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This white paper addresses issues of a general nature related to the federal RCRA regulations. Persons evaluating specific circumstances dealing with hazardous waste regulations should review state and local laws and regulations, which may be more stringent than federal requirements. In addition, the assistance of a qualified professional should be enlisted to address any site-specific circumstances.

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New Hazardous Waste Pharmaceuticals Regs

The hazardous waste pharmaceuticals rule was promulgated by EPA on February 22, 2019. [84 FR 5816] This action establishes a new Part 266, Subpart P to regulate the management of hazardous waste pharmaceuticals (HWPharms) under RCRA. The rule defines and regulates two entities—healthcare facilities and reverse distributors—who must comply with the new subpart when it becomes effective in their state.

The rule contains four additional pharmaceutical-related provisions that are discussed in this paper: 1) a prohibition on sewering, 2) a conditional exemption for DEA-controlled substances, 3) a new definition of RCRA-empty for pharmaceutical containers, and 4) a revision to the P075 listing description for certain nicotine replacement therapies.

In addition to finalizing new regulatory requirements, EPA used the preamble to this rule to provide significant guidance and best management practices for healthcare facilities and reverse distributors managing HWPharms. The guidance is sprinkled throughout our discussions below, and a summary of best practices is given at the end of this paper.

1 Background on Pharmaceutical Wastes

Before promulgation of this final rule, compliance with the RCRA hazardous waste regulations had been a challenge for healthcare facilities, such as hospitals, doctors’ offices, and pharmacies. Unlike a typical manufacturing facility that may generate a few hazardous waste streams in large quantities, a healthcare facility generates a wide variety of hazardous wastes in smaller quantities. Many of these hazardous wastes are pharmaceuticals, and a healthcare facility may have thousands of different pharmaceutical products in its inventory. [84 FR 5819]

Nurses, doctors, pharmacists, and others working in healthcare facilities typically do not have the knowledge or training to make a hazardous waste determination for discarded pharmaceuticals. This has led to inconsistent RCRA compliance and periodic enforcement. [84 FR 5820]

Another challenge arises when a discarded pharmaceutical is a P-listed acute hazardous waste. A facility that generates more than 1 kg (2.2 lb) of acute hazardous waste in a calendar month is regulated as a large quantity generator (LQG), significantly increasing its RCRA regulatory requirements.

The purpose of the pharmaceuticals rule is to solve the problems noted above; newly promulgated Subpart P is designed to help healthcare facilities, and the reverse distributors who receive pharmaceuticals, maintain RCRA compliance while protecting human health and the environment.

2 Materials Subject to the Rule

Previous EPA policy allowed pharmaceuticals to be sent from healthcare facilities to reverse distributors for manufacturer credit as products—not solid and hazardous waste (see November 25, 1980; 45 FR 78540–1, December 2, 2008; 73 FR 73525, and RO 11012 and 11606). Based on subsequent research, however, the agency now understands that in almost all cases, prescription pharmaceuticals sent to a reverse distributor are ultimately discarded. Thus, EPA’s new policy, codified in the 2019 final rule, is that once the decision is made to send a prescription pharmaceutical from a healthcare facility to a reverse distributor, a decision to discard has been made and the pharmaceutical is considered a solid and potentially hazardous waste. [84 FR 5828–9]

However, the pharmaceuticals rule makes a clear distinction between the management of prescription vs. nonprescription pharmaceuticals. Prescription pharmaceuticals sent to a reverse distributor are solid and potentially hazardous wastes. Nonprescription pharmaceuticals sent through reverse logistics systems are not solid wastes if they have a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for their intended purpose) or reclaimed. [§266.501(g)(2), 84 FR 5832]

Similarly, in the preamble to the final rule, EPA established a policy that other unsold retail items that are sent through reverse logistics are not solid wastes at the retail store if they have a reasonable expectation of being legitimately used/reused or reclaimed. [84 FR 5827]

Figure 1 (page 2) illustrates these concepts. Part 266, Subpart P requires healthcare facilities to send potentially creditable HWPharms (see definition in Section 4) to reverse distributors as hazardous waste—not products. However, such transfers are subject to minimal RCRA requirements, as detailed in Section 5.1 below. If the healthcare facilities send HWPharms directly to a TSD facility, these non-creditable HWPharms must be managed under more-stringent Subpart P standards, as discussed in Section 5.2.

Before diving too far into the new pharmaceuticals rule, people should first carefully evaluate whether they are
Figure 1: Overall Management and Regulation of Hazardous Waste Pharmaceuticals

<table>
<thead>
<tr>
<th>Healthcare facility (defined in §266.500) that generates above VSQG quantity thresholds(^1)—must determine if its HWPharms(^2) are:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Nonprescription—Do HWPharms have a reasonable expectation of legitimate use/reuse or reclamation?</td>
</tr>
<tr>
<td>• Yes → to 1</td>
</tr>
<tr>
<td>• No → Non-creditable HWPharms management (see below)</td>
</tr>
<tr>
<td>2. Prescription—Do HWPharms have a reasonable expectation of receiving manufacturer credit?</td>
</tr>
<tr>
<td>• Yes → Potentially creditable HWPharms management (see below)</td>
</tr>
<tr>
<td>• No → Non-creditable HWPharms management (see below)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Potentially creditable HWPharms management</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Hazardous waste managed according to §§266.502(a), 266.503 (minimal stds), and 266.505–266.507.</td>
</tr>
<tr>
<td>2. No accumulation time limit.</td>
</tr>
<tr>
<td>3. to 3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Non-creditable HWPharms management</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Hazardous waste managed according to §§266.502 (comparable to SQG stds) and 266.505–266.507.</td>
</tr>
<tr>
<td>2. May be accumulated for up to 1 year.</td>
</tr>
<tr>
<td>3. to 2</td>
</tr>
</tbody>
</table>

1. Not solid waste—no manifest/no LDR required

2. Designated hazardous waste TSD facility—treatment and disposal

3. Potentially creditable HWPharms—ship per §266.509; no manifest/no LDR required

4. Evaluated HWPharms—ship per §266.508; manifest/LDR required

Reverse distributor (defined in §266.500)—does not need a RCRA permit if in compliance with §266.510(a–c) (comparable to SQG stds)

<table>
<thead>
<tr>
<th>Potentially creditable HWPharms management</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Hazardous waste managed according to §§266.505–266.507, 266.509, 266.510(a–b).</td>
</tr>
<tr>
<td>2. Must be evaluated within 30 days of receipt.</td>
</tr>
<tr>
<td>3. Once evaluation is complete, the material becomes known as evaluated HWPharms.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Evaluated HWPharms management</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Hazardous waste managed according to §§266.505–266.507, 266.510(a, c).</td>
</tr>
<tr>
<td>2. May be accumulated for up to 180 days.</td>
</tr>
<tr>
<td>3. to 4</td>
</tr>
</tbody>
</table>

HWPharms = hazardous waste pharmaceuticals; LQG = large quantity generator; SQG = small quantity generator; TSD = treatment, storage, and disposal; VSQG = very small quantity generator.

\(^1\)A healthcare facility determines whether it is above VSQG quantity thresholds by counting both its HWPharms and nonpharmaceutical hazardous waste. \(\$\$262.10(n), 266.501(a–b), 266.504\) A healthcare facility that is a VSQG when factoring in both HWPharms and nonpharmaceutical hazardous waste is subject to §§266.505 and 266.507. Its nonpharmaceutical hazardous waste is subject to management per §262.14. Its HWPharms may be managed per §262.14, §266.504, or the opt-into Subpart P provisions of §266.501(b,d). [84 FR 5858]

\(^2\)Nonhazardous waste pharmaceuticals are not subject to the RCRA Subtitle C hazardous waste regulations. But, a healthcare facility may manage its nonhazardous waste pharmaceuticals according to Part 266, Subpart P if it so chooses. \(\$\$266.502(c), 266.503(a), 84 \text{ FR} 5840\)

Source: McCoy and Associates, Inc.
managing materials that meet the new definitions of pharmaceutical and hazardous waste pharmaceutical; these terms are defined in Section 4 below. Also, there are several exemptions that can keep a facility from having to manage its pharmaceuticals under new Subpart P. Figure 2 (page 4) is a logic diagram to help people work through the twists and turns of the new rule to determine its applicability to materials managed at the site.

3 Affected Facilities

The pharmaceuticals rule is a sector-based regulation that applies to the management of HWPharms that are generated and managed by healthcare facilities and reverse distributors (see definitions for these two entities in Section 4 below). The rule applies to all healthcare facilities that generate more than the very small quantity generator (VSQG) monthly quantity thresholds found in §262.13. Healthcare facilities that are not VSQGs must comply with new Part 266, Subpart P for the management of their HWPharms—opting out of Subpart P in favor of traditional hazardous waste management under Part 262 is not an option. [84 FR 5855]

All healthcare facilities that are subject to Subpart P (i.e., those that are not VSQGs) are regulated in the same way, regardless of the quantity of HWPharms generated. In other words, there are no LQGs or small quantity generators (SQGs) within Subpart P, but a healthcare facility will be a VSQG, SQG, or LQG for its nonpharmaceutical hazardous waste management. [84 FR 5863]

All reverse distributors are subject to Subpart P instead of Part 262 for the management of HWPharms, including those that would have been considered VSQGs under Part 262. Therefore, a reverse distributor subject to Subpart P will no longer have to keep track of the amount of HWPharms that it generates on a monthly basis. [84 FR 5934]

Even though they are receiving hazardous waste, reverse distributors in compliance with Subpart P are not required to operate under the regulations for permitted or interim status TSD facilities in Part 264 or 265, nor are they required to get a RCRA permit under Part 270. [84 FR 5857]

There are some complexities within the new rule when determining its applicability to a specific facility. Figure 3 (page 6) is a logic diagram that will help facility personnel determine which (if any) of the rule’s provisions apply.

A list of potentially affected entities, identified by NAICS code, is provided in Table 1 to help facilities determine if they are impacted by this rule. To determine if your facility is subject to the pharmaceuticals rule, examine Table 1, the applicability criteria in Figure 3, and the definitions in Section 4.

3.1 Determining Subpart P Applicability and Part 262 Generator Category for Healthcare Facilities

While all reverse distributors are subject to the new Subpart P regulations, a healthcare facility that is a VSQG when counting all of its hazardous waste, both pharmaceutical and nonpharmaceutical, has limited requirements under Subpart P.

And the pharmaceuticals rule has another provision that adds complexity when determining Subpart P applicability and Part 262 generator category for healthcare facilities. A healthcare facility does not have to count its HWPharms (that are subject to or managed in accordance with Subpart P) when determining its generator category. [new §262.13(c)(9)] As a result, a healthcare facility may experience a change in RCRA generator category for its nonpharmaceutical hazardous waste. For example, a healthcare facility that generates above one or more of the VSQG quantity thresholds and is, therefore, subject to Subpart P for its HWPharms management could become a VSQG for the management of its nonpharmaceutical hazardous waste, since it is no longer required to count its HWPharms toward its generator

---

Table 1: NAICS Codes of Entities Potentially Affected by the Pharmaceuticals Rule

<table>
<thead>
<tr>
<th>NAICS code</th>
<th>Description of NAICS code</th>
</tr>
</thead>
<tbody>
<tr>
<td>4242</td>
<td>Drug wholesalers</td>
</tr>
<tr>
<td>44511</td>
<td>Supermarkets and other grocery (except convenience) stores</td>
</tr>
<tr>
<td>44611</td>
<td>Pharmacies and drug stores</td>
</tr>
<tr>
<td>452311</td>
<td>Warehouse clubs and supercenters</td>
</tr>
<tr>
<td>54194</td>
<td>Veterinary services</td>
</tr>
<tr>
<td>6211</td>
<td>Physicians’ offices</td>
</tr>
<tr>
<td>6212</td>
<td>Dentists’ offices</td>
</tr>
<tr>
<td>6213</td>
<td>Other health practitioners (e.g., chiropractors)</td>
</tr>
<tr>
<td>6214</td>
<td>Outpatient care centers</td>
</tr>
<tr>
<td>6219</td>
<td>Other ambulatory health care services</td>
</tr>
<tr>
<td>622</td>
<td>Hospitals</td>
</tr>
<tr>
<td>6231</td>
<td>Nursing care facilities (e.g., assisted living facilities, nursing homes)</td>
</tr>
<tr>
<td>623311</td>
<td>Continuing care retirement communities (e.g., assisted living facilities with onsite nursing facilities)</td>
</tr>
</tbody>
</table>

Various NAICS codes

Reverse distributors

Figure 2: Applicability of Hazardous Waste Pharmaceuticals Rule to Materials

START

Does the material meet the definition of pharmaceutical in §266.500?

Yes

Is the pharmaceutical being legitimately used/reused (e.g., lawfully donated) or reclaimed?

No

Is the pharmaceutical being managed 1) under an FDA or CPSC recall, 2) according to a preservation order, or 3) during an investigation or judicial proceeding?

No

Is the pharmaceutical an investigational new drug managed under an FDA application per 21 CFR Part 312?

No

Is the pharmaceutical a household waste pharmaceutical (as defined in §266.500), including those collected during a take-back event per §266.506(a)(2)?

Yes

Is the pharmaceutical hazardous because it exhibits a characteristic or meets a listing description?

No

Is the HWPharm generated or managed at a facility that is a healthcare facility or reverse distributor (as those facilities are defined in §266.500)?

Yes

Does the HWPharm also meet the state or local definition of a medical waste?

No

Does the HWPharm also contain a radioactive component subject to the AEA?

Yes

Is the HWPharm listed on a schedule of DEA-controlled substances in 21 CFR Part 1308?

No

Is the HWPharm a nonprescription pharmaceutical?

Yes

Does the prescription HWPharm have a reasonable expectation of receiving manufacturer credit?

No

The material is a potentially creditable hazardous waste pharmaceutical subject to §§266.502(a), 266.503, 266.505, 266.507, 266.509, and 266.510.9

Yes

If it’s a solid waste, the material is subject to §262.11 for evaluation and, if hazardous waste, it’s subject to all applicable hazardous waste regulations.

No

Is the material an “other unsold retail item”?1

Yes

Is the material sent through reverse logistics for evaluation with a reasonable expectation of legitimate use/reuse or reclamation?2

No

The material is not a solid or hazardous waste.3

No

The pharmaceutical is not subject to the RCRA Subtitle C hazardous waste regulations.

Yes

Nonhazardous waste pharmaceuticals are not subject to the RCRA Subtitle C hazardous waste regulations. But, healthcare facilities may manage their nonhazardous waste pharmaceuticals according to Part 266, Subpart P if they so choose.

Yes

The material is subject to the Part 262 hazardous waste generator regulations.

No

The HWPharm component may be managed under Part 266, Subpart P. The medical waste component must be managed in accordance with state and/or local medical waste regulations.

Yes

The HWPharm component may be managed under Part 266, Subpart P. The radioactive component must be managed in accordance with AEA regulations.8

No

Is the material sent through reverse logistics for evaluation with a reasonable expectation of legitimate use/reuse or reclamation?2

Yes

The material is a non-creditable hazardous waste pharmaceutical subject to §§266.502, 266.505, 266.507, and 266.508.10

No

Sources: McCoy and Associates, Inc. [Footnotes on next page]
“Other unsold retail item” can include any nonpharmaceutical unsold retail item from a retail store that if discarded would meet the definition of hazardous waste. Examples include aerosol cans, pool chemicals, mercury-containing light bulbs, some pesticides, certain cleaning products, paint thinner, ammunition, and fireworks. However, this term does not include unused pesticides that are suspended or canceled and recalled; these materials can be managed as universal waste under Part 273. [84 FR 5827, 5834]

Nonprescription pharmaceuticals and other unsold retail items that have expired, but are in their original, intact packaging, are not considered solid wastes if they have a reasonable expectation of being legitimately used/reused or reclaimed. (Nonprescription pharmaceuticals and other unsold retail items cannot be sent through reverse logistics if they are broken, damaged, or leaking.) If a reverse logistics facility or other subsequent entity makes the decision to discard the material, the material becomes a solid waste subject to §262.11 for evaluation and, if hazardous, subject to all applicable RCRA rules. [84 FR 5832–5]

If nonprescription pharmaceuticals and other unsold retail items are not managed and stored in a manner that prevents releases to the environment, they may be considered solid and hazardous waste under RCRA Sections 3007, 3013, and 7003. [84 FR 5834]

Once the FDA or CPSC approves the destruction of recalled pharmaceuticals, the material becomes a solid waste subject to §262.11 for evaluation and, if hazardous, Part 262 for management under RCRA. Once the preservation order, investigation, or judicial proceeding has concluded and/or a decision is made to discard the pharmaceuticals, they are considered solid waste, and, if hazardous, are subject to Part 266, Subpart P if they are discarded by a healthcare facility or reverse distributor. [§266.501(g)(3–5), 84 FR 5834, 5862]

When a decision is made to discard/destroy the investigational new drug, it is considered a solid waste, and, if hazardous, is subject to Part 266, Subpart P if the investigational new drug is discarded by a healthcare facility or reverse distributor. However, if the investigational new drug is returned to the manufacturer for discarded/destruction, it is subject to Part 262. [84 FR 5862]

Hazardous waste pharmaceuticals may also pose a biological hazard and are thus subject to both RCRA and applicable state or local medical waste regulations. Some examples include partially administered syringes containing hazardous waste pharmaceuticals (e.g., phystostigmine) or intravenous (IV) bags containing residues of a hazardous waste pharmaceutical that are attached to the tubing and needles used to administer the pharmaceutical. [84 FR 5837] The §266.500 definition of pharmaceutical does not include sharps (e.g., needles from IV bags or syringes, syringes with needles) because sharps are considered medical wastes. [84 FR 5842]

Nonprescription pharmaceuticals include over-the-counter pharmaceuticals, dietary supplements, and homeopathic drugs. [§§266.500, 266.501(g)(2)]

Prescriptions that have already been dispensed to a patient and free samples given to healthcare facilities do not have a reasonable expectation of receiving manufacturer credit. [84 FR 5848]

Potentially creditable HWPharms that are not destined for a reverse distributor must be managed as non-creditable HWPharms; that is, they are subject to §§266.302, 266.505, 266.507, and 266.508. [§266.501(d)(1)(ii), 84 FR 5856]

If the material is a residue remaining in a non-empty container, it must be managed as a non-creditable HWPharm under Subpart P—see §266.507 and Figure 4. If the material is personal protective equipment (PPE) contaminated with pharmaceuticals, it must be managed as non-creditable HWPharms only if the PPE is hazardous under EPA’s “contained-in” policy (because it is contains hazardous waste). The agency included contaminated PPE in the definition of pharmaceutical to require management of PPE (that contains HWPharms) in the same way as other types of HWPharms. [84 FR 5842]

Source: McCoy and Associates, Inc.

category. Such a generator is what EPA refers to as a “Subpart P VSQG.” [84 FR 5859] To help healthcare facilities determine with which regulations (in Part 262 and Part 266, Subpart P) they must comply, the agency has provided a table in the rule’s preamble, which we have reproduced as Table 2 (page 7).

As noted above, all healthcare facilities operating under new Subpart P are regulated in the same way, regardless of the quantity of HWPharms generated. As such, if a healthcare facility chooses to manage its nonhazardous waste pharmaceuticals as HWPharms (see Section 5 below), that decision will not affect the facility’s hazardous waste generator category. [84 FR 5840]

3.2 Small Health Clinics at Large Industrial Facilities

Large industrial facilities (e.g., refineries, chemical plants, automobile assembly plants) often have small health clinics onsite that are staffed by healthcare professionals on a full- or part-time basis. These clinics typically provide first aid for minor incidents and stabilize personnel prior to transfer to an offsite hospital or other healthcare facility during major incidents. The industrial facility is typically an LQG for the generation of nonpharmaceutical hazardous waste (although it could be an SQG), but it often generates very small amounts of HWPharms. Do the new Subpart P standards apply to HWPharms generated at these small, onsite health clinics at large industrial facilities?

Personnel at large industrial plants (that are LQGs or SQGs) should carefully read the definition of healthcare facility (see Section 4 below). If a small, onsite health clinic meets the definition, then it appears from Table 2 that the clinic would be subject to Subpart P for the management of its HWPharms—regardless of how much HWPharms it generates monthly. The management of the industrial facility’s nonpharmaceutical hazardous waste would continue to be subject to the traditional hazardous waste management program in Part 262. [84 FR 5841, 5860]

One commenter on the proposed rule asked EPA to promulgate the rule to allow manufacturing sites that are SQGs or LQGs the option to manage their HWPharms under the existing generator requirements and be exempt from Subpart P. In its response, the agency said “[h]ealthcare
Figure 3: Applicability of Hazardous Waste Pharmaceuticals Rule to Facilities

- Does the facility generate, receive, accumulate, and/or evaluate HWPharms anywhere on its property (from fence line to fence line)?
  - Yes ➔ The facility is subject to Part 266, Subpart P. Any hazardous waste management remains subject to Part 262.
  - No ➔ The facility is not subject to Part 266, Subpart P. Any hazardous waste management remains subject to Part 262.

- Is the facility a farmer, rancher, or fishery?
  - Yes ➔ The facility is subject to Part 266, Subpart P. Any hazardous waste management remains subject to Part 262.
  - No ➔ The facility is not subject to Part 266, Subpart P. Any hazardous waste management remains subject to Part 262.

- Is the facility an independently located coroner or medical examiner?
  - Yes ➔ The facility is subject to Part 266, Subpart P. Any hazardous waste management remains subject to Part 262.
  - No ➔ The facility is not subject to Part 266, Subpart P. Any hazardous waste management remains subject to Part 262.

- Is the facility a reverse logistics center that evaluates nonprescription HWPharms with a reasonable expectation of legitimate use/reuse or reclamation?
  - Yes ➔ The facility is subject to Part 266, Subpart P. Any hazardous waste management remains subject to Part 262.
  - No ➔ The facility is not subject to Part 266, Subpart P. Any hazardous waste management remains subject to Part 262.

- Is the facility a TSD facility?
  - Yes ➔ The facility must ensure that HWPharms received are treated to meet applicable LDR treatment standards and comply with the LDR dilution prohibition. See Section 8 of this paper.
  - No ➔ The facility is subject to Part 266, Subpart P. Any hazardous waste management remains subject to Part 262.

- Is the facility a household?
  - Yes ➔ The facility is subject to Part 266, Subpart P. Any hazardous waste management remains subject to Part 262.
  - No ➔ The facility is not subject to Part 266, Subpart P. Any hazardous waste management remains subject to Part 262.

- Is the facility a group home, independent living community, assisted living facility, or the independent or assisted living portion of a continuing care retirement community?
  - Yes ➔ The facility is subject to Part 266, Subpart P. Any hazardous waste management remains subject to Part 262.
  - No ➔ The facility is not subject to Part 266, Subpart P. Any hazardous waste management remains subject to Part 262.

- Is the facility a manufacturer of over-the-counter or prescription pharmaceuticals?
  - Yes ➔ The facility is subject to Part 266, Subpart P. Any hazardous waste management remains subject to Part 262.
  - No ➔ The facility is not subject to Part 266, Subpart P. Any hazardous waste management remains subject to Part 262.

- Does the facility meet the definition of a reverse distributor in §266.500?
  - Yes ➔ The facility is subject to Part 266, Subpart P. Any hazardous waste management remains subject to Part 262.
  - No ➔ The facility is not subject to Part 266, Subpart P. Any hazardous waste management remains subject to Part 262.

- Does the facility meet the definition of a long-term care facility (LTCF) in §266.500?
  - Yes ➔ The facility is not subject to Part 266, Subpart P. Any hazardous waste management remains subject to Part 262.
  - No ➔ The facility is subject to Part 266, Subpart P. Any hazardous waste management remains subject to Part 262.

- Does the facility generate above VSOQ quantity thresholds?
  - Yes ➔ The facility is subject to Part 266, Subpart P. Any hazardous waste management remains subject to Part 262.
  - No ➔ The facility is not subject to Part 266, Subpart P. Any hazardous waste management remains subject to Part 262.

- Has the LTCF demonstrated that the LTCF generates above VSOQ quantity thresholds?
  - Yes ➔ The facility is subject to Part 266, Subpart P. Any hazardous waste management remains subject to Part 262.
  - No ➔ The facility is not subject to Part 266, Subpart P. Any hazardous waste management remains subject to Part 262.

- Does the LTCF have 20 beds or fewer?
  - Yes ➔ The facility is subject to Part 266, Subpart P. Any hazardous waste management remains subject to Part 262.
  - No ➔ The facility is not subject to Part 266, Subpart P. Any hazardous waste management remains subject to Part 262.

- Has the LTCF demonstrated that it generates within VSOQ quantity thresholds?
  - Yes ➔ The facility is subject to Part 266, Subpart P. Any hazardous waste management remains subject to Part 262.
  - No ➔ The facility is not subject to Part 266, Subpart P. Any hazardous waste management remains subject to Part 262.

- The LTCF may dispose its HWPharms (excluding contaminated PPE or clean-up materials) in an onsite DEA-authorized collection receptacle.

- A healthcare facility that generates within VSOQ quantity thresholds is subject to §§266.505 and 266.507. Its nonpharmaceutical hazardous waste is subject to management per 262.14. Its HWPharms may be managed per 262.14, §§266.504(a–b), or the opt-into Subpart P provisions of §§266.501(b, d), 84 FR 5858

Source: McCoy and Associates, Inc. [Footnotes on next page]
DEA = Drug Enforcement Administration; HWPharms = hazardous waste pharmaceuticals; LDR = land disposal restrictions; PPE = personal protective equipment; TSD = treatment, storage, and disposal; VSQG = very small quantity generator.

3 EPA recommends that, whenever possible, households utilize pharmaceutical take-back events as the preferred disposal option for their unwanted pharmaceuticals. For consumers without access to a pharmaceutical take-back event, the Food and Drug Administration provides step-by-step guidance for disposing pharmaceuticals in the household trash. See http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm. [84 FR 5836]

This includes any reverse distributors that would have been considered VSQGs under Part 262. This also includes third-party logistics providers when they perform the function of a reverse distributor. [84 FR 5857]

A healthcare facility determines whether it is above VSQG quantity thresholds by counting both its HWPharms and nonpharmaceutical hazardous waste. [§§262.10(n), 266.501(a–b), 266.504]

4 A healthcare facility, which generates above one or more of the VSQG quantity thresholds and is, therefore, subject to Subpart P for management of its HWPharms, may become a VSQG for its nonpharmaceutical hazardous waste. This unusual situation results because new §262.13(c)(9) states that a generator is not required to count its HWPharms managed under Subpart P toward its generator category. Section 266.504 does not apply to a healthcare facility that become a VSQG as a result of not having to count its HWPharms. Such a healthcare facility is a VSQG with respect to its nonpharmaceutical hazardous waste only and must manage its HWPharms under Subpart P. [84 FR 5859, 5890]

This is true even if the HWPharms are not DEA-controlled substances. [84 FR 5902] After collection, the contents must be stored, transported, destroyed, and disposed in compliance with all applicable DEA regulations for controlled substances. [§266.504(c)]

5 Nonhazardous waste pharmaceuticals are not subject to the RCRA Subtitle C hazardous waste regulations. But, a healthcare facility may manage its nonhazardous waste pharmaceuticals according to Part 266, Subpart P if it so chooses. [§§266.502(c), 266.503(a), 84 FR 5840]

6 A VSQG that elects to use any of the optional provisions of §266.504 will not be considered to be opting into Part 266, Subpart P. A VSQG may opt into Subpart P in lieu of operating under §262.14 or §266.504 by complying with §266.501(d), including notification as a healthcare facility. A VSQG healthcare facility may choose this option if it does not want to keep track of how much HWPharms it is generating on a monthly basis or if it generates an unpredictable or fluctuating amount of HWPharms each month that might exceed one or more of the VSQG quantity thresholds. [84 FR 5858]

Source: McCoy and Associates, Inc.

Source: Adapted from 84 FR 5866.

Table 2: Applicability of Subpart P and Part 262 Generator Category for Healthcare Facilities

<table>
<thead>
<tr>
<th>HWPharms</th>
<th>Nonpharmaceutical hazardous waste</th>
<th>Total hazardous waste</th>
<th>Subject to Part 266, Subpart P?</th>
<th>Part 262 generator category of healthcare facility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute</td>
<td>Nonacute</td>
<td>Acute</td>
<td>Nonacute</td>
<td>Acute</td>
</tr>
<tr>
<td>Any amount</td>
<td>+ &gt;1 kg and/or ≥1,000 kg</td>
<td>≥1 kg and/or ≥1,000 kg</td>
<td>Yes</td>
<td>X</td>
</tr>
<tr>
<td>Any amount</td>
<td>+ ≤1 kg and &gt;100 and &lt;1,000 kg</td>
<td>≤1 kg and &gt;100 and &lt;1,000 kg</td>
<td>Yes</td>
<td>X</td>
</tr>
<tr>
<td>&gt;1 kg and &gt;100 kg</td>
<td>+ ≤1 kg and ≤100 kg</td>
<td>≤1 kg and &gt;100 kg</td>
<td>Yes</td>
<td>X</td>
</tr>
<tr>
<td>≤1 kg and ≤100 kg</td>
<td>+ ≤1 kg and ≤100 kg</td>
<td>≤1 kg and &gt;100 kg</td>
<td>Yes</td>
<td>X</td>
</tr>
<tr>
<td>Long-term care facilities with ≤20 beds</td>
<td>+ ≤1 kg and</td>
<td>≤1 kg and</td>
<td>No¹</td>
<td>X³</td>
</tr>
</tbody>
</table>

¹All healthcare facilities that are VSQGs are subject to the prohibition on sewering of §266.505 and the empty-container standards of §266.507.
²The healthcare facility is a VSQG for nonpharmaceutical hazardous waste management only (i.e., a “Subpart P VSQG”). It must comply with the full Subpart P regulations for the management of its HWPharms.
³The healthcare facility is a VSQG when counting both HWPharms and nonpharmaceutical hazardous waste. The facility may manage its HWPharms 1) per §262.14, 2) per §266.504(a–b), or 3) per the opt-into Subpart P provisions of §266.501(b, d). [§266.501(b), 84 FR 5838] See Section 5.3.
⁴The facility is presumed to be a VSQG for both HWPharms and nonpharmaceutical hazardous waste.

facilities that are not VSQGs will be required to manage all hazardous waste pharmaceuticals generated at their facilities in accordance with the new part 266 subpart P (see § 262.10(n)) in lieu of the part 262 generator regulations even if they are located at a manufacturing site.” [Emphasis added. The Response to Comments document is available at http://www.regulations.gov. See comment number: EPA-HQ-RCRA-2007-0932-0249-25] Further clarification from EPA on this issue would be helpful.

When addressing this issue in the preamble, EPA said that some commenters were concerned that this rule would impact their established programs for managing hazardous waste pharmaceuticals. The agency pointed
out that, in some cases, compliant practices by health-care facilities under Part 262 would also meet the standards under Part 266, Subpart P. [84 FR 5856]

Note that a healthcare facility that is a VSQG, when counting both its HWPharms and nonpharmaceutical hazardous waste, is not subject to Subpart P (with some exceptions as noted in Table 2). [§266.501(a–b)] See Section 5.3 below for a more complete discussion of this issue.

3.3 Episodic Generation Provisions for Affected Facilities
A healthcare facility that is a VSQG for both HWPharms and nonpharmaceutical hazardous waste can use the episodic generation provision of Part 262, Subpart L for all of its hazardous waste, including its HWPharms. For example, if a healthcare facility is operating under §262.14 as a VSQG but has an episodic event, it could comply with Part 262, Subpart L rather than comply with all of the Subpart P provisions for the short duration of the episodic event. However, if a VSQG healthcare facility generates hazardous waste in excess of the VSQG quantity thresholds and it chooses not to use the episodic generator provisions, it would become subject to Subpart P for the management of its HWPharms.

A healthcare facility or reverse distributor operating under Subpart P for its HWPharms may not use the episodic generator standards of Part 262, Subpart L with respect to its HWPharms. On the other hand, if a healthcare facility or reverse distributor is operating as a VSQG or SQG for its nonpharmaceutical hazardous waste but has an episodic event, the facility may use the provisions in Part 262, Subpart L for its nonpharmaceutical hazardous waste. [84 FR 5935]

4 Definitions
To understand the applicability of the pharmaceuticals rule, we have provided the new definitions promulgated in §266.500 (with some modifications for clarity).

Evaluated HWPharm—a prescription HWPharm that has been evaluated by a reverse distributor and that will not be sent to another reverse distributor for further evaluation or verification of manufacturer credit.

Hazardous waste pharmaceutical—a pharmaceutical that is both a solid waste per §261.2 and exhibits a characteristic or is listed per Part 261, Subpart C or D, respectively. A pharmaceutical is not a solid waste, and therefore not a hazardous waste, if it is legitimately used/reused or reclaimed. An over-the-counter (OTC) pharmaceutical, dietary supplement, or homeopathic drug is not a solid waste if it has a reasonable expectation of being legitimately used/reused or reclaimed.

Healthcare facility—means any person that is lawfully authorized to 1) provide preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or 2) distribute, sell, or dispense pharmaceuticals, including OTC pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals. This definition includes, but is not limited to, wholesale distributors, third-party logistics providers that serve as forward distributors, military medical logistics facilities, hospitals, psychiatric hospitals, ambulatory surgery centers, health clinics, physicians’ offices, optical and dental providers, chiropractors, long-term care facilities, ambulance services, pharmacies, long-term care pharmacies, mail-order pharmacies, retailers of pharmaceuticals, veterinary clinics, and veterinary hospitals. This definition does not include pharmaceutical manufacturers, reverse distributors, or reverse logistics centers.

Household waste pharmaceutical—a pharmaceutical that is a solid waste per §261.2 but is excluded from being a hazardous waste under §261.4(b)(1).

Long-term care facility—a licensed entity that provides 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, nursing, and skilled nursing facilities, and the nursing and skilled nursing care portions of continuing care retirement communities. Not included within the scope of this definition are group homes, independent living communities, assisted living facilities, and the independent and assisted living portions of continuing care retirement communities.

Non-creditable HWPharm—a prescription HWPharm that does not have a reasonable expectation to be eligible for manufacturer credit or a nonprescription HWPharm that does not have a reasonable expectation to be legitimately used/reused or reclaimed. This includes but is not limited to investigational drugs, free samples of pharmaceuticals received by healthcare facilities, residues of pharmaceuticals remaining in empty containers, contaminated personal protective equipment, floor sweepings, and clean-up material from spills of pharmaceuticals.

EPA gave the following examples of non-creditable HWPharms in the rule preamble: pharmaceuticals that
have been removed from the original container and re-packaged for dispensing purposes; pharmaceuticals in their original packaging when the packaging is leaking or otherwise damaged; a pharmaceutical refused by a patient after an attempt was made to administer it; pharmaceuticals generated during patient care; dispensed pharmaceuticals returned to a pharmacy after the pharmacy already received compensation by a third-party payer (e.g., health insurance company); and pharmaceuticals that are more than one year past their expiration date. [§§266.502(c), 266.503(a)]

Nonhazardous waste pharmaceutical—a pharmaceutical that is a solid waste, as defined in §261.2, but neither exhibits a characteristic nor is listed per Part 261, Subparts C and D, respectively.

Nonpharmaceutical hazardous waste—a solid and hazardous waste that does not meet the definition of pharmaceutical.

Pharmaceutical—any drug or dietary supplement for use by humans or other animals; any electronic nicotine delivery system (e.g., electronic cigarette or vaping pen); or any liquid nicotine (e-liquid) packaged for retail sale for use in electronic nicotine delivery systems (e.g., pre-filled cartridges or vials). This definition includes, but is not limited to, dietary supplements, as defined by the Federal Food, Drug and Cosmetic Act; prescription drugs, as defined by 21 CFR 203.3(y); OTC drugs; homeopathic drugs; compounded drugs; investigational new drugs; pharmaceuticals remaining in non-empty containers; personal protective equipment contaminated with pharmaceuticals; and clean-up material from spills of pharmaceuticals. This definition does not include dental amalgam or sharps.

Potentially creditable HWPharm—a prescription HWPharm that has a reasonable expectation to receive manufacturer credit and is 1) in original manufacturer packaging (except pharmaceuticals that were subject to a recall), 2) undispensed, and 3) unexpired or less than one year past expiration date. The term does not include evaluated HWPharms or nonprescription pharmaceuticals including, but not limited to, OTC drugs, homeopathic drugs, and dietary supplements.

Reverse distributor—any person that receives and accumulates prescription pharmaceuticals that are potentially creditable HWPharms for the purpose of facilitating or verifying manufacturer credit. Any person, including forward distributors, third-party logistics providers, and pharmaceutical manufacturers, that processes prescription pharmaceuticals for the facilitation or verification of manufacturer credit is considered a reverse distributor.

5 Standards for Healthcare Facilities

Healthcare facilities are subject to two different sets of standards when managing HWPharms, based on whether such pharmaceuticals are “potentially creditable” or “non-creditable” (see definitions in Section 4). Nonhazardous waste pharmaceuticals are not subject to RCRA’s hazardous waste standards, but healthcare facilities may manage nonhazardous pharmaceuticals under Subpart P if they so choose. [§§266.502(c), 266.503(a)]

5.1 Standards for Healthcare Facilities Managing Potentially Creditable HWPharms

The final rule allows healthcare facilities to send potentially creditable HWPharms to reverse distributors, provided they meet the minimal requirements in new §§266.502(a) and 266.503. These requirements primarily include notification, recordkeeping to ensure proper delivery, and spill response.

EPA believes that potentially creditable HWPharms are less likely to be released to the environment and so has decided to impose minimal management standards during their accumulation. Some of these new standards need additional clarification as follows:

- All healthcare facilities that send potentially creditable HWPharms to reverse distributors must notify using EPA’s Site Identification Form (Form 8700-12). This notification requirement is not in §266.503 but is in §266.501(d)(2), which specifies notification per §266.502(a). [§§5855–6] The only exception to this requirement is a healthcare facility that is a VSQG and is choosing to manage its HWPharms in accordance with §262.14.

- Although §266.503(a) requires that hazardous waste determinations be made for potentially creditable pharmaceuticals, that section also notes that a healthcare facility may choose to manage its potentially creditable nonhazardous waste pharmaceuticals as potentially creditable HWPharms. This latter provision allows the facility to commingle all potentially creditable pharmaceutical waste, whether or not it is hazardous, and manage the commingled pharmaceuticals under Subpart P; this option eliminates the need to make individual hazardous waste determinations. [§§5885]

- A healthcare facility may accept potentially creditable HWPharms from an offsite VSQG healthcare facility if 1) the receiving healthcare facility is under the control of the same person (as defined in

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§260.10) as the VSQG healthcare facility, and 2) the standards in §266.503(b) are met.

- There are no accumulation time limits, container management standards, or container labeling requirements for potentially creditable HWPharms in §266.503.

5.2 Standards for Healthcare Facilities Managing Non-Creditable HWPharms

Since they have no further value, non-creditable HWPharms will be sent to a designated TSD facility for treatment and disposal. Therefore, they must be managed by healthcare facilities in accordance with the numerous requirements in new §266.502. These requirements are comparable to the standards for traditional hazardous wastes managed at SQGs and include:

- Notification as a healthcare facility using EPA Form 8700-12 is required as part of the facility’s next biennial report, or if not required to submit a biennial report, within 60 days of becoming subject to the new regulations.

- Training is required so that all personnel that manage non-creditable HWPharms are thoroughly familiar with proper waste handling and emergency procedures.

- Hazardous waste determinations must be performed, unless the healthcare facility chooses to manage its hazardous and nonhazardous waste pharmaceuticals together as non-creditable HWPharms. Hazardous waste codes need not be identified, except as noted below.

- Containers used to manage non-creditable HWPharms are subject to standards similar to those found in Part 262 for hazardous waste containers, including the requirements to be structurally sound, compatible with their contents, specially managed if holding ignitable or reactive wastes, closed and secured to prevent unauthorized access, and labeled “Hazardous Waste Pharmaceuticals.” If a healthcare facility chooses to accumulate its HWPharms in a 90/180-day hazardous waste accumulation area, the HWPharms will only be subject to the requirements of Part 266, Subpart P and not to the Part 262 hazardous waste generator standards. [84 FR 5872]

- Pharmaceuticals prohibited from being combusted due to the dilution prohibition of §268.3(c) must be accumulated in separate containers and labeled with all applicable hazardous waste codes.

- Waste accumulation time is up to one year; the accumulation time must be demonstrated either by marking or labeling the container with the date the non-creditable HWPharms first became waste or by maintaining an inventory system.

- Compliance with the land disposal restrictions (LDR) program in Part 268, including completion of generator LDR paperwork per §268.7(a), is required although no hazardous waste codes need to be identified on these notifications.

- Healthcare facilities must immediately contain and clean up spills. Spill clean-up materials must be managed as non-creditable HWPharms in accordance with the requirements of Subpart P.

- If a healthcare facility receives a rejected shipment from a TSD facility, it must terminate the manifest. This includes providing the transporter with a copy of the signed manifest and sending a signed copy back to the rejecting TSD facility within 30 days. Rejected shipments from the designated facility may be managed for up to an additional 90 days at the healthcare facility.

- Non-creditable HWPharms do not have to be included in biennial reports (if required by the facility’s generator category). However, copies of hazardous waste determinations (if required), manifests, exception reports, and LDR paperwork must be maintained for at least three years.

- A healthcare facility may accept non-creditable HWPharms from an offsite VSQG healthcare facility if 1) the receiving healthcare facility is under the control of the same person (as defined in §260.10) as the VSQG healthcare facility, and 2) the standards in §266.502(l) are met. A VSQG healthcare facility that chooses to send its HWPharms for consolidation to an offsite healthcare facility is not considered to be operating under Subpart P and does not need to notify as a facility operating under Subpart P. A VSQG healthcare facility may send its HWPharms to a healthcare facility in another state provided both states have adopted this provision. [84 FR 5883–4]

5.3 Standards for Healthcare Facilities That Are VSQGs

Referring again to Figure 3, a healthcare facility that is a VSQG when counting all of its hazardous waste, including both its HWPharms and its nonpharmaceutical hazardous waste, remains subject to §262.14 for the management of its nonpharmaceutical hazardous waste but has the option of managing its HWPharms in one of three ways: 1) per §262.14, 2) per §266.504(a–b), or 3) per the opt-into
Subpart P provisions of §266.501(b, d). [§266.501(b), 84 FR 5858] Additionally, VSQGs are subject to the prohibition on sewerage in §266.505 and the empty-container standards in §266.507. [§266.501(a)]

Note that the second option noted above of managing HWPharms per §266.504(a–b) does not apply to “Subpart P VSQGs”—healthcare facilities that become VSQGs as a result of not having to count their HWPharms. Such facilities are VSQGs with respect to the management of their nonpharmaceutical hazardous waste only and must manage their HWPharms under full Subpart P. [84 FR 5890] The §266.504(a–b) standards allow a VSQG healthcare facility (when counting both HWPharms and non-pharmaceutical hazardous waste) to send its:

- Potentially creditable HWPharms to a reverse distributor without having to comply with all of the Subpart P standards (i.e., the VSQG is not considered to be “opting into” Subpart P). [84 FR 5858]
- Potentially creditable and non-creditable HWPharms to an offsite healthcare facility, provided the standards in §266.504(b) are met. [84 FR 5927]

The third option for VSQG healthcare facilities is to opt into Subpart P and comply with all of the §266.501(d) standards, including notification as a healthcare facility. [§266.501(b)] A VSQG healthcare facility that opts into Subpart P for managing its HWPharms must still keep track of its monthly generation of nonpharmaceutical hazardous waste to verify that it is, in fact, a VSQG. Assuming it is a VSQG, the healthcare facility can manage its nonpharmaceutical hazardous waste under §262.14. [84 FR 5858]

Long-term care facilities (LTCFs) are included in the definition of healthcare facilities and so may be subject to Subpart P. However, most LTCFs are VSQGs and can take advantage of the reduced requirements discussed above. Additionally, LTCFs that are VSQGs can use an onsite DEA-authorized collection receptacle for the disposal of their HWPharms. [§266.504(c)] This and other LTCF standards are discussed in Figure 3.

6 Standards for Reverse Distributors

Reverse distributors act as intermediaries between healthcare facilities and pharmaceutical manufacturers. They receive shipments of potentially creditable HWPharms from healthcare facilities and, on behalf of the manufacturers, facilitate the process of crediting healthcare facilities for these pharmaceuticals. Any facility that is performing the function of a reverse distributor, even if it is a small part of their business, needs to operate under the reverse distributor standards in Subpart P. Conversely, wholesale distributors receiving returns from their customers are not considered reverse distributors, because wholesale distributors do not facilitate manufacturer credit. [84 FR 5845]

Sometimes, there are multiple reverse distributors in the HWPharms management and evaluation chain before the waste is ultimately shipped to a TSD facility. For example, a HWPharm may sometimes be sent from a healthcare facility to a reverse distributor, but a final evaluation of credit cannot be determined or issued. The reverse distributor then needs to send the HWPharm to a second reverse distributor. Depending on where the HWPharm is in the reverse distribution chain, it will be considered either “potentially creditable” or “evaluated” (see definitions in Section 4). Both are considered HWPharms, but they are managed differently under Subpart P. [84 FR 5915–6]

To keep the HWPharms reverse distribution process under a reasonable degree of control, Subpart P clarifies that there is a limit of three transfers of potentially creditable HWPharms before the waste must be transported to a TSD facility. The three types of transfers are:

1. A healthcare facility may send potentially creditable HWPharms to a reverse distributor, which may or may not be a pharmaceutical manufacturer.
2. The first reverse distributor may send the potentially creditable HWPharms to a second reverse distributor, which may or may not be a pharmaceutical manufacturer, for further evaluation. Alternatively, the first reverse distributor may complete the evaluation and then manage the evaluated HWPharms under §266.510(c) before shipment to a TSD facility.
3. The second reverse distributor may send the potentially creditable HWPharms to a third reverse distributor (for further evaluation), but the third reverse distributor must be a pharmaceutical manufacturer. Alternatively, the second reverse distributor may complete the evaluation and then manage the evaluated HWPharms under §266.510(c) before shipment to a TSD facility. [§266.510(b), 84 FR 5926]

The §266.510 standards for reverse distributors in Subpart P bear a resemblance to those in §262.17 for LQGs of hazardous waste. The standards are broken into three groups: 1) requirements for the management of potentially creditable and evaluated HWPharms, 2) regulations (as noted above) for potentially creditable HWPharms that will be sent to another reverse distributor for further evaluation of manufacturer credit, and 3) provisions for the management of evaluated HWPharms that will be
sent to a TSD facility. These three sets of standards are briefly summarized below.

1. Reverse distributor standards for managing both potentially creditable and evaluated HWPharms [§266.510(a)]:

☐ Notification as a reverse distributor using EPA Form 8700-12 is required within 60 days of becoming subject to Subpart P.

☐ The reverse distributor must evaluate each potentially creditable HWPharm within 30 calendar days of receipt. Once the evaluation is complete, the material becomes known as an evaluated HWPharm. If the evaluation cannot be completed and the pharmaceutical is to be sent to another reverse distributor for further evaluation, it must be managed in accordance with §266.510(b).

☐ A current inventory of both potentially creditable and evaluated HWPharms must be maintained. Potentially creditable HWPharms must be inventoried within 30 days of receipt. This inventory must include the pharmaceutical identity (e.g., name) and quantity. This requirement is waived if the reverse distributor already meets the inventory requirements of the State Board of Pharmacy or another regulatory body.

☐ After evaluation, evaluated HWPharms may be accumulated for up to 180 days. Therefore, the HWPharms can be accumulated at each reverse distributor for no more than 210 days in total after arrival. [84 FR 5921–2] Unexpired pharmaceuticals that are creditable but are awaiting expiration (i.e., aging in a holding morgue) can be accumulated for 180 days after expiration. These aging pharmaceuticals must be managed in compliance with §266.510(a) and container standards in §266.510(c)(4)(i–vi).

☐ Reverse distributors must prevent unknowing, and minimize unauthorized, entry to the HWPharms accumulation areas. This requirement is waived if the reverse distributor already meets the security requirements of the State Board of Pharmacy or another regulatory body.

☐ The contingency plan and emergency procedures of Part 262, Subpart M must be in place.

☐ The notification and container area closure performance standards of §262.17(a)(8)(ii) and (iii) must be followed when closing an area where HWPharms were accumulated.

☐ Within 45 days of receipt, an unauthorized waste report must be sent to EPA if the reverse distributor receives waste from offsite that it is not authorized to receive (e.g., nonpharmaceutical hazardous waste, regulated medical waste).

☐ Recordkeeping is required, including maintaining copies of notification paperwork (Form 8700-12), current inventories, shipping papers, delivery confirmations, and any unauthorized waste reports.

2. Additional reverse distributor standards when managing potentially creditable HWPharms destined for another reverse distributor [§266.510(b)]:

☐ Within 180 days of evaluation, the reverse distributor must ship the potentially creditable HWPharms received from a healthcare facility to another reverse distributor for further evaluation or follow §266.510(c) for evaluated HWPharms.

☐ Within 180 days of evaluation, the second reverse distributor must ship the potentially creditable HWPharms received from the first reverse distributor to a third reverse distributor that is itself a pharmaceutical manufacturer or follow §266.510(c) for evaluated HWPharms.

☐ Shipments from one reverse distributor to another must be in accordance with §266.509.

☐ Delivery confirmations and DOT shipping papers, if applicable, must be retained for three years.

3. After evaluation of potentially creditable HWPharms has been completed, the reverse distributor becomes subject to additional requirements for the management of evaluated HWPharms in §266.510(c), including:

☐ An onsite accumulation area must be designated so that evaluated HWPharms are segregated and clearly distinguished from potentially creditable HWPharms. This designated area must be inspected at least once every seven days, looking for leaking or deteriorated containers or signs of diversion.

☐ Training is required for personnel managing evaluated HWPharms according to §262.17(a)(7).

☐ Containers used to manage evaluated HWPharms are subject to standards similar to those found in
Part 262 for hazardous waste containers, including the requirements to be structurally sound, compatible with their contents, kept closed (if holding liquids or gels), specially managed if holding ignitable or reactive wastes, and labeled “hazardous waste pharmaceuticals.” Accumulation start dates are not required on container labels, because the reverse distributor’s inventory will likely be used to verify the accumulation start date. [84 FR 5929]

□ Containers must be marked with applicable hazardous waste codes prior to shipping. Pharmaceuticals prohibited from being combusted due to the dilution prohibition of §268.3(c) must be accumulated in separate containers and labeled with all applicable hazardous waste codes prior to shipping.

□ If a reverse distributor receives a rejected shipment from a TSD facility, it must terminate the manifest. This includes providing the transporter with a copy of the signed manifest and sending a signed copy back to the rejecting TSD facility within 30 days. Rejected shipments from the designated facility may be managed for up to an additional 90 days at the reverse distributor.

□ Compliance with the LDR requirements in Part 268, including completion of generator LDR paperwork per §268.7(a), is required. Hazardous waste codes need to be identified on these notifications, since reverse distributors are subject to the same LDR standards that apply to LQGs with respect to their evaluated HWPharms. [84 FR 5931]

□ A reverse distributor that ships evaluated HWPharms offsite must comply with the biennial report requirements in §262.41.

□ Records (i.e., logs) of accumulation area inspections and copies of manifests, biennial reports, exception reports, and LDR paperwork must be maintained for at least three years. Additionally, personnel training records must be maintained per §262.17(a)(7)(iv).

6.1 Conditions That Trigger a RCRA Permit for Reverse Distributors
Reverse distributors are required to operate under the regulations for permitted or interim status TSD facilities in Part 264 or 265 and to get a RCRA permit per Part 270 if they:

1. Do not meet the conditions of §266.510,

2. Accept manifested hazardous waste from offsite, or

3. Treat or dispose HWPharms onsite. [§266.510(d)]

If a reverse distributor is not determining manufacturer credit, EPA views it as managing hazardous waste pharmaceuticals that do not have monetary value; thus, it would be subject to TSD facility regulations. If a reverse distributor begins to routinely receive non-creditable hazardous waste pharmaceuticals, then it is serving as a TSD facility. [84 FR 5848]

7 Shipping Standards
As noted in Figure 1, there are two sets of shipping standards in Part 266, Subpart P. The first set is for shipping non-creditable and evaluated HWPharms and is found in §266.508. The second set is for shipping potentially creditable HWPharms and is found in §266.509. The purpose of each set of standards is similar—maintain DOT and import/export regulatory compliance. The differences between the two sets of provisions reflect the value of the HWPharms being shipped:

- Non-creditable or evaluated HWPharms are shipped to a TSD facility for disposal. There was either no credit allotted to begin with or, if there was credit, it has already been issued. No further evaluation is necessary; the materials have no value, and are waste headed for disposal. Additionally, once credit for HWPharms has been verified, the potential for mismanagement is greater because evaluated pharmaceuticals no longer retain any value and will cost the reverse distributor money to dispose. [84 FR 5910–11] Thus, these HWPharms must be shipped with a hazardous waste manifest and LDR form.

- Compare this to a potentially creditable HWPharm, which is shipped to a reverse distributor for evaluation. The material may have value and is not being sent for disposal. Thus, these materials do not have to be shipped with a hazardous waste manifest, and no LDR form is needed.

Each of these two sets of standards is summarized below.

7.1 Standards for Shipping Non-Creditable and Evaluated HWPharms
The standards for shipping non-creditable and evaluated HWPharms to a TSD facility in §266.508 are similar to the manifesting and pretransportation standards for hazardous waste generators found in Part 262, Subparts B and C, respectively. Because there are some differences, we discuss the standards for shipping non-creditable and evaluated HWPharms separately below.
7.1.1 Standards for Shipping Non-Creditable HWPharms
- DOT-required packaging, labeling, marking, and placarding are required for shipments of non-creditable HWPharms that meet the definition of a DOT hazardous material. Additional RCRA marking is required when shipping containers with a capacity of 119 gal or less per §266.508(a)(1)(iii)(B).
- A hazardous waste transporter and uniform hazardous waste manifest must be used to ship non-creditable HWPharms to a designated TSD facility, with the word “PHARMS” entered in Block 13 of the manifest. The “PHARMS” code is for manifesting and reporting purposes only. It is not an official EPA hazardous waste code. This code may be entered into the e-manifest system. [84 FR 5909]

7.1.2 Standards for Shipping Evaluated HWPharms
- DOT-required packaging, labeling, marking, and placarding are required for shipments of evaluated HWPharms that meet the definition of a DOT hazardous material. Additional RCRA marking is required when shipping containers with a capacity of 119 gal or less per §266.508(a)(1)(iii)(B).
- A hazardous waste transporter and uniform hazardous waste manifest must be used to ship evaluated HWPharms to a designated TSD facility, with applicable waste codes entered in Block 13 of the manifest. [84 FR 5909, 5911]

7.2 Standards for Shipping Potentially Creditable HWPharms
The standards for shipping potentially creditable HWPharms are in §266.509 and do not require that a manifest or LDR notification form accompany the shipment. The standards are summarized below:
- Healthcare facilities must meet the applicable DOT hazardous material shipping requirements only when shipping potentially creditable HWPharms that meet the definition of DOT hazardous material. Because shipments of potentially creditable HWPharms do not require a manifest, they are not considered hazardous waste under DOT regulations. Therefore, DOT shipping requirements (including a DOT shipping paper) will apply only when the HWPharms are otherwise classified as DOT hazardous materials (i.e., DOT Hazard Class 1–8). [84 FR 5914]
- The receiving reverse distributor must provide confirmation of receipt of the HWPharms, indicating that the shipment has arrived at its destination and is under the custody and control of the reverse distributor.
- If confirmation of receipt has not been received within 35 days from the ship date, the healthcare facility must contact the transporter and intended recipient (i.e., the reverse distributor) to determine the status of the shipment.
- Healthcare facilities may use nonhazardous waste carriers, such as USPS, UPS, and FedEx, for shipments of potentially creditable HWPharms to reverse distributors, as long as personnel are present to receive and take control of the shipments upon arrival. EPA believes that such carriers are able to provide safe shipment, since these potentially creditable HWPharms present low risk of release during transport. [84 FR 5913]

8 Effect of Subpart P on TSD Facilities
The primary impact of the pharmaceuticals rule on RCRA-permitted and interim status TSD facilities has to do with the treatment of HWPharms to meet LDR treatment standards. [84 FR 5836] There are three LDR treatment issues that EPA had to address [84 FR 5876–8, 5909]:
1. Most non-creditable and evaluated HWPharms are ultimately incinerated at receiving TSD facilities. However, the following HWPharms are prohibited from incineration due to the §268.3(c) dilution prohibition: the characteristic metal wastes (i.e., D004–D011), U151 (mercury), U205 (selenium sulfide), and P012 (arsenic trioxide). [These HWPharms are not prohibited from incineration if the wastes contain greater than 1% total organic carbon—see §268.3(c)(6).]
2. Seven HWPharms have concentration-based LDR treatment standards: U044 (chloroform), U052 (m-cresol), U075 (dichlorodifluoromethane), U121 (trichloromonofluoromethane), U129 (lindane), U187 (phenacetin), and U188 (phenol). These seven will likely be incinerated at TSD facilities, since none of them are prohibited under §268.3(c). However, since
healthcare facilities sending non-creditable HWPharms to TSD facilities are not required to identify hazardous waste codes on their containers (except as noted in Item 1 above) or LDR notifications, how will personnel at hazardous waste incinerators know when they should be analyzing their ash for these constituents?

The final Subpart P standards do not require that healthcare facility personnel segregate the seven HWPharms noted above or notify the TSD facility when they are in a shipment, although a waste management company could include such requirements in its contract with a healthcare facility. The pharmaceuticals rule is not providing any relief to TSD facilities that incinerate any of the above-noted HWPharms. The incinerator ash must be analyzed for these seven organic constituents to demonstrate compliance with the LDR treatment standards before that ash can be land disposed. As they could possibly be present in any shipment of organic HWPharms, TSD facilities must test their ash for these seven constituents based on procedures and frequencies specified in their existing waste analysis plans.

3. As noted in Section 7.1.1 above, the word "PHARMS" must be entered in Block 13 of the manifest when a healthcare facility ships non-creditable HWPharms to a TSD facility. The PHARMS identification is for manifesting and reporting purposes only and is not an official EPA hazardous waste code. Because it will be entered in Block 13—the same place that official EPA hazardous waste codes are entered—it may be referred to colloquially as a "hazardous waste code." However, it does not modify any existing LDR treatment standards, nor does it create any new or alternate LDR treatment standards for HWPharms.

9 Additional Provisions

Embedded in Part 266, Subpart P are three additional pharmaceutical-related provisions. The pharmaceuticals rule also made a change to the listing description for P075 nicotine wastes found in Part 261, Subpart D.

9.1 Prohibition on Sewering

The rationale for this prohibition is multifaceted. Flushing leftover medication that is hazardous has become a common practice used in lieu of proper hazardous waste management. Because there are no CWA pretreatment standards for discharges of pharmaceuticals, sewered HWPharms then flow to the publicly owned treatment works (POTW). POTWs are designed to remove conventional pollutants, such as suspended solids and biodegradable organic compounds; they are not designed to remove pharmaceuticals from wastewater discharges. Thus, these constituents often pass through POTWs into the nation’s waterways. These bioactive compounds that enter the environment are known to have a negative effect on aquatic ecosystems and on fish and animal populations. [84 FR 5893]

For these reasons, §266.505 in Subpart P prohibits all healthcare facilities and reverse distributors from discharging HWPharms to a sewer system that flows to a POTW. This ban extends to pharmaceuticals that are substances controlled by the Drug Enforcement Administration (DEA) and mixed waste pharmaceuticals (i.e., those that are both RCRA hazardous and radioactive).

To further underscore this prohibition, EPA modified the language in the domestic sewage exclusion at §261.4(a)(1)(ii) to reference the §266.505 prohibition on sewering. The added language emphasizes that the prohibition on sewer ing HWPharms in §266.505 does, in fact, supersede the exclusion in §261.4(a)(1)(ii). [84 FR 5895]

Healthcare facilities that are VSQGs are generally not subject to Subpart P. However, EPA estimates that 81–86 percent of healthcare facilities are VSQGs, and discharges of pharmaceuticals from these facilities into the sewer could have significant impacts on the environment. Therefore, the §266.505 prohibition applies to all VSQG healthcare facilities.

9.2 Conditional Exemptions for DEA-Controlled Substances and Household Waste Pharmaceuticals

Section 266.506 provides a conditional exemption from the RCRA regulations (Parts 262–273) for HWPharms that are also DEA-controlled substances listed in 21 CFR Part 1308. The exemption is intended to eliminate any duplicative regulations for pharmaceuticals that are both RCRA hazardous wastes and DEA-controlled substances. To make use of the conditional exemption, the HWPharms must 1) not be sewered, 2) be managed in compliance with all DEA regulations for controlled substances, and 3) be destroyed by a method that meets DEA’s non-retrievable standard of destruction or combusted in one of five specific units.

A second exemption in §266.506 applies to household waste pharmaceuticals collected in a take-back event or program, including those that are collected by a DEA-registered authorized collector. To avoid confusion, EPA clarified in the preamble that when discarded directly at a residence, household waste pharmaceuticals remain excluded under §261.4(b)(1), without any conditions; however, when household waste pharmaceuticals are collected in a take-back event or program, they...
must be managed and destroyed in accordance with the conditions in §266.506 to remain exempt. [84 FR 5863]

It is important to note that the conditional exemption for household waste pharmaceuticals cannot be used by pharmacies disposing their own HWPharms. A pharmacy can use a DEA-authorized collection receptacle to collect pharmaceutical waste generated at households and brought to the pharmacy. But the HWPharms that the pharmacy itself generates must be managed under either Subpart P or §262.14 (if it is a VSQG). [84 FR 5900]

At the time the pharmaceuticals rule was finalized, EPA was aware of only a handful of pharmaceuticals in common usage that are both hazardous waste and DEA-controlled substances; these are listed in Table 3. The agency is aware of three other drugs that are hazardous wastes when disposed and that are DEA-controlled substances: paraldehyde, paregoric, and opium tincture; however, these three are not in common usage, although there may be legacy supplies remaining at healthcare facilities. [84 FR 5897]

### 9.3 New Definition of “RCRA-Empty” for Pharmaceutical Containers

The existing “RCRA-empty” container definition in §261.7(b) can be difficult to meet in the healthcare industry. Sometimes, it is hard to determine if pharmaceutical residues remaining in unit-dose containers, syringes, intravenous (IV) bags, and other containers meet the criteria in §261.7(b). Additionally, if the HWPharm is an acute hazardous waste, rendering the container RCRA-empty generally requires triple rinsing. EPA previously addressed this concern in 2011 guidance via RO 14827, which provided some relief for the management of residues in containers holding P-listed pharmaceuticals—especially P001 (warfarin).

Building on that previous guidance, §266.507 in Subpart P provides a new definition of “RCRA-empty” for HWPharm containers that applies to all pharmaceuticals and all container types. [EPA has added new §261.7(c), which points users to §266.507 for determining whether containers of HWPharms are RCRA-empty.] This new definition makes it easier to dispose (as nonhazardous) containers that still hold residues of HWPharms but that don’t necessarily meet the existing definition of RCRA-empty in §261.7(b). There are RCRA-empty provisions for four types of HWPharm containers in §266.507, all of which are detailed in Figure 4 (page 17). A healthcare facility can use the new empty-container definitions in §266.507 when determining whether they generate enough hazardous waste to become subject to Subpart P. [84 FR 5908]

Note that the new empty-container regulations in §266.507 are not limited to healthcare facilities and reverse distributors operating under Subpart P. Sections 261.7(c) and 266.507 define when containers of HWPharms are empty and apply regardless of whether they are being managed by a healthcare facility, a reverse distributor, or another entity. [84 FR 5859]

### Table 3: Pharmaceuticals Used in Healthcare That Are DEA-Controlled Substances and RCRA Hazardous Wastes

<table>
<thead>
<tr>
<th>Name of drug</th>
<th>Other name(s)</th>
<th>Medical uses</th>
<th>Hazardous waste code</th>
<th>DEA-controlled substance schedule</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chloral; chloral hydrate</td>
<td>Trichloroacetaldehyde, Aquachloral, Noctec, Somnote, Supprettes</td>
<td>Sedative</td>
<td>U034</td>
<td>IV</td>
<td>Used in hospital pediatric units; common ingredient in vet anesthetics</td>
</tr>
<tr>
<td>Fentanyl sublingual spray</td>
<td>Subsys</td>
<td>Analgesic</td>
<td>D001</td>
<td>II</td>
<td>Ignitable due to alcohol content</td>
</tr>
<tr>
<td>Phenobarbital</td>
<td>Bellergal-S, Donnatal, Luminal</td>
<td>Anticonvulsant</td>
<td>D001</td>
<td>IV</td>
<td>Ignitable due to alcohol content</td>
</tr>
<tr>
<td>Testosterone gels/solutions</td>
<td>Androgel, Axiron, Fortesta, Testim</td>
<td>Hormone</td>
<td>D001</td>
<td>III</td>
<td>Ignitable due to alcohol content</td>
</tr>
<tr>
<td>Valium injectable/gel</td>
<td>Diazepam, Diastat</td>
<td>Anti-anxiety</td>
<td>D001</td>
<td>IV</td>
<td>Ignitable due to alcohol content</td>
</tr>
</tbody>
</table>

1This table is for informational purposes only. The listed drugs do not appear by name in the Subpart P regulations. According to EPA, these drugs are still in common usage. According to EPA, these drugs are still in common usage. Source: 84 FR 5900.
Figure 4: Applicability of Hazardous Waste Pharmaceuticals Rule to Pharmaceutical Containers and Residues

START

Is the HWPharm container a stock bottle, dispensing bottle, vial, or ampule? Yes

Is the HWPharm container a unit-dose container? No

Is the HWPharm container a syringe? Yes

Have the pharmaceuticals been removed by fully depressing the syringe plunger? No

The syringe is not RCRA-empty and must be placed into a container that is 1) managed as a non-creditable HWPharm under Subpart P, and 2) managed under any applicable federal, state, and local requirements for sharps containers and medical waste. §266.507(b)

No

Is the HWPharm container a syringe? No

Is the HWPharm container an IV bag? Yes

Have the pharmaceuticals been fully administered to a patient? No

Did the IV bag hold nonacute HWPharms? Yes

Is the IV bag empty as defined in §261.7(b)(1)? No

The IV bag is not RCRA-empty and must be placed into a container that is managed as a non-creditable HWPharm under Subpart P. §266.507(c)

No

Did the IV bag hold nonacute HWPharms? No

Is the IV bag empty as defined in §261.7(b)(1–2)? No

The container is not RCRA-empty and must be managed as a non-creditable HWPharm under Subpart P. §266.507(d)

No

Did the container hold nonacute HWPharms? Yes

Is the container empty as defined in §261.7(b)(1–2)? No

The container is not RCRA-empty and must be managed as a non-creditable HWPharm under Subpart P. §266.507(d)

Other HWPharm containers, including delivery devices.

Source: McCoy and Associates, Inc. [Footnotes on next page.]
Acute HWPharms = all hazardous waste pharmaceuticals that are P-chemicals; HWPharms = hazardous waste pharmaceuticals; IV = intravenous; nonacute HWPharms = all hazardous waste pharmaceuticals except for the P-chemicals.

1If the RCRA-empty container is a syringe, many states have medical waste regulations that require the treatment of regulated medical waste, including sharps containers, to render it noninfectious. This is often achieved by autoclaving prior to disposal as solid waste. [84 FR 5907]

2Examples of a unit-dose container include a unit-dose packet, cup, wrapper, blister pack, or delivery device. [§266.507(a)]

3The empty-container provisions in §266.507(a) apply to containers that held either nonacute or acute HWPharms. These containers are considered RCRA-empty once the contents have been removed using the practices commonly employed to remove materials from this type of container (e.g., all pills have been removed). For containers that once held nonacute HWPharms to be considered empty, it will not be necessary to measure the remaining contents. For containers that once held acute HWPharms to be considered empty, it will not be necessary to triple-rinse the containers or demonstrate an equivalent removal method. [84 FR 5905]

4The pharmaceuticals can be removed from the syringe in three ways: 1) fully depressing the plunger of the syringe by administering the contents of the syringe to a patient, 2) fully depressing the plunger of the syringe by injecting the contents of the syringe into another delivery device (e.g., an IV bag), or 3) fully depressing the plunger of the syringe by emptying the remaining contents into a hazardous waste collection container. [84 FR 5906]

5Other containers, including delivery devices” include, but are not limited to, inhalers, aerosol cans, nebulizers, tubes of ointments, gels, or creams. [§266.507(d)]

Source: McCoy and Associates, Inc.

9.3.1 Empty Containers May Be Non-Creditable HWPharms
As noted in Section 4, the definition of non-creditable HWPharms includes “residues of pharmaceuticals remaining in empty containers.” Although EPA did not elaborate on this issue in the rule preamble, we think the agency is saying that if a HWPharm container appears empty, but does not meet the specific RCRA-empty provisions in §266.507, then the pharmaceutical residues (and the container itself) remain subject to Subpart P as non-creditable HWPharms. You can clearly see this outcome in Figure 4.

For example, a small container of nicotine-containing e-liquid is not a stock bottle, dispensing or unit-dose container, syringe, or IV bag. Thus, it falls into the “other HWPharms containers” category and is considered RCRA-empty (and no longer subject to the RCRA Subtitle C program) if the standard in §266.507(d) is met. But, since nicotine-containing e-liquid is an acute HWPharm, Figure 4 shows that when the container is to be discarded (no matter how much or little residue remains), it must be managed as a non-creditable HWPharm under Subpart P.

9.4 Revision of the P075 Listing
Criteria for determining if a chemical substance should be listed in §261.33(e) as an acute hazardous waste are based on LD50 and LC50 values contained in §261.11(a)(2). According to comments submitted to EPA when the P075 listing for “nicotine, & salts” was established in 1980, the only nicotine products being marketed at that time that met these criteria were pesticides containing up to 40% nicotine sulfate. Neither smoking cessation products, also called nicotine replacement therapies (NRTs), nor e-cigarettes and e-liquids had been developed, and, therefore, they were not considered when EPA listed nicotine as an acute hazardous waste. [84 FR 5822]

Fast forward to today—there is a large market in the United States for both NRTs (e.g., nicotine dermal patches, gums, and lozenges) and e-cigarettes and e-liquids (e.g., vape pens and cartridges). Responding to questions from the regulated community, EPA issued guidance in RO 14817, 14850, and 14851, noting that when a facility disposes unused NRTs or e-cigarettes/e-liquids, even though those products contain relatively low concentrations of nicotine, they are unused commercial chemical products containing nicotine as the sole active ingredient; therefore, they are disposing listed hazardous waste P075. Once one of these products is used for its intended purpose, it is no longer considered a commercial chemical product and, thus, is not listed hazardous waste P075 when discarded. However, non-RCRA-empty e-liquid containers still carry the P075 code.

Retailers of NRTs and e-cigarettes/e-liquids believe that the low concentrations of nicotine in their products do not meet §261.11(a)(2) criteria and so do not warrant an acute hazardous waste classification. They therefore petitioned EPA to exempt these products from the P075 listing as part of the pharmaceuticals rulemaking.

Based on an updated review of available toxicity data for nicotine and nicotine-containing products, and in consultation with the Food and Drug Administration (FDA), EPA concluded:

- Nicotine is acutely toxic to both humans and animals and meets the §261.11(a)(2) criteria under the RCRA hazardous waste regulations. Thus, it must continue to be listed as acute hazardous waste P075 under §261.33(e). [84 FR 5824]

- NRTs are regulated as drugs by FDA. FDA has reviewed and approved over-the-counter (OTC) NRTs as being safe and effective for people to use without a prescription. Furthermore, FDA-approved OTC NRTs
have been in the market for over two decades and although some serious adverse events have been reported, based on the available information, EPA has concluded that the serious adverse events do not meet EPA’s criteria for acute toxicity under §261.11(a)(2). Therefore, EPA has amended the P075 listing in the pharmaceuticals rule, stating that “this listing does not include patches, gums and lozenges that are FDA-approved over-the-counter nicotine replacement therapies.”

- EPA also reviewed prescription NRTs, which cannot be used without the guidance of a healthcare professional. The agency found that prescription NRT products can contain nicotine at much higher concentrations and in a more readily available form (i.e., in liquid and mist), which acts faster on the body, than the nicotine contained in FDA-approved OTC NRTs. Therefore, EPA is not exempting prescription NRTs from the P075 hazardous waste listing. But, prescription NRTs may be managed as HWPharms under Subpart P when they are discarded. [84 FR 5826]

- e-Cigarettes/e-liquids are regulated as tobacco products—not drugs—by FDA. As a result, FDA has not been able to evaluate the health risks of e-cigarettes/e-liquids to the same extent as it has been able to for drugs. Additionally, the concentrations of nicotine in e-cigarettes/e-liquids are not limited by any FDA regulations or approval process and are therefore unpredictable. [84 FR 5825]

“Therefore, without controls on the concentration of nicotine in e-cigarettes and e-liquids or FDA’s approval of these products as being safe and effective for people to use, [EPA] lacks adequate information and certainty to conclude that these nicotine-containing products will not pose the risks similar to those for which the P075 listing was established.” [84 FR 5826]

For this reason, EPA is not exempting e-cigarettes or e-liquids from the P075 hazardous waste listing. But, these materials will still be eligible for management as HWPharms under Subpart P when they are discarded.

### 10 Effective Date and State Authorization

The entire final rule will become effective in the non-RCRA-authorized states (i.e., Alaska and Iowa) on August 21, 2019. For the 48 authorized states:

- The prohibition on sewer HWPharms will become effective in all states on August 21, 2019, since this is the one rule provision that is promulgated under HSWA authority.

- All other, non-HSWA rule provisions will not take effect until the state adopts equivalent state requirements. Taken as a whole, EPA considers new Subpart P to be more stringent than the current federal standards. Therefore, authorized states will be required to adopt the new provisions. When a state adopts Subpart P, if elements of the existing state program are more stringent than this new subpart, the state has the option of retaining those more-stringent elements. Likewise, when a state adopts this new subpart, the state has the option of adding elements that are more stringent or broader in scope than this new subpart. [84 FR 5936]

- The change to the P075 nicotine listing is the one new provision that is less stringent than the pre-existing RCRA requirements. Thus, authorized states are not required to adopt this change, although EPA encourages all states to do so to promote national consistency.

### 10.1 HWPharms as Universal Waste

In 2008, EPA proposed adding HWPharms to the federal universal waste program in Part 273. [73 FR 73520] This rule was not finalized, but some of the ideas included in that proposal were modified and included in the final pharmaceuticals rule.

States can add waste streams to their state universal waste program, even when the waste stream has not been added to the federal universal waste program. Florida and Michigan previously added HWPharms to their state universal waste programs. Because EPA considers the new Subpart P provisions more stringent than either the “traditional RCRA” or universal waste standards, both Florida and Michigan will be required to modify their programs to adopt an approach at least as stringent as Subpart P. Furthermore, because the agency has determined that it is not appropriate to add HWPharms to the universal waste program, both Florida and Michigan must remove HWPharms from their universal waste program when they adopt this new subpart, although they may continue to regulate nonhazardous waste pharmaceuticals under their universal waste program. [84 FR 5936]

Finally, EPA added §273.80(d) to reflect its decision that states may not add HWPharms to their universal waste program.
11 Best Management Practices for Healthcare Facilities and Reverse Distributors

Although not required by the regulations, EPA identified a number of “best management practices” for healthcare facilities and reverse distributors managing HWPharms in the preamble to the 2019 final rule:

- If a healthcare facility decides to segregate hazardous and nonhazardous waste pharmaceuticals, EPA recommends that it follow the best management practices outlined in “Managing Pharmaceutical Waste: A 10-Step Blueprint for Healthcare Facilities in the United States,” for the management of its nonhazardous waste pharmaceuticals. In particular, the agency endorses the Blueprint’s recommendation of hazardous waste incineration for nonhazardous waste pharmaceuticals that possess hazardous waste-like qualities. EPA also endorses the Blueprints recommendation of municipal solid waste incineration or medical waste incineration for any nonhazardous waste pharmaceuticals, even when they do not possess hazardous waste-like qualities. This document is available at https://practicegreenhealth.org/sites/default/files/upload-files/pharmwasteblueprint.pdf. [84 FR 5840]

- There are no accumulation time limits, container management standards, or container labeling requirements for potentially creditable HWPharms in §266.503. However, a best management practice to minimize the potential for spills or leaks is for healthcare facilities to place original containers, and packaging containing liquid and aerosol pharmaceuticals, in separate individual containers (e.g., sealed storage bags) before placing them in the accumulation container. [84 FR 5887]

- Shippers of potentially creditable HWPharms should provide advance notice to recipients to the extent practicable. [84 FR 5913]

- Although EPA does not have the statutory authority to apply the prohibition on sewering in §266.505 to nonhazardous waste pharmaceuticals, the agency strongly recommends that no waste pharmaceuticals from any source or location be discharged to a sewer. This recommendation also applies to nonhazardous radioactive pharmaceuticals and patient waste containing radioactive pharmaceuticals. [84 FR 5894-5]

- After pharmaceutical containers are rendered empty per the new §266.507 definition, EPA encourages healthcare facilities to use best management practices, such as locked dumpsters and defacing labels, to prevent the diversion of the empty container for illicit purposes. [84 FR 5905]

- Per §266.510(a)(9)(i), a reverse distributor must submit an unauthorized waste report if it receives waste from offsite that it is not authorized to receive (e.g., nonpharmaceutical hazardous waste, regulated medical waste). Once a reverse distributor determines that that is the case, in order to prevent exposing personnel to unnecessary risk, EPA recommends that personnel minimize the sorting of shipments that contain unauthorized waste, since the shipment may include hazardous waste, infectious substances, or radioactive waste. As a result, it is possible that a reverse distributor that receives a shipment that includes non-creditable waste may be unsure whether the shipment includes hazardous waste. In such cases, EPA recommends that the reverse distributor assume the shipment includes hazardous waste and submit an unauthorized waste report. [84 FR 5925]

- Only containers holding evaluated HWPharms that are liquids or gels must be kept closed during accumulation. [§266.510(c)(4)(iv)] However, EPA recommends that reverse distributors also keep containers of evaluated HWPharms that are in solid form closed during accumulation. [84 FR 5928]

- Although not regulated under Subpart P, EPA recommends that assisted living facilities, group homes, independent living communities, and the independent and assisted living portions of continuing care retirement communities develop voluntary pharmaceutical collection programs for both hazardous and nonhazardous waste pharmaceuticals, as allowed by DEA regulations, to ensure their proper management, avoid flushing, and minimize the potential for accidental poisonings, misuse, or abuse. [84 FR 5882]

12 Additional Information

EPA has provided a summary of the final rule and answers to frequent questions at https://www.epa.gov/hwgenerators/final-rule-management-standards-hazardous-waste-pharmaceuticals-and-amendment-p075.