healthcare Facilities (HF) as defined in R315-266-500(a)(3)
- Long-Term Care Facilities as defined in R315-266-500(a)(5)
- Reverse Distributors (RD) as defined in R315-266-500(a)(11)

Three Types of HWP

- Non-Creditable HWP
 - "a prescription HWP that does not have a reasonable expectation to be eligible for manufacturer credit or a nonprescription HWP that does not have a reasonable expectation to be legitimately reused or reclaimed"
 - For example: investigational drugs, free samples of pharmaceuticals received by HFs, contaminated personal protective equipment (PPE), etc.
- Potentially Creditable HWP
 - "a prescription HWP that has a reasonable expectation to received manufacturer credit and is:
 - In original manufacturer packaging, except pharmaceuticals that were subject to recall
 - Undispensed
 - Unexpired or less than one-year past expiration date"
 - Note: Potentially Creditable HWP does not include evaluated HWP or nonprescription pharmaceuticals including, but not limited to over-the-counter drugs, homeopathic drugs, dietary supplements, etc.



- Evaluated HWP
 - "a prescription HWP that has been evaluated by a Reverse Distributor (RD) in accordance with R315-266-510(a)(3) and will not be sent to another RD for further evaluation or verification of manufacturer credit"

Can HWP be Sewered? (R315-266-505)

- No. HFs including, Very Small Quantity Generators (VSQGs) operating under R315-262-14 in the place of R315-266-500 through R315-266-510, and RDs are prohibited from discharging HWP to a sewer system that passes through to a publicly owned treatment works.
- HFs and RDs remain subject to the prohibitions in 40 CFR 403.5(b)(1)
- Utah adopted the Prohibition of Sewering HWP in September 2020.

What are the Training Requirements? (R315-266-502(b) and R315-266-510(c)(3))

- All personnel that manage Non-Creditable HWP shall be thoroughly familiar with the proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies.
- Personnel at a RD that handle Evaluated HWP are subject to the training requirements in R315-262-17(a)(7).

What are the Record Keeping Requirements for a HF Managing Non-Creditable HWP? (R315-266-502(j))

- Maintain signed manifests for 3 years ensure they are readily available for review upon request
- Maintain exception reports that have been filed for 3 years ensure they are readily available for review upon request
- Maintain Hazardous Waste Determination documentation for 3 years ensure they are readily available for review upon request

What are the Record Keeping Requirements for a RD Managing Evaluated HWP? (R315-266-510(c)(10))

- Maintain a log (written or electronic) of weekly container inspections for 3 years ensure they
 are readily available for review upon request
- Maintain signed manifests for 3 years ensure they are readily available for review upon request
- Maintain copies of Biennial Reports (BR) for 3 years ensure they are readily available for review upon request
- Maintain exception reports that have been filed for 3 years ensure they are readily available for review upon request
- Maintain the LQG training record requirements in R315-262-17(a)(7)(iv) ensure they are readily available for review upon request



Common Acronyms When Dealing with Hazardous Waste Pharmaceuticals:

- **HF:** Healthcare Facility

- **HWP:** Hazardous Waste Pharmaceutical(s)

HW: Hazardous WasteRD: Reverse Distributor

- **VSQG:** Very Small Quantity Generator

SQG: Small Quantity GeneratorLQG: Large Quantity Generator

- BR: Biennial Report

- LDR: Land Disposal Restrictions

- TSDF: Treatment, Storage and Disposal Facility

Note: The Division has created a Hazardous Waste Pharmaceuticals Generator Checklist available on our website at (insert link when available)